Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) MEETING

June 15, 2023 9:30 AM – 4:00 PM ET

VIRTUAL & IN-PERSON

Speakers

Name	Organization	Role
Medell Briggs-Malonson	**UCLA Health**	**Co-Chair**
Aaron Miri	**Baptist Health**	**Co-Chair**
Shila Blend	North Dakota Health Information Network	Member
Hans Buitendijk	Oracle Health	Member
Sarah DeSilvey	Gravity Project; Larner College of Medicine at the University of Vermont	Member
Steven Eichner	Texas Department of State Health Services	Member
Cynthia A. Fisher	Patient Rights Advocate	Member
Lisa Frey	St. Elizabeth Healthcare	Member
Hannah Galvin	Cambridge Health Alliance	Member
Rajesh Godavarthi	MCG Health, part of the Hearst Health network	Member
Valerie Grey	State University of New York	Member
Steven Hester	Norton Healthcare	Member
Jim Jirjis	HCA Healthcare	Member
Bryant Thomas Karras	Washington State Department of Health	Member
Kensaku Kawamoto	University of Utah Health	Member
Steven Lane	Health Gorilla	Member
Hung S. Luu	Children's Health	Member
Arien Malec	Individual	Member
Anna McCollister	Individual	Member
Clem McDonald	National Library of Medicine	Member
Deven McGraw	Invitae Corporation	Member
Aaron Neinstein	UCSF Health	Member
Eliel Oliveira	Dell Medical School, University of Texas at Austin	Member
Kikelomo Oshunkentan	Pegasystems	Member
Naresh Sundar Rajan	CyncHealth	Member
Alexis Snyder	Individual	Member
Fil Southerland	Yardi Systems, Inc.	Member
Sheryl Turney	Elevance Health	Member
Thomas Cantilina	Department of Defense	Federal Representative

Name	Organization	Role
Adi V. Gundlapalli	Centers for Disease Control and Prevention	Federal Representative
Ram Iyer	Food and Drug Administration	Federal Representative
Meg Marshall	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
Andrea Palm	United States Department of Health and Human Services	Deputy Secretary
Micky Tripathi	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 Sweeney 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	Executive Director, Office of Technology
Seth Pazinski	Office of the National Coordinator for Health Information Technology	Director, Strategic Planning and Coordination Division
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Anastasia Perchem	Office of the National Coordinator for Health Information Technology	Presenter
Lisa Wagner	Office of the National Coordinator for Health Information Technology	Presenter
Ashley Hain	Office of the National Coordinator for Health Information Technology	Presenter
Tricia Lee Rolle	Office of the National Coordinator for Health Information Technology	Presenter
Mariann Yeager	The Sequoia Project	Presenter
Alan Swenson	Carequality	Presenter
Sherilyn Pruitt	Office of the National Coordinator for Health Information Technology	Presenter
Maggie Wanis	Office of the National Coordinator for Health Information Technology	Presenter
Charletta Washington	Office of the National Coordinator for Health Information Technology	Presenter
Kimberly Baker	University of Texas Health Science Center	Presenter

Name	Organization	Role
Beth Myers	Office of the National Coordinator for Health Information Technology	ONC Support Staff
Kyle Cobb	Office of the National Coordinator for Health Information Technology	ONC Support Staff
John Rancourt	Office of the National Coordinator for Health Information Technology	ONC Support Staff
Sara McGhee	Office of the National Coordinator for Health Information Technology	ONC Support Staff
Kate Tipping	Office of the National Coordinator for Health Information Technology	ONC Support Staff

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

Michael Berry
Good morning, everyone, and welcome to the June 2023 HITAC meeting. We are so excited to see everybody in person for the first time in three and a half years! We really welcome you. We also welcome the members of the public who have joined us here in the room, and we also welcome everyone that joined us virtually. As you know, our meeting is open to the public, as are all of our HITAC and task force meetings, and your comments are welcomed. You can either use the Zoom chat feature to enter your comments or you can use the verbal public comment period that is scheduled towards the end of our meeting.

So, I am going to get started, and I would like to welcome ONC's executive leadership team to the meeting, and with us today is Mr. Steve Posnack, our Deputy National Coordinator, Elise Sweeney Anthony, the Executive Director of the Office of Policy, and Avinash Shanbhag, the Executive Director of the Office of Technology. Micky Tripathi, our National Coordinator, will be joining us a little bit later this morning. I would like to begin rollcall of our HITAC members, so when I call your name, please indicate if you are here. Even though I see you in person, for the record and our captioner, please verbalize that you are present. I will start with Mr. Aaron Miri.

Aaron Miri
Good morning.

Michael Berry
Medell Briggs-Malonson?

Medell Briggs-Malonson
Good morning, everyone.

Michael Berry
Shila Blend?

Shila Blend
Good morning.

Michael Berry
Hans Buitendijk?

Hans Buitendijk
Good morning.

Michael Berry
Sarah DeSilvey?

Sarah DeSilvey
Good morning.

Michael Berry
Steve Eichner?

Steven Eichner
Present.

Michael Berry
Cynthia Fisher? Hannah Galvin?

Hannah Galvin
Good morning.

Michael Berry
Raj Godavarthi?

Rajesh Godavarthi
Good morning.

Michael Berry
Valerie Grey?

Valerie Grey
Good morning.

Michael Berry
Steven Hester? Jim Jirjis?

Jim Jirjis
Here.

Unknown Speaker
They said they are unable to hear the mic.

Michael Berry
Oh, my mic turned off by itself. Okay, well, we will note in the Zoom attendance who is here for those I may have missed. Bryant Thomas Karras?

Bryant Thomas Karras
Present.

Michael Berry
Ken Kawamoto?

Kensaku Kawamoto
Good morning.

Michael Berry
Steven Lane?

Steven Lane
Good morning.

Michael Berry
Hung Luu?

Hung S. Luu
Good morning.

Michael Berry
Arien Malec? Anna McCollister?

Anna McCollister
Good morning.

Michael Berry
Clem McDonald? Deven McGraw?

Deven McGraw
Good morning.

Michael Berry
Aaron Neinstein?

Aaron Neinstein
Good morning.

Michael Berry

Eliel Oliveira?

Eliel Oliveira
Good morning.

Michael Berry
Kikelomo Oshunkentan?

Kikelomo Oshunkentan
Good morning.

Michael Berry
Naresh Sundar Rajan?

Naresh Sundar Rajan
Good morning.

Michael Berry
Alexis Snyder?

Alexis Snyder
Good morning.

Michael Berry
Fil Southerland?

Fil Southerland
Good morning.

Michael Berry
Sheryl Turney?

Sheryl Turney
Good morning.

Michael Berry
And now, our federal representatives of the HITAC. Thomas Cantilina? Adi Gundlapalli?

Thomas Cantilina
Good morning.

Michael Berry
Ram Iyer? Meg Marshall? Michelle Schreiber?

Michelle Schreiber

Good morning.

Michael Berry
John Garguilo?

John Garguilo
Present, good morning.

Michael Berry
Great. Thank you so much, everyone, and now, please join me in welcoming Steve Posnack for his opening remarks. Steve?

Welcome Remarks (00:03:14)

Steve Posnack
I usually do not need a microphone, but I will take it. I have my remarks in a sealed government manila envelope here. Good morning, everybody. It is a pleasure, as Mike noted. We have to keep an eye on Mike's mic. So, it is a pleasure to be with you in 3D. I almost feel like saying, "Live from ONC studios." This is our first meeting here in this new conference space that is part of the building. We all work on the seventh floor in this building, so it is great to have you here. Should the meeting go well today, I think we will look to host here in this space again, and we know you have your choice in advisory committees. In fact, I think the National Vaccine Advisory Committee is over in the Humphrey building, but we are glad you chose this advisory committee today.

Briefly, I just wanted to say good morning to everybody online. Thank you for joining. This is our first hybrid meeting in real life plus virtual, and we are really energized to meet with you today. I would almost say it feels like the first day of school, but for many of us, it is the second to last or last day of school in the Maryland area, and you can feel that nervous excitement, though I know many of you have been itching to get a chance to meet each other and have that Stormin' Norman, which I think will occur over the better part of the next few hours.

We are here today to cover an ambitious agenda, but we also need to recognize as well that it has been about two months since we released the HTI-1 Proposed Rule, and we have done a lot on the ONC side to help advance the work that we have done in terms of education and outreach. We have hosted a number of listening sessions, we have had a number of dedicated, topic-focused webinars and sessions as well, so we have been encouraging public comment, but as we have all Proposed Rules, the public comment period is fast approaching, so for those of you who have been procrastinating, speaking for myself as well, now is your time to shine. You have until June 20th to get your comments submitted through the *Federal Register*'s website.

We also wanted to thank our task force members who, as we jokingly like to describe each of our advisory committees, are the hardest-working advisory committee members in HHS. You have convened 22 times over the past seven weeks to review the proposals and RFIs outlined in the Proposed Rule, and we are going to hear about recommendations that you all have been working on developing as well, so I especially want to thank Steven Lane and Steve Eichner, and it is only fitting that another Steve thanks you. I also

want to note that their names are spelled correctly like mine, with a V, just to say, and I want to thank their leadership with respect to being co-chairs of a task force, too.

So, we look forward to the dialogue and discussion today, and to receiving recommendations from the HITAC on the HTI-1 Proposed Rule. Just as a final reminder, comments will close as of June 20th, so please take your opportunity to do so. The other thing I would mention, which you always do as well, is that you do not have to comment on the entire Proposed Rule. I know sometimes, we emphasize how many pages it is. Focus on the sections that you have an interest in, focus on the sections that you have an expertise in. It does not need to be comments across the entirety of the Proposed Rule.

I just wanted to flag for everyone's awareness that the comment period for the USCDI+ Quality data element list has been extended to June 30th, recognizing that we had a number of deadlines, so we granted everyone some extra time if you are focused on USCDI+ Quality. That is an initiative among a few of the others that we have been working on in the USCDI+ portfolio space, so, definitely take advantage of that additional time for the USCDI+ Quality, which you will hear about a little bit later during today's meeting. And then, there are a few events to call to everyone's attention. Please mark your calendars for the 2023 ONC annual meeting. It will be in person for, if I am not mistaken, the first time in four years because we did take a cycle to get into the preparing stage, for those of you who have done meetings like this, so it will be December 14th and 15th. I cannot guarantee anything on the weather, but we can guarantee that the discussion will be lively, especially for an in-person event.

So, you can go to HealthIT.gov/events, and that is where you will also find information about some of the other webinars and sessions that we have on a running basis, which I will call to your attention. This summer, we will be having an ONC tech forum where we will host Lighting the Way for FHIR API Implementation on August 18th, so if you would like some additional information on that, you can go to our event page as well. Equally, ONC and HL7 are cohosting and planning a two-day virtual session for HL7 FHIR security education for healthcare professionals on August 8th and 9th, so that is another virtual opportunity for everybody from a health IT security perspective. It will host two tracks, one for the architects, developers, and engineers, and a second track for those who are described as "less technical" in my notes, but anybody else who does not fall into the first bucket is welcome to attend that second track, which could include organizational leadership, health professionals, clinicians, and the like. More information will be made available on HealthIT.gov, which I will keep plugging.

In closing, we are also delighted to host Deputy Secretary Palm, who will join us later this morning to speak to you all. She has had a long history with ONC, having done a prior tour of duty coming on board when the HITECH Act was first implemented, and I have had the pleasure of working with her over the past several years, so we very much look forward to having the deputy secretary join us as well. She has been a big supporter of our work. With that, I will turn it over to Aaron and Medell. Thank you for making the journey to Washington, D.C. and letting us host a home game here in person, and with that, over to you.

Opening Remarks, Review of the Agenda and May 17, 2023, Meeting Notes – HITAC Vote (00:09:18)

Aaron Miri

All right, good morning, thank you all, and welcome to the first in-person HITAC in quite a hot minute. Welcome to be here. I am glad to see all of your smiling faces this morning. We are going to have some great discussion today. I am very excited, Medell, about what is to come and what we will talk about. I do want to also thank the ONC team for doing an excellent job. This is a wonderful conference space, by the way, Steve, so, well done, and I appreciate your team as always for helping organize and herd all of us together to get here in D.C. so we can have this discussion. I look forward to today, and Medell, I will turn it to you.

Medell Briggs-Malonson
Thank you so much, Aaron, and I also want to say welcome, everyone. This is just a monumental time, the very first time that we as the HITAC have been in person, but it is also a reflection of even the past three years we have all gone through with the pandemic, where we could not meet in spaces like this due to safety, but one of the main things that this shows is another beacon, a beacon for all of us as HITAC, in order to think about what is needed for the future in order to ensure that we are continuing to increase the overall health and wellbeing of our populations. And so, I also want to thank all of our ONC leadership, specifically Micky, Steve, and Elise, as well as Mike and the rest of the leadership for bringing us all together, and then, of course, the amazing ONC staff that makes everything seem so flawless and so seamless. We thank you all for all your work, and thank you, everyone, for also coming to be here in person for the full HITAC committee. We have a wonderful meeting ahead of us. So, let's go ahead and jump right on into the next piece. Aaron, why don't we go through the agenda?

Aaron Miri
Absolutely, let's get going here. All right, the agenda for today. As you can see here, we are going through our opening remarks now. The first team up will be the FHIR-Enabled Social and Health Information Platform. We will be talking through that, and Eliel and team will give a good update on what is happening there. At 10:30, we have the USCDI+ Quality update, which will be a great discussion on some dynamics, then the Pharmacy Interoperability and Emerging Therapeutics Task force, which is a really exciting one.

We will break around 11:10, come back for some welcoming remarks by Deputy Secretary Andrea Palm, as we mentioned earlier, and then, around 11:35, we have the Trusted Exchange Framework and Common Agreement, TEFCA, which is always a fun topic we like to talk about here. We will have lunch around noon. Around 1:00, we will have the Public Health Informatics and Technology Workforce Development Program update. We will break around 1:40, and at 1:50, we have the Health Data Technology Interoperability Certification Program updates and take a vote, which is a big one. As Medell's eyes show, our favorite topic here, the Annual Report Workgroup update, will be next. We will tell you how we have kicked that back off. We will go to public comment around 3:50 and end the day by about 4:00 with final remarks. Busy day.

Medell Briggs-Malonson
It is, but it is going to be exciting. So, we are going to go ahead and move on in to our first order of business. I would like to call a motion for the approval of the main meeting notes. Can I receive a motion?

Jim Jirjis
I move to approve.

Medell Briggs-Malonson

Excellent. So, there was a motion on the floor from Jim Jirjis in order to go ahead and approve the May 17th meeting notes. Can I receive a second?

Deven McGraw
Second.

Medell Briggs-Malonson
We will take the second from Deven McGraw. So, the motion has been properly placed on the floor, as well as seconded. I would like to open it up for discussion. Any discussion? Not hearing any, let's move towards the vote. All in favor of the approval of the May 17 meeting notes say aye.

Several Speakers
Aye.

Medell Briggs-Malonson
All opposed? Any abstentions? The motion is carried unanimously, thank you.

Steve Posnack
Can I make one programming note? I do not know if we have confirmed yet, but we may have a maximum number of microphones that can be live at the same time. Otherwise, it starts kicking off, which is what I think happened to Medell and Mike earlier, so if you are done talking, just try to keep good mic hygiene.

Medell Briggs-Malonson
Thank you, Steven. I like "mic hygiene." So, let's move on in to our very first presentation. This is going to be a very exciting presentation this morning. I would like to go ahead and introduce Anastasia Perchem from the Strategic Initiatives Branch Chief of the Office of Technology of ONC, and also our very own Eliel Oliveira, who is the Director of Research and Innovation at Dell Medical School, who will go over a bit more about some of our FHIR-Enabled Social and Health Informatics Platform. So, Anastasia, as well as Eliel?

FHIRedSHIP: Integrating a closed-loop social services referral system into electronic health records in Federally Qualified Health Centers using FHIR (00:13:52)

Anastasia Perchem
Thank you. Good morning, everyone. It is my pleasure to introduce Eliel Oliveira to present on the LEAP FHIR-Enabled Social and Health Information Platform, FHIRed-SHIP, integrating a closed-loop social services referral system into electronic health records in federally qualified health centers using FHIR. Eliel is the Director of Research and Innovation at the Department of Population Health at the Dell Medical School at the University of Texas at Austin, where he leads the Health Informatics Division. He also serves as a member of the board of directors of Connxus, the Central Texas Health Information Exchange, and is a member of HITAC.

Eliel was previously the Chief Information Officer for the Louisiana Public Health Institute and the Louisiana Cancer Research Center in New Orleans. He has a long history of supporting the development of data standards for use in healthcare clinical and research activities, and in his most recent work, which you will hear more about today, he and his team have implemented a FHIR-based social and health information

platform to test in real settings SDOH standards that are part of the USCDI to help inform future system design and standards development. Now, let's welcome Eliel.

Eliel Oliveira
Thanks, Stasi, and good morning, everyone. It is great to be here and see all of you in person for the first time after so long. I hope you are all caffeinated, that you got your coffee. I am not usually entertaining, so do not fall asleep, but you signed up for HITAC, so this is what you get. This is what we call FHIRed-SHIP, FHIR Social and Health Information Platform. As you can see, it is a LEAP-headed project that we started in 2021, and this is our team here that is working on the project. Next slide, please.

These are our partners. Again, ONC, thank you for supporting this project. Again, it built on years of work in central Texas that I will go over in a bit. These are our partners. We have Mental Health Authority, Integral Care, our FQHCs, People's Community Clinic, and eventually, as you are going to hear in a bit, we selected the Central Texas Food Bank to support us. They serve 21 counties in Texas, so it is a large operation. They were very critical during COVID. We are partnered with HIEs as well, Connxus being one, which is piloting this right now in real settings, and I will talk about the both the HIE vendors that I used to manage and the HIE in the Bergen Valley as well in Texas that is adopting the platform as part of the project. I am very thankful for the advice of the technical group EMI throughout the process, and we did partner with findhelp and Unite Us as well to help establish the APIs on their end. Next.

So, these are the aims that we had for the project. The first was to develop these open-source, closed-loop referral systems using FHIR standards and integrate that in real settings with the clinics, but as you can see, as well with our CBO to make sur that we can communicate directly with all involved. You are going to see in a second as well that the patients are a key part of that communication and coordination. The second aim was to then pilot the Gravity use case package. If you have not seen that, there is a great PDF online that they released that shows real example use cases step by step and what pieces of technology need to be in place to be able to allow that coordination of social services. Finally, the goal was that if we build this and test it, can we share it with others, and are other regions able to adopt it? So, that is why the HIE vendors in south Texas convened. They are doing that right now, taking the code to deploy and test it out. In their case, it is not going to be in real settings because trying to get an IRB to cover three regions was going to be too hard, but they will test it to provide us feedback on how that deployment went on. Next, please.

So, we **[inaudible] [00:18:16]** here from the Gravity Project. As you can see, in 2019, they started coming up with standards for all SDOH domains that are out there. It has been a lot of work, as you know, and they feed into the USCDI today, which is great, but there is quite a bit. Next, please. So, we are not really focused on just the security aspect in this pilot, so we will not get very granular, and you are going to see why, but as you can see here, this is why there are many to test, so our goal is to test how this works in a real setting, and I would love to see other programs trying to do the same thing. Next.

So, what are we allowed to do, then? We decided that we are going to try to pilot the full closed-loop referrals of the supplemental notation assistant program. We did not come up with that right away, so we talked to our clinical providers about what key problems they are faced with in Austin. Housing and homelessness was a key one, but very hard to deal with. The second one was food insecurity, but that accounted for about 80% of the referrals, so we thought that sounded like the best problem to address, and

that is when we heard from them what the providers of food service are in the region, and Central Texas Food Bank came up as the key one, given their size.

In discussions with the Central Texas Food Bank, we learned that they serve not only 21 counties and have several services, but 80% of their services are getting people just to sign up for SNAP because that provides the greatest value in the long term, so we thought that would be the problem to address. Besides the fact that it already serves millions of Americans, there are still over 30 million Americans that could benefit from such a program, so it made a lot of sense. By reviewing the literature, we learned that community-based organizations can actually increase access, and that is what the food bank does. They have a specialist there to help you with your application. But, these referral systems that we have in place have only marginally increased the access to about 68%, so we found that the research shows that data shared between the clinical providers and the social providers can improve this process a bit so that we can understand what is going on, and that is, again, why SNAP came about as the challenge to fix. Next.

So, why did we come up with the name "FHIRed-SHIP"? So, it is a combination of tools, one called FHIRedApp, which is another LEAP project that was awarded to **[inaudible] [00:20:58]** in 2019 that I will talk about in a bit, and the Social Health Information Platform, which is a platform that was funded by the Michael and Susan Dell Foundation in Austin, and we integrated it too so that we have something to actually test the real exchange of data through FHIR Gravity APIs. Next. So, this is the high-level view of the platform, and as we envisioned it, in order to be able to test these APIs that are so recent, we knew that EHRs are not necessarily going to be able to use them, or it would be too hard to integrate. The CBA may be utilizing all kinds of other systems. In this case, we found out later that the food bank used Salesforce, and so on and so forth. We brought in FHIRedApp so that the patients would be part of their own social care coordination.

And then, of course, there are the HIEs in the referral systems. So, the initial goal was that we knew that findhelp and others would basically plug into the platform, so we would know who had been referred to what and know that level of detail as well, but after six months or so, we realized that they were not going to have their APIs ready either, so we decided to then build this module, but in such a way that is modular **[inaudible] [00:22:16]** so that when findhelp and Unite Us are ready, they can just plug into the platform and deliver the same value. So, that is an overview of that platform. Can we go to the next slide quickly? These are the standards that we ended up testing throughout the process, and used the CORE IG questionnaire response and the SDOH clinical care IG as well, again, to match what is in the Gravity Project use case package. Next.

This is just a high-level view of how we have been working on SDOH coordination in central Texas for a while. You will see that even before 2015, the Michael and Susan Dell Foundation was helping build a school system coordination for social services that serves over 25,000 students today, but for a school system that has close to 100,000 patients. And then, with the creation of the Marcos School, we looked around and said, "Okay, how can we do the same as such a successful program, but in healthcare?" That is when we started with a pilot project in 2017, specifically for asthma, but I will talk to **[inaudible] [00:23:31]** and that led to the creation of a social and health information platform. The brown boxes at the end basically mean they are now transitioned from research to real application in real settings, so it is deployed at the health information exchange at the clinical sites, and folks actually use this.

The same thing happened with the funding from ONC that you see on the top in 2019. It filed **[inaudible] [00:23:53]**, which now is transitioned into real settings and is used in a few locations, and then, FHIRed-SHIP today combined with this. So, in order to think about those, we have the clinical tool, the patient tool, and now the CBA tool so that everybody is communicating in real time. Next.

