The Office of the National Coordinator for Health Information Technology

Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) MEETING

February 10, 2021, 9:30 a.m. – 1:05 p.m. ET

VIRTUAL

Speakers

Name	Organization	Role
Aaron Miri	**The University of Texas at Austin, Dell Medical School and UT Health Austin**	**Co-Chair**
Denise Webb	**Indiana Hemophilia and Thrombosis Center**	**Co-Chair**
Michael Adcock	Magnolia Health	Member
Cynthia Fisher	PatientRightsAdvocate.org	Member
Lisa Frey	St. Elizabeth Healthcare	Member
Valerie Grey	New York eHealth Collaborative	Member
Steven Hester	Norton Healthcare	Member
Jim Jirjis	HCA Healthcare	Member
John Kansky	Indiana Health Information Exchange	Member
Kensaku Kawamoto	University of Utah Health	Member
Steven Lane	Sutter Health	Member
Leslie Lenert	Medical University of South Carolina	Member
Arien Malec	Change Healthcare	Member
Clem McDonald	National Library of Medicine	Member
Brett Oliver	Baptist Health	Member
Terrence O'Malley	Individual	Member
James Pantelas	Individual	Member
Carolyn Petersen	Individual	Member
Raj Ratwani	MedStar Health	Member
Abby Sears	OCHIN	Member
Alexis Snyder	Individual	Member
Sasha TerMaat	Epic	Member
Andrew Truscott	Accenture	Member
Sheryl Turney	Anthem, Inc.	Member
Robert Wah	Individual	Member
Amy Abernethy	Food and Drug Administration	Federal Representative
James Ellzy	Defense Health Agency, Department of Defense	Federal Representative
Adi V. Gundlapalli	Centers for Disease Control and Prevention	Federal Representative

Jonathan Nebeker	Department of Veterans Health Affairs	Federal Representative
Michelle Schreiber	Centers for Medicare and Medicaid Services	Federal Representative
Ram Sriram	National Institute of Standards and Technology	Federal Representative
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
Beth Myers	Office of the National Coordinator for Health Information Technology	Deputy Director, Office of Policy
Avinash Shanbhag	Office of the National Coordinator for Health Information Technology	Executive Director, Office of Technology
Lauren Richie	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Al Taylor	Office of the National Coordinator for Health Information Technology	Presenter
Carmen Smiley	Office of the National Coordinator for Health Information Technology	Presenter
Chris Muir	Office of the National Coordinator for Health Information Technology	Presenter
Wanda Govan-Jenkins	Office of the National Coordinator for Health Information Technology	Presenter
Larry Jessup	Office of the National Coordinator for Health Information Technology	Presenter
Phil Beckett	HASA	Presenter
Eric Heflin	Texas Health Services Authority	Presenter
Bill Marella	HealthShare Exchange Pennsylvania	Presenter
Elizabeth Scoles	HealthShare Exchange Pennsylvania	Presenter

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

Operator
All lines are now bridged.

Lauren Richie
Good morning, everyone. Welcome back to our second meeting of the year here. We have had quite a bit of news and activity from the ONC side, including our new National Coordinator, so we are looking forward to hearing from him a little later. As a reminder, especially to our new members, please remember to use the "raise hand" function in Adobe if you would like to make a comment or a question. It is in the upper left/middle of your screen. So, this will not be as long as our meeting last month, but we have some important content to cover, so with that, I am going to get started with roll call. Aaron Miri?

Aaron Miri
Good morning.

Lauren Richie
Denise Webb?

Denise Webb
Good morning.

Lauren Richie
Michael Adcock indicated he would be absent today. Lisa Frey?

Lisa Frey
Good morning.

Lauren Richie
Cynthia Fisher?

Cynthia Fisher
Good morning.

Lauren Richie
Brad Gescheider? Sorry about that. Valerie Grey?

Valerie Grey
Here, good morning.

Lauren Richie
Steven Hester?

Steven Hester
Good morning.

Lauren Richie
Jim Jirjis? Not yet, okay. John Kansky?

Unidentified Speaker
Give me five minutes. I need to give my roll call and then come.

Lauren Richie
Okay, I do not think that was John. Was that either Jim Jirjis or John Kansky? Okay, we will circle back. Ken Kawamoto?

Kensaku Kawamoto
Good morning.

Lauren Richie
Steven Lane?

Steven Lane
Good morning.

Lauren Richie
Les Lenert?

Leslie Lenert
I am here.

Lauren Richie
Arien Malec?

Arien Malec
Good morning.

Lauren Richie
Clem McDonald? Not yet. Brett Oliver?

Brett Oliver
Good morning.

Lauren Richie
Terry O'Malley? Not yet, okay. James Pantelas?

James Pantelas
Good morning.

Lauren Richie

Carolyn Petersen?

Carolyn Petersen
Good morning, everyone.

Lauren Richie
Raj Ratwani?

Raj Ratwani
Good morning.

Lauren Richie
Abby Sears?

Abby Sears
Here.

Lauren Richie
Alexis Snyder? Not yet. Sasha TerMaat?

Sasha TerMaat
Good morning.

Lauren Richie
Andy Truscott?

Andrew Truscott
Good morning.

Lauren Richie
Sheryl Turney?

Sheryl Turney
Good morning.

Lauren Richie
Robert Wah?

Robert Wah
Present. Good morning, everyone.

Lauren Richie
Michelle Schreiber?

Michelle Schreiber

Good morning. Present.

Lauren Richie
James Ellzy?

James Ellzy
Good morning.

Lauren Richie
Ram Sriram?

Ram Sriram
Good morning.

Lauren Richie
Adi Gundlapalli? Not yet. Jonathan Nebeker?

Jonathan Nebeker
Good morning.

Lauren Richie
And, Amy Abernethy? Okay, not yet. And then, from our ONC leadership side, we have our new National Coordinator, Micky Tripathi, Deputy National Coordinator Steve Posnack, Executive Director of Policy Elise Sweeney Anthony, and Executive Director of Technology Avinash Shanbhag. And, before we turn it over to the National Coordinator, I will turn it over to our co-chairs to start with a few opening remarks, and then we will jump into the meeting. Denise and Aaron?

Remarks, Review of Agenda and Approval of January 13, 2021 Meeting Minutes (00:03:41)

Aaron Miri
All right, fantastic. Welcome, everybody, to the February edition of the HITAC. I guess this is our Valentine's edition. We would do something around health policy valentines, but we will spare all of you that joy. So, welcome, and I look forward to today's meeting. Denise? Denise, are you there?

Denise Webb
Oh, I apologize. I must have hit my mute button. Good morning, everyone. Welcome to our second meeting of the year. We have an ambitious agenda this morning, and we are especially looking forward to welcoming our new National Coordinator, Micky Tripathi, after we approve our minutes, and then we are going to go into a vote. We are ready to vote on our FY20 Annual Report. Following that, we are going to have our co-chairs, Steven Lane and Terry O'Malley, give an update on our USCDI Version 2 task force work. We have had two meetings so far. Then, we are going to get a presentation from ONC on Project US@.

Following that, Larry Jessup from ONC is going to introduce two of our cooperative agreement recipients of the STAR HIE program – they are two of five. That will be the Texas Health Services Authority and the

HealthShare Exchange Pennsylvania. And then, our final presentation will be on the interoperability standards priorities. Then, we will go to public comment. We want to stay on track so we do that on time, and then we will conclude with any final remarks and adjourn. Before we have Micky welcome himself and make some remarks, I am going to turn it back over to Aaron for any other remarks he has and to approve the meeting minutes.

Aaron Miri
Absolutely. So, let me first say welcome to all of you again for joining, and I am really honored and pleased on behalf of the HITAC to introduce you all to our newest National Coordinator, Micky Tripathi. Micky, congratulations on your appointment. Welcome to the HITAC. I know that you are an alum from the standards committee days and the wonderful work you did there and your later focus on outcomes, which will be very welcome to our group here. The HITAC is a group of brilliant clinicians, technologists, healthcare professionals, and patient advocates, and you coming and joining us is a phenomenal addition, and we really welcome that. And, we also look forward to collaborating with you on some of the newest classic rock mix tapes I am certain that we will all collaborate and come up with. So, welcome, Micky, and I will turn over the floor to you.

Denise Webb
Before we do that, Aaron, can we approve the minutes? Sorry, I do not mean to interrupt. Can we get a motion for approval of the minutes?

Aaron Miri
[Laughs] Approved, and a second. All those in favor, say aye.

Several Speakers
Aye.

Aaron Miri
Any voting nay, say nay. All right, minutes are approved. It would not be health IT without some little kerfuffle. Micky, over to you, sir.

Denise Webb
Oh, you are so excited.

Welcome Remarks (00:07:24)

Micky Tripathi
Let the minutes record that the minutes were approved. Thank you so much, Aaron and Denise, and welcome. This is my first HITAC meeting as the National Coordinator, and I really want to welcome and thank everyone for joining. It is just fantastic to see so many familiar faces and friends from over the years, and also some new faces that I know just by name and reputation, but I look forward to getting to know all of you and working with you.

I have worked with a number of you over the years, but I know a number of you may not have a good sense of my background and what brought me here, so I just thought I would give a little bit of background, and that begins with something that many of you may not know. I have past federal service. I worked as a

federal employee a while ago, for six or seven years in the Pentagon in the Secretary of Defense's office and on the air staff – in the Air Force Chief of Staff's office – where I was a Presidential Management Fellow, and I worked in the federal government for roughly six years before leaving to go back to academia and on to other things. But, it is really exciting to be back working directly in the people's work. I really could not be more excited about doing that, particularly at this time in the industry, with all of the great opportunities that we have ahead of us as well as the challenges.

I have worked in health IT. My beginnings were working in Indianapolis, where I was able to work with the Regenstrief Institute and some of those legendary figures there, like Clem McDonald, who I know is here on the phone. Imagine learning health IT from Clem McDonald directly. That was one of the greatest opportunities ever. But, helping there with launching Indiana Health Information Exchange through leading the Massachusetts eHealth Collaborative for a number of years, which was a collaboration of Blue Cross/Blue Shield in Massachusetts, the Massachusetts Medical Society, and the American College of Physicians, to collaborative industry initiatives over many years, such as the Argonaut Project, HL7, and Sequoia Project. I feel like I have spent my career in health IT working on collaboration and trying to bring everyone together on the things that we can agree on and that we can move forward on. So, I could not be more excited about the capital C part of the National Coordinator's role and what I can help with here.

What is in interesting is that in just my short time – I will just remind everyone that I am on business day 15 of my current job, and as closely as I have worked with ONC over the years – you think that you know everything, and then you just cross that little border, and then you are on the other side of it, and you look around and say, "Huh, there is a lot here that I am familiar with and a lot that I am not familiar with." So, I am really excited about the learning opportunities here to be able to exercise everything that we can do from the National Coordinator's side, and I am very grateful to the fantastic team that ONC has, many of whom I knew from before, but we really have an amazing team here, and I am really grateful that this team is here and can keep everything moving very rapidly.