So, just quickly here, back on this project so you understand where we got that data, the FHIRedApp was the API-based application patient engagement platform, and we say that because it is both a mobile and a web-based app where patients get access to their data as described in the 21st Century CURES Act. Next, as I said, as a patient engagement technology, what we were trying to do there is simply say, "Okay, individuals have rights to access their data, so how can we make that easy for underserved populations, and once they have access, how can they share that data with others without special effort?" You guys know that term very well.

So, that is why we started the design of this platform with our community members using community engagement studies, which is something that comes out of **[inaudible] [00:25:08]**. It is not like focus groups, where you meet one time and hear what people are saying. They become part of the research with us. They met with us for over a year and a half, explaining their needs, interests, and so forth, so we really met those communities' need to have such a platform. So, we met with African Americans, Latino Americans that are Spanish speakers and English speakers, and Asian Americans, so there were four groups over a year and a half **[inaudible] [00:25:38]** to be able to understand well what the challenges are for underserved community. And of course, we used **[inaudible] [00:25:44]** to get to the results we have. Next.

This is just a screenshot of those meetings. We started with FHIRedApp right when the pandemic had started. We had one meeting in person, then all the other ones were online. This is just to highlight that work. Next. This is how the platform was designed to work. What if we get the HIE the other time? Just think about 2019. None of them had FHIR yet, so let's transform the HIE data into FHIR first, put a FHIR server there, expose that, and then, as the patients come into the clinic, we are going to validate their identity, link them to their own data from the HIE, and deliver that data to them. Just keep in mind that this was done, and in order for us to aggregate that data from the HIE to be able to transform to FHIR, under research, we cannot have identifiable data, so there were a lot of tricks here to get data that was deidentified and then link that data, with the patient's consent, to be part of the project. And then, once they get there, they can share with the third-party apps, as you can see here on my screen. Next.

So, these are some screenshots. The app is available on iOS and Google Play. I have an article that we published in a journal about it, and you can see that the first few screens are about data access of your records, there are some tools, like communication message features that you can communicate with your clinics, but on the right side are the app plugins. That is where individuals would be able to share their data with others. We piloted two things. One was a study app, a way to recruit individuals into studies, and the second one was basically integrating with Aunt Bertha, which today is called findhelp, as you know. The way that that worked was you would start the plugin, and Aunt Bertha would ask you, "Can I access your ZIP code and your condition from your records?", and if you say yes, Aunt Bertha would send back the results of the list of services in your neighborhood that are very focused on rare medical conditions.

The funny thing here is that Aunt Bertha does not know who you are. It is just an API exchange. There is EHI, there is clinical data that is going around, but they do not know who you are. And then, at any point in time, if you do not want them to access this information anymore, you are going to start a plugin, and that access is gone. Next.

So, on a social health information platform, the vision is that we need something that needs to bring data from all sectors in one place so that we can build intelligent ways to help clinicians on how to take care of their patients, and that is tough. Next slide, please. You see here what that meant in the pilot project, which was about pediatric asthma. So, you can see there on the screen that it is a dashboard that is ingesting data to help clinicians care for kids that have asthma. We are basically ingesting data from EPA centers across central Texas and Weather.com, you see a map there, so you know the location where the kid goes to school and where their home is because that also can affect their symptoms. We do an assessment of the situation at home to know if they have mold or roaches or what is going on at home, but in synthesis here, all these pieces of information, as you can imagine, are not so safe to bring inside of an EHR.

There are many pieces of data here flying in real time, and second, they are in an EHR, so then it becomes a really hard problem to solve. But, the clinician, having all that summarized in this way, can make a decision more clearly on what is causing asthma attacks for that kid. It might mean that they need a new mattress at home or pest control service as opposed to new treatment. So, that was the vision of SHIP, and done in such a way that it does not interfere with the physicians. You may not see it, but there is a little popup in the corner of the screen, but basically, just by the clinician going into someone's record, they basically get the CDS, the clinical decision support. There is a little popup here that you can click to see the pediatric asthma patient dashboard. So, that is the vision, and that is what we were working on. Next.

With SHIP, we started combining data from findhelp, from needs assessments collected across the community, and are getting quite a few organizations, and then, the clinical data from the HIE as well to basically look at medications, visits to the doctor, admissions, and so on and so forth. Next. This highlights a little bit how much is going on there, so this is just a glimpse of the names of the partners that are fitting the data into the design, and again, this was initially a research project using patient-privacy-preserving solutions to be able to link the data and share those dashboards with consent, so it took quite a bit of work to get there. Next.

This is just a quick example. There are many dashboards like this that have been developed informed by communities, CHWs, and users. This one is just saying if a CHW opens this at the front desk, they can see which patients need to complete the needs assessment, which ones have been referred to something, which ones need a follow-up from the referrals that have been made, and so on and so forth. Again, there are several like this, but I am not covering all of that today. Next.

This is a very important slide. After combining all that data across a community, what we find, if you look at the yellow bar, is that between 50% to 70% of the referrals stay open. We do not know what happens to them. The reason for that is that the referrals are pretty much giving a phone number or email to the patients or maybe to the CBO and expecting that they are going to figure it out and that we are even going to hear that they actually got the services completed, so that is not necessarily the case. Next. Back to these, again, just remember that we are plugging all these organizations and individuals together through APIs, so it is real data flying in real time so we can analyze what is taking place. Next. So, if you think about it, there are

three legs of a stool. We are hoping for a fourth leg at some point, which will be Medicaid or other health plans, but we have the patient with the mobile app, the community health workers in the clinics with SHIP, and now the CBOs as well using SHIP as an application that allows them to coordinate. Next.

So, the first step in the process is that comes into the clinic. This is still a research project, so they come in, they need to be validated with their identity and who they are, they are linked to FHIRedApp, they have to consent to the research project, and then they are in. Next. The second step is instead of getting the community health worker to ask them questions and fill the answers into the needs assessment survey, we ask the patient to complete it themselves on their mobile device, and I can understand how folks can feel like the community health worker might be able to do a better job, but there are advantages. If you have the assessment done by the patient, if their needs change at that point in time, they can change them in the mobile app, and the community would know that the needs are changing across the community. They do not need to wait for somebody to show up back in the clinic to ask them the same questions again. Next.

So, the CHW receives the answers in real time on FHIRed-SHIP, they assess if the need is not being filled, and if so, they place the referral. Next. At that point, the CBO, the Central Texas Food Bank, receives the referral, and they have to accept because not every CBO has the capacity to accept all referrals. In their case, they do, but once they accept, that is when things start. The patient gets a survey of five or six eligibility questions on their mobile app that they need to answer before moving to the next step. Next. That survey, those five or six questions, are just trying to make sure we can proceed with this operation. These are questions like “Are you a citizen?”, which is a requirement for SNAP, “Does anyone in your family receive SNAP currently?”, and if yes or no, those questions are going to be sent to the food bank so they can make a determination that they can proceed with this person and meet in person in a scheduled meeting.

So, in the next step, two things happen at the point when they say yes to that patient. The patient gets a calendar tool in the app where they can select the date and time that they are going to meet with the community health worker at the food bank, and they can say if they need a translator, and if they do, then the meeting is an extra hour longer, and if they want to do it remotely or in person, and once they submit that, everything gets booked with the person they are going to meet, and the second thing is they are allowed to take pictures of their documentation that is needed for the application and upload it to the system so the food bank can start preparing so that when they meet, they actually have the documentation necessary. If they do not have all the documents necessary, then they have to communicate with each other until they gather the information before doing the meeting. Next.

[Inaudible] [00:35:08] here, the food bank has other services that they provide individuals, and they usually do another assessment of needs. In this case, because it is already captured in the platform, the food bank has access to that and can refer them to other services. The piece that is missing here is that we do not know when patients actually get accepted into SNAP. In order to do that in real time, they would have to have an interface with Medicaid. We are working on that with Texas Medicaid, but what we did instead was that we know that patients get a letter in the mail. The food bank does not even know if the patient received the services or not. They get a letter, and we can text them in about 45 days from when we expect that the letter came in, or after, and ask them, if they get a letter from Medicaid, to take a picture with the wrap-up letter so we can see if they are approved are not, and if not, the food bank can go back, talk to this individual again, and document these steps so that we know what is going on.

So, with all that said, the important thing that I want to do here to address the problem that I highlighted earlier is to get a grip on what is taking place, why we are basically hearing that people that are referred do not even know if they got the services or not, and for what reasons. Is it because they are ineligible to start with, because they do not have the right documentation to be able to apply, and so on and so forth? So, we hope that we get the knowledge necessary through an API-based system like this. Next.

I will leave this table here for you. I would love to leave some time for questions if we can, but this table highlights the things that I had in the previous diagram and what enhancements we have made in terms of the patient filling out the assessment themselves and seeing notifications in the app, and that may not seem too important, but the way that is done right now, that you track that there is actually communication between the CBA and the patient so they can be reimbursed is by getting a report from the CBA saying, "How many calls have you done? How many notices have you sent to the patient? Did you text them?" and so on and so forth. This would basically bring you to a platform where you can actually have real information of what the communication is at any point. Next. In the next slide, there is just another list of additional enhancements, the picture upload of the documents to kind of prepare the meeting, and the follow-ups I have done. Next.

So, this is just a screenshot. It is real, in real settings where we are recruiting patients into the study, and on the left side, you see that I screenshotted the mobile app, and on the right side, I screenshotted the FHIRed-SHIP. The community health worker can see everyone in a dashboard, where they are in the process, and what the next step is. Next. Some of the accomplishments that we feel we made so far, though the project is not done, were identifying those gaps and delays in the food referral and coordination in the workflow, so we did that workflow. We validated the FHIR IG for those, we helped with the Gravity standards with the real-world pilot, and we found some misalignments in terms of need assessment, and I will go over that in a second. It is a very important aspect of the learning here. We learned that tech improved their staff capacity quite a bit, and that is great. In addition to the advisory groups and disseminations, we believe those are great accomplishments, so we are talking to you here today and sharing this work. Next.

So, these are the lessons learned, that a truly closed-loop referral would require an individual case-by-case workflow analysis, and then technical development. What you just heard about SNAP is just about SNAP. There are several other food programs, and the workflow is likely going to be different. Electronic systems that support these referrals are even less prepared than we thought to be able to adopt this Gravity API-based solution. And then, the harmonization of needs assessment was something that we knew was there, but we did not really realize how difficult it was going to be. Next slide, which may be my last on that point.

This is data showing the questions and answers for a specific needs assessment for one of our providers, for PCC specifically. They have 36 questions, and we needed to match them with the Gravity standards to see which ones are part of the standard or not, and as you can see, we found 13 perfect matches with the questions and answers, four that were partial that we needed to figure out exactly what the answers meant, but 53%, the great majority, are not even part of a standard at this point, and to us, that was a big challenge, which means that in order for us to be able to report across our community, all these needs assessments are going to have to talk to each other. They are going to have to use normal language so we can know what the real problems are, and that means menial work, sitting down with the clinical providers to

understand what they meant by these questions and what possible answers we had in this standard that we can map to.

Now, you may think we can just get everybody to adopt the same assessment nationally, and that is a tough call as well. Keep in mind that many of these organizations have already integrated these into their EHRs, their data warehouses, and their analytics platforms, and stripping out the assessments of needs that they do today would be pretty tough. Harmonization in a vacuum may be a good thing, but in any case, we have the opportunity to possibly avoid what happened to labs. You may remember that back in COVID, we could not necessarily match labs very clearly because hospitals oftentimes did their labs internally, and they did not necessarily link. I know that well because, again, I helped build PCORnet, and we had a lot of challenges to normalize labs. So, before we get too far with SDOH, needs assessments are something that I think we need to think about in terms of data harmonization. With that, I think that is my last slide. The next one is references for you, and thank you so much again for having me.

Aaron Miri
Great job, Eliel. Thank you. All right, so, we have about seven minutes here to ask any questions, and Eliel, I will say congratulations again to you, your team, and your investigators. Excellent job. It also shows the power of the LEAP awards and grants that are available through ONC to really blaze new trails and do phenomenal, groundbreaking stuff, in Austin, Texas, in this case. So, with that, Medell, I believe you are first up with a question.

Medell Briggs-Malonson
Excellent presentation, Eliel. This is such an important topic, especially because we know the social drivers of health make up such a significant proportion of overall health outcomes. You mentioned some of the various different challenges, and this is work that all of us have to do throughout the country, and especially now that they are both mandated by our regulatory agencies and our accrediting bodies, but it is also good for patient care. What type of additional financial and health information support do you think that our community-based organizations need to have in order to make sure that we can use the FHIR APIs and also have that level of interoperability that we know is so incredible essential for this?

Eliel Oliveira
Thanks, Medell. Great question. I think there are probably different ways to answer that. The community-based organization incentive is one specifically. I think we are still in a chicken-and-egg situation where we know that SDOH impacts health quite a bit, but we have not done research that proves what specific programs, what the level of impact is, and what the finances involved are so that you can say, “Okay, for this specific challenge here, let’s incentivize this specific CBA this way.” I feel like many of the health plans are struggling because they do not have data that proves what the outcomes are and how that benefits them financially, so everybody is trying to understand how this is going to work.

I think one aspect is that there is some research already done, like you can find some research done that is really interesting on the SDOH outlier calculator from the Commonwealth group that shows articles that say for these specific food delivery services, there is a PMPN of about $530.00 a month for patients, and that makes it **[inaudible] [00:44:03]** that CBA that is delivering those meals that are in a very specific type of food service, we can incentivize them by this much, and by having a platform like this where they basically

watch everything that is going on in real time, that becomes even more important. So, **[inaudible] [00:44:20]** the CBA is really providing the services that are needed.

I think that a piece of this number is the fact that to implement a platform like this, as you can see, it is not the job of just the CBA, it is community work. There are the coalitions, the data aggregation, the governance of that data, where ONC has some great assets in the SDOH field that talks about that, so there is a lot that needs to come together in a community be able to incentivize CBAs to be part of this.

Aaron Miri
Wonderful, thank you. Again, we are running close to time here, so we have about three minutes left, so I am going to try to make this as fair as possible and do one question from each side of the room, if you can be brief. Hannah, why don't you go first, on the right-hand side?

Hannah Galvin
Thank you. Great presentation and excellent work. I am wondering if you have data on the completion rate of your questionnaire using the app and any comments on digital literacy and language barriers in that completion?

Eliel Oliveira
Not yet. So, we just started recruiting recently. We were supposed to start recruiting last year, but Texas came out with Texas RAMP, which is the equivalent of the FedRAMP for cloud environments, so we needed to make sure the platform was secure first before it released, so the recruitment just started. We will probably get some real results on that front towards the end of the year in terms of the completion rate. There was another piece to your question, Hannah.

Hannah Galvin
Just any thoughts around the use of the app in terms of digital literacy and language barriers in the digital device.

Eliel Oliveira
So, that is something that was addressed in the first LEAP Project in 2019, so we learned that folks really needed language access and they want trustworthy content, so that is one of the pieces of things that we did. We did quite a bit of work in terms of the human-centered design. That is what we did to test how simply we could interact with these individuals, so there was a lot of work on that. The app turned out to be a great tool to use, but there is still a lot to be done. Language is definitely one that everybody is asking about, but trusted content is as well.

Aaron Miri
Wonderful, thank you. One last question. Michelle, do you want to go ahead?

Michelle Schreiber
Thanks. Great presentation. These are really very interesting. Are these proprietary? Does the patient or the plan have to pay to participate? Part of the reason I ask is whether or not this is extendable to something like if the government can ask you or can support using these to close social-drivers-of-health loops or do patient-reported outcome measures, which we cannot do in proprietary services.

Eliel Oliveira
Right. As far as the platform itself, it is being released as open-source. In fact, ONC has the Git repositories in their hands. They are putting together some Twitter announcements there, so you should be getting that soon. I just will highlight, though, that we have a mobile app as part of the ecosystem, but it is not like a mobile app that is just push-button style. You are going to need some experts to put that together in the community to make it work, but it is open source.

Aaron Miri
Wonderful. With that, we are at time. Once again, please give a round of applause for Eliel and team. Excellent job. I know there were a lot of questions here, it was a great, great presentation, but I am sure he can take questions from you offline at some point. With that, I want to transition us over to Lisa Wagner and Ashley Hain to go through the USCDI+ Quality update.

USCDI+ Quality Update (00:48:02)

Lisa Wagner
I think I am supposed to test, right? Is that correct? Do I need to go closer? We are good? Okay, cool. Good morning, all. I had to switch my little notecard because it said "good afternoon," but it was a quick switch, and a first for HITAC in person. I think this is the first in-person presentation for me since the start of the pandemic, too, so it is good to see all your faces. My name is Lisa Wagner. I am a senior advisor in ONC's Office of Policy, and I am joined virtually by my colleague Ashley Hain, who is in the Office of Technology at ONC. We are here to present on USCDI+ Quality. I think it is a great transition from the previous presentation that is talking about interoperability needs, and that is what we are going to be focusing on here with USCDI+. We do have a few questions for the discussion at the end of the slide presentation, and it is going to be a fairly short presentation, so hopefully we will have some time for good discussion. Next slide, please.

So, USCDI+ was launched in the fall of 2021. It has been going on for about a year and a half, close to two years now, and it was really to address the extension of the need beyond USCDI for specific programs or use cases that do not traditionally fall into the USCDI space. USCDI+ is intended to establish standard data element lists and implementation guides to harmonize and align data needs across all sorts of partners. For the first part of USCDI+, we have been focusing primarily on Public Health, Quality, which we are here to talk about today, and more recently, we have also been looking into maternal health needs and cancer needs as well. Our current partners have included CMS, CDC, HRSA, FDA, and NIH within HHS, as well as a number of private partners we have engaged, and we really started this initiative based on the need for alignment. So, kind of what we were talking about a little bit around the needs assessment in the previous presentation, we are really looking to expand this work over time. Next slide, please.

So, USCDI+ is meant to be an iterative process just like USCDI, so we are intending to make changes on a rolling basis, and we are also intending to expand partners within and outside of government that are working in the same program area to include this harmonized set of data standards. Next slide, please. Now, we are focusing on Quality for the remainder of the presentation. ONC began working with CMS and HRSA to identify our USCDI+ Quality data elements for our initial data element list that we are going to talk a little bit about later in the presentation. We started working with CMS around their specific needs for their CMS FHIR quality reporting initiatives.

While quality measures at CDC are an important component of USCDI+ Quality, we have also looked to broaden some of that work as well, so we have engaged many other public and private partners in the quality measurement space who do support quality reporting and quality improvement. Over time, we do intend USCDI+ Quality to support quality measurement data elements for the broader quality community, including specialty registries, payers, quality improvement organizations, and quality improvement models. Next slide, please.

So, just to say a little bit about the creation of our USCDI+ Quality data element list, our first draft includes the review and analysis of both existing quality data elements and existing implementation guides, and we also looked at what is in the pipeline in these spaces as well, specifically to understand gaps, the overlap, and the need for harmonization across these different data sources. Next slide, please.

So, this slide is just showing where our current analysis started and where we are intending to go. We analyzed data from a variety of sources to develop our draft data element list. We have reviewed requirements for electronic clinical quality measures, or ECQMs, that are currently used in CMS programs. We also reviewed data elements included in draft and published HL7 FHIR implementation guides for various use cases, such as long-term and post-acute care, cancer, and federally qualified health center reporting, and we conducted a series of meetings with partners to understand their priority data elements in the quality measurement space. Next slide, please.

So, as USCDI+ Quality matures, we anticipate it changing the quality measurement narrative by coordinating measure developers and steerers to consistently and universally specify to USCDI and USCDI+ Quality so that gaps in harmonized quality measure data elements may be identified. Through the different meetings that we have had, we have heard a few different themes come out from them. One is the need for a standardized data element list to build out new quality measures, the need to narrow the data element list to eliminate redundant data elements, and the need for these efforts to support interoperability like USCDI, facility aggregation, and improved analytics. Now I will turn it over to my colleague Ashley for our next part. Next slide.

Ashley Hain

Thank you, Lisa, and good morning, everyone. Now we will turn to some additional USCDI+ Quality and how it applies in the real-world setting. Next slide, please. We released the first draft of the USCDI+ Quality data element list at the beginning of May 2023 for public review, comment, and feedback on the ECQI resource center. I would like to emphasize that this first draft is a starting point and has been based on work described earlier, as well as the data elements currently used in existing ECQMs from the CMS IQR and Quality Payments reporting program. We anticipate feedback on this draft set to include comments on data classes and elements, as well as gaps for what is missing and what can be added. Over time, we will establish a consistent review and publishing process similar to USCDI to build on this work. Next slide, please.

Here is a quick snapshot of what is included in the first draft of the USCDI+ Quality data element list. You will see the four columns, which include data class, data element, the level, and the source of the data element. Next slide, please. So, what is included in this first draft of the USCDI+ Quality data element list? There are several new proposed data classes, including care experience, outcomes, and communication.

There are also close to 100 data elements in this data element list that are not included in any version of USCDI, data elements such as medication administration and date of onset. There are also many data elements at the comment level that we are seeking feedback on important and potential burdens. Next slide, please.

We are requesting feedback from our government and industry partners on the draft data element list and welcome any and all comments. Please submit your comments and feedback on the ECQI resource center by June 30th. In particular, we are requesting feedback on the completeness of the data element list, keeping in mind that we intend to continue to build on the USCDI+ Quality data element list to build out a full quality programmatic data element list. We also want to know what level of specificity is necessary to make this data element list most helpful. Does this data element list provide clear guidance about data priorities that would incentivize the capture of data elements relevant to quality measurement within electronic systems? As we mature the USCDI+ initiative, we will provide additional details on how new versions are developed and timelines for comments, as this will be a transparent process, similar to our USCDI annual process.

Our current thinking is that we will have this initial six-week comment period, followed by a three- to six-month development for the next version, but we also encourage stakeholders to provide feedback on this cycle as a part of our comment on this initial draft. ONC will also provide an update on established process as we determine the specifics for the entire initiative moving forward. Next slide, please. This concludes our updates on the presentation, and we have a few questions here to help guide the discussion with the HITAC, including the level of specificity to consider, potential levers for advancement and adoption of these programs, and use-case-specific data elements and the frequency with which we should make updates to this list. Thank you, and I will turn it back to the room and our participants on the line for answers to any questions on the USCDI+ Quality data element list.

Medell Briggs-Malonson
Wonderful presentation. Thank you so much, Lisa and Ashley. We are going to open it up for questions. I see Ike has a question.

Steven Eichner
Thank you so much for the wonderful presentation. I have been working in USCDI and USCDI+ since both were conceived, I think. One of the questions I have, though, is it looks like you have a number of proposed elements that are Level 2 that I would consider probably to be on the USCDI regular roadmap. One thing that has been a concern of mine for some time is the relationship between the USCDI and the USCDI+, whether an element is supposed to be in one or can be in two, and how that gets resolved down the line if you are going down a path to things like medications, which are now in USCDI+ Quality.