I am particularly grateful because we are all working remotely right now, so if any of you may wonder where command central is for ONC, we are here in Newton, Massachusetts in my study, and as administration policy, we are going to be fully remote for a while. We have an emphasis on maximizing workplace safety, so all of the ONC staff is working remotely, including me, and will continue to do that until there is a change at the administration level in terms of how we are going to manage the slow return based on the data and workplace safety considerations.

I will say I so deeply respect the work of the FACAs, as Aaron pointed out, having lived on the other side of it for many years with the HIT policy committee and the HIT standards committee, and I appreciate the energy, expertise, and experience that the FACAs can bring to the table, and I also appreciate how much work it is because for all of you, it is volunteer work. I appreciate it so much, and I have lived how much work that is, and we try not to abuse the privilege with you, but we greatly respect all the contributions that you have made and will continue to make looking forward.

We do have an incredibly busy year ahead of us. I think Denise laid out the agenda that we have today. So, there are a few things I just want to raise for your awareness, and then I will turn it back to Aaron and Denise for any final comments and to begin the agenda. First, as I pointed out, I'm on business day 15, so while I was able to hit the ground running, I hope you appreciate that I am on business day 15, so I just

want to give you a little bit of awareness here, but there will be more to come as we start to shape the program and move forward with it.

First off, COVID is the top priority of the administration, ONC included, period, full stop, and there are a number of excellent executive orders that I think you all have seen and are familiar with, and there is a government-wide effort and an HHS-wide effort now to build the structure for executing those executive orders, so we are working with all of the other operating and staff divisions to break all those down into workstreams and then to implement those. So, we will certainly have more to share on that once the dust settles and it is fully in place, but that is active work going on that is rapidly getting launched here.

You will start to see that we are starting to build the educational program and the outreach program to support the CURES Act final rule. We have the April 15th applicability day coming up. You were hopefully able to participate in the frequently asked questions webinar that we had last week. The recording is available. That was available on February 4th. You will start to see more and more from ONC in terms of education and outreach, and we really look forward to working with all of you on that.

As I think was discussed at the last HITAC meeting, we anticipate the need to engage a number of new task forces this year, but again, we appreciate all of your interests in those, and we are now figuring out which ones need to get launched in which priority order and where they will go, but we really appreciate that, and that will be a very active part of what we do going forward. The newly reconstituted USCDI Version 2 task force has already met twice, and I think we are going to hear from them today, and that is exciting for us because the USCDI process is an incredibly important part of the many things that we do here at ONC. And then, finally, I would be greatly remiss if I did not remind everyone – you probably got emails and tweets about this – to save the date for the ONC annual meeting, which is coming up on March 29th and 30th. The registration information should be coming shortly, but I absolutely wanted to make sure that all of you were aware of that, and I really look forward to your participation there.

So, again, I want to especially thank our new co-chairs, Aaron and Denise. I really look forward to working with you, as does the entire ONC team. I also want to offer thanks to Robert and Carolyn, and I know I can extend thanks with confidence from my predecessor, Don Rucker, as well for your leadership over the past few years. Again, I know it is a lot of work and responsibility, and we really appreciate everything you have done, and we look forward to working with Aaron and Denise going forward. So, again, I just want to thank everyone. I am really delighted to be here. I just could not be more excited. I look forward to working with each of you together and individually, and please reach out any time. Let me turn it back over to Denise and Aaron now for any additional remarks before we get started.

Aaron Miri
Thank you, Micky. We appreciate that, and we appreciate the comments and look forward to it as well. So, with that, Denise, unless there is anything you would like to add, we should go on to the next item.

Denise Webb
I would just like to thank Micky for his introduction and remarks, and again, welcome and congratulations. Aaron and the rest of the committee, I apologize, but I am having camera problems, so I will see if I can remedy that. We are going to take a vote today on the Annual Report. The workgroup has done a fantastic job. ONC has provided tremendous support for us to get to this place today, and thank you to our co-chairs

Aaron and Carolyn. So, I think we can proceed with our discussion for a vote on our Annual Report workgroup, and I think you have a little presentation before we take our vote, Aaron. Is that correct?

Aaron Miri
Yes, ma'am, we do.

Denise Webb
Okay, I am going to turn it over to Aaron and Carolyn.

Aaron Miri
Sure. Carolyn, do you want to kick us off?

HITAC Vote on Final FY20 Annual Report (00:16:58)

Carolyn Petersen
Sure. Good morning, everyone. It is great to see you again, and as Aaron said, happy Valentine's Day. Could we have the next slide, please? So, today, we are here to look at the revised draft of the Annual Report, which we revised based on your comments in the January meeting, and hopefully we will take a vote on that. Can we have the next slide, please, and the next slide?

So, as you are familiar with our schedule, today, we are just about at the point of voting and moving the report forward to the National Coordinator. Next slide, please, and the next slide. So, today really is just some time for us to discuss – answer any questions that you have or have any further discussion about what is in the report, and Aaron and I are happy to answer your questions.

Aaron Miri
Maybe we could ask the Accel team to pull up the final report on here. And, while that is being done, I want to take a moment and thank Michelle, Elise, Lauren, and the entire ONC team. As Carolyn and I have been saying over the past several years, this work product has all the HITAC feedback and the feedback from the public that goes into it. It really is just a heroic effort and work product by the ONC team, so we really thank them tremendously from the bottom of our hearts for their amazing ability.

Carolyn Petersen
Absolutely.

Aaron Miri
With that, I would like to really talk about this because this is the meeting where we need to approve this and then move it forward or have further discussion. So, let us just open it up to general questions. Any questions from any HITAC member? Do not all talk at once, okay. I see Steven Lane.

Steven Lane
This is really more of a comment than a question, Aaron. This is such a labor of love that you all have put together, and everyone who provided input and comments along the way – it is really a marvelous document and a great thing to hand over to a new administration and new leadership at the ONC to fully describe the depth and the breadth of consideration that has been taken, and really, the enthusiasm that the HITAC has

for contributing to the work of the ONC and helping to move that forward. So, I really want to give a big thank you to the team who assembled this.

Carolyn Petersen
Thanks, Steven. We appreciate it.

Aaron Miri
Thank you, Steven. So, I will say for this report – as we have always done every year, we get better, we continue to learn, so feedback, comments, and all of that have been captured and logged, even comments that are going to go to a future edition. As you can see over the years, we always reference the comments from the HITAC, and it feeds year over year. Sometimes, we are waiting for a rule to be finalized or whatever else so we cannot put it in the report, but it is not like it is forgotten, so please, even as you prepare to start planning the next year's report, please feed them to us. Please feed us your thoughts and let us know what is going on there.

The other welcome addition to this year's report, as I mentioned in the last meeting, is that we synthesized a real-world story for each of the sections of each of our charges and what it would look like once we solve the interoperability or privacy and security challenges, so try to look at those stories. We are trying to connect the policy leaders, technical comments, and interoperability explanations into what this means for a clinician, a patient, and for the general public. Those are important because they begin to anchor our work and all the bits and pieces. This is not easy, but the more we can conversationalize these challenges and look for leaders to work through them, the faster we can get to the goal as an industry and take care of patients at a much better rate. Any more comments from the HITAC?

Denise Webb
If we have no further comments, we might be ready for a vote, Aaron and Carolyn.

Aaron Miri
I believe so. Carolyn, what do you think?

Carolyn Petersen
Absolutely, if there is no further discussion.

Denise Webb
Okay. Well, if there is no further discussion, could I have someone make a motion for approval of the HITAC Annual Report for fiscal year 2020?

Unidentified Speaker
I vote for approval.

Unidentified Speaker
Second.

Denise Webb
All those in favor, say aye.

Several Speakers
Aye.

Denise Webb
Those who are not in favor, say nay. Any abstentions? Well, it looks like we have approval for our Annual Report for fiscal year '20. Congratulations for all the hard work.

Aaron Miri
Well done, HITAC, well done.

USCDI v2 Task Force Update (00:22:45)

Denise Webb
All right. Up next, we have an update from our USCDI task force co-chairs. I will turn it over to Steven and Terry.

Steven Lane
Thank you so much. Terry, did you join us? I did not hear him in the initial roll call.

Denise Webb
I thought I saw him.

Steven Lane
Well, let me forge ahead and thank everyone for relaunching the USCDI task force and giving us an opportunity to meet again. We have pulled together a marvelous group of people this time. On the next slide, you have the roster of folks who are involved in our task force, a number of you from the HITAC as well as additional folks who have been involved in other efforts within and beyond ONC, so it is really quite an engaged group.

As you have heard, we have had two meetings thus far, and have really started to dig in already to the charges of the task force. This is the third iteration of the USCDI task force this year. We have had two prior groups that have met and worked through a number of issues, but this time, the group was pulled together specifically to address the draft Version 2 that was published earlier by ONC to collect comments, observations, and suggestions and bring them forward to the HITAC by mid-April in the same timeframe that the public comment is being collected, and then there will be a set of recommendations brought here for extension on to the National Coordinator. I apologize if you hear my dogs barking in the background. My wife is trying to get them breakfast.

On the next slide, you will see the task force charges, specifically to review and make recommendations on the draft Version 2 of USCDI, as I mentioned, but then we have broken that down into a number of sub-charges. The first focus between now and April is to evaluate that Version 2 draft and provide recommendations around changes that have been made from or in the USCDI Version 1 categories that have already been out there in the public space for a long time. We have been focusing on this initially. There are also a number of applicable terminology standards that apply to those Version 1 data classes and elements, so those have been proposed to advance as those versions have advanced. We are then

starting to dive into the new classes and elements that were proposed to be in draft Version 2 by the ONC, and then, also looking at all of the data elements that were leveled at Level 2 that were felt to be technically ready and feasible to bring into the USCDI, but only a subset of those were actually suggested in the draft Version 2 for advancement.

After April, once we have worked our way through that, we are going to be refocused on the USCDI expansion process to provide recommendations back here to HITAC about the ONDEC system that was built to collect suggestions, the evaluation criteria and process used to assign those suggested data elements and classes to levels, and then, the prioritization process, which I think is really key. I think many stakeholders were struck by the modest size of the changes in draft Version 2, and that has raised a lot of questions about how ONC decided to approach this and how to prioritize items that are technically ready to be brought forward into the USCDI. So, the group has already said that they are interested in developing a recommended set of guiding principles that can be used to inform that prioritization process, and I think people are really engaged in that.

So, on the next slide, we do mention here what is out of scope for the task force, and I think some task force members were disappointed by this, but we have not been asked to look at suggested data elements and classes that were leveled as Level 1 and Level 2. We have come to learn that a lot of work has been done by the ONC to evaluate the many, many submitted data classes and elements to look at their technical readiness, the degree to which they have been utilized in connectathons and the production system, et cetera, so there were many elements that were set at the comment or Level 1 level within ONDEC, and the task force has been invited to submit individual comments through the ONDEC system regarding those, but we are not going to be looking at those at the task force level.

On the next slide is a graphic that displays all of the items currently in USCDI draft Version 2. Those with the stars or the little arrows next to them are those that have changed since Version 1, so the starred items are either new or moved. I guess all the starred items are new, which is to say we have created – or, the ONC has suggested – two new data classes around diagnostic imaging and encounter information. They moved over a couple of data elements from other classes to be consistent there, and then, there has been a small number of new data elements that have been proposed, which we will come back to.