Lisa Wagner
Sure. I can speak to the USCDI+ part of it. I cannot necessarily speak to what they are planning for USCDI, but from a policy perspective, USCDI+ is inclusive of USCDI, so even if it is not specified specifically on a Plus Quality list, the intent is that USCDI is included inherently.

Steven Eichner

But just as a very quick follow-on, there are elements here that are included in this initial draft of USCDI+ that are going to end up in the USCDI, so how does that get reconciled down the line? Are we going to see stuff listed in both places, or is there going to be a methodology for moving from one to the next?

Lisa Wagner
I think that is still to be determined, but I would say that the idea for USCDI+ is to identify these program area needs that might be missing off of USCDI. It is not to say that only USCDI+ Quality will be USCDI+ Quality. It is possible that those data elements can move into USCDI, as you are implying. I do not know the roadmap for USCDI, but I do not think one will be on the other or not on the other because the intent is that they will be inclusive of USCDI data elements.

Steven Eichner
Thank you.

Ashley Hain
We also have Beth Myers raising her hand as well, and she mentioned in the chat, "Please unmute me so I can support the Q&A."

Medell Briggs-Malonson
Great, and we will do so. Thank you so much. We were just working on that.

Lisa Wagner
I think Kyle has a follow-up. Kyle?

Kyle Cobb
Could I just do a follow-on to that? What you are asking really specifically is about the harmonization of USCDI and USCDI+, and as Lisa said, this is a new program. We are very much aware of the importance of the harmonization between these two data sets, and as USCDI changes and elements that are in Level 2, Level 1, or comment move, the USCDI+ data sets need to reflect that. And so, that is very much part of the program charge for USCDI+ and being able to balance those things, but at the end of the day, USCDI+ is an extender for USCDI, and so, there will always be elements of USCDI that are part of a USCDI+ data set. It just builds upon it, and it will reference USCDI.

Medell Briggs-Malonson
Thank you for that. We are also going to go directly to our Zoom. Beth Myers, you have your hand up as well.

Beth Myers
Sure. Actually, Kyle said most of what I was going to say. I was trying to support the Q&A for this particular session. I think the last thing for supporting Ike's question and how to think about this is going off of what Kyle just said, which is that we recognize that the USCDI itself has limitations on how quickly it can expand. You all are aware of this, we have been talking about it for a long time, and the task force has done a lot of work to try and figure out how to keep that balance, and part of the goal with USCDI+ is to accelerate that process.

So, as Kyle mentioned, there may forever be things that are showing up in USCDI+ data sets, both in Quality but also in Public Health, that are in the ONDEC system for the USCDI, but have not necessarily been incorporated into the USCDI "yet," which I will put in quotes, and Steve Posnack can kick me, and that we are intending to leverage the USCDI+ space that has harmonization across these different use cases to potentially advance that and put that out for a little bit further acceleration and a little bit quicker movement for more advanced use so that it can be made more ready over time more quickly for potential expansion into the USCDI itself. So, it is a thing to keep in mind. We do very much see this as an interplay, and not creating silos, but creating several new onramps to help accelerate the movement toward a broader set more quickly.

Medell Briggs-Malonson
Excellent. Thank you so much for that clarification and the future roadmap. Anna, did you have a question as well?

Anna McCollister
Yes, I do, and I just want to make sure I am understanding this. Quality measures are incredibly important. I have done NQF advisory committees for about 12 years at this point, and now we are migrating to Patel. I come to this as somebody with Type 1 diabetes and all its complications, so I use a lot of things that generate data outside of the clinic, and I spend very little time in the clinic, but to date, none of that data could be incorporated into any of the quality measures, which is very limiting when you are talking about a disease like diabetes, hypertension, or other things. So, that has been a huge frustration for me for the past 12 years, and it is still frustrating to me that we have not figured out how to incorporate home-based data collection. So, would this be an opportunity to introduce those sorts of new data classes and elements into the process that could then be used to actually develop a more meaningful quality measure?

Lisa Wagner
I think we are open to any and all comments, so if you do have specific data classes or elements that you would like to propose, please do submit them through comment and I will make sure I note down your comment here as well. We have been working with NQF as well, and I think we intend to continue to work with them, so maybe there are opportunities to see what other groups we can tap into there to make sure that we are getting different perspectives.

Anna McCollister
For some of the stuff, the clinical utility of the data is actually less important because device companies have come up with hacks and ways for doctors to be able to see the data, and the community has come up with different hacks, but none of that will get considered for quality measures until it is actually incorporated into these data classes and elements, so that is a significant concern for me, and if this is a great vehicle for doing that, then I would love to let people know.

Lisa Wagner
Kyle has hers up for a follow-up.

Kyle Cobb
Just to follow on, I think you are hitting the nail on the head. USCDI+ Quality allows us to expand the available data elements beyond what we have right now for ECQMs, and we did work with the CORE

Measure Collaborative at NQF, as well as the care coordination for Jerry Lamb's committee, but we had worked with them early on when we were setting up USCDI+ to really understand these other possible data elements. Again, to Lisa's point, if you do not see them within the proposed or the initial draft data element list, it is important to put them in and get them on our radar.

Medell Briggs-Malonson
Excellent. Thank you all so much for that. I see Steven, Clem, and Michelle, and we only have about 10 minutes left, so I want to make sure we fit everything in. Steven?

Steven Lane
I just wanted to respond to the specific questions that you have raised here. Having been also involved in the USCDI process since its inception, we have spent a lot of time establishing what is the level of specificity necessary to add a data element to the USCDI core, and I think it is important that USCDI+ utilize similar standards. As you say, it is kind of a policy decision as to whether something is included in core or Plus, and in my opinion, they should advance together on the same annual cycle once Plus is well established, but similarly, I think the level of specificity for an element should be the same so that it can easily be moved from Plus to core when that is appropriate.

I gather there is not a lot of cross-membership between the Plus team and the core team, but ideally, they should be working off the same protocols, standards, and timeline so that as it is appropriate, and of course, Quality is just one piece, but there are also lots of really interesting domains within USCDI+ that I think a number of people would like to see brought into core over time, so having it all ready to go so that more work does not have to be done to then move it over from one to the other would be really helpful.

Medell Briggs-Malonson
Thank you for that comment, Steven. Let's go on over to Clem.

Clem McDonald
I would like to just point out that the quality rules are a lot different than the static data elements. It is not just a diabetes measure, it is readmission rates within 24 days, and they are often statistical, so I just want to make people aware that they are not just the same thing as some simple data elements.

Medell Briggs-Malonson
Excellent. Thank you for that. Michelle?

Michelle Schreiber
First of all, thank you for all the work that has been done. CMS is very excited about this, actually, and our hope is that the USCDI+ for this becomes part of USCDI because frankly, that is the authority to make sure that organizations are using this. It is that authority that we need through certification, so the hope is exactly that, that they will transition forward. I think your point was great. As we think through the next round of what quality measures of the future look like, we have been having discussions of how you include things like downloadable device data, and I think maybe organizing this into a category for USCDI+ might be a way to start. Finally, just building on this harmonization, I also want to put a plug in that there are many USCDI+es, and more are developing, so how is ONC going to address the harmonization of USCDI+ for quality, cancer, public health, research, and so on and so forth, and how do those all move forward in a

timeline, and how do those then funnel up into the USCDI core, which, again, is where, for all of us, the certification and the statutory authority comes? Thanks.

Medell Briggs-Malonson
Great points. Did anyone want to respond to that?

Lisa Wagner
I will defer to Kyle on that. Thank you.

Kyle Cobb
Sure. Yes, we have harmonization of USCDI+ on our radar as well, so, in July, we will be launching a USCDI+-specific website that will look at ONDEC as well, but it will have the data element lists. We will start with public health and quality, and I believe there may be some other domains that will be added as well, but there are others that are coming soon. All of those new domains, again, are harmonized across, so there will be things like metadata for each data element where you will be able to see the breadcrumbs, that it appears in this domain and that domain. We will also have information about leveling and how it relates to USCDI, so I think it will be at least comprehensive enough to get us started with understanding how the harmonization of these data elements work.

Medell Briggs-Malonson
Thank you for that comment. Jim?

Jim Jirjis
Just a quick question about the USCDI standards version advancement process and USCDI+. Do those interdigitate, or is it more orthogonal how USCDI+ might actually enter into becoming a USCDI data element?

Lisa Wagner
The answer is yes. Oh, go ahead, Beth.

Beth Myers
I can jump in. So, the standards version advancement process is a policy construct for certification, so if there are things that are an updated version of USCDI, those elements may be incorporated into USCDI+, and if you look at the current draft data list that is up, you will see that there are some of the draft Version 4 elements crossed over and that are included in USCDI+. So, USCDI+ is not yet part of certification; however, those elements that are crossover would be part of a standards version advancement as we move those versions forward through that process, so it is just something to keep in mind, that they definitely interrelate in the manner that we were sort of talking about with Ike's question earlier, but that the SVAP process is also specifically related to the certification program so that if a developer voluntarily moves forward, they are essentially updating criteria leveraging those data elements, and there are certificates to say they are using the new version.

So, it does not create a knockout scenario, like when standards version advancement for draft 4, for instance, would move forward, it would not knock those elements out of USCDI+ Quality, again, because we want USCDI+ Quality to be based on the regulatory construct plus the things that are needed for quality

because it is not yet, and I will say "yet" so Michelle does not kick me either, incorporated into certification for quality measurement at this time.

Jim Jirjis
But if you had a USCDI+ element that you thought was a candidate for certification, it would go enter that same standard advancement process, correct?

Beth Myers
If it is in a USCDI version, then the USCDI version is actually what would trigger that, rather than USCDI+. If, at some point in the future, we have adopted a version of USCDI+ into regulation, then yes, it would fall under the same pathway, and to Steven Lane's point earlier, we are seeing these as similar pathways and thinking that we should be leveraging the same constructs.

Medell Briggs-Malonson
Great, thank you. We have Steve now with another comment as well.

Steve Posnack
The other Steve. I am happy being the other Steve. So, unsurprisingly for HITAC, many of you are asking vision questions, and this is something that we have thought deeply about in terms of both curation and maintenance of USCDI, which I like to call prime as a Transformers fan, as the staff can attest to, so for USCDI+, as there are different domains, which you could view as verticals or whatever other metaphor you want to use, at its heart, USCDI+ is a coordination service for the rest of our federal partners, and that is us executing on our mission because as Michelle mentioned, there is working going on in Quality.

We are also doing USCDI+ Public Health and working with HRSA. I guarantee you there are data elements that are the same in name and spirit that are the "same" across those three domains, but they are not the same, and that means coordination for the beneficiaries of those programs and the people doing the work, and that is a lot of the behind-the-scenes effort that we do with our federal partners to say to everybody, "Hey, all of you have specified this data element, you all want it as part of our USCDI+, but actually, we need to work on harmonization among those three sets, and then equally look at it and ask if it is relevant to be a regulatory baseline to raise everyone's expected guarantee that USCDI prime provides?" That is part of the vision going forward, so there will be these opportunities.

If you look at USCDI prime as the trunk of the tree or the main part of the river, there are other streams feeding into that as they mature through the USCDI+ process, so you can look at the USCDI+ data sets, and I do not want to use a baseball metaphor here, but as the triple-A field teams, which are major league for their own purpose, like USCDI+, but as they feed in certain data elements, like certain players, into the main USCDI prime, that is one thing we have to work on in terms of cycle, timing the maturity cycles with our federal partners to make sure that, as they want to reference them in their programs, to the point Kyle and Beth made earlier about acceleration, all of you know, since you have been neck deep in our regulatory work, that takes a number of cycles, and it takes years to put… USCDI Version 1 just went live this year, right?

We regulated that three years ago, so there is a difference between putting it in USCDI prime and the regulatory impact versus CMS working on measures at NQF right now, and we can use the USCDI+ data

set that everybody agreed on and build those out into annual measure updates. So, there are different cycles that you can look at in the spirals of life here that each of them serves a purpose for.

Medell Briggs-Malonson
Excellent. That is a wonderful way for us to wrap up this discussion, so thank you all once again so much for giving us the update on this. We are going to transition directly into Tricia Lee Rolle, who will speak about the Pharmacy Interoperability and Emerging Therapeutics task force updates.

Pharmacy Interoperability and Emerging Therapeutics Task Force 2023 (01:17:58)

Tricia Lee Rolle
Thank you so much. Good morning, everyone. I hope my audio is clear for you. I gave a presentation on this last November, just orienting us and introducing this topic, and it is my privilege and pleasure to return today to charge the HITAC with forming this new task force on pharmacy interoperability and emerging therapeutics. We got overwhelming interest. On the next slide, I will share with you our current roster, and we are really excited because there is a wide depth of expertise here. You will note you will be able to find bios for individuals on the HITAC membership website for this task force, but we were really so thrilled that our existing committee members volunteered for this in addition to a number of external SMEs.

I want to thank ONC leadership and our HITAC committee staff for the work that they spent in reviewing and vetting individuals, and at the end of this presentation, I will also share more information for individual HITAC members who may still be interested in joining on how they can do so. You will note that our number of external SMEs is limited and capped by the number of HITAC committee members that participate, but overall, I think that we have a great roster for this task force. As I make this charge, I will just be reorienting us to the different tasks and our goals, and then I will wrap up by sharing the work timeline for the task force. Next slide.

The overarching charge for this new task force on pharmacy interoperability and emerging therapeutics is to identify recommendations to support interoperability between pharmacy constituents and the exchange of information necessary for medication management, patient safety, and consumer engagement. Our recommendations will be due on November 9th, and specifically, we have four areas to cover. The first is on public health emergency use authorizations and prescribing authorities. In the short term, we want to identify critical standards and data needs for pharmacists and interested parties to participate in emergency use authorizations and emergency interventions.

We want to also understand what actions ONC can take to support data exchange and support public health emergency use cases. For example, we saw and learned a lot from COVID, and we are still learning a lot from that, about how we can better enhance public health infrastructure and integration with pharmacists. Looking long-term, we want to think about that as well and have recommendations on what we can do to support pharmacy systems and their use of data for public health surveillance reporting and different public health interventions. On the next slide, I will review Tasks 3 and 4.

Our second charge is to identify opportunities and recommendations to improve interoperability between pharmacy constituents, which includes a whole list there in parentheses, the prescribers, pharmacists, PBMs, dispensers, payers, everyone, for how we can really get better at pharmacy-based clinical services and care coordination. Specifically, what can ONC do to help facilitate the adoption of standards that are

needed to exchange to support these pharmacy-based clinical services, what priority pharmacy use cases should we be focusing on, what technology gaps exist for pharmacists to participate in value-based care, and what can ONC do to address drug inventory transparency for prescribers and consumers? I will pause on this one because this is new since the last time I presented this.

So, in November, this had not really been on our radar to this extent, but we really recognize the importance of this task force and included this. We want to better understand what ONC and industry at large can do to understand as far as transparency in inventory for end users and consumers. So, we are aware that there is a whole thing right now with drug shortages, and we are talking about being able to educate patients, providers, and consumers in real time that if you have a prescription, is it available at the pharmacy of your choice? How can we better understand the data needed to make that a reality? Our third charge is to identify standards needed to support prescribing and management of emerging therapeutics. This includes the following: Specialty medications, digital therapeutics, and gene therapies.

Lastly, we want to identify policy and technology needs and considerations for direct-to-consumer medication services. It is a whole lot, but we know that those individuals that are shared on the previous slide are really up to the challenge and up to this charge. On the next few slides, I will briefly give some more background on why these specific things are so important. First, when we consider public health emergency use authorizations and prescribing authorities, we have the real example of what has really been happening right now with COVID-19 treatments. What is shown on the screen right here is an example of a fact sheet from one of the emergency use authorizations for one of these COVID-19 treatments, and this particular emergency use authorization allowed pharmacists to prescribe this treatment to patients, assuming they have access to certain information about those individuals' medical histories. This particular treatment has received FDA approval.

However, the emergency use authorization is still in place for children and certain other populations, so, as you can imagine, thinking about public health emergencies, it kind of complicates the landscape for pharmacists and prescribers navigating how to get patients on treatments when we have prescribing approvals as well as these prescribing authorities, for example. Next slide, please. Here is a bit more information about why we have this second charge included. If you really think about where we are with moving from transactional exchange, which is really the ubiquitous use at this point of electronic prescribing, to where we really want to go, the goal is coordinated care. The goal is having information at the point of care for any healthcare provider to really act on it to make sure we are maximizing patient outcomes.

If we think about pharmacy interoperability, we are just kind of right in the middle that we have clinical pharmacy services that are being provided, whether it is through collaborative practice agreements, through blanket standing orders that some states put in place, thinking about here in the District of Columbia, the role of pharmacists in prescribing and managing certain birth controls or other types of reproductive health medications for patients, and so, you look across the country, and different jurisdictions are doing things a little bit differently, but one thing is clear, that more and more pharmacists are delivering clinical pharmacy services, and we really want to get to a place where it is coordinated, that it is not happening in silos, and that it is really integrated very well into what is happening with a patient's primary care physician team. Next slide, please.

Here is some more information on why we have this third charge, looking specifically at specialty medication, digital therapeutics, and gene therapies. It is pretty exciting that medicine changes and evolves, and we live in an era where there are all kinds of cool and amazing things that are coming out, and we are really seeing the ability not just to treat and manage care well, but also to cure disease and to really change individuals' lives. And so, when we think about specialty medications, it is maybe about two to four percent of prescriptions overall, but about 50% to 60% of drug costs. When you look at Part D spend particularly, it is about 40% of new Part D prescription and 88% of CMS Part D costs, and so, it is a huge, growing area, but most of that prescribing takes place through fax, portals, and limited electronic routing, and we do not want that. We really want things to be more seamless, like what we see with e-prescribing in general.

When you think about digital therapeutics, there really is no standard definition, but yet there is increasing use of not just sensors and devices, but software that helps manage illness and disease. Gene therapy is growing and growing. FDA has previously estimated that there could be as many as 10 to 20 new gene therapy approvals in the next few years, and so, these are therapies that are really going to require more of our attention when you think about how they are prescribed, how they are managed, and how data on them is available in EHRs or health IT in general for the whole care team.

On our next slide, I will share a bit more background on our final charge, looking at direct-to-consumer medication services. We think this one is really important because we want to be consumer-friendly, we want to be patient-centric, and we want to remove barriers to care and access to care, so there is this whole area now where there are ways, maybe through telehealth or even just these messaging platforms, that you can get prescriptions to your door. In some cases, it is meant to be discrete, in other ways, it is just meant to be convenient, but we want to understand, as consumers continue to use these types of direct-to-consumer medication services, what information should be available to the rest of the care team on what those patients are on, what they are taking, and how they can better manage them as a whole.

As we wrap up on the next slide, if all that sounded quite wonderful to you, there is still time to join this task force. Please contact Mike Berry if you are a HITAC committee member and you are interested in being a part of this awesome, historic work of the HITAC committee. Please let him know. That will also allow us to potentially add more external SMEs as well. You will see that our plan right now is to have this meeting on Wednesdays. We are going to kick off next week on the 21st, and periodically, we will have updates to the full committee, the first update being on August 17th. So, with that, I want to thank you for your time. I am super excited. I will be serving as our task force staff program lead. I am very much looking forward to working with all of you on these specific charges and to the wonderful recommendations that we can expect to share back with the full HITAC in November.

Aaron Miri
Excellent job, Tricia. A round of applause for her, please. Thank you for that. We have about four minutes or so before our very important break, so let's take a couple of quick questions. Hannah, I see you are up first.

Hannah Galvin
Thanks. Tricia, I am really excited about this work. I wish I could be a part of the workgroup, but is there any thought about having pricing transparency in the scope? I see that there is inventory transparency. Any

thoughts around 340(b) availability and other pricing transparency to be in scope for this work, or is that out of scope?

Tricia Lee Rolle
Specifically, it is out of scope. I think that with our co-chairs, Shelly and Hans, who I should also thank for volunteering to be co-chairs, I imagine we will have a parking lot for things that are important but not in scope. I will mention that we have the current HTI-1, and the RFI is out right now on real-time benefit tools, and there are opportunities in there to make some comments on transparency issues broadly, but because there are some other vehicles where we can get feedback from the public on transparency-type issues, we are focusing this task force on some areas that we think are really unique that we really need that expert guidance on. So, you are correct, that would be out of scope for this, but we would be happy to note if the task force wants to put that in a parking lot.

Aaron Miri
Great, thank you very much. Next up is Deven, and then Clem.

Deven McGraw
Thank you for this great presentation. I recall that when we first discussed forming this workgroup back in January at one of our first meetings, pharmacogenomics was a topic, but I do not see it on these slides. Did that also get pushed to the side or considered to be part of another task force?

Tricia Lee Rolle
Great question. So, that is Charge No. 3, where we talk about emerging therapeutics. It says, "including but not limited to," and we just specifically call out specialty medications, digital therapeutics, and gene therapies. If the task force finds areas of emerging therapies that should be discussed, you can bring those up. I would imagine that in the discussion on gene therapies that the issue of pharmacogenomics would be relevant there.

Deven McGraw
Well, yes and no. I guess it depends on the definition of gene therapy. I am in the workgroup, so we can take that up. I will not take any more time.

Aaron Miri
Great observation, Deven. Excellent. Clem, wrap it up for us.

Clem McDonald
I just had to clarify what was meant by "direct-to-consumer treatments." Is that when the patient goes and buys it off the shelf over the counter, or is that where you leave out the physician, and the pharmacist prescribes it?

Tricia Lee Rolle
Great question. We were really looking for a catchall phrase to encompass this, but really, what we are talking about is there is a whole host of services that are available online or through mobile apps where you can request a particular medication or you input certain symptoms that you might be experiencing. You may or may not have a conversation or video conference with a prescriber who would then allow you to get

that through the mail. So, this is not the usual workflow for going into a physician or prescriber to get care, but really, there is just a whole area that people are inputting symptoms, may or may not speak to a clinician, and are then receiving medication to their door. A lot of this is happening around sexual and reproductive health needs. STD and STI treatments are one large area where this is happening, and erectile dysfunction is another area where this happening a lot, but again, there is a lot of marketing to different groups that might want to receive certain types of treatments and not have to go into a provider to do so.

Aaron Miri
Thank you, excellent. So, with that, we are going to hold to time here. We have a 10-minute break, but I will ask you to be brief. Try to be back in your seats about a minute or two before 11:20. We do have Deputy Secretary Andrea Palm coming to speak with us. We want to be respectful and give her the full floor and the full time. So, with that, we will go to break. If your mics are on, please turn them off. Recording will still continue, but your mics need to be off. Thank you, and we will see you here in nine minutes.