On the next slide, as I mentioned, are the applicable terminology standards that have advanced between the time of publication of Version 1 and today, so our task force has already gone through these, and it was felt that these were appropriate to update. Some of these may update even further before the April timeframe – for example, I think we heard SNOMED might have another version – but we will come back to the HITAC with recommendations about these.

On the next slide, you will see the recategorization or reclassification of a few data elements into these new data classes specified for diagnostic imaging and laboratory. On the next slide, you see the truly new data elements that have been proposed for inclusion in USCDI Version 2. As you can see, it is really quite a modest list. The approach here really came from the recommendations from prior USCDI task forces and the ONC to really keep the iterative changes quite modest so that the industry could adapt to them. I think our task force is going to spend a lot of time discussing whether these were the appropriate items to add, whether there are others that should be added to this list or swapped out, and again, those recommendations will come back here for review prior to advancing them to ONC.

On the next slide is a good graphic representation of the timeline that we are in the midst of. This describes the annual review process or cycle that we are going through. Again, here, we are kind of just in this first red and blue box, where the HITAC – through our USCDI task force – is collecting comments and preparing the report, as well as collecting public comments. It ends up that all the comments that come forward to the HITAC will need to be made part of the public record, so as we are reaching out to various folks across the community, we are inviting them to submit their comments through the website, so as those come in, all of us have the chance to review those in their native form as well as the discussions that we are having in our task force.

Once we finish our work in April, ONC will review all of our and the public's comments and come out with a final USCDI Version 2 in the middle of the year, after which that will be considered for addition to the standards version advancement process. I am sure we will get more detail on that again when that time comes on. And then, as you see, it starts the next cycle, so I think a lot of the work that our task force is going to be doing will really be to inform the next cycle, this being the first recycling of the USCDI after its initial publication – again, in the midst of the pandemic and with everything else going on, this is probably going to be a relatively modest change, but I think there is a lot of energy to see this moved forward in the future to support nationwide interoperability, and hopefully, our work will set us up for the next cycle as well.

On the next slide, you just see what we have laid out. We have a pretty ambitious schedule of weekly meetings, and as Micky said, being on a FACA or FACA task force is a lot of work, but I think our team is up for it. Most of the folks on the team are really quite seasoned at this, and they have jumped in with both feet. So, I will stop there and ask Al Taylor from the ONC staff, who is really providing primary support and is really the engine behind USCDI, to add anything that I might have left out.

Al Taylor
No, Steven, thank you. I think you covered everything every well, and should there be any questions, taking those questions through the task force or through the comment system, as Steven mentioned, or directly through ONC is what we would like to see.

Steven Lane
Great. Well, if there are no questions, we will hand it back to you, Denise and Aaron.

Denise Webb
Steven, this is Denise. I am on the task force, and I just have a question or comment. I was wondering – did you want to highlight any of the meatier topics that we have already gotten into and mention those to the committee for any reflection from the entire committee, or do you think that is premature.

Steven Lane
Well, we certainly can. I do not know how much time we have. It looks like we are ahead of schedule as it is, but again, as I intimated, the main issue that has come up – and, I am sorry I was not sharing my camera earlier; I thought I was – the main issue that has come up has really been, again, the modesty of the rather small additions. So, there have clearly been key groups and constituencies who have come forward and said, "Gee, there are all these other things that are so important that we really should consider adding," and Micky, I do not mean to put you on the spot, but in your new role, you are going to be in a position to help

inform ONC's approach to this. Are we going to keep this a small list before the purported benefit that brings to providers and vendors, or are we going to be more ambitious? There has clearly been input that the pandemic response itself would be highly benefited by making USCDI more robust more quickly, that driving the specific exchange of identified priority data elements could really help us in the response.

So, I think there was a large and thoughtful submission from the public health community about what was needed to support that. I was involved in putting that together. Similarly, so much work has been going on in the area of social determinants of health, which, of course, also overlap with pandemic response given the issues of equity and the impact that race, ethnicity, and socioeconomic status have had on the effects of the virus in our communities. And, you can go on and on – the research community, the transplant community – there are a number of communities that are looking forward to USCDI advancement as an opportunity to move data to support their use cases and their constituencies.

So, I think we need to really dig deep and make a decision as to whether USCDI will be an opportunity to really advance things more quickly or a little bit of a follower, following to see where the industry is going and bringing that into standards. Just a reminder that once the USCDI is versioned each year, there has been the decision as to whether to make it part of the standards version advancement process. That process is a little more complex than I think some of us originally appreciated. It is kind of a one-way door where a vendor says, "Okay, I am going to embrace USCDI Version X," and when they do, that means they have to do all of it at once. But, vendors can advance individual standards and add individual data elements, so the USCDI still creates a roadmap whether or not one actually takes advantage of the standards version advancement process.

And then, of course, in the future, there needs to be rulemaking by ONC, CMS, and others that will point to the advancing standard and essentially require it. So, what we are doing is essentially building up the floor upon which interoperability will occur. I think there are also questions about what is the scope of applicability for USCDI – that is to say, is this really just focused on EHR-type data, or is this going to be used to address the needs of other communities – the long-term, post-acute care, you name it? There are many communities that are not dealing with EHR-certified applications, so there is a complex relationship between USCDI, things like information blocking, CMS rules, and health IT certification. So, the teams at ONC and CMS who are pointing to this standard are all also trying to work in concert so that it moves forward apace. Denise, I think that is what you were getting at. Was there something else you wanted to bring forward?

Denise Webb
No. Absolutely, thank you for those comments, and I would have to echo that that complexity has been challenging for a number of healthcare CIOs to really understand what the intent is of the USCDI. Oftentimes, I have heard, "Well, if all of this is added to our EHR, then we are required to collect this information," and I think there is a lot of confusion about the fact that the USCDI is trying to raise the bar on interoperability and exchange of those data elements, but of course, once those elements are in the USCDI, they then become the domain of other programs, such as CMS programs, to then require certain things from healthcare providers. So, I think the complexity that you described has created some confusion amongst a number of healthcare organizations about the goals, objectives, and exact intent of the USCDI.

Steven Lane
Yeah, and I think that – go ahead, Aaron.

Aaron Miri
You are exactly right, Denise, and I also think that speaking from an academic healthcare perspective, especially as we do contact tracing and vaccination as a major vaccine hub for the city of Austin, there are data classes and data elements that we really need to do a better job of exchanging. You still hear the traditional "Just fax it over to me," and I just shake my head. You have to be kidding me. Are we still living with fax machines? USCDI has to be a mechanism to push forward, and the more clarity we can bring – and, Steven, I appreciate your leadership in this and your help to ground us, just like you did with all your phenomenal work over the summer with the CDC – is just critical. Micky, exactly to what Steven was just saying, this is an area of great opportunity and great interest, both for the vendor and provider communities. Steven, were you saying something?

Steven Lane
Right. I think other communities as well – CMS has come forward and said, "Gee, we would really like to see additional elements in USCDI Version 2 to support our work as well," so I think thinking about this as the complex linchpin of interoperability that it can be and how to right-size it so that it balances the needs of all of these communities, constituencies, and use cases is going to be very important. I think that our task force's work will contribute to that, but it is really not the key charge of the task force. We are more down in the weeds, looking at the individual data elements and data classes, and I think we are going to do that well, but as we come back with reports to the HITAC, it will be a good opportunity to raise these issues and see how ONC intends to respond to them.

Aaron Miri
Excellent, all right. I see some questions and engagement from the team here. First up is Arien Malec.

Arien Malec
This is a surprise. Apologies for not putting video on. It is still early in California, and you probably do not want to see my background right now. So, this conversation that we just got into is a really grounding conversation, and I might go so far as to say that if something is in USCDI, the expectation should be that it is something that is routinely collected and used in practice. The classic example that I have pointed out is the mapping that should have been and still could be done between clinical quality measures and EHR data. I think this is an area that Micky knows quite well. Let me turn my – I am getting an echo here, so you have my apologies if I stumble through my words.

So, yes, my expectation would be that if we add an element into USCDI, we should have a **[inaudible] [00:43:04]** collected for the purpose for which it is used for interoperability, that we think about the downstream consequences of adding things into USCDI – what the data will be used for – and we do not make the mistake of adding something that aspirationally, we would like to do without thinking through the clinical workflow implications and the downstream interoperability workflow implications of adding data into USCDI.

One of the ways that I frame this is that if a medical society wants to put things into a clinical quality measure, they should also do the work of making sure that their clinicians routinely collect and capture that item if it is relevant for quality measures. I pick on quality measures because it is an egregious example here, but as Aaron just noted, we did work back in May or April on where demographic data was going for COVID

testing, and one of the things that became pretty obvious there is that the expectations of bidirectional ordering and the expectations of data use for bidirectional ordering had not been mapped across the ecosystem, so even though data were available, lab partners were not routinely being passed that data to referred to be passed downstream into public health. So, we really need to take an ecosystem approach to USCDI, have an expectation that if there is a data element in USCDI, that it is collected, and also think through the policy levers and incentives for that data to be used downstream into USCDI. Thank you.

Denise Webb
All right. The next question is from Les Lenert.

Leslie Lenert
A comment more than a question. One is that I think as USCDI progresses, we have to prioritize the patient use case for this, the idea that people could obtain a standardized amount of clinical data for their own access, for their use on their smartphone, or however they want to be able to use it to organize their healthcare records and to do a better job with that. I believe that is the core of what 21st Century CURES is trying to get us to do, and that while it is super important to be able to do things like quality measures and other things, we have to take on one use case at a time and prioritize that.

Second, I want to point out a tension that I have already seen in my brief time on this committee that is very important. There is a difference between the specifications that are needed for the CCDC format – for doing things as a CCD XML comprehensive summary document for patient – and doing things on the FHIR standard, which is a much more object-oriented and available piece of **[inaudible] [00:46:26]** that until we resolve, there is always going to be this inherent problem with the USCDI specification, that what works in the FHIR world may not work very well in the CCD world, and that it is kind of like trying to design a motorcycle and a bicycle at the same time. They are just different vehicles of transportation. Things that work with one just do not work very well with the other just because of differences in the structure and implementation of the two approaches. There is a legacy that is involved with one that is very important to respect, but I am just not sure it is possible to optimize for both at the same time. So, CCD versus FHIR is going to be an ongoing problem.

Steven Lane
Les, let me just respond to your comment about the patient use case and patient perspective. We specifically did reach out to identify participants for the task force who have been asked to represent the patient perspective. We have Leslie Kelly Hall, who has joined us and is quite engaged, and we actually just had one member of the task force step down, and we are thinking of inviting yet another patient advocate representative to fill that space who has already been participating in the task force. So, I think that there is this keen awareness of the importance of the patient use case and the patient perspective in terms of how USCDI should be moving forward to support all users.

Leslie Lenert
Agreed. I am just channeling Leslie Kelly Hall, as we share the same first name.

Denise Webb
All right. The next person in the queue is Clem McDonald.

Clem McDonald
Thank you. Can you hear me?

Denise Webb
Yes, we can, Clem.