Break (01:33:32)

Michael Berry
All right, welcome back, everybody, from our short break. I am going to turn it over to our co-chairs to kick off our next segment.

Aaron Miri
Absolutely. I am pleased to introduce Dr. Micky Tripathi, our National Coordinator, to give his remarks.

Welcome Remarks (01:33:43)

Micky Tripathi
Great, thank you. I am going to be very brief because I am really delighted to introduce Deputy Secretary Andrea Palm. Deputy Secretary Palm has a very distinguished and long resume. I am not going to go through all of it, but just to go back two chapters, she is the Deputy Secretary of the Department of Health and Human Services, obviously. Immediately before this, she headed the Department of Health and Human Services in the state of Wisconsin, and before that, she served under President Obama and Vice President Biden, both in the White House as well as in the Department of Health and Human Services.

I will say that Deputy Secretary Palm has just been tremendously supportive and helpful in providing ONC and me personally support and guidance in almost everything we are doing, both with respect to building the department itself, everything from the health IT alignment policy, and also, I cannot think of a time where we have asked for her time for something and she did not make the time, including two days ago, when she was standing right here, speaking to our staff. So, she has been tremendously supportive, and has also been really supportive in all of our mission activities as well. So, let me get off the stage here and introduce Deputy Secretary Palm. Thank you.

Andrea Palm
I am a little bulkier than maybe this is allowing for. Good morning, everybody. Thank you, Micky. Thank you to the co-chairs. Thank you to all of you. I understand it is your first in-person meeting since pre-pandemic. That is fun! I really am pleased to be here, and I really want to thank all of you for your contributions to this advisory committee, and it is such a beautiful day. I really appreciate the excuse to walk across the street

in the sunshine and spend a little time with you. I so rarely get the chance to get up from my desk and go other places, so I do appreciate that. I want to recognize that you all have full-time jobs, and that this is a volunteer endeavor for you, and that the work you do for us, the advice you give us, the guidance, and the engagement is above and beyond, so there is much appreciation from us at HHS for doing that work with and for us. It is really important that we have external voices, experts, and private-sector partners who can help us do our work smartly, more efficiently, and in the right way, so I appreciate that.

To that end, I do not need to tell you what you all have been doing, but the productivity of this advisory committee since its inception is quite remarkable, and I really do appreciate all that you have done to help with the development of TEFCA, all the regular rulemaking, our certification program work that you have done, and info blocking. The book of business that ONC has is much larger than it was during my previous tour of duty here, so I am sure that the volume of work that you all are doing in partnership with us has also increased.

Obviously, we live in this world now that was like the before and the after, and we think a lot now about how we do our work in light of what we experienced with COVID and what lessons we can and should take from that experience, and one of the things we learned here in government, both at the state and federal level, that while necessity is the mother of invention, the muscle we built around working together and needing to do that work in a different way is something that, since my return to HHS, I really have tried to institutionalize and make sure that we do not fall back from the muscle that we have built. It is easier to do the work in the individual pathways, but we do the work much better when we lift up leverage against each other and do the work together, so from my perspective, one of the most critical things that we proved was that we could do that work. It is harder work, but we can do it differently and better in that the outcomes and the way we serve the American people is enhanced in doing the work in a more connected and leveraged way.

Beyond that, there are the lessons we all talk about, but how do we think about the other things we can and should be doing coming out of the pandemic? We are faced with things like artificial intelligence and advanced analytics. How are we, as a department and your assistance, thinking about how we mitigate risk and maximize potential? How are we thinking about our data initiatives more broadly? Again, we learned we can build systems that allow CMS, ASPR, and CDC to work better together, whether it was nursing homes, hospitals, or surveillance? The things we learned about the way we use data and how to do that better and in a more integrated way are things we should double down on. What is the next turn of the crank to get human services data more integrated into those systems? Again, when we think about putting the people at the center of what we do, how do we marshal all our resources to do that kind of work better?

One thing I lose a lot of sleep about that is different from the last time I was here is really in the cyber space and how are we as a department not only thinking about the data that we hold and the trust that the American people have placed in us around the privacy of that data, but also how, we a partner to the sector, are we leaning in and leading so that hospitals or healthcare infrastructure are best positioned to serve their patients, to protect their privacy, to not have to go on diversion because of ransomware, etc.? So, how do we as a department, again, lift up and do the work with the partnership in this sector in this space so that the health and wellbeing of all the people that we serve can continue to move in the direction that we need it to? Again, that is all fundamentally based on the forcing mechanism that was COVID about how we do our business here at the department.

So, I am very excited about all of those opportunities. Those are spaces where ONC and the work of Micky and his team live, and the way they have leaned in to provide guidance and expertise to the department as we have tried to think about these issues has been very, very helpful, and I know that they stand on the shoulders of this advisory committee and all that you bring to the table for us. So, beyond how I think about looking forward and the really exciting opportunities we have to do work better and differently, again, I think it is really important for me to acknowledge, as volunteers, all the progress we have made over the last year with your guidance and input, and I noted TEFCA, but it is no small accomplishment that we have seven organizations which have networks covering so much in the healthcare sector, such as hospitals and tens of thousands of providers, that process billions of transactions across all 50 states. That is a significant bit of progress, and the QHINs and that advancement are an important thing for us to acknowledge and build on.

We talked a little bit about Proposed Rules. We really have thought about how we think about, again, based on pandemic experience, the public health piece of our health IT infrastructure and how we bring that more into what has traditionally been an EHR-based model, and that work is really important for our preparedness and for thinking about how we put people at the center of what we do, and we have made significant progress there, and we are grateful for your input in that space as well.

Micky noted our health IT alignment policy. I think it is important for us to walk the walk. If there are going to be standards in certification, we ought to insist that the products we purchase, the ways in which we move our money and our contracts, and the leverage that we have as a purchaser at HHS reinforces those requirements and helps us move the ball, move the market to a place where we are more integrated, where data flows more easily, and where we are, again, walking the walk as it relates to this work.

I know we will benefit more from your guidance and input. I am grateful for that. I know we have upcoming Proposed Rules on prior authorization, we have more info-blocking work to do coming out of the 21st Century CURES Act, and Micky and the whole HHS team have really been thinking about how we center equity, and so, ONC has really done important work in health equity by design to ensure that our health IT benefits really are equally felt across this country. So again, I just want to thank you for coming together, for volunteering your time, and for participating in these really important efforts. I have a true soft spot for the work of ONC and the way it fits into the broader work of the department. It very much is glue for us, and this is enabling to the way we do our work better. So, I really do want to express my appreciation to you and to the ONC team, and with that, I am happy to turn it back over to the co-chairs, and I serve at the pleasure, so if there is anything additional I can do for you, please let me know.

Aaron Miri
Wonderful. Thank you very much.

Medell Briggs-Malonson
We would love to ask questions, but we were told you have a short limit on time.

Andrea Palm
I do not control my life!

Medell Briggs-Malonson

Thank you, deputy secretary. We really appreciate you.

Aaron Miri
Thank you again.

Medell Briggs-Malonson
Wonderful. Well, that was a great, wonderful treat that we had, so we are going to go and continue on with our agenda, and also bring up another wonderful, esteemed colleague as well, Elise Sweeney Anthony, who is going to give us a quick update with the rest of her team on TEFCA.

Trusted Exchange Framework and Common Agreement Updates (01:45:13)

Elise Sweeney Anthony
Thank you, everyone. As was stated, I do not know about "esteemed," but I am Elise Sweeney Anthony, the Executive Director of Policy here at ONC, and if you all know me, you know I love my job, and one of the things I love talking about is TEFCA. The reason why is we have come so far, and even before the CURES Act and thinking about how to approach governance, how to approach the flow of information and the exchange of information, to then having TEFCA as part of the CURES Act, and then going through a process of getting feedback initially on broad concepts of what is helpful and where the gaps are, and we did that through public engagement, and I have to say that ONC, we truly believe in that engagement.

We believe in engaging with the public and with those who are working on the ground, and all of that advance work, the drafts that we put out, the early drafts, if folks remember going all the way back to the minimum required terms and conditions, to where we ended up in terms of January 2022, finalizing, and having in place a common agreement in the *Federal Register*, formal, legal language that can be signed onto between the RCE and QHINs. It is an amazing place, and I know that given how we are pushing toward to our deadline of moving forward with QHINs, sometimes I just want us to stop and think about the process, how we got here, and how much public engagement there was to make sure we are putting together a product that is viable and will actually help people receive care, engage, and have the information they need as part of the landscape.

So, it is a very exciting place where we are. As of January 2022, we have now this common agreement, and as we go through the process of implementation, as we say, we are very fortunate to have the Sequoia Project as our recognized coordinating entity, who is working not only with the public, but also the QHINs, and that is on both sides of it because the common agreement lays out not just the legal concepts, but it embodies the policy of what we want to see in terms of supporting trusted exchange, and then the technical framework that makes that a reality, that translates that into the actuality of information moving from one place to the other, what are the means, what are the reasons why, the purposes for which that can happen, and how we are going to do that. So, we are in an exciting place with seven QHINs now in the process for onboarding, an amazing place, so we are really excited about that. As the deputy secretary noted, the expanse of coverage just in those seven potential QHINs is really exciting.

I just wanted to start by thanking not only Mariann for the presentation she is about to give and the Sequoia Project, but also for the informed engagement of the HITAC over the years. TEFCA as a concept, TEFCA as a body of policy and technology, has been brought to the HITAC on numerous occasions to get feedback and help us build to that final document, and we really appreciate that engagement. So, we wanted to make

sure in our first in-person meeting in quite a number of years that we had an opportunity to share with you the progress that has happened and what is also on its way. With that, let me turn it over to Mariann.

Mariann Yeager
Thank you, Elise, Micky, co-chairs, and all of you for inviting us to speak with you today. I do have a colleague, Alan Swenson, who is joining us remotely. I have had the pleasure of leading the RCE team for the past four years. I actually remember a kind of funny call with Mike Berry where he told me we were awarded the contract, and I think I was getting school supplies for my kids, and I ran out to call back. It is remarkable progress, and it is not only an honor to serve in this role, but it is a true pleasure to work with such an amazing team at the ONC on the RCE, and it is through that collaborative spirit I think we have been able to make such progress, not only doing something that has such a hefty vision for nationwide interoperability, but has also been tempered with a heavy dose of practicality, and if you want progress in our world, that is what it takes.

So, I think Micky was laughing and said, "Oh my gosh, we only have two slides!" Well, we would keep it as a roundtable, we can provide color on any number of topics on anything that may be of interest, but before we do anything further, if you go to the next slide, I do have to share the disclosure that we are working with ONC under the auspices of a cooperative agreement, so anything we say here is not an official position of the federal government.

So, if we go to the next slide, what we thought we would do is talk a little bit about where we are with respect to working with those who are interested in seeking this very special QHIN designation status, and I do not know if anybody here has taken the time or has the interest of reading the really extensively detailed onboarding and designation SOP, but if you did not, it is a rigorous, rigorous process. It is not for the faint of heart, and the reason is that QHINs, once designated, will have a very special government-designated status, and that means they have to have the level of trust, performance, and rigor that you would expect for a backbone. Just like we expect for telecom and banking, this is our version of that for healthcare.

So, the process starts with an organization having to submit a letter of intent to apply. This is how they officially get gated into the process and have a call with our team. There are five organizations who expressed an interest and intent to apply, and after looking at it, they thought this was not really for them. Maybe they did not understand what TEFCA was about, so they are inactive, and at some point in time, we do cycle them out. So, there are three perspective applicants that are working on their process, working actively with the RCE team, and submitting an application. Right now, we do not have any applications in the review process, though we are processing one application that has been accepted, meaning that those are the seven candidate QHINs, the six that we announced at the February in-person event and the one that was just accepted and is preparing to do conformance testing.

So, basically, we have seven candidate QHINs who are testing actively as we speak, and they have to complete conformance testing, and then, once successful, they move to partner testing. That gets us closer to real-world connectivity, and it is more than the technical side. They have to demonstrate that they completed all the outstanding items that they did not have completed when they applied. That could be anything from high-trust certification to having audited financials. Most of it, frankly, is having governance defined, established, and implemented. Believe it or not, very few of the candidate QHINs actually have network governance that meets the expectations for TEFCA, and it is because the expectations for

governance are substantial and important to make sure they can actually operate in a way consistent with the common agreement, and consistent in a way that engenders, again, public good. So, once they have that, then we will have designation.

So, we have regular communication calls. I do participate some, though Alan and his team are more conversant in the day-to-day, and I can tell you that they take this very seriously, they are moving forward with intent, diligence, and a sense of urgency, and six of the candidate QHINs did declare at the in-person public media meeting that they do intend to go live by the end of the year, so we expect and hope that if all goes well, we will have the first production-designated QHINs by the end of 2023. Before we go on to facilitated FHIR, Alan, is there anything you wanted to add to that? I know you and your team are closest to it, and I do see we have some questions here already in the room.

Alan Swenson
Nothing major to add. Can you hear me all right in the room there?

Mariann Yeager
Yes, you sound good.

Alan Swenson
Perfect, thanks. Nothing major to add there. I am sure there will be some questions around it, but I think you covered the onboarding process, and we can keep going from there.

Mariann Yeager
Okay. Why don't we move to the next two slides and get to the slide that talks about the FHIR pilot? We know that there is tremendous interest in enabling TEFCA to also support FHIR-based exchange, and this is an opportunity that is really tremendous to move the market and to make sure that FHIR is road-tested and really scalable, and so, Alan, would you just walk us through the activities to date and where we are with the FHIR IG?

Alan Swenson
Sure. So, as noted on the slide here, we participated in the HL7 FHIR connectathon, which was here just last month. We also had a track at the IHE connectathon earlier in the year, so we have had a number of organizations that have participated. You can see on the slide here there were nine that participated in the HL7 FHIR connectathon. There were a few different ones that participated in the IHE connectathon. Most of them crossed over and participated in both, but there were a few that participated in one or the other, so there are more than just those nine that participated, but among those who participated, we did largely validate the specifications in the FHIR implementation guide. Again, this is primarily for the purpose of facilitated FHIR, which will allow a participant or subparticipant in one QHIN to communicate directly with the participants or subparticipants in another QHIN in a point-to-point manner using the trust, the directory, and things like that, but essentially communicating point-to-point without traversing a QHIN gateway, which is the way that TEFCA will work for the initial largely CDA-based exchange with IHE standards to start with.

So, it highly relies on the UDAP specification for dynamic registration, and we were able to validate that between the participants of the two connectathon events. We did some testing with how they manage and interact with the directory and get that information in some specific clinical scenarios. All in all, as currently

implemented and tested, the implementation guide largely works. There was some request for clarification and simplification of how things are in that document because today, it is a standalone document that we were using for these testing purposes, but the intention moving forward is to now take the requirements from that document and incorporate them into the QHIN technical framework, and potentially some additional specific guidance for participants and subparticipants. We are working through that process between the RCE and ONC teams, which will naturally simplify the language, make it consistent with language in those other documents, and address any of those requests for clarification and concerns that came up. There is nothing technical at this point preventing us from being able to move forward.

Mariann Yeager
And so, on that, just to add additional color, for those who are not as technically inclined or familiar with the many acronyms we threw out there, blowing it down into layman's terms, we actually facilitated testing at connectathon events in March and May, I guess, and what that did help was to test out that this is implementable, which we understand it is. What folks may not realize is that this dynamic registration, UDAP, is necessary to automate and make FHIR scalable. Believe it or not, it had never been tested by two unaffiliated entities until March of this year.

And so, when we talk about why FHIR is not live now, it is because we have more work to do and need a universal target, and with Micky's and ONC's leadership, we have that, so we are working with the candidate QHINs to understand what type of approach they intend to employ. Do they want to be an intermediary where they broker the FHIR messages or do they want to enable point-to-point connectivity, which is how the RESTful protocol is really designed? So, we understand that there is a mix, that they have different approaches that they plan to take, and that some of them have aggressive timeframes, maybe being ready to go live in early 2024. Others said maybe late 2024, and others said they did not know yet and had not even scoped it out.

So, the reason why I mention that is it is going to be really important to be incremental, to start with what is minimally viable, to get some traction, lessons learned, refine, and scale up, so I think it is very exciting, but I also want to have tempered expectations there. That is all we actually officially have prepared. We have plenty of other updates to provide, but at this point, I think we can just turn it back to the group for any questions you would like to pose.

Aaron Miri
Fantastic, thank you very much. As a time check, we have about nine minutes here, so, try to keep questions brief, please. Up first is Ike.

Steven Eichner
Hi, thank you so much for your work on TEFCA. There are others working on developing a bunch of the SOPs, especially public health, and there has been a workgroup to put together some public health educational documents. One of the challenges, especially for a public health SOP, is that it is beyond pure technical exchange, so there various laws that are multijurisdictional and are jurisdictional-specific that have to get addressed, so how is public health being engaged in the early-on development of the SOP so that we are up front about those policy drivers so that you are developing an SOP on the technology side of it that supports and respects those laws?

Mariann Yeager
Excellent question. So, just in terms of what we have done to date, in conjunction with ONC, we have facilitated pretty extensive discussion of a large group of public health stakeholders because we understood and recognized how there are different elements of that than what we might see in treatment-based exchange provider to provider, so having those extensive discussions was important to level-set on the intent for how TEFCA is intended to operate to identify what types of use cases TEFCA could support in support of public health, and also having a healthy respect for the policy boundaries under which public health operates. We have a drafting group that started meeting at the beginning of June, and we will work with them through August of this year. We are making great progress, and it is super exciting. Because we did that early socializing, gathering input, we found that it is actually quite easy to honor the body of law, regulation, and policy in which public health operates because we are not supplanting that, we are simply allowing them to operate under the authority that they do today. So, we are really excited by the progress.

Steven Eichner
I guess my question is how is public health participating in the development of the SOP as part of this drafting process?

Mariann Yeager
So, it is a group of the candidate QHINs, and their public health participants are in the initial drafting. Of course, everything we put out is put out for stakeholder feedback, and that is where we believe there will be very organized and targeted outreach with public health specifically at that is socialized, before it is finalized, of course.

Steven Eichner
Thank you.

Mariann Yeager
You are welcome.

Aaron Miri
Fantastic, thank you. Next up is Jim.

Jim Jirjis
Thank you, and thank you for all the wonderful work and the progress you have made. I know many in the room have worked really hard on it. My question is really about use cases and content. So, as many of us try to champion among some skeptics back home about the usefulness of health information exchange and the data, a few things come up, a few observations that lead to a question about the content of what is being exchanged and whether or not we need to wait for FHIR to solve the following problem. So, if you look at clinical use cases, imagine yourself being a cardiac transplant surgeon seeing a patient for the first time who has been referred from another system, and right now, both are connected, say, through a future QHIN, through an exchange, but unfortunately, it is a push model, and right now, I do not think there is much guidance on what is sent.

So, when we look at what we are receiving, we are seeing many people just send data collected at the very last encounter for their institution. So, going back to that cardiac transplant surgeon who is hungry for the

cardiac info, if the last visit at, for example, the Vanderbilt institution was a dermatology appointment and the 37 visits before it were rich with information about echoes, etc., then what is received by that cardiac transplant surgeon is just dermatology info. So, do we have to wait for FHIR where, then, the recipient can request certain info, or is there any work that can be done in the push model to address that?

Secondly, even in the FHIR model, is there any assurance of how deep the provider of information has to go? Think, for example, about colonoscopy. When was the last colonoscopy, as a use case? I might want to know as a primary care doc who just got a new patient. Well, if I ping the patient's last organization and they are only going to provide a year's worth of info, there are nine years of potential colonoscopy I do not have access to. So, I give those examples to put a little flesh on the bone. They are not abstract. They are causing many of their providers to roll their eyes a little bit when we try to champion the use of the HIE viewer. Are there any comments, either from yourself or the ONC, on addressing that data issue?

Mariann Yeager
Do you want to address that, Micky? I have a response, but I feel like **[inaudible – crosstalk] [02:04:09]**.

Micky Tripathi
Sure, I guess I have just one response. It is kind of a question back. Jim, I think what you are getting at is a multifaceted or multilayered problem, which is the optionality allowed in C-CDs, the variation in the ways that vendors have implemented them, the variation in which those have been configured by the provider customer, and all of those things connected together, compounding each other, are what you end up with, and there is a variety of ways that variation gets generated, so you are not getting consistency. Is that fair, from your perspective?

Jim Jirjis
Yes, I think that is the question. You are exactly right, and what I am saying is without addressing it, some of the most important use cases in this critical time where it is getting a lot of attention with QHINs coming up, as people begin to use it, you begin to hear a little bit of "Well, it never has in it what I want," and my first thought is do we need to wait for FHIR, and if so, even then, what makes us think that the participant is actually going to include enough depth of data in their FHIR repository for the requester of information, and is that an opportunity for regulatory work? That is the question.

Aaron Miri
And standardization, right? Absolutely. Good questions, Jim. Thank you. Aaron, do you want to wrap it up?

Aaron Neinstein
Yes, thank you. Maybe building a little bit on Jim's comments, it is very exciting to see this moving forward and all of the work coming to fruition. Everyone in this room is a policy wonk. I was just at a conference before I came here with about a hundred CIOs of health systems, and even they, who are very deep in this space, do not have a great understanding of TEFCA and what it is going to provide, so I am curious what the plans are for communication as the QHINs start to come online. How are we going to educate people in health systems and the general public about what they are going to be able to achieve as this gets launched?

Mariann Yeager
We are developing a very robust, multifaceted stakeholder engagement strategy and plan that we really needed to get enough QHINs far enough along that it had some real-world context, so we did outreach, of course, to all these stakeholder groups initially over the past couple of years, educating on the value proposition, but now, it is going to be very resource-, person- and time-intensive, and it is important because you are exactly right, and we acknowledge that. We know there is not a high degree of awareness. We think we have probably gotten the most awareness, actually, with the public health community because of the recent socializing around their particular use case. We have a lot more work to do.

Aaron Miri
Good point. Real quick, Meg?

Meg Marshall
I do not think you necessarily have to answer this. I am Meg Marshall with FDA, and I want to build on something. You had mentioned point-to-point versus brokered, and I think to the question around communication and facilitation, a lot of health systems are moving forward with their API strategies now, and not just around clinical data, but they are working with trading partners across the region, so those types of decisions, approaches, and timelines in particular would be incredibly helpful as you move forward with your communication, so I just wanted to make a note about that.

Mariann Yeager
Thank you.

Aaron Miri
Wonderful, and real quick, Dr. Steven Lane.