Clem McDonald
I liked a lot of the comments, especially Les', but I would like to just highlight a little about the quality thing and some issues that are peculiar. I sat through a lot of the meetings where the rules came up, and there are a couple things that are positive – you are going to find something on – and then, there are a gazillion exceptions, and that creates a lot of burden on data collection. It came out that there are a zillion exceptions. Some people argued that if you get 90% of it, it is good enough – we are measuring a phenomenon – but some of the big care system wanted to look the best they could possibly look and wanted all those exceptions, so we kind of shot ourselves in the foot.

We have to be careful about the cost of data collection on all this kind of stuff and the burden it puts on, and a couple rules – I do not know if they are still there – were really stupid. One of them that would be accepted – they would not have to nurse in the hospital if they had smallpox – not smallpox, if they had herpes on their breast. Now, they are going to hold the baby with their hands – no mention about herpes on the hands – and why not just take a diagnosis of herpes? So, we have to be a little bit careful about being slavish to some of the quality rules.

Aaron Miri
Well said, Clem.

Denise Webb
Thank you, Clem. We have Sasha in the queue next.

Sasha TerMaat
Good morning, this is Sasha. I wanted to build on the comments that Arien made a little bit earlier in the discussion about setting an expectation that anything that is incorporated into USCDI has an expectation of data capture. While I do think that it could be very effective as a mechanism of prioritization, it seems like we have enough things we should expect capture of that we prioritize those in USCDI first. I do think we are going to need to build nuance into USCDI over time to accommodate the variance in data classes that will be used for more specific purposes and might not be applicable in the current format of HIT certification to every type of product that might be presented for certification.

And so, as we include types of standards that might be bidirectional standards where one product plays one role or the other, certification would have to be accommodating of that in a way that the current certification of USCDI is not. As Steven mentioned, you have to certify to all the data classes in USCDI if you will certify to any of them. And so, at some point – and, it may not be in USCDI Version 2, it may be something we think ahead to for Versions 3 or 4 – I do think we will need to come up with a mechanism in USCDI to say some things are specific to certain scopes – ambulatory or inpatient – or certain specialty scopes, or payer products versus electronic health records, or other types of ways that we would differentiate the expectations for data classes based on the intended use in that way.

Aaron Miri
And Sasha, that issue or perspective has been brought forward by many commenters – the idea that pediatric head circumference is really important if you are taking care of pediatric patients, but if you have a product or service that does not address pediatric patients, pediatric head circumference is not something your system should necessarily need to collect or exchange.

Denise Webb
Thank you. We have Michelle Schreiber in the queue next.

Michelle Schreiber
Hi, thank you. Since there has been a lot of talk about quality measures, I thought maybe I would comment since I lead that at CMS and recognize the many challenges, and actually, in a way, the conversation of USCDI gives me pause, having watched what has happened in the quality measurement space, where we have had a bunch of one-offs where we have nonstandard measures at times, we even have nonstandard definitions – even of what is diabetes out of control – because people always want something different. Frankly, we are looking to the USCDI to be a way to standardize in the hope that we can do that because otherwise, as we put out quality measures, CMS is going to have to put out definitions that organizations must follow, and then USCDI will put out data element definitions that we have to follow and are going to be even more confusing for the ecosystem.

Regarding the simplification of measures, we are all for it. We have made a commitment that all quality measures will be digital, and to us, this is the path forward, and we are open to reexamining what the definitions and the standards are, and I really hope there is one way that we can come to consensus – not that we build something different, then USCDI builds something different, then another proprietary organization builds something different.

Steven Lane
And, I will add to that, Michelle, that there have been numerous conversations between ONC and CMS on this topic. At your prompting, we have scheduled more, and I hope that Terry and I, representing the task force, will have the opportunity to participate those to provide a bridge between the task force and that discussion between the federal agencies, but I do think it is very important to get that right.

Michelle Schreiber
Thank you.

Denise Webb
Les Lenert has his hand up.

Leslie Lenert
I just wanted to say that since we are focused on COVID-19 this year – and, I am really glad to hear Micky say that because it is so important that we have some focus – maybe we should be working out the USCDI V.1 and V.2 from the perspective of exchanging data about COVID vaccination status, particularly for a population. We have quality measures there that could be very similar to influenza vaccine **[inaudible] [00:54:49]**, we could have electronic definitions of the cohorts that comprise targeted populations, and then,

the ability to document receipt of one or two vaccinations from that, all within the context of the USCDI to supply the relevant clinical details, and then maybe we think about some outcome information as well. So, I think this would be helpful to drive refinement of USCDI from some of these very practical use cases.

Denise Webb
All right, thank you. Steven, unless you have any final concluding remarks, I do not see any other committee members in the queue.

Steven Lane
I will just close out by saying how happy I am to be able to work with such a great team of the ONC team and the members of the task force. Terry O'Malley is a wonderful co-chair and has deep appreciation and experience related to this space, and we are looking forward to digging deep into this and bringing back some useful comments to the HITAC.

Denise Webb
Thank you, Steven.

Aaron Miri
All right, Steven. Thank you again for your leadership there, and this is a fun committee, and it looks like the conversation is going to be a very robust HITAC discussion, which is great – the whole point of the committee. All right, let us get on with the agenda, then. Next we have Beth Myers and Carmen Smiley related to Project US@. I will turn it over to you.

Project US@ Presentation (00:56:43)

Beth Myers
Great, thank you. Can we go to the first slide? My name is Beth Myers. I am the Deputy Director of Policy at ONC, and I have the honor of getting to be the policy lead for Project USA or US@ – we have not worked out the kinks on pronouncing it yet – but that policy role basically means that I get to sit on the sidelines and learn from my tech colleagues a lot, so that is what I will be doing in this presentation after just a moment of providing some background to you all. I will be passing to Carmen Smiley, who is the technical lead.

I wanted to give a little bit of background to the federal advisory committee on this project because some of this stems from work that you are all familiar with from the work that you have done in inputting, reviewing, and analyzing our proposed rule in preparation for our final rule, including – apropos to the most recent comment – some of the pieces that we put into the USCDI Version 1 and adopted in that rule, including the expansion of demographic information, specifically address.

During that rulemaking process for the address field within the USCDI and the demographic data class, we did consider what we heard from multiple commenters about using the existing United States Postal Service Publication 28 and potentially address-matching tools to try and come to a more normative, agreed-upon address format for healthcare purposes. Our analysis at that time determined that that was not going to work terribly well. There are some benefits to those resources and tools in terms of getting some basic guidelines around preferred approach for certain types of address formatting, but they really did not meet the full need that we had for healthcare, where patient matching is such a high issue for patient safety.

So, because of that, we have been having a lot of dialogue, and in our rule, we actually indicated a bit that we intended to continue to work with the standards community, healthcare community, and health IT developers to encourage and incentivize the ongoing exploration of address and how we could get to a unified standard, normative, consensus-based process for healthcare purposes that would allow for better address formatting, and that is really what the birth of this project is. So, I wanted to give you all that policy background to remind you of this conversation that we had during that rulemaking cycle, and in just a moment, I am going to pass it off to Carmen Smiley to walk you through the project launch.

I did want to make a shameless plug on the policy end as well for one more piece, which is that the goal of this project is to come to this address formatting for healthcare and get to that end product. What we would love to hear from you all and what my team has to consider is where we go from there. How do we ensure the success of this initiative through future endeavors that might encourage, incentivize, or support widespread adoption of this particular initiative in this healthcare format to get us to widespread use? So, with that, I will pass it off to Carmen Smiley.

Carmen Smiley
Thanks, Beth. Next slide, please. Thanks. So, as Beth described, is a really important part of this effort is actually the unifying nature of the effort. This will be the first unified standard in the industry for patient address, which we are really excited about. We are really touched and excited about the number of partners we brought on to the project. If you have received the slide deck, which I believe you have, there is a link to our confluence page, which now has a list of over 103 partners who are part of our larger group, and this is a very wide range of partners, from standards development organizations, to health IT vendors, to researchers, to a wide range, and we would like to – and, what we are really striving and working hard to do – is to collaborate with them, especially the standards development organizations, because we would like to find ways in which the specification – after it is complete – could be integrated into future versions of standards that are already widely used across the industry.

So, we are engaging with these partners on a monthly basis. All of you are welcome to attend those calls and provide your input, of course, and at our next call in February, we will be covering lots of updates from the technical workgroup, which I will cover next. We really want to be able to build industry commitment around the specification because we believe that if everybody is on board and they have the opportunity to provide input, we are more likely to increase widespread adoption, and you could argue that it is really more important that we are all doing the same thing than precisely how we are doing it in some ways, which is an interesting approach, I think. And, as I mentioned, we really want to reach across the industry, so some of our partners are involved in immunization registry, and some of them are involved in prescription networks, some of them are involved in EHRs or patient-facing systems. Next slide, please. Thanks, next slide.

So, the technical workgroup, which is a much smaller group – right now, we have about 17 members, which I know is large for a workgroup, but many of the members are representing the United States Postal Service, and we really appreciate their engagement in this project, especially because where we are starting with the technical workgroup is with Publication 28, and we are either going to be able to expand or further constrain it for the purposes of patient matching. That is really important to our work, but our annual goal is to improve patient matching success across all of the systems across the industry.

So, we have representation from the postal service, as I mentioned. We also have representation from the CDC, we have two HIEs, some NPIs, patient matching vendors, standards development organizations, Surescripts, and other technical subject matter experts. We meet on a weekly basis, and as we are going through developing the specifications, the incredible level of expertise and experience from the members of the workgroup is truly impressive, and we really appreciate their engagement. Volunteering their valuable time to provide input into the development of the specifications has really been appreciated.

And, as I mentioned, our approach is to start with Publication 28. We are also doing a comparison across a number of standards just to be able to depict how addresses are depicted across a number of standards, and we are making some very large, high-level decisions regarding scope and small, detailed decisions regarding what would be included in the specifications. Some examples – and, a little bit of a spoiler alert for the February monthly meeting, where we will be providing some updates next – we want to be able to do the specifications as well as possible and as quickly as possible, so, we hope the first phase of the project, which is when we will actually release the final version of Project US@ as a specification, will be released in the summer. We know we will finish this year, but the first phase will focus specifically on domestic and military addresses, which falls in line with what Publication 28 guidance provides. And then, in the second phase, we will explore the feasibility of addressing international addresses. So, we may start with any of the other countries that are physically contiguous to the United States.

I believe I mentioned military addresses. We will also include those in Phase 1. We have also chosen to develop constraints around parsing of data elements for address representation, which is important for matching purposes. There are many standards across the industry. We just have one long string that is available to represent address. We have also discussed metadata representation of both current and historical addresses and group living situations because often, group living situations will create a high degree of false positives by matching algorithms because the algorithm may inadvertently think that patient records are duplicates when, in fact, they are two very different patients.

Billing address versus physical or home address – we hope to also find ways to represent in a way that systems are able to differentiate or possibly filter between those two. Sometimes those will be different, but most often, health systems are focusing on what the billing address is or how the address is represented on the patient's insurance form – or, insurance card, rather – and also find ways in which we can indicate that patients are known to be homeless. This is also important for the timeliness of the data and also helps in matching across otherwise difficult-to-identify patients.