Steven Lane
Just building again on what Jim was saying about the importance of having some flexibility around how you are sharing data, Mariann, I was wondering if you could say anything about the push method of exchange inside of TEFCA. Are we going to see that from the beginning? Your cardiac transplant surgeon could have somebody push data across TEFCA to them instead of just simply being able to query for that last C-CD document, and as you well know, the Sequoia Project data usability implementation guide includes the ability to be able to exchange encounter-level documents. Is that something we are going to see early on?

Mariann Yeager
I hope so. We know that right now, the candidate QHINs are starting to line up and get commitments from their customers to participate in TEFCA. It ultimately depends on what they are expected or wanting to support, but candidate QHINs have to support both push and query out of the gate. I will say very quickly that we will get to these very practical discussions once we are in production, and it is really going to be a collaborative community to start working on improving and making sure TEFCA has value.

Aaron Miri
Wonderful. Thank you very much, and at this point, we are at time. Please give our speakers a round of applause. Thank you very much, Mariann. All right, so, here are some important quick updates before we go to lunch here. No. 1, I want to repeat what Medell said earlier. If you leave the conference center, you

must be escorted by ONC staff. Remember, this is a federal building, and they take security very, very seriously. If you reenter the conference, either wait at the conference center entrance for an escort, so if you leave the building for whatever reason during lunch, you will need to go through the security process again. Those who ordered lunch can gather in the kitchenette to gather up their meal, and attendees, you need to be back to resume the meeting at 1:00 sharp. With that, Medell, I think we are at lunch. Enjoy!

Lunch Break (02:09:43)

Michael Berry
Hello, everyone, and welcome back from our lunch break. We are getting ready to start the second half of our program, so I will turn it over to Aaron and Medell to get us started.

Medell Briggs-Malonson
Thank you so much, Mike, and welcome back, everyone. I hope that everyone has some wonderful nutrition in them as well as a cup of coffee because this is going to be an exciting second half of our HITAC meeting. First up, during our second half, we are going to have an update from our Public Health Informatics and Technology Workforce Development Program, so I will turn it directly on over to Sherilyn and Maggie.

Public Health Informatics & Technology (PHIT) Workforce Development Program – Update (02:10:15)

Sherilyn Pruitt
Hi, everyone. I am really, really happy to be here again. I am Sherilyn Pruitt, one of the co-leads for the PHIT Program.

Maggie Wanis
I am Maggie Wanis, the other co-lead.

Sherilyn Pruitt
Together, we run the PHIT Program, the Public Health Informatics and Technology Workforce Development Program. We are really happy to be here this afternoon. Maggie and I will give you a little bit of overview of the program from ONC's perspective, and we are very excited to have two representatives from the PHIT Program. One is going to be in the room, Dr. Charletta Washington from UDC, who will be speaking after us, and then we have somebody who will be speaking from UT Health Houston, Kim Baker, who will be coming in on Zoom. After Maggie and I do our overview, we are going to get up and walk over there. We are not leaving the room, we are just making room, and Dr. Washington will come over and present from here, and then we will go ahead and have Kim Baker from UT Houston provide her remarks. So, I am going to turn it over to Maggie to get started.

Maggie Wanis
Great, thanks, Sherilyn. Next slide, please. So, a little background on our Public Health Informatics and Technology Program that we so endearingly call PHIT. This program came about in 2021 as a result of the American Rescue Plan, and ONC made awards totaling $75 million to 10 awardees. These awards mainly stemmed from what we saw from the pandemic, which evidenced that there were huge public health data reporting gaps in communities, especially in under-resourced communities. Through these awards, we are hoping to create a pipeline of students trained in public health informatics and technology who are trained

and can then sustain our public health workforce. The 10 awards went to minority-serving institutions to develop consortia. These consortia have a requirement that they have a local or state public health department attached to them as well as a clinical component, so that could be a community health center, an FQHC, a health system, or what have you. Through this pipeline, they will train at least 5,000 students over the course of the next four years. Next slide.

Sherilyn Pruitt
When we got the money, we were very, very excited, and we were tasked with creating a program that would diversify the workforce and increase the expertise of public health professionals with informatics and technology. The first thing we did was meet with other federal agencies to find out if they had something similar because we wanted to make sure we did not duplicate what was already out there and complement what was already in existence, so we put out the notice of funding opportunity.

In the middle of the summer, nobody was even looking for this opportunity because it did not exist before, and we received about 70 applications and were very happy that 20 scored between 90 and 100, so we had really, really great applications that were put together in the middle of the summer, and we were able to get a group of 10 that you see on the map, and one of the things that we love about it is that we could not have gotten a better distribution. We have East Coast, West Coast, north, south, tiny schools, HBCUs, and mega institutions. Some of the reach of some of the institutions is statewide, some of the institutions have partners that are across the country, so the term that keeps coming up as we look at a program is "diversity." We have a diversity of approaches and a diversity of recipients, so we are extremely happy with the way that the distribution turned out for the applicants. Next slide.

Maggie Wanis
And so, with regards to the programs that our 10 awardees are putting together, the awardees are all across the spectrum with regards to their existing programs and what they are planning on doing as part of the PHIT Program, so we have awardees who are enhancing their existing programs and departments, we have some that are expanding and going into other areas, as we mentioned earlier, an interdisciplinary approach, so we have some who are pulling in computer science departments, the nursing department, and what have you. We also have some schools who are starting from scratch, who do not have a public health informatics program, and who are building programs from the ground up.

So, most of the programs are focused on undergraduate students, and then we have a handful who are focusing on training graduate students, and lastly, we have a limited number of certificate programs that are geared towards training incumbent healthcare workers, and the requirement that we have is that those incumbent healthcare workers be currently in a public health setting. I will add one more thing that I failed to mention earlier on. Another requirement that we had set forth in this award program was that there be paid internships for students who are trained as part of this program, which is a huge and key component of PHIT. Next slide.

Sherilyn Pruitt
And so, in terms of our program milestones, the first program milestone was to continue to develop your consortia. We know that the applicants put their application together during the summer, and they may not have had all their consortia partners really nailed down. They may not have known what exactly the PHIT Program was, "Okay, sounds good, I will sign my name here," but then we said, "Now that you have the

money, get your consortia together." So, that has continued, and Maggie talked about the three components of the consortia. The applicant had to be a minority-serving institution, or, if not, they had to partner with a minority-serving institution and the state, local, and county health department and any clinical care organization, like Maggie mentioned, and those are the minimum criteria for the consortia.

We have consortia that may include community colleges, primary care associations, and community health centers. There is a wide range of different consortia members, and one of the roles of the consortia members is to provide those internship, and we think it is a great idea. If it is a health department that is providing the internship, they get trained staff, and if it is one of the hospital systems, again, they are training staff, so we are really excited about that. The next step in the program milestone was to get the curriculum approved through the departments. Like Maggie mentioned, some institutions already had the curriculum, and what they are doing through their PHIT Program is sharing that curriculum with another institution. Some of the other ones are developing their curriculum from scratch, so there is a wide range of where people are in the development of the curriculum, and if anybody has worked in an academic institution, it takes a while to get the curriculum through. So, some people are done with that and some organizations are still making their way through in terms of getting that curriculum approved.

The next part is the student recruitment. We think that is key. They say to build it, and they will come, but we have to make sure that they come because that is what this program is all about, so student recruitment is going to happen throughout the whole thing. One of the things Maggie did not mention is that some of the institutions have a high school outreach component, and we think that is really important because a lot of people do not know what public health is, they do not know what health informatics is, and they certainly do not know what public health informatics is, what you do, and what kind of career you can have with that, so there are some programs that do outreach with high schools to build a pipeline so that by the time we get to the end of the four-year period, some of those people that they reached out to in high school might be enrolling in those programs.

And then, there is student training and placement, and like Maggie said, the paid internship is a key component. All students are welcome to participate, but we are making a concerted effort to reach out to underrepresented minorities, and some people in that group do not have the luxury of working for free, so we want a paid internship component, which is very important, so they can get paid and get work experience in their field. And then, there is sustainability. This is one and done. It would be lovely if we had another $75 million to do this again, but we do not know if that is going to happen, so we have to make sure that the money that has been invested into this program will be used to continue the program after the federal funding ceases.

And then, in terms of our program evaluation, the programs will do an internal evaluation and evaluate themselves, and we are also doing an overall programmatic evaluation where we are going to look at the curriculum that is developed by degree level, like how many undergraduate, graduate, and doctoral programs we have. We are looking at degree level, course type, where they had their internship, what kind of training they received, and, most importantly, career placement. Are they being placed into careers? Because that is the goal. And then, we are looking at qualitative and quantitative data. Next slide.

Maggie Wanis

At this time, we just wanted to say thank you from the program side at ONC. I am very excited to hand it off to one of our awardees, who is local here, Charletta Washington. Thank you.

Medell Briggs-Malonson
We do. We want to make sure that everyone on Zoom can also hear you.

Charletta Washington
Awesome. My mom once said I was loud enough for everyone to hear me. So, again, thank you for having me. My name is Charletta Washington, and Ms. Pruitt, thank you for calling me "doctor." Not yet, though. I am still working on it. I am the program director for the PHIT for D.C. program. Next slide, please. This afternoon, we are going to do a couple of things. We are going to talk about PHIT for D.C. What does that mean to you and to us? We are going to talk about our goals and objectives. We are going to talk about our community statistics. One of the things you heard was that we wanted to serve an under-resourced population, so you will get to understand why we wanted to take that path. Our student body is defined. What are our classes made of? There are our program pathways, and also our program statistics, where we are today, and where we see ourselves going. Next slide, please.

The PHIT for D.C., or Public Health Informatics Technology for D.C., program is a marriage of Howard University and the University of the District of Columbia, the only two HBCUs in D.C. In addition to that, our consortium partners are CRISP for D.C., which is the health information exchange for the region, D.C. Primary Care Association, which is the governing body for the FQHCs here in the district, as well as Zane Networks, which is a district owned and operated public health informatics company. Next slide, please.

The educational institutions: I know some of you may have heard of that small HBCU, Howard University, before in your passing here in Washington, D.C. It was founded in 1864 and has 120 areas of study in 13 schools and colleges. And then, the University of the District of Columbia was founded in 1851, and when I took this job, I did not know it was older than Howard University, has 81 degree programs. It also has a unique pathway called Workforce Development. This is a division of the University of the District of Columbia that is a no-cost pathway certificate program pathways for citizens and residents of the District of Columbia, and it also has a community college division.

So, PHIT for D.C. Next slide, please. We set out with four goals and objectives in mind. The first one was to engage our students. We wanted to engage our Howard University students and our University of District of Columbia students into public health informatics, but most important, we wanted to engage our community. We wanted to upskill the communities that we served. Secondly, we wanted to develop an interdisciplinary curriculum, one that was culturally responsive. So, if we were going to bring students together from two institutions, that was great, but how would we develop a curriculum that would speak to the community, those individuals that may have never stepped foot in a college course? Thirdly, we wanted to develop pathways. I have you in the class or I have you on the right path to public health informatics, but is that path the right one for you at this time? And then, we wanted to develop sustainability, not just give you a skill, but give you a pathway to a nationally recognized certification, to internship, and potentially to full-time job placement. Next slide.

So, why did we want to focus on our community? These are statistics that were taken from D.C. Health Matters. We know that in Wards 7 and 8, 17% of the population is unemployed. We know that the median

household income was $47,000.00, compared to that of $104,000.00 in the rest of the city. Twenty-one percent of the families in Wards 7 and 8 live below the poverty line, 13% of them have less than a high school diploma, and 25% of them are considered front-line workers; however, they live below the District of Columbia's 200% poverty line. While our program will not solve all of these ills, we wanted to have an impact. Next slide, please.

Our student body is broken up into three categories. First is the healthcare career starter. This is someone that is interested in a career in the healthcare industry. This could be a community member, a high school student, or a veteran looking for their second career. Then we have our healthcare advancer and scholar. This is someone that may have two or more years of experience in healthcare. They can be enrolled in a postsecondary program, such as technology, life sciences, or an active healthcare profession. And then, we have our professional level. These are individuals with five or more years of experience and/or who possess a postsecondary degree in technology, life science, and healthcare. Next slide.

The core of our program is our PHIT for D.C. experiential course. This course is open to any one of those members in the student body. This is a 15-week course that emerges the students into a program that talks about revenue cycle, behavioral health, the health information exchange, and interoperability. We also do a sandbox so that the students are getting hands-on experience in an electronic health record. In addition to the 15-week course, we then add on a two-week certification course through HIMSS. This two-week boot camp gives the students an advantage and a study guide to be ready to take the HIMSS certification course, so they have the opportunity to walk away with a nationally recognized certificate. Next slide, please.

As we know, every student may not be ready for an experiential course, so what we did was develop clean pathways for our student body. The first one is our workforce development program at the UDC southeast campus. This is a way for individuals to get emerged into healthcare. The second one is our Intro to PHIT course. This is another way for community members to come in that may not want to do a three-semester path to get into our experiential course. We also have developed a new degree program at the University of the District of Columbia, which would be an associate's degree in PHIT, public health informatics technology. At Howard University, we have the applied data science program, and we also have PCMH content expert programs at Howard. Next slide.

Our enrollment goal at PHIT for D.C. is 560. Today, we have enrolled 128 students. Seventy-one have completed the program. Right now, we have nine students that either have been employed or in an internship after the first year. Twenty-two percent of our population of students were Hispanic, 3.8% were white, we had 18.2% preferring not to say, with 56% being African American. In enrollment by gender, 7.8% did not identify, 17.2% were male, and 75% were female. Understanding our statistics is also gearing us to know what our next recruitment efforts will be. I was just talking about how we are doing a barbershop meeting next week where we are going out into the community to give individuals the information about this program, and these programs are at no cost to this community, so we want to make sure we are providing them an upskill option. That is it.

Medell Briggs-Malonson
Our next presenter will be Kim Baker, and hopefully she is on.

Kimberly Baker

I am.

Medell Briggs-Malonson
Awesome. Okay, great, thank you!

Kimberly Baker
Good afternoon, everyone. I am Kim Baker from UT Health Houston. I am the Assistant Dean of Practice there at the School of Public Health, and am super excited to share with you all about our efforts with GET PHIT, Gaining Equity and Training for Public Health Informatics and Technology, here in Texas. Next slide. So, I will be presenting on behalf of our team. I co-direct this project along with Dr. Susan Fenton, who is at the School of Biomedical Informatics at UT Health Houston, so this was a joint venture. We have two co-PIs, both of our deans at our institutions, my dean at the School of Public Health and Dr. Fenton's dean at the SBMI.

We partnered together on this initiative so that we could reach the entire state of Texas. So, the UT Health Houston School of Biomedical Informatics is the only school of biomedical informatics in the state of Texas, and the UT Health Houston School of Public Health is the largest school of public health in Texas. And so, our reach is broad, and we are excited about that because Texas is becoming increasingly one of the most diverse states in the country, and this is an opportune time, particularly from what we are facing in terms of state education in the South around equity, to be centering initiatives around equity for health disparity elimination, so we are excited. Although our institution is not minority-serving, we were intentional about partnering with minority-serving institutions. That orange star that you see in the southeastern part of Texas is Houston. That is where UT Health Houston resides. That is our main campus. The navy blue stars that you see are all of our consortium partners, all of which are minority-serving institutions in north Texas, central Texas, the border region, and west Texas.

Part of our initiative is threefold. We are developing curriculum and expanding curriculum and curriculum integration within these partner consortium institutions and within our own institution, establishing certificate programs and 4-plus-1 programs with these undergraduate institutions. We are also carrying out professional development activities across the state with most of our local and county health departments, including our state health department, and then, finally, doing internship placement and career prep. And so, we prioritize both undergraduate and graduate students in our initiative. Next slide, please.

And so, here are our consortium partners. All of these institutions are minority-serving institutions. Huston-Tillotson University and Prairie View A&M are HBCUs. Prairie View is one of the largest HBCUs in the state of Texas, and the remaining are Hispanic-serving institutions. In all of these institutions, with our program development and curriculum integration strategy, we are working with departments of nursing, computer science, math, applied health sciences, biology, medicine, and new programs of public health. In fact, Prairie View just celebrated the start of their new public health program this year. And so, there are several strategies that we are working with each institution so that they can expand and develop new curriculum. Our faculty from each institution work on teams to develop and modify curriculum offerings, and we are really excited about that. Next slide, please. I will talk about the integration and the boot camp.

Here is just a brief overview of our goals. Our goal is to train 1,200 students through this new curriculum and our boot camps, and so, either students attending those institutions, getting the new curriculum or

expanded curriculum, and in the summer, we host boot camps at each institution. And so, this summer is our second year of hosting boot campus. We hosted three boot camps last year, we are hosting another three this summer, and then, we are going to host three more next summer. We also are providing 400 students with paid internships, and that is within health departments, nonprofits, hospital systems, private industry, mostly in Texas, but we do have some national partners where we are placing students in these internships as well, and we do that year round, all semester, every semester, and then, we are providing 500 professionals with workforce development training. We target our host sites, and so, the staff that work with our students where we place to take our professional development training love it and need it, and we also target many of our health departments as well, as that was a need that came out of our needs assessment in year one in terms of skills that they needed for public health professionals. Next slide, please.

This is our curriculum delivery and integration in boot camps. Each of our institutions are developing new curriculum course content or expanding on the current curriculum into their institution each semester, so knowing, as you saw on the former side, that we have eight consortium partners, this is a major feat, but we are excited because we have a really strong consortium team who is working hard and diligently to go through all the processes and the administrative red tape of approving new curriculum and programs, but that is the work that is getting under way this past year especially, accelerating as we move into the fall, so we are super excited about that.

I shared with you about our boot camp. Here is a flyer of the boot camp. Students spend two weeks in this boot camp, faculty from the institution that host it facilitate the boot camp, but we do sometimes have other consortium members from a neighboring city. Just this past month, where we hosted Prairie View, we had faculty from UT RGV, which is five hours away, coming to attend that boot camp, and also, students from UT RGV attending Prairie View's boot camp. So, we really appreciate the connection, the networking, and the learning that our students get, so even though it looks like Texas, of course, is a huge state, our students get to know each other, and they get to network even across the state, which is very important because we are talking about areas that are considered rural, urban, and suburban, so they are meeting all the various needs in the diversity of our state. Next slide, please.

Students who successfully complete the boot camp are given certificates around the completion of the boot camp, and then, students who are also enrolled in curriculum programs at their institution that are approved by the GET PHIT consortium are eligible to participate in the internship, and that has been one of the main draws of the GET PHIT program, honestly, at each of our consortium partners' campuses, even at our own campus of UT Health School of Public Health.

And so, the summer boot camp is not necessarily a firm prerequisite for the internship, so some students who have taken courses in health informatics, data analytics, and public health can also apply for these internships, so the internships usually last between 10 to 13 weeks, depending on the semester and the host site needs, it is paid, and we hosted 55 students this summer. We have an application out for the fall, and we already have had 55 students apply for the fall, and they have another month to apply, so there is a lot of interest across the state for these internships, and our host sites truly agree about the need for having students being placed within their team, even if it is just for a couple months. Next slide, please.

I just want to share with you briefly about what our interns are saying after they participate at their site. Seventy-four percent of the students who are placed in internships state that this is their first public health-

related internship ever, so that is great. Many of our students, as I mentioned, are majoring in nursing, computer engineering, or are pre-med students. They run the gamut, so this entrée into public health and then the layer of informatics is very exciting for these students. Seventy-eight percent of them were able to receive mentoring at their host site from those with similar backgrounds as them.

So, when we say equity, we really mean it. We are really working with our host sites to make sure that they are intentional, that they have mentors at that host site that are of the same gender, race/ethnicity, first-generation college status, or background as the interns that are placed there because our students need it and it is really great for the team and the relationship that is built over the project. Seventy-seven percent of our internships are remote or hybrid because some of our public health departments do require our students to come in at least three times during their placement. Next slide, please.

Here are the top three skills that our students are saying that they are gaining through this internship. Because the internship is really like the last hurrah. They get training through boot camps, through curriculum, and then we place them in internships. The first is data visualization and analysis. They are very eager to get project management and leadership skills. We make sure that our host sites are leaning into those student needs and allowing them to attend meetings and trainings even outside of the informatics and public health part so they can get that. Then, there are the communication skills as well. Next slide.

Just briefly, here is what our host sites are saying. Every semester, we take an assessment of our host sites to see how the experience went for them. Eighty-nine percent rated students' competency level in public health informatics to be good to high. This is what we want to hear and what we are trying to work towards: Eighty-nine percent of them said that they would likely hire an intern if positions were available. Ninety-nine percent of students felt that they were prepared to enter the workforce. Next slide, please. Here are some example projects from the GET PHIT internship. Some of our host sites, which is a successful host site, will make sure that student is working on a project or deliverable at the end of that internship because that is just another way that they can gain skills. Next slide.

Students receive certificates, and they also receive accreditable badges that they put on their LinkedIn profiles because we encourage them to use that as a tool to network, build their portfolio, and continue to engage with host sites or other future employers. Just to share, we have a couple GET PHIT internship success stories. These interns also received employment after their internships in these three settings. You can go to the next slide. Christina received a position, and she just talks about her experience there, the next slide is Abby Parmer, who received a position and is now working at the Houston Health Department, and then, I think Anastasia Jones is working at our state health department on the next slide. Thank you, next slide. This shows you some of the courses for professional development that we now offer. We have a total of 238 folks registered. These are people working in the current workforce taking these courses here through that offering. Next slide.

Finally, we are hosting our first annual GET PHIT public health summit, where many of our students will present their posters on the work that they have been doing, and then our host sites will be in person, really hosting a career fair, networking with students, and telling them about opportunities and jobs that they should be applying for. I think that may be the end. That is our website, yes, thank you. I have enjoyed sharing with you more about the work that we are doing in Texas. Thank you for your time.

Aaron Miri
Wonderful, thank you. Good job, excellent job. So, we are going to try and multitask here. I know that we are in our break period, so if people need to step away, go ahead, but I want to leave the floor open for questions. So, if folks do not mind multitasking, if you need to step away to use the restroom or whatever, please feel free to, but I also want to allow HITAC to ask questions. This is a very important program and a very meaningful program, so with that, let's see. I did not see who went up first, so I will just go with what I saw here. Bryant, you are up first. Thank you.

Bryant Thomas Karras
Thank you for the great update. I have a very vested interest in public health informatics, and I love seeing this investment in the workforce. You mentioned there were 20 applicants that scored very high, and I love that there is diversity across the U.S., but there are still some empty spots where we could fill in some gaps. Maybe this is a quandary to ONC. Is there any hope for additional stimulus dollars coming down to expand this program or grow this program, or is this a one and done?

Steve Posnack
This is where I step in and answer the question, right? The money came from a one-time legislative body of law, so we have been advocating, based on the success of our presenters virtually and in person, as well as the leadership from Maggie and Sherilyn, that this is a really successful program that we think should continue, and we have partnership opportunities with our federal sister agencies that have longer, more well-established workforce programs and the opportunities to leverage some of their budgets, but at this stage, I do not currently see a pathway where there is additional funding coming down the pike, especially in the current financial environment in which we find ourselves, but we are making the good advocacy pitch that this is an important program, and we have seen a lot of success with it. Your help can help with that too.

Aaron Miri
Well said. Next up is Eliel, I believe.

Eliel Oliveira
All right, thank you. Great presentation, great update. For the UT Houston folks, I am in UT Austin. I am waiting for your students to come to my informatics program, so I would love to host them and actually get them on the LEAP Project. It would be great to get these students to work for ONC as well. My question is if you have information enough at this point, because based on the previous question, how do we take this to the next level? How are we going to sustain this? Are we going to see programs like this nationally that are going to continue to attract students and place them? So, there are a lot of financial aspects there for these schools to say, "Once this funding is over, are we keeping the programs? How are we sustaining it? How are we placing these students? What salaries are they getting?" It is a tough field being in informatics and something related to tech because you can always be stolen for something else. It is really hard to keep people around. I am just trying to understand if you have any visibility at this stage on how we are going to sustain and scale this to other organizations in other parts of the country. Thank you.

Maggie Wanis
Thank you. Very good question. So, as we mentioned earlier, one of the key tenets of this program was sustainability, and the awardees that were selected had a sustainability proposal in place that we felt was

solid and that would continue through. I know one of the things that we are also currently engaged in is an evaluation plan that is looking at some of these things, taking a look at students who have been trained, whether it be through the curriculum, and who have been placed at internships, similar to some of the information that Dr. Baker presented on their satisfaction and if they would hire these students. I can think of two awardees, University of Texas at Houston being one, who are actually working at the state level and thinking through sustainability and how they can build an infrastructure that would support public health informatics training throughout the state. Some of them are looking at developing core language and job placement through the state and local public health departments. Kim, feel free to jump in.

Kimberly Baker
Sorry, I did not get to that point in my presentation, but the chair of the Texas Workforce Commission has worked with Dr. Fenton to establish this, so they are providing support to implement a similar model off the heels of this, so we are super excited about that. Also, just so you all know, as we think about paid internships, we are looking internally at our policies in terms of how we place students and having requirements in place for those required internships, so this is fueling that, and our host sites are seeing that need as well.

Elise Sweeney Anthony
This is Elise. I just wanted to add to that. I agree with everything Maggie said. I think the evaluation is a key part of the program. One of the things that we also try to do is identify interim lessons learned and opportunities to share, so the PHIT grantees are going to be meeting next week, and that provides them with an opportunity to share what they are learning already in terms of curriculum development and how they are working with students, so there is that component.

As Steve said, we would be excited about the opportunity to continue the program and spread it farther, but even amongst the grantees, having that information exchange is a key part of what we are doing, and also being able to share that, not only here in terms of the HITAC, but we use a number of different mechanisms with our programs to share the information more broadly. For example, with another program we have, called the STAR HIE program, we have a number of blogs where we share the information and the lessons learned about the successes and how the programs were put together, and I think that is another opportunity here in terms of the PHIT program to share that information, not only at the end, but also along the way.

Aaron Miri
Wonderful. Thank you for that update. Shila?

Shila Blend
Thank you. I really want to applaud your efforts. This is great. I had a quick question. I have taught adjunct nursing informatics, and one thing I see, even with nurses who work with EHRs and different things, is someone intimidated to go into an informatics degree because they say, “I am not a computer scientist or a programmer.” Maybe you will find this in your evaluation next week, but have you found any really good strategies, especially in the beginning aspects of entry-level into public health informatics, to really get people to recruit and give these programs a chance?

Charletta Washington
One of the things with our nurses as well as our pharmacy students is that you do have that fear. That is one thing they are not comfortable with when coming in, saying, "I know medicine, but I do not know the information technology side of it," and partnering with D.C. Primary Care Association, we have been able to integrate what they have learned in the classroom in a real-life setting, so they are working in the FQHCs, so they are understanding how medicine and the informatics piece come together, especially when we are talking about reporting, when we are talking about new HEDIS measures here in the city, when we are looking at CMS requirements, I am finding that the 16-week introductory course that we have really gives them a foundational purpose to say that this all connects to one another and that to move forward, we are going to need to be able not just to supply the medicine piece, but also do the data reporting.

Aaron Miri
Thank you.

Kimberly Baker
I just wanted to add two strategies that we have been doing. I mentioned the mentorship piece, which was key once we had already recruited students, but prior to that, many of our institutions use student ambassadors who can speak to the program and talk about the feelings of impostor syndrome and addressing that to get folks to feel comfortable seeing themselves in this role and in this field.

Aaron Miri
Good deal, thank you. Dayo?

Kikelomo Oshunkentan
Thank you. I am very impressed with this program. I love to hear and see things like this. The only question that I have for you is there is an education gender gap that seems like it is widening, and your slide underscored that. I am not quite sure I understand why women are going to college and graduating from college much more than men. In 1970, it was the very opposite. I love that transition, but I would like to see the men come up more. Is there any way that we can…not flip the script, but bring them up? I do not know what you guys have to say in regards to that.

Charletta Washington
Even in the application process, we see more women than men applying to the program itself, and our approach has been really focused on the community and going out, so we see the direct opposite happen in a technology field when it is just technology. You see more men than women. Healthcare in itself in general has been more female-driven in the last several decades or so, so I think that is where we see the gap when we start to combine the two programs together. One of our focuses has been going to where the men are, ideally, just making sure we are hitting the community at places where we know we can draw that attention to say this is a program for everyone. While the word "healthcare" is considered caring, and by nature, women are nurturing, we want our male students and those that identify as male to understand that this also is a program for them and that it is open, and our focus in the community over the next semester or two will be just that, driving that message home to that community.

Kikelomo Oshunkentan
Thank you.

Aaron Miri
Wonderful updates. I apologize, I know there were so many more questions, but we are at time on this topic. Once again, a round of applause for this fantastic presentation. Great job, and great work. It is so impactful. Okay, I hope you all ate your Wheaties. Now it is time for a really good discussion. We are going to talk about the HTI-1 Proposed Rules, and Medell, I believe this is your section. No? Is it mine? Okay, perfect. I am introducing Dr. Steven Lane, Steve Eichner, and Dr. Hung Luu.

HTI-1 Proposed Rule Task Force Recommendations – HITAC Vote (02:55:33)

Steven Lane
Is the audio okay? Great, all right. Well, thank you all for the opportunity to come and talk about the HTI-1 Proposed Rule Task force and the work that we have done over the past couple of months trying to pull together some recommendations. Ike and I have been leading this, but Hung stepped right in at the very beginning and offered to lead one of our workgroups, so the three of us are up here presenting for the group. We have a big chunk of time in front of us. It was interesting. When we were planning this with Mike, we thought 45 minutes would be enough, then it turned to an hour, then maybe more, and I think just last night, they rejiggered the agenda again. I think we have lots of time. We may or may not need it all, but I think we are going to have fun jumping into this. So, who is advancing the slides? Are we? Excel has it? Okay, because I cannot see behind me.

Ike asked me to kick us off here in the interests of time to keep things moving along. We are going to talk about the task force, the roster, and the charge, make some key observations, and then go through what it is that we reviewed, the various topics that were in the rule, and then we have a whole host of recommendations. I think we are up to 68, I think there is one that got snuck in even today, so we will try to go through those rather quickly, and then we will have time for Q&A and hopefully bring this to a vote. I think we have decided it would be best to hold questions until we get through presenting all the recommendations, so keep your bingo card going if there are items that you want to come back and visit. You all received the report. There is always a text report. This includes all of the rationale and the commentary behind each of the recommendations within the slides, and in our oral comments, we are going to focus on the recommendations themselves. So, you can follow along in the report if you want to read the rationales as we are going, and/or we can review some of those as we get to them.

So, that is our plan. This next slide is our task force. I really want to acknowledge that the ONC team did a great job putting together this task force from the volunteers that came forward. The group was broadly representative and highly engaged. We had great dialogue and discussion, and I think it shows in the recommendations that came through. I want to particularly acknowledge Anna, who came through and played the role of the patient representative advocate in the discussion. I think she really brought a dimension to the discussion that was very helpful and really led to some deeper thinking on the part of the ONC team, which we will talk about as well.

So now, we will go through the charges on the next slide. The charge was really to review the NPRM and to provide recommendations back to all of you today. Specific charges were related to the various components of the rule, the renaming of the certification program to ONC Certification for Health IT, and getting rid of the year-themed editions, establishing USCDI V.3 as the new baseline for certification, implementing the EHR reporting program, which led to a lot of good discussion, and enhancing information

sharing using a number of changes related to the information-blocking rules. On the next slide, going on through the charge, looking at a number of very specific proposals having to do with electronic case reporting, new certification standards, the assurances condition, and maintenance and certification requirements, and then, there were a number of RFIs, requests for information, where we had the opportunity to dig into a number of areas.

So, we are at the end of the work of this task force, bringing our recommendations back to HITAC. The public comment period is still open for a bit, so if there is anything any of you want to individually add, I am sure ONC would love to hear it. So, on the next slide, we speak of the approach that was taken. Because of the volume of information that needed to be reviewed, we broke into three different workgroups, each of us leading one of those. Most of the members of the task force selected one or the other. Some signed up to participate in all three of the workgroups, and I will call out Hans, so he was with us all week long and had the opportunity to have a lot of impact on these recommendations.

I want to say there was pretty good public participation in the workgroup meetings as well. Some of you know Mark Savage, who has served on ONC committees in the past. He also attended every single workgroup meeting as a member of the public, and a number of folks from ONC and elsewhere were participating as well. Basically, we broke up the work and sent it through the workgroups. No surprise there. As usual, we invited external subject matter experts to participate in the discussion to inform the workgroup and task force members, and here we are with the recommendations.

I do want to point out that the ONC team was particularly responsive in terms of their support of the task force and its work. I have had the chance to serve on and co-lead a number of task forces, and every time, the team just gets sharper. It is really impressive. The team came forward really open to new suggestions. We implemented a couple of new approaches. One was where they pulled out the segments of the NPRM that related to each of the topics we were covering so that task force members did not have to be looking between the preamble, the rules, and this and that, so really, they helped to organize the information to make it easier to review.

Also, I mentioned Anna and the patient perspective. There was a lively discussion that came up about how we really get public patient input into these things. It is hard for patients and their caregivers to read through a rule like this, so the ONC team stepped right up and repurposed one of these scheduled public sessions to be really focused on the patient perspective, so it was a really impressive partnership, and I just cannot thank the ONC team enough for that. Okay, Hung, I think we were going to have you go through reviewing what topics we reviewed as we went through, so go to the next slide.

Hung S. Luu

The topics that were reviewed by the three separate task forces including the ONC Certification for Health IT and discontinuing the year-themed editions, so this is the renaming of the rule, and also the naming of USCDI Version 3 as the baseline version moving forward, C-CDA companion guide updates, the electronic case reporting decision support interventions and predictive models, standardized API for patient and population services, United States CORE Implementation Guide STU Version 5.0.1, patient-requested restriction certification criteria, and lastly, requirement for health IT developers to update their previously certified health IT.

Steven Lane
We have two more.

Hung S. Luu
Oh, two more. Also, there were assurances, condition and maintenance of certification requirements, and Insights condition and maintenance of certification. There were a variety of requests for information, including laboratory data interoperability RFI, pharmacy interoperability functionality within the ONC Health IT Certification Program, including real-time prescription benefit capabilities RFI, the Clinical Decision Support Hooks RFI, FHIR subscriptions, FHIR standard for scheduling, and SMART Health Links RFIs. Next slide, please.

And then, there were also topics on information-blocking defined terms proposals, information-blocking infeasibility exception proposals, including revised existing conditions, uncontrollable events, and also new conditions, such as third parties seeking modification of use, and new conditions, including manner exceptions exhausted, and also information-blocking manner exception TEFCA manner proposal, and RFIs, including additional exclusions for offer health IT, possible additional TEFCA reasonable and necessary activities, and lastly, health IT capabilities for data segmentation and user patient access RFI.

Steven Lane
Thank you for that, Hung. On the next slide, we have just a few key takeaways that we bubbled up out of this that we will just share before we dive into the detailed recommendations. The first one was that overall, we really did feel that the Proposed Rule was excellent, that it really did help to advance and refine interoperability standards framework, and was very appropriately focused on serving patients as well as the needs of populations. It clearly has a focus on expanding and clarifying a number of questions that have come up through the discussions about the information-blocking rule, and I think it added some clarifications there, which were very helpful, and adding the recommendation for standards for electronic case reporting. We were very supportive of that, having seen that functional requirement existing for some time now. I think the Insights condition of certification also led to a lot of discussion.

As you can imagine, different stakeholders had different perspectives on that, but I think it really does move forward the EHR reporting program that HITAC has considered a number of times over the years, so it is good to see that moving forward. There is a proposed information-blocking TEFCA manner proposal, which the group actually had some concerns about. We felt that it might inadvertently disincentivize participation in TEFCA, so that has led to a recommendation that runs a little bit counter to what is in the NPRM that we are hoping the ONC will consider, and then, we spent a lot of time on the RFIs and got a lot of input there. So, as I said, we are going to go through the recommendations one by one. What we are going to do is tag team back and forth based on which one of us was leading the workgroup that led to the recommendation. So, we will advance to the first recommendation, which is going to be for Ike.

Steven Eichner
It is looking at discontinuing the use of the themed editions and looking to a more incremental approach to standards. The task force supports the approach, but does recommend that if that approach is pursued, that there be a dictionary, table, or framework set up that identifies what the current standards are for each particular criterion, what is the next upcoming standard, and similar information to help providers and all parties understand if they are meeting current requirements and what is coming down the line so they can

get to a place where they are ready for the future components. In a similar nature, looking at Recommendation No. 2, we do recommend that ONC examine the impact of shifting from edition-level adoption to adoption moving forward on independent standards because of the interrelationship between the different standards. If we continue to move forward at the edition-level approach, it becomes easier to reconcile differences between the different components. If each component is moving at its own timetable, it becomes more difficult to ensure that everything remains in sync.

Recommendation No. 3 looks at shifting the high-level standard they have on the exchange data between certified and noncertified technologies, there is an awful lot of data exchange that occurs between certified and noncertified systems, and keeping pace may be a challenge for some implementers. Looking at the next recommendation, looking at discontinuing themed editions, just looking at clarifying what "certified" means, that becomes important for a variety of programs, especially looking for systems or HIT modules that may be used by some specialty providers for their purposes. Though they may not need or use every aspect of a fully certified system, can there be a change or an adoption of the common definition for what certification means to support providers in a variety of environments, including for things like MIPS programs, where specialty programs may be reporting for public health purposes, but for their business reasons, they may not need a fully certified system, but it means they cannot participate in programs like MIPS. Hung, I think it is your turn.

Hung S. Luu
For Recommendation No. 5, the task force was supportive of moving to USCDI Version 3. Next slide, please. However, we made a recommendation, Recommendation 6, in which the task force recommends that ONC, in conjunction with the change to USCDI Version 3, establish a practical means of framework by which specialty EHRs and non-EHRs can certify to applicable certification criteria. The thinking behind this recommendation is that there are some specialty EHRs and non-EHR health IT that do not necessarily produce or need to manage the full scope of the USCDI Version 3, and so, having some flexibility in terms of being able to accommodate and transmit, but not necessarily have to manage or report on, the full spectrum of data elements, might encourage participation and ability for these specialty EHRs and non-EHR health IT to also participate in the certification. Next slide, please.

Recommendation 7 recommends that ONC work with industry to clarify and communicate that even though the capability to exchange USCDI data elements may exist, the exchange of all USCDI data elements is not required in all circumstances, especially where data is deemed sensitive or until or unless mature standards are available to support granular data segmentation. There was a concern that there was a presumption in the industry that because the ability exchange data exists, there is also a concurrent requirement to exchange all the data, and this is not true, especially where the patient has specifically requested that it not be exchanged, and so, providing education and clarification around that point might be helpful.

Steven Lane
If I can just chime in there, Hung, I think there is also a misconception in parts of the industry that just because something is in USCDI, it must be collected, and Clem has done a great job over the years in pointing out that we do not want to add burden to providers forcing them to collect data that is not necessary for them, so, again, this has come up repeatedly in our USCDI discussions about the need, so this was all

engendered by advancing to a more robust USCDI version, bringing up a lot of discussion about how we can make sure the USCDI process is as efficient as possible.

Hung S. Luu
Next slide, please. Recommendation 8: The task force is supportive of the adoption of HL7's CDA/C-CDA templates for clinical notes, STU Companion Guide Release 4, U.S. Realm, which implements USCDI Version 3. Next slide, please.

Steven Eichner
Looking at Recommendation 9, with respect to electronic case reporting, the task force is recommending that if a provider certifies to either CDA or to FHIR-based transmission, they should also look to a third party to support the module that they do not certify to. They are certainly welcome to certify to both, but we are recommending that if they only certify to one, they identify a third party that is capable of transformation to the other standard. This is to support providers that may interface with a variety of different public health agencies and other trading partners that may only support one, but not both, technologies to help avoid issues down the line so that a provider has technologies that they cannot use to meet reporting requirements.

Similarly, on the reportability response, Recommendation 10 is that a technology can be certified to one, but again, it needs to be able to work with a third party to receive data if it only certifies to one, again, supporting a provider that may be working with a health department that only supports one technology, again, trying to avoid incompatibilities. Recommendation 11 looks at updating real-world testing so that, rather than looking at strictly real-world testing that emulates testing in the laboratory environment, there be actual real-world testing with public health entities and other organizations to ensure that the technology actually works in production. Recommendation 12 recommends that ONC define and implement transparency requirements related to patient characteristics and attributes in DSI development.

Recommendation No. 13 looks at including in certification requirements for DSI the production of warning messages to the user by the DSI when certain things occur, such as the correctly input data supplied by the HIT module or the DSI user is missing and that the DSI cannot produce a result because it does not have sufficient information coming in, secondly, the data provided to the DSI is outside the range or code set expected by the DSI, again, ensuring that the DSI is producing usable results, and third, the use of a particular DSI is contraindicated by the field value or combination of data, there be similar warning message so that, again, looking at results from the DSI being appropriate to the patient that is being considered.

Recommendation No. 14 recommends that ONC collaborate with the FDA and other stakeholders to develop certification and DSI approval criteria requiring the participation of the patients and clinics for the identification of relevant data inputs and outputs to the DSI module, again, to ensure the utility of the DSI. Recommendation No. 15 recommends that ONC collaborate with DSI and other HIT developers, FDA, and other stakeholders to enable better standards-based approach for sharing machine-readable and human-readable information about the DSI's attributes. Again, this was the goal of helping HIT developers integrate DSIs into their tools so that providers understand the availability and functions of what DSI modules may be available and similar functions for patients, again, making sure that that information is publicly accessible so it is not behind protected websites, that it is findable and indexable so that you can actually have a catalog of enabled DSI resources. Go to the next slide.

Recommendation 17 looks at recommending that ONC collaborate with the FDA to require DSI developers to include the ability for clinicians and patients to provide feedback to DSI developers if there is an issue in applying the DSI. Recommendation 18 recommends that ONC limit interfacing or incorporation of large language models or AI in certified technology unless the DSI developer can clearly articulate the data sources used. We are almost there. Recommendation 19 looks at ONC clarifying the distinction between "enables" and "interface," and we do have an additional 19A. Steven, can you address this?

Steven Lane
Do we have a slide? There we go. This is a recommendation that Medell brought forward. We wanted to make sure we got it in front of the group here. Basically, the idea is to develop a process whereby DSI can be reviewed and look at the impact that it has in the real world on broad population segments to make sure it is not having unintended consequences and developing a process for doing that on a regular basis to really monitor the impact of the DSI on patients. It is an add-on that was plugged in, and the task force supports this going forward.

Steven Eichner
Now we turn the floor over to Hung.

Hung S. Luu
Recommendation 20 is that the task force supports the proposed changes to the standardized API for patient and population services. Recommendation 21 is that the task force supports adoption of FHIR US CORE 6.0.0. However, we do note that additional critical updates in proximity with adoption of the final rule may be required, and so, the ONC should consider the then-most-current version as part of the final rule, and, if needed, rapid inclusion in the SVAP. Recommendation 22 goes back to Ike.

Steven Eichner
Recommendation 22 recommends that ONC use a standards-based approach that incorporates some of the four different standards related to data segmentation for exchanging information. The next recommendation using that data to work with stakeholders to develop a maturity model for the implementation of segmented data exchange. Recommendation 23…

Steven Lane
Sorry, I think we are on 22-2. There were five parts.

Steven Eichner
Can you address that a little bit further?

Steven Lane
Sure. So, again, Recommendation 22 has five different parts in it, so we had separated those out. Again, they are all based on the presumption that this is what we felt was required for ONC to really be able to support the restrictions certification. Again, just to back up in context, first, we did answer the question of what the appropriate technical standards to utilize were. That was Recommendation 22 prime, if you will, and then, there were sub-parts that we felt were required to accomplish that, so, as Ike mentioned, putting together a maturity model, supporting the development of that **[inaudible – background noise] [03:23:15]**

in process in the industry. The second part was collaborating with industry to support pilots and, in particular, a pilot that was looked at through one of the LEAP grants of a hub-and-spoke infrastructure where patient preferences could be maintained in one spot and other systems could access that information, but there are other models as well, so we are really encouraging ONC's continued engagement in that. I think we want to be on Slide 23. Oh, I think you are in the slides… There are too many places to look.

So, Item 3 of 5 was, again, adopting the maturity model for implementing data segmentation and granular consent supporting progressively better capabilities, recommending specifically as a first step to require developers using the certified health IT to gain meaningful experience with the standards for a limited scope of functionality and data classes to prepare for future expansions, really, starting small and expanding over time rather than trying to bite off everything in the first iteration. There were specific recommendations to look at in that first iteration, specific USCDI data classes that were of particular importance to patients for restricting, specifically demographics, problems, medications, test results, clinical notes, and health status assessments. This was one of the key questions in the NPRM, was how we do this practically.

The next piece of this was 4 of 5, limiting the scope to require certain subsets of existing standard codes for security labels. Again, we had SMEs come in and walk us through this, looking specifically at confidentiality flags, sensitivity flags, and instructions, or what are called obligations and refrains in the standard, and then we looked again at, within each of those domains, which specific flags would be most valuable as a starter set as we implement this. And then, the last part of Recommendation 22 was to include in regulations that disclosure limitations selected by the patient should apply to a wide range of exchanges, not just C-CD and FHIR exchanges, but also document exchanges as those occur, so, again, trying to assure that we protect the confidentiality and privacy of the data regardless of how it is being exchanged. Do you want to pick it back up with 23, Ike?