Right now, we are discussing whether or not to include special characters in the specification, so this has been a really interesting discussion because you always have to think about how the algorithms are reading, how the address is being captured, and if there are also hyphens, apostrophes, or other characters that may affect the performance of certain – though not all – algorithms. Some algorithms have the capacity to handle it. So, we may end up deferring to how the USPS is handling special characters and punctuation. Typically, in their normalization process, they remove all special characters, including the one between city and state. Next slide. Just to give you an idea of timeline for the specifications, as we mentioned, we hope to finish the final specification for Phase 1 on May 21, and we hope to complete Phase 2 in 2022, but this year, we will finalize the Project US@ specifications for domestic and military. Next side, please.

As I mentioned, there is a link to the confluence page in your slide deck. You will find a list of all of our partners, the background on this project, and a list of everybody that is in the technical workgroup. You will find copies of the meeting minutes if you are not able to make all of the meetings and just catch up and keep up with other advancements in where we are and the status of our project. Next slide, please. And, I think that is it for me. If anybody has any questions, let us know. I really appreciate this time. Thank you for having us.

Aaron Miri
Great job, excellent. Thank you very much for the presentation. Before we get into questions, I would just remark on the importance of some sort of patient matching or whatever and the barrier and impediment it is, much like some of the other HITAC members are saying, even in a public health emergency, and to give you a real-world example, we are doing contact tracing, we are doing the healthcare provider perspective with the hospitals, clinics, and whatnot, and we are providing vaccines, and you would be amazed at the difficulty there is to match individuals or records in a timely fashion and the issue that compounds where you suddenly have multiple types of vaccines in the market and trying to figure out what that exposure is and where you are as a city, so this is very timely, and I really appreciate the conversation here. So, let us get into some questions from the team. First up, I see Clem McDonald.

Clem McDonald
Thank you. Can you hear me?

Aaron Miri
Yes, sir.

Clem McDonald
So, there are two issues. One of them is the nasty question about a national patient identifier, which might reduce the need for this intense care about matching. But, I would like to ask specifically – I had understood that Medicare was working on a Medicare health identifier for their individuals. I would like to know if that is true or not. But, the second thing is that I would worry that if we make a health address specification, if we are not consistent with the rest of the industry's address specification, we are going to be running upstream, and clearly, there are special issues in the health space. If you go to UPS or any of the sites or you order something on the web, they correct your address. There are databases and systems behind this that know everything about addresses, and it is deep into industry, so I hope we do not conflict with the industry approaches to this just through healthcare.

Aaron Miri
Great points, Clem. Thank you very much. Related to the question, Lauren, I do not know if that is something we should work through here or maybe get back to Clem on the question he asked.

Lauren Richie
Yeah, let us finish going through the questions, and then maybe we can have a sidebar with commenting.

Aaron Miri
Perfect, and Clem, that will get answers to your questions. Is that okay with you?

Clem McDonald
Yes, thank you.

Aaron Miri
Perfect, okay. So, next up, then, we see Arien.

Arien Malec
Hey. So, I basically had the same question as Clem. Maybe I will phrase it slightly differently. I thought that the presupposition of Project US@ was that we would be able to leverage the ecosystem of tools that were broadly available for address normalization, and the worry or concern that I would have is that if we decide that those tools are insufficient because USPS Publication 28 is insufficient, then we are making the mistake of creating a healthcare silo without taking advantage of that ecosystem of normalization. So, I think it is appropriate to think about special considerations for patient matching that go above and beyond the USPS address normalization, but I think we should also recognize that it is far better to use the ecosystem of tools that exist and then maybe optionally do something on top of them than it is to forego that ecosystem because healthcare is special. Thank you.

Aaron Miri
Beth or any of the team, would you like to answer that?

Beth Myers
Sure, and this actually goes to Clem's question as well. I will start, and then I will make sure that Carmen is filling all the things I get slightly off or wrong. But, starting from USPS is actually the foundation for what we are looking at. There are tools out there, including application programming interfaces that the USPS with worked with in different industries. Some things that come to mind are banking and things like that that have taken a look at these types of tools. What we learned from our analysis of these tools is that even while you are using one of those services that you type your address in and it gives you a normative version back, that is actually still a variant. None of those tools are coming to a universal or old standard, and this is based on work we have actually done with USPS to try and understand exactly how these tools work and how their various files where they keep cold standards for address connect into those types of tools.

So, the challenge still becomes that in one location, you can input address into one of those tools using a colloquialism for your local street. Maybe you are using a cardinal direction for your city name – west whatever city versus that centralized name for that city – and each of those are going to come back to a correct address to which you can have a package delivered, but it would not necessarily be the same address if it is input slightly differently in a different way.

So, especially when you are looking across networks or across systems, you can end up with – as Carmen mentioned – two different patients being linked together because the address is normalized to something very similar, or the same patient having duplicate records that are not being connected with vital health information being lost. The idea behind this is not to create a new, entirely separate, or siloed address format, it is to try and reconcile those variances that currently exist in the tools that are out there so that we can get to a closer, more unified approach to these types of standards for healthcare purposes. So, it is, in fact, built on those underlying tools and trying to further reconcile them and further specify them, and I will pass to Carmen to make sure I got that right.

Carmen Smiley
That was perfect, thank you.

Arien Malec
Thank you very much. That was very helpful.

Aaron Miri
All right. Next, I see Jonathan.

Jonathan Nebeker
Thanks. This is Jonathan. I am the acting CMI of Veterans' Affairs, and as you know, we have been in this business for a long time, having had 130 differences of our EHR in the last 30 years. It seems like – I have been working with Pew and other organizations as we are moving our own patient identifiers forward. Is there – and, I just wanted to foot-stomp the last explanation about the problems with USPS. I live at 1307 3rd Avenue, and depending on whether I type in "east" – there is no West 3rd Avenue, but if I type an E there, I get an entirely different address for the human-readable form, but the ZIP plus four is still the same.

So, is there an effort by ONC to rack and stack the bright ideas in this area with evidence of benefit and to prioritize the bright ideas – I am not arguing at all against this, but there are a lot of other bright ideas, and I am a fan of identifiers with multiple information – the broadest information we can get – and then, I think probabilistic matching is probably the cheapest and most accurate. But, I beg the ONC to rack and stack priorities against evidence and then create a plan to get us to a place that is objective and not full of all the biases that each of us have. So, I will just wonder – maybe that is a question for Elise and company. Has that happened? Because I have not seen it, nor have my colleagues in this industry.

Aaron Miri
ONC team?

Beth Myers
I am pausing to see if Elise or Steve wants to jump in here.

Aaron Miri
Beth, at this time, maybe if you want to quickly comment – we can also take this conversation on the side, and if it is really deep, we can also come back to it.

Beth Myers
It is really deep, and I think that it relates to some work that we are doing more broadly across, frankly, a lot more initiatives on patient matching and figuring out some of those broader scopes, including the work that Congress directed us to do over the past year related to exploring and analyzing patient matching scenarios across healthcare settings and health IT systems, so there is quite a bit of work going on there, and I think we intend to continue that process. Unfortunately, I am not one of the ones working on that particular effort, so I am not as well versed on what it is, so I do think a follow-up would be appropriate, and we can dig further in, but I will say this is not being done in a silo. This is a focus on the address piece of it because obviously, loud and clear – and, I see that the Pew link was put in there; we have, in fact, been

connecting with Pew on this, and they have supported this effort as well. So, the piece and focus on address is just one piece of it. We see the entire larger picture and are working on various efforts in that area.

Aaron Miri
Thank you very much, and Jonathan, I will say that in the Annual Report, we do also call attention to this issue as it relates to public health, so perhaps there could be tie-in there synergized to really focus on this area in an upcoming HITAC, so we could definitely look at that.

Micky Tripathi
Right. Hi, this is Micky. I just wanted to add – Jonathan, we really appreciate your points on that, and we will absolutely take a look at that in that context. I think it is a great comment, thank you.

Jonathan Nebeker
Thanks.

Aaron Miri
Fantastic. Okay, Jim, I see you next.

James Pantelas
Yeah, I just have a quick question on this. First Nations populations – there is a fairly large percentage of their population that does not have an address, and I am wondering whether or not you have thought of how to not marginalize that population further within this effort.

Carmen Smiley
This is Carmen. I would like to answer that, if possible. As I believe I mentioned before, in Phase 1 of the project, we will be doing domestic and military addresses, and Phase 2 will be international addresses plus geolocation data. So, my mother lives in an area where she does not have a physical address either, and she is in the same area of the country. I completely understand the need and the value that it would bring. We simply just need a little bit more time to delve into it and make sure that that data could be supported because with everything that we consider, we also have to consider feasibility for adoption, but we are certainly not ignoring it, and I appreciate the comment.

Aaron Miri
Actually, I think that is a great question, and to add to that, there are other different socioeconomic challenges – people living together, large families living under one roof or one address – if we start using this as only the primary key to link people, you could have challenges there, but as I have always said in these HITAC meetings, any direction forward is good direction, so I applaud your work there, ONC, Carmen, and Beth. Next on the list we have Abby Sears.

Abby Sears
Hi. I was actually going to ask something similar to Jim, but I am going to expand on his question as well. Our patient population has a higher propensity of testing positive for COVID, a higher propensity of being some of the most complex patients in the entire system and some of the most expensive to treat, and they have the highest propensity to not match when we move their data to other parts of the delivery system,

often because of the nomenclature on their names and surnames, but also because of address challenges, and not just because they do not live in a location where there is an address, but because they are mobile.

So, if you are looking at seasonal migrant workers, they do not have a single location where they live, and it changes from time to time, and it is difficult to keep track of, so if that becomes a major component of the tracking and the patient identification process that we are going to use as a country, I think we are going to miss some of the most expensive, complex, and challenged patients, and we are actually going to add to the divide around diversity, equity, and inclusion that we have as an inherent challenge in the system. I know I am bringing up a topic that is incredibly difficult to solve, but I am just curious what you had thought about related to that because I do not think geomapping is going to solve that, so have you given any thought to that, Carmen?

Carmen Smiley
Yes, we have thought about it a great deal, and I do not want to give the impression that we are assuming that geolocation or geomapping would answer many of the challenges that we face, but we also have to consider timing of the victories that do add up, that do make a difference. So, I think the combination of geolocation data and considering also straightening address information that is in other languages – we are not addressing patient names, we are staying laser focused on patient addresses for this purpose or for this specific project, but we are certainly considering it and working closely with USPS, as Beth mentioned, to understand how they handle packages or mailing to casual or nonspecific addresses, and I hope you will tune in to our next partner meeting so that you can receive some updates on our ongoing progress.

Beth Myers
This is Beth, just to add the broader comment that we made earlier as well. Again, as Carmen mentioned, this is laser focused on this particular piece. We are not saying this is the only piece, and we are not intending for this to become a magic bullet. We do not believe that it is. We think that this is one part of the puzzle, that there are challenges, and that those challenges can be addressed, so we are specifically – no pun intended – addressing those challenges, but there is a broader picture, and there are conversations that we are part of and that we are learning more and more about as we go about how many – even if we are just talking about addresses beyond the actual normative standard for the address format itself, how many past addresses are we storing? How are we connecting those together for individuals? What other types of information are there? How many data points can we get to ensure that we are getting appropriate matching, including things like race and ethnicity that can help with some of the risk scoring that we have been talking about for COVID? So, I think there are bigger pieces to this, and we are very much trying to focus on getting this piece more correct and more useful.

Aaron Miri
Well said. Thank you very much. So, I just want to ask for any other questions from the community members. I am looking for any hands. Okay.

Denise Webb
Do we have anybody just on the phone, Aaron, so we do not miss anybody? If there is anybody just on the phone…okay.

Aaron Miri
Good catch, thank you. I was looking for hands. You are right, we have folks on the phone who cannot raise their hands, so thank you for that. As I was saying, Beth, Carmen, ONC team – high five to all of you. This is a very deep topic that you can tell we are all very passionate about from our perspectives, so please keep up the good work and continue to trek forward and enlighten us. We look forward to further talking about this and other topics related to it. Good job. Okay, keeping on – and, we are running a little ahead, which is good because we can go back for discussion much later on – is related to the STAR HIE program progress, and I believe up first with this – we are going to have a multi-phased approach here with various speakers in different wonderful organizations – we are going to start with Larry Jessup.

STAR HIE Program Progress Update (01:25:06)

Larry Jessup
Can you hear me?

Aaron Miri
Yes, sir.

Larry Jessup
All right, great. Good afternoon, everyone.

Denise Webb
We can hear you now, Larry.

Larry Jessup
Excellent. Thank you, Denise. I would like to begin by saying that we are very excited about this program and proud of the work done so far, and it goes without saying that every awardee of the STAR HIE program – similar to all of you – are supporting the country in the COVID-19 response effort while also being confronted with this issue in their communities and with their families and friends, so this work is greatly appreciated. Again, as I mentioned, my name is Larry Jessup, and I am a branch chief in the state and interoperability innovations branch in the ONC Office of Policy, and I lead the team of individuals who are responsible for the day-to-day messaging of this award.

The STAR HIE program was designed to strengthen uses of health information via HIEs to support public health agencies, including in their COVID-19 response. So, as you all are aware, there was about $5 million from the CARES Act, which was signed March 27th, 2020, that came our way for this program, and this was announced in two buckets, if you will. The first bucket was announced on September 30th, 2020, and this was $2.5 million to support five HIEs in creating services that benefit public health agencies. On January 19th of 2021, there was a supplement of $2.5 million, and this potentially meant that we were able to supplement four of the original five HIEs with $123,000.00, and this also allowed us to award $123,000.00 to an additional 17 HIEs, increasing our total award recipients to 21 health information exchanges in total, all with the goal as part of this supplement to specifically support increased data sharing between immunization information systems and HIEs.

The ultimate goal of this program as a whole, however, is to do two things. The first is to build innovative health information exchange services that benefit public health agencies. So, by strengthening the existing

health information exchange infrastructure with these innovative services, we believe that will allow public health agencies to better access, share, and use health information. The second goal is to improve the health information exchange services available to support communities disproportionately impacted by the COVID-19 pandemic. This pandemic has further exposed the many health inequities that exist across certain patient demographic groups, and we will be working to minimize these gaps in quality of care that is delivered as well.

As you all heard us say, we are very confident in the ability of the HIEs to align with public health agencies to conduct this work, and this is important because we recognize that the extensive clinical data held by HIEs are, in many cases, not accessible by public health agencies, so we want to make sure that in everything we are doing, we are supporting public health agencies by making sure they are able to utilize services that HIEs are well situated to provide. For example, we know that HIEs serve as data hubs from a multitude of sources. We know that HIEs have a strong understanding of and experience with local healthcare environments, including the policies that dictate use for public health agencies, and we also know that HIEs actively support public health agencies with public health reporting, and even improving data quality.

So, in the end, we want to make sure that the public health agencies have the necessary data and health information to respond to and recover from current and future public health events. Given where we found ourselves as a country in late December and early January as it relates to the increased role that immunization information systems are playing, we were excited that federal dollars were available to fund the additional 17 recipients to support efforts to increase data sharing between jurisdictional immunization information systems and health information exchanges.

So, the STAR HIE program now includes more specific clinical and population health efforts, which includes making improvements to, for instance, the ability to identify high-risk patients who have not yet received the vaccination, improving the methods for tracking and supporting COVID-19 vaccination administration, and also includes monitoring long-term health effects, adverse reactions, and reinfection rates across entire populations. So, when you think about this holistically with everything we are doing with ONC, this is just a plug here, but this also speaks to the importance of the work that we are doing with the Trusted Exchange Framework and Common Agreement to ensure that the appropriate technical and legal infrastructure exists across the country for the broad sharing of health information to occur, particularly during public health emergencies.

So, with that, I would like to introduce you all to those who are actually doing this critical work out in the field, and you will first hear from the Texas Health Services Authority. They are piloting a national strategy for hospital situational awareness information. We have Phil Beckett, who is the CEO of HASA, which is a health information exchange in Texas covering multiple regions, and we also have Eric Heflin, who is the CTO and CISO of the Texas Health Services Authority. Once Eric concludes, he will turn it over to their partners on this cooperative agreement, HealthShare Exchange Pennsylvania. They are supporting COVID-19 response in the Delaware Valley, and we have Bill Marella, who is the director of data analytics and quality, and we also have Elizabeth Scoles, who is the project manager. So, just very special thanks to these individuals. They have been nothing short of fantastic thus far, so I am honored to kick it off to Phil and Eric. Thank you all.

Eric Heflin
Thank you, Larry. This is Eric Heflin, THSA. With that awesome introduction, I will actually skip a few of our slides. Just a quick audio check – is my audio okay?

Aaron Miri
Yes, we can hear you.

Eric Heflin
Okay, very good. So, if you could go to the next slide – so, what Dr. Beckett and I are going to talk about is very briefly and very quickly touch on a few key points about the details of the program that Larry just announced and introduced quite eloquently. So, we are going to talk really about THSA's statewide perspective on health exchange within Texas. I am just going to touch on one slide very briefly, skip over the sections about the cooperative agreement and leave those for your reference since we covered that before, and then drill down a little bit to the details – the technical details, business case, use case, how we can help patients and providers toward the quadruple aim, which Dr. Beckett will talk more about as well.

Also, our goal is to be a pilot to share both positive and negative lessons learned with the rest of the country, and so, we are going to start some of that today as well, sharing some challenges we can maybe work on together, and then we will switch over to Dr. Beckett's presentation, talking about a perspective for a large, multi-region health information exchange within Texas. Go to the next slide.

I also want to thank Larry Jessup for his incredible support, and also Dr. Tara Tessler for her outstanding work on program management. I know we have already finished the topic about U.S. address, but I also want to thank Carmen Smiley for involving Texas in that as well. We found it to be very helpful to make sure that we have real-world involvement perspectives to offer in the hope we can all build on each other's shoulders for that. So, I will leave this slide for your reference. There is a link down on the bottom of Slide 3 that actually has the announcement of the STAR HIE program. Go to the next slide, please.

So, the Texas Health Services Authority was actually largely created to help foster connectivity like this, so we actually were awarded this cooperative agreement program on September 30th, and we are very happy to be a strong advocate and participant within this process. And so, THSA's role in this project really is to act as the award recipient, then also to act as the coordinator among multiple organizations that are involved with this project, including our very strong partner, HASA, that Dr. Beckett runs, as well as working with the industry standards bodies. Again, we are trying to create something that will hopefully be a pilot and serve as a model for the United States to allow hospitals to report their situational awareness data in close to real time to public health authorities throughout the country and throughout the state as well. Go to the next slide, please.

So, the technical objectives and workflow objectives of this project are to provide hospital majors reporting, and this is designed to be configurable so it is not a one-and-done approach that we are stuck with. The intent is to be flexible, and so, we are establishing a pattern in technologies that are designed to be future-proof to a large extent. For example, if another epidemic were to occur with different characteristics or another national disaster – even a state disaster – actually, this program would allow for those majors to be configured on the fly with the stakeholders **[inaudible] [01:34:01]** exchange hospital capacity information with public health.

Another **[inaudible] [01:34:10]** for this project is really to reduce the burden to hospitals. Today, some of these majors are conveyed manually in many cases, and we hear from our valued hospital colleagues that they are very burdensome for the hospital to report to public health, and so far, the objective here is very explicitly to make this burden go away and to automate this process if not 100%, very close to 100%. We also want to reduce time lag. Right now, as I mentioned, some of these processes are manual, and of course, manual processes have a whole lot of baggage associated with them. That includes potentially rekeying or OCRing scanned images, and those are time-consuming, they are expensive in terms of human resources, and they introduce accuracy and time-delay issues, so we are trying to address all this with one fell swoop.

In addition, we are looking at this being an open standard. We are participating for the public good. We are trying to create something that the country can build on and learn from our successes and our mistakes, which we will certainly have, so among other things, we are trying to build this upon international and United-States-based standards. For those following remotely, you can see where I mentioned down on Slide No. 5 that we are involved very heavily with HL7 and the FHIR workgroup, and also HIE USA, which, for those not familiar with it, is a standards body designed to take lower-level standards and create a higher-level standard on top of those to stitch the lower-level standards together into things like a complete clinical workflow – for example, document sharing across health information exchanges or with the public and private sector and so on.

So, we worked very closely with HIE USA as well as HL7 to make sure that these standards were publicly vetted, everything was transparent, there was no undue influence from anyone, particularly a stakeholder, that basically had a very balanced, transparent, and open process. So, nothing about this development was hidden. It was all out in the public, and I think we are going to be stronger because of that process, which was sometimes painful, but it is worthwhile to make sure the end result has critical assessments and analysis, especially right now, while we are still in the design phase.

And, we found there was a gap in terms of standards, and so, we worked with our valued partner in HL7, Audacious Inquiry, to remediate that gap, and we created a new one together called SANER, which is a Situational Awareness for the Novel Epidemic Response, but it really can be used for more than just COVID. That just happens to be the current, obviously very important driver. This project is also intended, frankly, to build on existing federal investments into health information exchanges. There have been a lot of funds invested over the last number of years to help build out EMRs, to help build out health information exchanges, and so, this is intended to reuse and leverage those existing investments. Next slide, please.

So, the THSA was a formal recipient – we actually are an authority, which means in layperson's terms – I am a techie, not an attorney – we are essentially like a state agency, but we do not **[inaudible] [01:37:27]** regulations, and we are actually in the private sector as a 501(c)(3) nonprofit, and that is very important because basically, it lets us straddle both sides. We can talk to our colleagues as a somewhat peer agency, and we can talk in the private sector as a private sector entity as well, so it lets us bridge that gap between private and public exchange, and it lets us be nimble, it lets us react very quickly to changes, and lets us take advantage of opportunities like this with ONC, HASA, and others.

Our approach – our mandate here – is to foster secure healthcare exchange connectivity within Texas, and we use a multiprong approach. I will not go into that in detail, but it is available on our website. Those whom we are trying to benefit include the citizens of the state – the individual patients, consumers, and people – but also providers. We want to make sure that this helps them help us be treated better. We want to make sure that this is not going to be burdensome to the humans or to the organizations that are involved in treating patients as well, too. As a matter of fact, this will hopefully have the opposite objective, and in fact will reduce the burden substantially by automation.