Steven Eichner
Sure, thank you for that. Recommendation 23 is that ONC ensure through HIT certification that when a patient's HIPAA right to request a restriction of data is expressed, it is included in the patient's record as a reason for restricting access and that information is shared electronically with the receiver to identify why the restriction was in place. Now, whether or not the provider can honor the patient's request can also be included in the metadata. Recommendation 24 adds a requirement that patient-facing certified HIT modules include the capacity to provide educational materials to the patient regarding the patient's options about disclosure. Recommendation 25 is that ONC clarify the technology support necessary for the exchange of flowdown requirements, including requirements with TEFCA. It looks at supporting the FHIR trust contract profile with label capacity statements for real-time verification that exists when stakeholders are found under agreements such as the eHealth Exchange and DRSIS.

Steven Lane
The next two have no comments.

Steven Eichner
Yes, the next two add no comments.

Steven Lane

We tried to be comprehensive in our presentation materials to touch on all the topics we were asked to address.

Steven Eichner
Hung, over to you.

Hung S. Luu
In Recommendation 26, the task force is supportive of the proposed implementation of the CURES Act-mandated EHR reporting program as the Insights condition and maintenance certification requirement. The task force does recommend that ONC coordinate with CMS's Promoting Interoperability programs to enable providers to really grant access to HIT module data to HIE developers for the generation of Insights measure reporting due to the fact that oftentimes, the data actually belongs to the client, and not to the developers. Recommendation 28 recommends that the ONC aligns the Insights program with real-world testing programs so that applicable Insight measures can also be used for the real-world testing program to reduce burden. Next slide.

Recommendation 29 recommends that ONC work with CMS to support the alignment of the definition of encounters between ONC's Insight program and CMS's Quality Measurement program to maintain consistency. There is some overlap between the two, but there are subtle differences that can pose some challenges in the reporting, and so, the suggestion overall is to align those two. Next slide, please. We recommend that the ONC reference a limited scope of the FHIR measures by including only the FHIR APIs supporting the US@ version referenced in the regulation. Also, for Recommendation 31, we recommend that ONC, in the definition of Insights condition document exchange metrics, require that all documents are counted, whether considered duplicates or not, because there is also work in handling duplicate documents that should be given credit.

Recommendation 32 recommends that ONC, in the definition of Insights condition volume measures, consider whether decreases or increases are truly indicative of desired advancement. Just because the volume might be going up or might be going down may not really correlate with the expected goals due to the fact that there could be processes in place that have been implemented that actually decrease the overall volume, but are promoting the workflow for the conditions, and so, just because the volume goes in a particular direction, it should not be construed that that is an advancement or not meeting the goals. Recommendation 33 recommends that ONC, in the definition Insights condition document reconciliation metrics, consider including documents reconciled not only by human users, but also recognize the use of automated tools, which reduce the need for manual review and reconciliation of data.

Recommendation 34 is that in addition to what is already in the Proposed Rule, that specialty and non-EHR HIT developers also be considered in the burden provisions and criteria of the Insights condition listed and base EHR criteria, that they be treated the same as what is in the rule. Recommendation 35 recommends that ONC consider and support the development of metrics regarding usage of interoperability standards, including versions and variations. The rationale behind this is that there are definitely a variety of versions and variations out there. Some of them might be mandated by local regulations, but having an insight into the difference versions and variations might, in the future, be able to consolidate those into the most popular versions and variations. I do not think the next one is mine.

Steven Lane
No? Okay. It must have gotten mislabeled. This is still related to the Insights condition.

Hung S. Luu
We recommend that ONC include in the Insights condition the proposed measure entitled "individual access to electronic health information."

Steven Lane
This is where Hung gets really excited. You thought he was excited before…

Hung S. Luu
So, this is very wordy, but the gist of it is that basically, while different standards are important, what we should really be focusing on is a data model that can effectively convey laboratory information on a very granular level to satisfy all use cases, including public health reporting, real-world evidence, and also comparability of data so that the clinician can have a complete longitudinal view of the patient. And so, the recommendation is that the ONC coordinate with HHS partners to help develop this data model, but also to ensure that the technological infrastructure and also the supporting standards are all aligned so that they can effectively support this data model.

And so, the next slide kind of gives the listing of the data model, in which the performable and ordering tests are represented by LOINC codes, that UCUM is used for units of measure for numerical values, SNOMED is used to map to qualitative results, and so, there is no ambiguity in what is actually being resulted, and also that we have compliance with CLIA in terms of having test abnormalities and also reference ranges, and also SNOMED for specimen information, and also, as a new element, UDI data for test kit and other relevant device data.

Recommendation 38, related to that, is that the ONC, in coordination with the FDA, standards development organizations, and manufacturers, including SHIELD, enhance the ability for test results to include identification of the instruments and test kits used to perform the test using the device manufacturer and model device identifier, or preferably the UDI, when that is sufficiently mature. Recommendation 39, related to that, is that there should be an authoritative source of truth for the mapping so that we can properly support and ensure proper, consistent coding of the standardized codes, including LOINC and SNOMED, and so, one way of doing that is to have an authoritative source of truth, such as the recommended laboratory interoperability data repository. Next slide. Recommendation 40 is to recommend that ONC focus on vocabulary, data quality completeness, and targeted adoption of LOI and LRI profiles, not necessarily the full guides, to optimize benefits using mature implementations.

In Recommendation 41, we have moved on to the pharmacy interoperability RFI, so Recommendation 41 is that the ONC actually use the RTPB Version 13 as the standard. Next slide. Recommendation 42, under pharmacy interoperability, is that we recommend that the ONC require that health information technology support both NDC and RxNorm. Next slide. Recommendation 43 is that we recommend that ONC require certified health IT to support either the XML or EDI format as a transitional step until all users are able to migrate to the final JSON format. Next slide. Recommendation 44 is that we recommend the ONC work with CDC and CMS to support the Prescription Drug Monitoring Program in being able to receive data utilizing the new standards. Recommendation 45 is that the ONC require use of ICD-10 as the primary

diagnosis code set within RTPB standard, with SNOMED added as an addition to, but not a replacement for, ICD-10.

In Recommendation 46, we move on to CDS Hooks, so we recommend that ONC adopt implementation that use CDS Hooks when sufficiently mature and available. The focus would be on implementation guides such as the prior authorization and using high-value hooks such as the patient view, order select, and order sign. Next slide. We recommend that the ONC focus on establishing implementation guides for high-value subscription use cases that would benefit from certification for the FHIR subscription request for information. Recommendation 48 recommends that ONC work with HL7 to determine the compatibility of FHIR R.5 subscription with FHIR R.4 subscription content. So, the rationale is that we really should be focusing on R.5. However, there needs to be a determination that the R.5 subscriptions will actually work with R.4 content moving forward. Next slide.

Recommendation 49, under the FHIR standard for scheduling request information, is that we recommend that ONC track and support the development and maturation of the SMART Scheduling Link standards and implementation guide. So, with this, the task force noted that there are several current barriers to widespread implementation, including the fact that not all providers use FHIR, and also that there are currently multiple approaches to requestion available slides for appointment, not all being suitable for every source of appointment, and so, certification towards one method may not be beneficial at this time. Next slide.

For Recommendation 50, this is related to the SMART Health Links request for information, and so, the task force recommended that ONC identify high-value use cases where quick-response encoding is valuable, while also recognizing the limitations, such as the currently available amount of data that can be encoded with a QR code. And so, we recommend that specific use cases and associated implementation guides be considered for certification as appropriate, and also that specific guides address not only protocol, but also the necessary content as well.

Steven Lane
That is it! So, as excited as Hung is, I am equally excited about information sharing. There are a number of items that were discussed with regard to supporting information sharing. So, Recommendation 51, under the information-blocking defined terms, was to have ONC clarify that providing access to registries and similar data services provided by public health authorities are not considered providing health IT, regardless of the route that is used to request the access. There was a long discussion about this section in the rule about what it means to provide health IT, and some recommendations for further clarification might be helpful, so this was one of those.

Recommendation 52 had to do with the uncontrollable events, and here, the recommendation was to expand the definitions within the uncontrollable events condition to include impediments of data access, exchange, or use because of any disaster which was declared by an authorized governmental agency or entity, the thought there being that there are things that are downstream effects of these disasters that also should be incorporated into the definition of uncontrollable events in the process of managing response and recovery after those events are completed. Recommendation 53 has to do with the new condition suggested called third party seeking modification, so we are talking about access, exchange, and use under use of health data, this notion of being able to modify the data.

So, the recommendation here is that ONC work towards updating certification requirements in a manner that will support providers' ability to utilize third-party applications other than the primary EHR with write access to USCDI data elements that are maintained within the certified health IT. This was actually an item that I was personally championing. I think providers do have a desire to be able to use FHIR write access in their EHRs. I had hoped that this proposal would support that. It ends up that it really does not; it actually makes it a little bit easier for the vendors to dodge that requirement, but I think in the future, as we look forward, trying to support FHIR writes by third-party apps would be very helpful.

Recommendation 54 recommends that ONC further clarify what is meant by "entities that are similarly situated to the requester" to clarify that responding actors are responsible to exchange data for the purpose and in the manner requested if they are able to do so, even if they are not in the habit of doing that. There was a concern that the way the Proposed Rule was worded, it might solidify existing practices, and we thought that there was a need for further clarification to make sure that just because this is what you are used to doing, it does not mean that that is what is expected. You need to be able to go outside your comfort zone in certain situations. This was Deven's recommendation, so if questions come up, we will direct them to her.

I referenced Recommendation 55 in my introductory remarks, about the TEFCA manner proposal. I think the TEFCA manner proposal is a really exciting proposal, as a way to further incentivize the use of TEFCA exchange to say that if you are using TEFCA, you are not going to be blocking information, but we were concerned in our task force that the way it was phrased could inadvertently disincentivize people from participating in TEFCA, and at this point in the game, we want to make sure that we do not create any barriers to TEFCA engagement.

There is a recommendation that in lieu of the manner proposal as it was presented, that ONC work with OIG to establish a general safe harbor for TEFCA participation, building a rebuttable presumption that an actor who participates in TEFCA as a QHIN participant or subparticipant is not information blocking for any exchange purposes supported by the TEFCA that has a final, published SOP, unless, of course, there is evidence that participation in TEFCA information-blocking with the requisite level of knowledge occurred. That is to say, the way the proposal is phrased, it says if you can exchange by TEFCA exchange, then you are good. If both parties are TEFCA participants, you have to, and it is phrased in such a way that it says for any purpose of use covered by TEFCA, even if the SOP is not complete, published, or defined.

So, there was a concern there that people would be forced to use TEFCA exchange for purposes that had not been fully defined, and were therefore perhaps more than they wanted to bite off. The other point in the proposal as presented in the NPRM was that the fees exception and the licensing exception were also taken off the table for these situations where you could exchange using TEFCA, and there, again, there was a concern that exorbitant fees or licensing could be extracted in the process of people using that TEFCA manner exception.

So, again, those were the concerns that were raised, and specifically in the case of IAS, individual access use cases, where no fees are permitted to be charged, the thought that getting out of that fees exception is not ideal as part of that manner exception. So, that was all under 55. So, that was all like, we did not like manner so much, what about this other approach? But, if you are going to go forward with the manner

proposal as proposed, we recommend that the ONC limit the requirement to utilize TEFCA exchange when offered to apply only to those use cases for which a TEFCA SOP has been finalized and published by the RCE, and for which responses are required and, in fact, operational in real-world use. Are we running short? Really? All that time.

Medell Briggs-Malonson
Five more minutes.

Steven Lane
I think we will make it. Actually, we will not. We are going to run a couple minutes over, I will tell you that right now.

Medell Briggs-Malonson
We have faith and trust.

Steven Lane
Okay, all right. Again, I mentioned this concern earlier that we want SOPs to be fully in place. So, No. 57, additional exclusions to offer health IT, we recommend that ONC clarify that a consultant organization providing health IT as work for hire should be treated like the provider themselves, which I think is pretty clear. No. 58 is that we recommend ONC clarify that meeting one or more exclusions in one role does not mean that they are not covered by the rules in other roles, again, just clarifying that. The next slide is one that we looked at and had no comments on, so we will skip over that.

Recommendation 59 recommends that ONC work with the HHS Office of Civil Rights, AHIMA, and other partners to develop standardized patient education materials and to support making those available when there are requests for data segmentation so individuals are fully aware of the implications and impact of their requests. Recommendation 60, again, recommends working with industry partners to develop recommendations and standards regarding the need to periodically review and validate any applied restrictions. Sometimes, a patient will say, “No, do not share that,” then years go by and their situation may have changed, so we have a process to go back and revisit those restrictions with the individuals. No. 61 recommends that ONC work with industry partners to explore how revocations of previously applied restrictions can be shared, so if a patient removes a restriction, how do you get that downstream to people who have received that data so they know that it is no longer restricted?

No. 62 is a mouthful. This, again, has to do with data segmentation, recommending that ONC work with OCR to implement the HITECH provisions. So, a lot of work was done before our committee came together to look at accountings of disclosures. Today, HIPAA has a very restrictive requirement for accountings of disclosures, but 10 years has gone by since this was last looked at in detail, a full set of recommendations were made 10 years ago about this, and we think it is high time that those be resurfaced and reinvestigated because as we looked at them, they looked like great suggestions that should still be moved forward. We already spoke a bit about Recommendation 63, the idea of a patient-centric hub-and-spoke consent registry model and looking at how that can be supported. It makes a lot of sense, and should be looked at in greater detail and piloted. Recommendation 64 is to say that information, again, that is exchanged via messages, such as V.2 and possibly NCPDP, should also be within the scope of patient restrictions as they go forward, in addition to C-CDA and FHIR exchanges.

Recommendation 65 recommends that ONC assure that information regarding restrictions be maintained and exchanged with the restricted data, and I think this is very important, that we receive these restriction requests, we either do or do not implement them, but then they do not get passed down when the data is shared, so it is the idea that the fact of the restrictions of restricted data should be shared with subsequent recipients of the data. Recommendation 66 recommends that ONC, in addition to their efforts to support patient restrictions requested under HIPAA, also develop future requirements for certified health IT to support four specific use cases where restrictions are applied. So, this is future-looking, not in the current rule, but this was part of the request for information. So, the four use cases in particular are outlined on the next few slides. One is when data is flagged as self-pay restricted, the fact of that flag should flow down with the data even though by the rules, the patient would be required to re-request that, but still, as a recipient of that data, you should know that. Data that is flagged as exceptional under information-blocking rules is a real frustration for me as a provider.

I go through a lot of effort to say this is a harm exception, a privacy exception, or whatnot. We restrict it in my system, but then another system requests and receives that data and does not know it was restricted, so that data should be able to flow down. The third one is when data is flagged as restricted based on adolescent confidentiality rules, and Anna is an expert in this, again, that those flags should flow down with the data, and finally, when a patient requests a delay in release to a portal or to APIs, that there, again, all these patient-requested restrictions should be able to be captured in metadata and flow down with the data.

Coming to the tail end here, Recommendation 67 has to do with, again, the last one on data segmentation, recommending that ONC include a requirement for certified health IT that incorporates patient-facing services, providing patients the ability to use patient-friendly terminology that is mapped to a concept model to select and place restrictions on the sharing of data, again, trying to really refine how these restrictions are applied, knowing that we need to have clear definitions.

All right, and there are a last few items that were a little bit outside of the charge, but that we discussed in detail and that we are referring to the Annual Report Workgroup, and they have gleefully agreed to accept these and discuss them, and these are on the last two slides, one having to do with information-blocking defined terms, a second having to do with the infeasibility exception, the third having to do with data segmentation and the accounting of disclosures, as we just discussed, and the last one having to do with predictive models, but in the interest of time and to have plenty of time for Q&A, I will let you read those and hear about them when they come back from the annual report workgroup. So, that was a long list of recommendations. Thank you for tolerating that, and we would welcome Q&A on not all of them, but any of them of particular interest.

Medell Briggs-Malonson
Well, first, I think that you all deserve a round of applause and our sincere gratitude to the co-chairs of this task force, both Ike and Steven, and also Hung as the Group 3 leader. This was an extraordinary amount of work, and thank you to the task force overall and our ONC staff. It is just amazing, so, again, thank you for all this hard work. So, we wanted to make sure we left enough time for discussions on this incredible body of recommendations. There are a couple of housekeeping items. No. 1, please speak directly into your mic and make sure that you say your name first so that we can get you on record. So, anyone that

has discussions or questions for our co-chairs as well as the Group 3 lead, please put your nametag up. The first one I see is Sheryl, who is sometimes in my blind spot, so we are going to go directly to you first.

Sheryl Turney

First of all, I just wanted to say, being part of this group and then getting COVID in the middle of it and other things, I feel like I did not pull my weight this time, but I really want to say thank you to the leadership because I really feel that they did a fabulous job, and this was a horrendous amount of work. I do have a couple of items, so I will list them one by one, but the first one is in Recommendation 16, where we talk about a label, I am just wondering if we need to strengthen the wording in the written recommendation relative to making that label part of the certification criteria because we do not exactly say that. We allude to it, but we do not say it exactly, so I am putting that on the table.

Also, although it is mentioned in the end, I do think there needs to be some statement relative to an overarching recommendation that looks at the patients' burden because when it comes to DSI, and I bring this up because it has happened to a family member of mine, but when you look at something as simple as the current process for choosing wisely, everybody looked at that and said most of the payers implemented all the recommendations, but if you have a patient who has rickets, then having a vitamin D test is not questionable. You have to have it. They have to have it at certain intervals in order to ensure that if they are vitamin D-resistant rickets, which my family member has, they have to fight every single quarter to get that test paid for because some DSI models say it is not needed for the average person, but you are not the average person.

This is the problem with DSI. I just want to put that on the table because when it affects payment, it affects the patient who is trying to get care, and if you cannot afford the $75.00 to pay for it yourself, they will not do it, and that is a problem, so we really need to look at it and say what burden are we adding to the patient when we are implementing DSI and what information is important for them to know so they know how to handle it when it happens to them because some of these challenges… I also do not want to say this, but they can take years. Who is going to be persistent to fight two years to get something paid for or to get a test run? And that has happened. So, I do think that is something that we need to consider as we are looking at the recommendations.

One other thing was as the overarching recommendation for the ONC for use cases, which Jim brought up and I think is really important, today, those EMR systems are sending the latest encounter, which may not be the information that is required relative to the condition that you are trying to communicate, so we need to add something to the certification criteria that speaks to what is the subject matter or the clinical condition that needs to be transferred, not just what is the USCDI data, but what does it need to relate to, and we do not talk about that at all in these certification criteria, so maybe there needs to either be a use case, an implementation guide, or something that talks about that process because, again, it impacts patient care because then they have to wait, as has happened to us, and then we have to go through the process of saying that they do not have all the information that they needed, they only got the last thing, and that patient had four things happen, and three of them did not apply to why they were being referred. So, those are my comments.

Steven Lane
If I may, just briefly, I heard in your first comment a recommendation for a specific change in Recommendation 16, where you I would argue that you are suggesting that we add the words "and eventually require this label," so I think we can do that as part of the transmission from the task force to the HITAC. I think your comment about feedback about special clinical cases is captured somewhat in Recommendation 17. I do not know if there is any specific language that you would recommend adding to that, but I think we did touch on that a little bit there.

Steven Eichner
I also think it is touched on in the DSI warning recommendation as well about where DSI should not be used.

Sheryl Turney
Right, but that recommendation, Steven, is more for feedback on how to improve or update the DSI, not for if it is impacting my care. How do I handle an impacted care situation? I am going to the next step.

Steven Eichner
Right, and that is explicitly why the warning component is there, to provide immediate feedback to the user that says this DSI is not appropriate, not useful, and that you might not want to use this here or rely on the results.

Sheryl Turney
That would work.

Steven Eichner
That is explicitly why the three-point recommendation was included.

Steven Lane
Sorry, which one are you referencing, Ike, just so we are clear if we need to make adjustments?

Steven Eichner
It is the DSI recommendation that speaks to the three warning conditions.

Steven Lane
Ah, yes, that is No. 13.

Medell Briggs-Malonson
Excellent, wonderful. Thank you so much, Sheryl, for all of those comments and revisions and for your advocacy. Clem, we are going to go directly on over to you as well for your questions or comments.

Clem McDonald
It is not a question, it is a compliment. I have never heard such a gloriously good summary of a lot of stuff about standards in all my standards days, so, congratulations, you guys.

Medell Briggs-Malonson
Well, that is a really great acknowledgement! Thank you, Clem. Eliel?

Eliel Oliveira
I totally agree, Clem. It is very specific on DSI and AI, the fact that the recommendation is to not necessarily allow too much to proceed there until we have certification for the methods, for the tools that are available out there that have not been tested in healthcare, so that is a commendation as well to the group for that recommendation.

Steven Lane
I think you are talking about Recommendation 18.

Eliel Oliveira
Eighteen, yes, the **[inaudible] [04:02:30]** recommendation. There is the one related to consent and account of disclosures. I think it was on 22 and 63, but it seems to be everywhere, and that is the point that I think I wanted to highlight there. I think we have been working through consent for quite some time. Years back, I remember looking at ONC's recommendations on how to do electronic consent, and I do not think we have gotten much done, and as you can see here, there is a lot to cover. I believe that we need a plan to at least pick one problem on the whole consent aspect and try to at least have an equal system that actually solves that electronically because, again, the variability and granularity of consent is great. We do not have a system with centrally distributed ways or hub-and-spoke that actually can do any consent at all, so I think we need to start somewhere first, and granular consent is going to get very tricky. I want to highlight that point because I do not know if that got into the recommendation clearly, but a plan of action, like almost a strategic plan for just consent to me would make sense to identify what we do for the next three, five, 10 years, so on and so forth.

The last comment I have is related, I believe, to 46 and 49, when we talk about CDS Hooks and SMART on FHIR, and from my perspective and some of the work that we do with SDOH providers, community health centers, and FQHCs, their EHRs, even today, cannot use CDS Hooks, or if it is there, they do not have the staff for it. I think there are still a lot of limitations on how we integrate things with EHRs. I think TEFCA provides a great opportunity because, being the repository, we do not need a lot of data from EHRs, we just maybe need to know the context, which physician is looking at what patient, and maybe look at TEFCA's FHIR APIs and get the context in place, which might solve the problems that Jim and Cheryl were talking about, where I need to know the whole history here in a summarized way, not a hundred-page CDA that I need to go through, so I highly recommend that we look at the opportunity to integrate with other systems because certified EHRs are not the only systems that we deal with today, and there is a place for CDS Hooks there, but I think we need a better way to expand on that, especially for these small providers, which are critical for underserved populations and for health equity.