And, we are also trying to connect to public health and help our state and federal agencies as well get better data faster and more accurately so that they can benefit and help us as well. I will mention our partners in this include HIEs in Texas, specifically HASA, the Texas Department of State Health Services, Medicaid, Texas Hospital Association, and Texas Medical association, and also with the CDC and others. Next slide.

The very highest-level objective is to pilot real-time automated hospital capacity gathering, and then to share that. Some of the areas we are focusing on include standards, as I mentioned, and discussing security considerations and privacy considerations to make sure this indeed meets or exceeds those objectives. We are starting to get public feedback and comments on these areas to make sure that everybody who wants to have a voice in this process is heard, and we are also dealing with policy and legal issues. Next slide.

This is probably my only slide for the techies out there. This is a conceptual architecture of how the data would actually flow. Since I am a techie, I apologize, I felt like I had to drop in at least one technical slide as well, too. So, the components of the senior project include a reporting component that generates the data. We have a presentation component that actually will visualize it. We have an adapter which specifically goes between hospital EMR systems and a FHIR server. We have a FHIR client end server, and there is also a database component.

If you look on the right-hand side of Slide 38 here, what would typically happen as far as data flow is in its normal course of business, the hospital would probably track inventory, immunizations, beds that are used, beds available, and so on, and the expectation is that there would probably be an API – an applications program interface – which is lingo for a way to automate systems between the hospital and the intermediary, which is represented by the middle box. So, what would happen is the hospital would send or make available capacity information such as number of beds available, ICUs free, ICUs busy, or ventilators available. It could even include more information, such as about some of the quality metrics previously discussed today.

That information would go to our partner, HASA, who would act as an aggregator. They would get data from all the region's hospital services within Texas. They would aggregate that data, ensure its quality, and then push it up to HIE Texas or Texas Health Services Authority using secure, HIPAA-compliant connections, of course, and then we would make that data available to public health agencies. Again, the intent here is for this all to be based on industry standards and all automated to the largest extent possible to distribute data, and all in close to real time. Next slide, please. So, the current status of the project is we have been working with our partner, Audacious Inquiry, and HL7 to create the SANER standard. It is available for review right now in various publication sources. We tested January 21st – I am getting an echo. Is my audio okay at this point still? Can everybody hear me okay?

Denise Webb
Yes, we can.

Eric Heflin
Very good, thank you. We tested this at the January 21 HL7 testing event, which they call a connectathon – somebody else mentioned that earlier. That is really a very valuable activity. For those who are not engaged in this domain much, a connectathon is basically where all the vendors, partners, potential customers, and so on actually come together in what is often a physical room – lately, of course, it has been a virtual room – and we basically focus on testing a workflow. In this case, we actually had a connectathon track focused just on SANER, so we actually had a couple EMR vendors, we had AI, we had ourselves, and some others at the table to test and make sure that we had some actual data flowing between actual test systems representing EMRs and FHIR servers in the prior diagram I just showed you.

That was successful. We did prove that connectivity was established, and our plan is to continue this testing at the HIE USE North America connectathon, which is virtual, and that starts the first week of March, so that is going to build on the HL7 connectathon, and our goal is to try to recruit more EMR vendors to be engaged with us at that testing event to really make sure we have multiple EMRs so it is technology neutral. And then, we are also seeking to test more majors. Go to the next slide.

As far as challenges and next steps, I promised earlier we would start sharing both positive and negative lessons learned, so a positive lesson learned is we have established some data flow with an actual EMR and hope to establish more next month. A challenge is that we actually have two Texas laws that are constraints we have to be aware of. One is related to data flow for immunizations data, and the other is data flow and use of the data with the Texas Health Services in particular, so we are just working with stakeholders and finding ways to support these constraints. The very next step is we are seeking to onboard pilot hospitals. We are seeking to continue SANER testing in coordination with HASA, HL7, HUSA, and, of course, our valued partner in this process, AI. So, with that, let me please turn it over to my peer and colleague, Dr. Phil Beckett. Thank you.

Phil Beckett
Thanks, Eric. I appreciate it. I may be the one causing the echo with my audio. I might have to go old-fashioned, but if the audio is good, I will start. Go to the next slide, please. We are a not-for-profit local health information exchange here in Texas covering several regions – San Antonio, Dallas/Fort Worth, Corpus Christi, west Texas – where our mission is around the quadruple aim: Improving outcomes, reducing costs, and improving the healthcare experience for both patients and providers. I say that just so you know our thinking where we are coming from, where we are always trying to partner both with Texas Health Services Authority, with Eric's team, with AI, with other vendors, and also with our hospital health plan and physician partners. So, what are the local goals, what are you trying to do, and how are you trying to change outcomes within our mission to do that?

So, we are always thinking workflow. As you well know, health information exchanges vary in where they get revenue. In Texas, we get it all from subscription fees, so we really have to focus on the value, and we think about that as well. In reference to the SANER project, how do we help Texans and our partners through doing this? Go to the next slide.

So, what is HASA? We have a centralized data model. Physicians, hospitals, and health plans send us data, which we store in a patient's longitudinal record. You were talking earlier about the MPI issues. Of course, we have those, too. How do we have a single record for a patient? We are a community partner, so how do we work with local governments and local goals? What are people trying to do? How do we help support them?

We have a very agile platform, so we try to meet everybody where they are, so if a hospital can send us a flat file – a CSV file to an FTP server – we will pick that up and turn it into FHIR API. We will try to be Swiss Army knife between and push standards at our level, but still empowering and enabling our customers to go to the level where they can go until they reach those standards. We are also value-driven, again. The only way we survive is if we deliver value back to our partners. Next slide, please.

This is just a map of where we are now across Texas. These are primarily hospital and physician groups. We have about 9 million unique patients in our master patient index, just under a third of the population in Texas. Next slide. We think nationally, so we are connected through the patient-centered data home, which is a strategic health information exchange collaborative initiative where we share demographic data based on ZIP code, so if a patient, for example, goes to a clinic in Oklahoma but they have a Texas address, that Oklahoma My Health Access Network will send us a notification – "Hey, we have data on your patient" – so now we can share clinical data between us based on that. So, between all the health information exchanges, we become a national network. One connection gets you the data on your patients across the whole country. Next slide, please.

We are also connected to the eHealth Exchange, again supporting the national networks, and the DOD and VA connections are very important to us in Texas. We have a lot of those facilities, and a lot of veterans go to both VA facilities and civilian facilities, so having that crossover and interoperability is a key value proposition. Next slide. This is my equivalent of Eric's techie slide. Really, what we do at the top level is add value to external events. That is the way I think about it. So, on the left, we have stakeholders, hospitals, and physician groups sending us data in whatever format they can. We always ask for FHIR, but if that is not possible, we will meet them where they are.

We get all kinds of data that way. We parse it out and normalize it. We know healthcare data is very variable, so we will standardize, for example, patient type. "Emergency" is always "emergency" no matter how it is coded locally. We have a master person index, we store that data, we analyze it, and then we turn around and deliver it – again, in multiple formats. But, thinking about the SANER project, on the left, you have resource information coming in to us from a hospital. We can turn around and expose that as a FHIR API with Audacious Inquiry and Texas Health Services. Next slide, please.

I wanted to give a couple of local use cases – again, how we are thinking of and partnering with a group. We have an FQHC here in San Antonio, CommuniCare. They are really trying to reduce preventable admissions in pregnancies. So, what we do with them – we are validating models, so they have models of what a high-risk mom is, and then we are going back and looking through the data and mapping their risk category to the number of preventable ED visits to improve the models, but then, also, the whole goal is to be able to notify them about external events so that in the end, they can prevent that admission rather than catching it out to us.

We are doing a lot of work on COVID-19 today, obviously, so we are tracking status on that – both infection and immunization. A lot of hospitals are asking us for that information, and we provide that back to them in real time. We are also doing a collaboration with the University of Texas Austin and the health information exchange there, ICC, and a clinic in Austin on vaccine forecasts. So, again, in your own electronic health record, you have a limited dataset of what you have seen on that patient. If you add to that what the health information exchange has from your community, you can put together a much more personalized forecast of what immunization that patient might need, so we are also doing that with STC. So, I just wanted to put those out there as some examples of what we are doing today to drive that mission in partnership with others. Next slide, please.

This is how we are envisioning the STAR SANER project. So, we have the hospital on the left, and they have multiple systems where they need to send data to us around resources. We will accept those in multiple formats – however they can get it to us – and just as I showed you on that other map, we will clean that up. There has to be a validation and review process – an approval process. Obviously, there are concerns about resources and effects on elective processes that drive revenue. Now, that is the FHIR format, and again, this is the HIE, SANER. I am including Texas Health Services Authority and Audacious Inquiry in that center block, and then we expose that as FHIR back to the health department, so now they have seen one standard, and it is in real time. And, we are leveraging both the existing technology connections that we have underneath and the existing governance agreements that we have. We have business associate agreements with all of these. We do not have to go rebuild that. We can leverage all that existing infrastructure, both governance and technology. Next slide, please.

So, again, we are thinking of this, and thanks to ONC's support and this grant, we are obviously reducing that manually administrative burden of reporting. How much of this can we automate while keeping the checks, balances, and guardrails in place? We retain local independence and control of what that report content is, leverage existing infrastructure, and then, on the public health end, faster access to more accurate digital data. I know I talked to one of our local health departments, and they had come in every morning to a stack of faxes, which is strange in 2021, but it happens, and if we can get more of that made digital so we have less manual reentry, we start to reduce the administrative burden on both ends of this process. So, that is our goal. Next slide, please. I will pass it. We are going to save questions for the end. Thank you again for the opportunity to talk to you all, and I will hand it over to Bill.

Bill Marella
Thanks, Phil.

Denise Webb
Thank you. Before we start the next presentation, we do have a few questions, or would you prefer to hold those until the end? I will leave that up to all the presenters.

Eric Heflin
No preference here from Eric. Whatever the ONC or managers would prefer.

Denise Webb
Okay. Well, we just have a couple questions. It might be smoother to just go ahead and have them ask their questions now, and then start your presentation. Les Lenert is in the queue.

Leslie Lenert
I would rather wait until the end, to be honest. It is more of a policy question.

Denise Webb
Okay, how about Abby? Abby, is your question specific to Texas's presentation?

Aaron Miri
It looks like she dropped her hand.

Denise Webb
Oh yes, she dropped her hand. Okay, let us continue. I apologize for interrupting.

Bill Marella
All right. Hi, everybody. Can you hear me okay?

Aaron Miri
Yes, sir.

Bill Marella
Okay, great. Thank you. Thank you for inviting us to address you this morning. My name is Bill Marella. I am the Director of Data Analytics and Quality at HealthShare Exchange. So, we are the HIE that is serving what we call the Delaware Valley. For us, that is basically southeastern Pennsylvania as well as southern New Jersey and northern Delaware. I am going to be joined by my colleague Liz Scoles, who is helping to manage this project with ONC. Go to the next slide.

So, before I get into this, I do want to say a quick word of thanks to ONC for having the vision to understand what HIEs could bring to the COVID-19 response. We have been really energized by what a crisis that hopefully none of us will have to live through again, but our membership has really rallied around us and gotten behind the activities that we are doing here, so I think we had something like 35 letters of support for our application to ONC, and I think all of our members also understood the data assets that HSX is the custodian of and how we could leverage those to achieve some of the goals that we had for population health. So, thanks to ONC for having that vision, and thanks to Larry and Tara Tessler, who have been helping us navigate this process as we have gotten the cooperative agreement started.