Medell Briggs-Malonson
Excellent, thank you. Steven, you wanted to respond to that?

Steven Lane
Yes, a little bit. I could not agree more, Eliel, and I think this did not really come up in our task force discussions. It was incorporated into the NPRM, I think very thoughtfully, where they said, "We are going

to start here," and then they asked for recommendations. I think you mentioned, for example, Recommendation 22, where they said, "What are the current technical standards that we could consider?", so the task force did recommend those. In CDS Hooks, similarly, they asked about that, and we gave a specific recommendation about starting with high-value hooks, starting small, and then building on that, so I think a lot of those ideas were incorporated. You made a point about the fact that not all health IT is certified. There was a lot of discussion about the importance of considering the full ecosystem of data exchange from certified to noncertified, from EHR to non-EHR health IT. Thank you.

Medell Briggs-Malonson
Thank you for that. I see Aaron, Bryant, and Jim. Again, we have about 10 minutes. I want to make sure we can get everyone's thoughts and recommendations in as well so we can be nice and concise. Aaron, we will first start with you.

Aaron Neinstein
I will be very quick because I am actually interested to hear more from you all because you are going so quickly through these. You made a comment during Recommendation 53 about write APIs, which is an area that is very important to providers and health systems, and that you were concerned that, as currently written, we might be headed in the wrong direction on write APIs, so I was wondering if you could spend a little bit more time talking through that.

Steven Lane
I do not think it is so much that we are headed in the wrong direction, I just had hoped that this would move us in the right direction, and it really did not. It just makes it a little easier for certified health IT developers to get out of it, so 53 really is a forward-looking recommendation to ONC to ask them to address this issue, that providers do want to be able to utilize write access to API data, and it has not been addressed yet, so you have another chance later this year. HTI-2 is coming.

Medell Briggs-Malonson
Bryant?

Bryant Thomas Karras
On the e-case reporting recommendations, specifically replacing real-world with live or systems specified by the public health community, I am sure that when it becomes a notice of Proposed Rulemaking, ONC staff will tighten that up because it seems like there are some big loopholes in there, with an "or" meaning that the vendor community could pick whichever one was easier as opposed to whichever one actually met the needs of the use case, and I am wondering if the timing might not work out, but in two weeks, we are having a discussion on these very topics at the Council of State and Territorial Epidemiologists, reviewing some of the previous recommendations that have come out of ONC, so we can bring this up with that public health community and see what they would like to be commented in there.

Steven Eichner
I think there is a text edit that tightens it down that we could consider now. That would be perfectly welcome.

Bryant Thomas Karras
Thank you.

Medell Briggs-Malonson
Thank you both. Jim?

Jim Jirjis
This is in regards to 22, which I think is patient-requested restrictions. One of the things I wanted to point out in the world of unintended consequences is that the way that EMRs are designed right now, if this means allowing patients to go into USCDI and select elements, like a lab test or an HIV result that they want to have restricted, it may not occur to them that in the narrative of a note, they may believe they are protecting that diagnosis when, in fact, they are not because the data model does not categorize things the way people think. So, one of the cautionary things, and maybe it is in the education, is the unintended consequence of a patient feeling like they hit that lab result, not realizing that there are 37 other places that are not structured or codified in the USCDI where that is transmitted. I think that is a big deal because how patients approach this cognitively and what they are thinking is a different layer of data abstraction than the EMR tools can do today, and I think there may be unintended consequences to the patient.

Steven Lane
Jim, I could not agree more, and I think you are right, that is where that educational recommendation came from, that patients deserve to have some standard understanding of what it means to restrict data, both what the limitations and the potential unintended consequences are.

Medell Briggs-Malonson
Very excellent observation there.

Steven Eichner
The draft recommendation is for creating the environment for the education materials, but we did not recommend specifically what those materials might be, and that may be a gap, but I am not quite sure how to fill it.

Medell Briggs-Malonson
All right. I just saw Anna.

Anna McCollister
On that note, that is one of the discussion points that we had in our subgroup around data restrictions, is helping patients understand who is accessing their data by making it a requirement that providers, niche provider organizations, or certified health IT vendors give patients a report on who has accessed their data, when, and why, because if you do not have a sense of who is accessing your data, you get scared and think you should restrict it from anybody accessing your data, whereas if you have a better understanding of why the data is being accessed, by whom, and for what purpose, they will be more likely to allow the data to flow and be interoperable because they will have less of a sense of fear that the wrong person could be accessing it. Right now, it is just this big black box. Everybody knows their data is being accessed, but nobody knows who is getting access to it, whether it is your provider at another institution or that stalker guy from Facebook. So, it is a concern.

Steven Lane

I think this was the genesis of the recommendation to go back and look at the prior recommendations literally from 10 years ago about how to make accountings for disclosures more robust, and those recommendations still hold water today. At the time, they were looked at, and the thought was that the technology did not exist to support it, but I think 10 years later, that is no longer the case.

Steven Eichner
Ten years ago, we were not focused as much on operationalizing information exchange between providers with the exchange that is currently occurring and that we are all working hard to make happen in the future would be that it either exists or should be made to exist rather simply and rather effectively that that information can be tracked and made available to patients.

Medell Briggs-Malonson
Excellent. So, this has been a wonderful set of conversations, as well additional ideas, and so, I want us to try to recap some of the different recommendations that just came from HITAC, and especially as it pertains to each one of the different recommendations. So, for instance, Recommendation No. 16 may have had some revisions, and there are a few others, so, Steven, I have a feeling you are writing these down. Do you mind recapping some of the recommendations that came from HITAC to the task force?

Steven Lane
The only one that I captured that I really think requires an edit, in addition to the one that you brought forward, is Sheryl's for Recommendation 16. I think the rest was really helpful commentary aligned with the recommendations that are here, but I think Sheryl's recommendation to eventually require the nutrition label for the DSI would be the one that, if we are making a motion to approve these, I would include in the motion.

Steven Eichner
I would say a friendly amendment to take actionable steps to, rather than eventually requiring. "Eventually" can be a very long time.

Medell Briggs-Malonson
Wonderful. Therefore, just to recap all of those items, we had one addition, which was 19A, and that was to ensure that it is required as part of certification that there is frequent monitoring post-DSI implementation to ensure that there are no unintended consequences for various different demographic groups, subpopulations, or rare medical conditions, and the other addition is adding from what Sheryl just mentioned to Recommendation 16, ensuring that that is also part of that certification piece in order for there to be very clear standard language, as what was just mentioned by Steven and Ike. Wonderful. So, those are the two additional recommended revisions. So, at this point in time, I would like to call for a motion to adopt the HTI-1 Task force recommendations with the just-spoken amendments. Do I have a motion?

Steven Eichner
I will make a motion.

Eliel Oliveira
I will make a motion.

Medell Briggs-Malonson

Since you are cochair, I will take Eliel to have made the motion. Is there a second?

Sheryl Turney
I second.

Medell Briggs-Malonson
Thank you, Sheryl. So, Sheryl seconded that motion. The motion has been properly placed on the floor and seconded. Any discussion? Not hearing any discussion, all in favor of adopting the recommendations by the task force with the amendments today say aye.

Several Speakers
Aye.

Medell Briggs-Malonson
All opposed? Any abstentions? Well, congratulations. The motion has been approved unanimously. Thank you all so much for this. Well, Aaron, I guess it is time for the next piece.

Aaron Miri
Next piece. Let's go!

Medell Briggs-Malonson
I do not know how we are going to top that, though.

Aaron Miri
Say you have 55 recommendations.

Annual Report Workgroup Update (04:16:27)

Medell Briggs-Malonson
Well, we will transition directly into the annual report, which is great. We are going to walk right through this, you all, and this is our last leg of the day. It has been fantastic. So, Aaron and I are very pleased to be able to be the co-chairs of this year's Annual Report Workgroup, and we have had a meeting. We wanted to go over some of the basic logistics of the Annual Report Workgroup. Next slide. Just to give a quick update, we are going to talk about this year's workgroup membership, as well as the meeting schedule and next steps, and then we will go directly on into the potential topics for the HITAC annual report for fiscal year 2023. Next slide.

So, this just gives an overview of the workgroup membership, as well as all the amazing ONC staff that is here to also support this work. Some of our additional members, besides Aaron and myself, are Hans, Hannah, Jim, and Eliel, so we appreciate all of you all for your contributions to this workgroup. Next slide. Just to go over some of the meeting schedules and next steps, this is actually an overview of the schedule for the entire Annual Report Workgroup, so during June, we actually met earlier this month, and we developed a list of potential topics for the annual report.

Also, next month, we will be developing the crosswalk of topics for the annual report, and we are going to continue that work all the way up through November. By the time we come back for November itself, the

plan is to develop the initial draft of that annual report, and that will also continue through December making sure that the full committee of HITAC actually does see it. And then, in January and February, the early beginning months, we will update that draft in order to submit it to HITAC for review and approval, and we really hope that by early spring, it is ready for transmittal to both Micky and to the rest of the various different stakeholders. Next slide.

This is also an overview of what we are going to do in terms of reporting out to the full HITAC committee, so today, we are going to give just a brief update on our status to date and discuss potential topics, including those topics that the HTI-1 Task Force actually recommended to be included in the Annual Report Workgroup. Next month, we will also continue to give updates of what we have been doing in the smaller workgroup, and that will also continue on until we are also able to discuss the crosswalk in September, and then, again, we are going to continue to bring all this information back to the full committee, review the draft in January, and ask for the HITAC's approval as of February. Next slide.

Just for some of the next steps, we are really going to focus on the crosswalk of topics, especially thinking about the gaps, opportunities, and any additional activities. For all the new HITAC members that are here, what you will see eventually is that we will literally have each one of the topics, some of the different rationales, as well as the recommended action steps for that as well, and we will present that draft crosswalk for discussion at our meeting on September 14th. Next slide. Aaron, I will turn it on over to you to talk about the topics.

Aaron Miri
Thank you much, Medell. Next slide. All right, these are some of the potential topics we are going to talk about in this year's annual report. We are going to be expanding on some of the topics from last year. First and foremost, off the top, design and use of technologies that advance health equity. I think you are hearing that loud and clear resoundingly, so we really want to double-click on that. We are looking at the electronic exchange of health equity and social determinants of health data, we have heard about that today, so let's really look into that, peel back that orange, and see where we can go with that. There are use of technology to support public health, such as ELR, electronic lab reporting, ECR, electronic case reporting, and syndromic surveillance. Interoperability, looking at interoperability standards priority uses, as well as telehealth and individual divide post-pandemic, privacy and security, which is always near and dear to my heart, and patient access to information. Next slide.

So, here are some of the HITAC members' comments to date, some of the items that we definitely have on our list to look into, design and use of technology to advance health equity, artificial intelligence-driven predictive models in healthcare, not like that is a hot topic right now or anything, use of technology to support public health, interoperability, privacy, and security, sharing sensitive health data in accordance with patients' wishes, which we have heard about today, patient access to information, and then a framework to review the safety and impact of mobile health applications. Next slide.

All right, this is a very preliminary discussion with you all to say that the report workgroup has kicked off, but we want to solicit your feedback. We are not putting you on the spot right now, but we will in the future, so I want you to really think hard about topics that we could be missing, items you have heard today that have gotten the brain juices going, or items that we should think about. Remember, it is our prerogative here and our importance that we look into every single item, comment, question, and thing you bring up.

We put it in our parking lot, we evaluate it, and we see if it can make the report or not. HITAC is critical in that feedback and synthesis of the report, and this report is read by the entire world. I can assure you that lots of folks read this, so it is great to dive into, peel back, and see if there is something here we need to consider that HITAC should evaluate for the future.

So, the three general questions for you all are if there are any questions or comments about what we have presented today, if there are any other topics that should be added to the draft topics list, and if any topics should be removed from the topics list. Again, we welcome your solicited feedback now or later. Email us, send a carrier pigeon, or whatever it is. Let us know your feedback and thoughts. We want that. So, with that, let's see. All right, any questions, comments, or feedback? Anna?

Anna McCollister
I would just like to underline the discussion we had previously, and it is part of the recommendations we just approved to ONC around transparency, about the reporting on use of individual data, but also, one of the things that has always driven me crazy over the years as somebody who comes to this first and foremost as a patient who believes that real-world evidence is critical and important, and that we need data to be accessible, is that there is no accountability or transparency about how all the different institutions that are using deidentified data actually use it, and what it is being used for.

I think it is important for patients to feel okay about the fact that the data is being used, and the reality is that most of the data is being used for really important research, but nobody has any idea whether it is being used for that or for something that they do not really appreciate. So, I think it would be beneficial for all of us and for the entire endeavor around interoperability, as well as promoting the incorporation of the stuff into real-world evidence, for there to be a requirement, like an annual transparency report, for each institution on that year's use of deidentified patient data.

Aaron Miri
So, use and granular consent, basically, both aspects of that? Is that what you are saying?

Anna McCollister
Well, I think granular consent is important, but I would say that is a different issue. This is more around how my data has been used specifically, which was one of the recommendations, but secondly, how this institution has used all the deidentified patient data that was collected for clinical purposes for something else. Was it sold to an insurance company? Was it used for cancer research? Was it contributed to an NIH registry or database? Again, in most cases, I think people would be excited to see that their data is benefiting health and healthcare in the way that it is, but it would also help allay some of the fears around restrictions and access to data. In our current social environment, there is such a low trust and such skepticism about data use, for very understandable and appropriate reasons, but that would go a long way towards promoting this entire ecosystem and preventing potential backlash.

Aaron Miri
Good deal. All right, we have that coming. Thank you very much. Alexis?

Alexis Snyder
Hi, thank you. I think I have been getting this one into the parking lot every year since my first term back in 2020, so I will mention it again today in 2023, that interoperability of EMRs and EHRs is only as good as the accuracy of those records, and to current data, it is very difficult when there are inaccuracies in records to have them corrected as a patient or a caregiver. Every healthcare system has its own rights, regulations, and rules surrounding when you can do that, if you can do it, how it gets done, and whether it is an addendum or actually gets replaced, and when there are errors in your record that get shared with other health systems, we keep repeating the errors, which is a real patient safety problem. And so, until there are universal practices and regulations put in place that every healthcare system handles, like inaccuracies and changes to medical records that come from patient caregivers and other family members and stakeholders, we are not going to fix these problems, and we are going to keep perpetuating errors that potentially are a great safety danger to patients.

Aaron Miri
Thank you. I do recall that being a topic, and I know we were waiting for the information-blocking rules, and there was some legislation pending, which is why it was getting put on the back burner, but we will definitely bring it up this year. Thank you, Alexis. Sheryl?

Sheryl Turney
Thank you for sending it over to me. One of the questions that had related to the topics for the annual report was basically focused on when we are currently looking at medications for public health, I keep reading about all of these cancer drugs that are no longer able to be provided to the patient because they are not available because of supply chain issues. I think we have learned a lot during the pandemic about understanding what we need to know about the drugs that are needed for services. I do not know about what is currently there that gives us information relative to the supplies, so I am just questioning whether that is something we should be looking at as to what are the systems that are available and what is needed in the public forum so that we can ensure that we know we have this many thousand patients with this type of cancer that are going to need some kind of treatment, but we do not have the chemo for them, or the formula for the babies. Whatever it is, there just seem to be a lot of those issues that are coming to the surface now, and I just think there needs to be something we can provide from a public health analytics perspective that would gather that data and make it available so that we can take the time because a lot of these things cannot be solved overnight. They might take months or years.

Aaron Miri
That is a great point, about other ancillary data, if that is the right word for it, in support of the healthcare industry.

Sheryl Turney
Right, and having that information when you need it to say, “Hey, in 15 months, we are going to run out of this. What are we doing in order to have that available?” It is kind of similar to what I was saying in last year’s meeting about physicians in certain specialties, like endocrinologists, and I know I keep picking on the things I am familiar with, but there are a lot of rural areas in this country that do not have endocrinologists, and people have to travel quite a distance to see them. How are we solving that problem? There are programs, but are there enough programs, and is the information available to the right people,

and are we providing a framework so that they can more easily share that information? It is that kind of thing.

Aaron Miri
Great point, thank you, Sheryl. We have that note. Excellent. Fillipe?

Fil Southerland
Thank you. I just wanted to pick up on the topic of design and use of technologies that advance health equity, and I wanted to point out that many of those technologies are specialty EHRs and non-EHR HIT, and I wanted to encourage us to continue to look at the scope of the certification program and the uptake within some of these specialty sectors to help ensure that we do have the incentive structures, to your point earlier, Medell, for these community-based services to pick up this certified HIT modular or full-base criteria, and as we look at continuing to develop the rule, that we consider HIT that is outside of the acute and ambulatory space so that we can create an inclusive program across the care continuum.

Aaron Miri
Great feedback. Aaron?

Aaron Neinstein
So, one item I would love to recommend be considered for inclusion relates to patient access to information. We know that more and more care is moving from the hospital to the ambulatory setting and from the ambulatory setting to the home, and one area of health data that continues to fall off the radar screen is patient device data. More and more people are using continuous glucose monitors, wearing pacemakers, wearing wearable devices, and using home spirometers, and those data remain very hard to access. We talk about transmission and use without special effort. Quite a lot of effort continues to be required to gain access to medical device data. So, in my own practice in endocrinology, when I sit down for clinic, I log on to seven portals, each with their own username and password, to access continuous glucose monitoring and insulin pump data. Every single clinic, every endocrinologist across the country logs into the EHR and seven different device maker portals because we are not making these data accessible via API.

Aaron Miri
Great example. Horrifying, but great example. Ike?

Steven Eichner
Sorry, I did not realize I was not mic'ed. Looking at HITAC's sphere of influence, looking at ensuring patient privacy and confidentiality, looking at these third-party tools that are not necessarily provided by healthcare providers, and helping patients really understand the impacts of who may have access to their information for these third-party resources is another key piece that we may want to look at. In the same vein as looking at health IT module certification and data standards that go outside of traditional healthcare, supporting things like situational awareness, how do we look at health IT module certification or certifying technology outside of global EHR space to support activities like situational awareness where there may be data coming out of inventory systems and human resource systems that need to be interactive with EHRs to support activities like situational awareness and other areas where the same information may have use for other health purposes? That is my little list. Thank you.

Aaron Miri
That is great, Ike. Thank you very much. I will also say that in the same context, medical devices, specialty wearables, digiceuticals, therapeutics, and other things, all the data there, how to make those interoperable, partnering with folks like the FDA, FTC, and others to work together under one umbrella are pieces that we have called out in prior reports that we can maybe pull forward and begin a double click, especially as we have more promulgation of the information-blocking rules, and now as HTI-1 gets finalized with all its items, to see where we can go with it as an industry, so that is great feedback.

Other comments, questions, or items? Again, I want to encourage you to please reach out to me, Medell, Michelle, or any of us with any items that pop in your head. If you are flying back and thinking about things like, "Oh yeah, this thing too, and one more thing," let us know. That is the point of these discussions. We are going to keep bringing this back to you meeting after meeting, just continuing to keep the brain hurricane going. Let's talk about it and really make this a good report this year so that we can synthesize something that is excellent, as we always have. Medell?

Medell Briggs-Malonson
Nothing else to add. That was perfect.

Aaron Miri
All right. With that, we are running a few minutes ahead. Mike? Sorry, Clem, I missed you. I apologize.

Clem McDonald
We really have time to just talk about other things.

Aaron Miri
Go for it.

Clem McDonald
Ships and sails and sealing-wax! There are lots and lots of science awards, this and that. There is nothing for standards. It is kind of a lonely, hard job, but if we could elevate it a bit by a prize or a label or something, that could be something you guys could create so that it would incent the crazy people who do this stuff to keep doing it, or the newer people who are not crazy yet.

Aaron Miri
The operative word is "yet."

Medell Briggs-Malonson
So, Clem, almost like a blue ribbon prize that goes directly on the standards?

Clem McDonald
I think you would like something a little different than a blue ribbon.

Aaron Miri
I cannot follow that up.

Medell Briggs-Malonson
Any other comments? If not, we turn it over to Mike. I am going to keep on brainstorming, Clem.

Clem McDonald
I was thinking of something you would not get at a state fair.

Aaron Miri
All right. Any other feedback or comments from the HITAC roundtable? Excellent discussion today. Mike, are you good with it?

Public Comment (04:37:09)

Michael Berry
I am good. We are going to open up the meeting for verbal public comment. If you are attending the meeting in person, please step up to the podium. If you are attending the meeting virtually, please use the hand raise function, which is located on the Zoom toolbar at the bottom of your screen. If you are on the phone only, press *9 to raise your hand, and once called upon, press *6 to mute and unmute your line. I see Shelly Spiro's hand raised. Shelly, you can unmute, and you have three minutes.

Shelly Spiro
Thank you very much. Can you hear me okay?

Michael Berry
We can.

Shelly Spiro
I am Shelly Spiro, the Executive Director of the Pharmacy HIT Collaborative, and I just want to thank the HITAC committee members and ONC for finally giving us a process for this new task group on the Pharmacy Interoperability and Emerging Therapeutics Task force. We believe this is very useful to the pharmacy profession, and on behalf of the pharmacy profession, I want to thank ONC for appointing me as one of the co-chairs to this important effort. Thank you.

Michael Berry
Thank you, Shelly. I wanted to also take the opportunity to thank the ONC SMEs, my team, and the ONC program leads, Dan Healy, Sara McGhee, Dustin Charles, and Michael Wittie for their really incredible efforts supporting the HTI-1 Proposed Rule Task Force. They have put many hours in to support the work, and I want to extend my thanks to all of them. I also want to remind everyone that our next HITAC meeting is scheduled for the middle of July, and also that the meeting materials for today, which I think all of you in the room have, but for those of you listening virtually, can always be located on the HITAC calendar at HealthIT.gov. With that, I am not seeing any further hands raised, so I will turn it back to Aaron and Medell.

Final Remarks and Adjourn (04:39:14)

Medell Briggs-Malonson
Thank you so much, Mike. Once again, thank you to the entire HITAC for an amazing day. We had some great, robust conversations, we made some great progress on the approval of our recommendations to

HTI-1, and thank you so much to our ONC leadership, as well as our ONC staff, for hosting us in your home. We look forward to so many more meetings like this in the future, so thank you.

Aaron Miri
Absolutely. I want to echo what Medell said. First of all, wasn't this fun? This was fun, right? All right! Well done to all of you. Well done to the ONC staff. Thank you, Micky, to your team, you, Elise, Steve, and the whole crew. That was fantastic. It does not happen without you all, though, roundtable HITAC, so be proud of today, be proud of the work we have going on here, and we have many more meetings to do and a lot of hard work in front of us, but it is exciting, so, safe travels, enjoy, and we will see you soon. Thank you! With that, we are out.

Michael Berry
All right, thank you, everyone. We stand adjourned.