So, I am not going to spend any time telling you about HIEs. I assume everyone on this committee is very familiar with them. What I will say about our network that is a little bit unique is we have pretty much saturated the market in terms of the providers and health plans in our areas, and we have really moved now to the point where most of the people we are bringing on today are post-acute care organizations and community organizations that are addressing things like social determinants of health. We have brought in a number of the area agencies on aging over the last year and are bringing more on this year, as well as other community service organizations that are addressing those social needs. So, I think we really are at the point where we are breaking down a lot of the siloes that exist between the different parties that all have relationships with the patients. Next slide, please.

Quickly about our network – so, we have about 12 million patients in our clinical data repository, including not only Pennsylvania residents or residents of the Delaware Valley, but also people who are coming here for care. We do have a national draw because of the institutions in our area. We have about 16,000 physicians and other midlevel practitioners that are in our provider directory, and we have about 450 different organizations that are connected to HSX in one way or another. Next slide.

So, I just want to paint a quick picture of where we started on this project and what things were like back in the early days. For us, it was around March and April when the pandemic really started to take off, and at that point, the public health agencies in our area – we had a relationship with the Philadelphia Department of Public Health, but really none of the outlying counties outside Philadelphia, and we had a couple informal connections. We were hearing things like that they were literally getting faxes, as a couple people had mentioned. They were literally getting faxes one patient at a time with individual lab results that they were manually typing into Excel spreadsheets. Fortunately, we were able to convince them to change their approach and start consuming the data that we could make available to them.

Even beyond the COVID pandemic, we are at a point now in the evolution of HIEs nationally where I think all of us are at the point of doing some higher-order things than simply moving data around for that transactional patient-level view, and some of the things that we are doing are around disease management, like projects we are doing on diabetes or matching seniors with benefit programs that they are eligible for. It is a partnership we have with the Department of Aging in Pennsylvania.

And, even before the ONC cooperative agreement came through, we had started developing the Delaware Valley COVID-19 registry, and some of our members are accessing that data to be able to answer questions like if I look at patients who have come through our emergency department and were diagnosed with COVID that we sent home, did any of those people wind up getting admitted somewhere else later? Those are the kinds of quality improvement types of studies that this data will enable. With that, I will ask you to go to the next slide, and I will turn this over to my colleague Liz Scoles, who is going to walk you through the outline of our project with ONC.

Elizabeth Scoles
Thanks, Bill. Good morning, everyone, and thank you for the opportunity to present this morning. As Bill mentioned, I do just want to add that while HSX has access to the clinical data on millions of patients, from our origins, it has been HSX's mission to be a community asset, so what we would really like to highlight today is with the help of grants and collaborations such as this one, HSX has been propelled into incredible opportunities in this last year that ensure that we are that data-sharing community asset that can support large-scale population health initiatives. It has given us a new opportunity to focus on data quality and analytics like we have never done before and explore new types of data connections that benefit public health agencies and the larger community.

So, the two main objectives of the STAR HIE program are to build innovative HIE services benefiting public health agencies and improve HIE services available to support communities disproportionately affected by COVID-19. So, in partnership with our local public health agencies, our members, and our board of trustees, we have developed a strategic portfolio of activities that will close gaps for our region's public health response to COVID-19 and prepare us for future threats.

So, this slide illustrates our four main areas of focus under this program. What we really plan to do is modernize our region's pandemic response by exploring new opportunities for data exchange. As you see up in this left-hand corner, that includes augmenting the ability to do case finding, contact tracing, and sharing immunization status. HSX is participating in that Robert Wood Johnson COVID-19 registry, and we are facilitating public health agency use of that tool. So, Bill will share more information later in the presentation, but in response to a request from the Philadelphia Department of Public Health and the Office of Emergency Management, HSX was able to create a dashboard of emergency department and inpatient volumes and activity. HSX is also committed to implementing new data connections based on public health priorities, including electronic lab reporting to local and state agencies and connecting to the American Public Health Laboratory AIMS platform for ECR reporting, as well as implementing new CCDCs.

HSX has a unique opportunity to close information gaps for our local public health agencies and our broader membership with data that is already at our disposal through existing HIE connections. We are enhancing our infrastructure with new capabilities and adding new data feeds that will fill many of the current gaps in public health surveillance systems. One of the big priorities for HSX was to establish a governance necessary to not just to respond to the COVID-19 emergency, but also to put structures in place so our efforts can persist after the emergency is behind us. So, in doing so, HSX created a steering committee that is comprised of HSX leadership and the public health agencies benefiting from this program to help govern and guide priorities. This approach includes our state, city, and local public health organizations to ensure alignment and success of the activities outlined in this program. Next slide, please.

So, for the purpose of this presentation, we would really like to drill down into the new data connection, as these are initiatives that are largely new to HSX since the pandemic began, and this effort has drastically improved data sharing with public health agencies. New data connections are automating previously manual processes, which improves reporting and reduces burden on providers. As Bill mentioned previously, we have heard that records are faxed over one patient at a time, there was a lot of manual connection being needed, and it was just largely inefficient and had too many options for user error. Demographic information may come over incorrect or missing altogether. The ONC STAR HIE grant has allowed HSX to facilitate meaningful, timely, and more complete and accurate information sharing with our local agencies. Next slide, please.

So, we included this slide here to illustrate the new data connections that HSX has either completed or is working on since receiving the ONC STAR HIE grant. It is important for me to just point out that the names listed on this slide are large health systems within our region, and each of them has multiple acute or ambulatory facilities under that umbrella. So, prior to the pandemic, ELRs were not going to the city of Philadelphia, or for the few that were, it happened infrequently, such as once daily. That is not very actionable or timely information that is useful for the city.

So, the request through this project was to make that a more timely, actionable feed, and today, the ELR feed from HSX to the city is in production, and we just have a few more organizations to onboard. We achieve one of two ways: Either utilizing the ELR feed that the member currently sends to the state and creating a new destination for the city or working from the existing direct lab fees we receive from the member and filtering that feed by COVID-19 LOINC codes and the Philadelphia resident's ZIP code.

Electronic case reporting is beneficial for both providers and public health agencies. HSX has never before supported transmission of this type of data, but now has the opportunity to do so under this grant. HSX is piloting the project with Temple Health, and hopes to have it in production in the next few weeks. As you all know, consolidated clinical documents are the rich, robust information that allow for more informed quality patient care, and CCDs contain that immunization detail that are extremely valuable for this pandemic and beyond. HSX is committed to increasing the number of CCD connections across our region.

Along those lines, the final data connection I would like to point out on this slide is connecting to our state and local immunization information systems. In the state of Pennsylvania, there are multiple registries, but there are currently barriers in place, and HSX believes can improve upon those. HSX has made it a priority to enhance data-sharing capabilities and ensure that our providers and public health agencies have access to the data that they need. Next slide, please.

So, we included this slide just to illustrate some of the other onboarding initiatives we have going on in 2021. It is important to note that these are under the PA state grant, not ONC, but that the COVID-19 work that we are doing today definitely benefits them indirectly. The slide is actually a little bit outdated, but what I can say is at a minimum, as I mentioned previously, HSX is working on receiving CCDs from various skilled nursing facilities, urgent cares, home health, primary care providers, and specialty care providers across the entire state of PA. We are working on increasing our branches beyond where we are today to add depth and richness to our data and close gaps for those facilities in the region. Next slide, please.

So, electronic case reporting automates a currently manual process via a module update within the provider EHR. So, over here on the left, we have the providers, and if the provider inputs a trigger, which can be a diagnosis, a problem, an order, lab test, lab result, medication, or immunization, an ECR will be generated. From those triggers, the system identifies possible reportable conditions and automatically sends that ECR XML to HSX. HSX then passes that information to APHL AIMS, where an algorithm determines if the condition is reportable. APHL AIMS sends the reportability response to the appropriate public health agencies based on where the care was provided and the patient residence, and also to HSX. HSX shares that document back with the source facility.

Today, there are two mechanisms for submitting ECRs to APHL, one being eHealth Exchange and the other being direct secure messaging, and we do intend to persist confirmed reportability responses in our clinical data repository, but we are still working through the technical details of how that will perform. Next slide, please. HSX is honored and grateful to have received the Immunization Information System's ONC STAR HIE supplemental award to connect to our state and local registries. As I mentioned previously, we have a number of registries in our state, and there are barriers in place that we really believe we can help improve upon.

So, at a high level, some of the immunization priorities that we have to tackle are listed on this slide. HSX aims to connect with our state registry via HL7 query and retrieve, and we plan to share vaccine data with and between our registries as well to improve information sharing. Finally, HSX hopes to receive from the registries a file of COVID vaccination administrations limited to patients within our community. Next slide, please.

Finally, this slide is a screenshot of a record within the HSX clinical data repository that illustrates how immunization data gets parsed into our system. HSX has started receiving some COVID vaccine data, and we are receiving the appropriate CDX code, and the data is parsing correctly from the facilities that we have received from so far. Bill, before I hand it over and we move on to the next slide, do you have anything you would like to add about immunization?

Bill Marella
Well, yeah. As you said, even the registries that are operating within our jurisdiction are not necessarily sharing information consistently with one another, so in addition to being able to get that data into HSX so that the providers and payers have access to it, we also want to make sure that we are helping the public health agencies that run the registries, so that is a big part of that. Thanks, Liz. Go to the next slide, please.

I just want to drill down a little bit and talk about some of the other aspects of our program. Just to give you a sense of where we are in the pandemic, we are just coming off of the second wave, which, as you can see through the stats here, was even larger than the first, but we managed it a lot more successfully and with a lot less pain than the first one. Everything is shifting now to getting needles in arms, so that is really the front line of everyone's COVID response. So, in Pennsylvania, I think over a million people have had at least their first vaccination, not quite a million yet in New Jersey, and of course, everything is hinging on the supply, but we feel like we are in a good place now, and the caseload is certainly manageable at this point, having come down from the second wave. Next slide, please.

So, throughout the pandemic, we have been doing surveillance reports to basically – to borrow Eric's phrase – provide some situational awareness to our members. They were all familiar with the numbers they were reporting into the local public health authorities, but in the early days especially, they were not really getting a lot of information back to let them know what was going on even in their immediate vicinity, so we tried to fill that gap, and we also did some analyses using some diagnoses that CDC identified as indicating people that would be at high risk should they get COVID, and we were able to map those diagnoses to the people in our master patient index, and indeed, we saw that people who had more of these risk factors had twice the risk of getting hospitalized if they got COVID, four times the mortality risk, and longer length of stay.

So, we are now translating that into a risk index that we can augment our MPI with, so we have been giving our MPI to some of the local health departments for contact tracing purposes. Now, we can kind of switch our focus to vaccines and show them people who are at the highest risk who maybe have not signed up to get the vaccine or have not yet been vaccinated because some of them will have the bandwidth to do some outreach to those people. Next slide.

This relates to the project that is going on in Texas with SANER that I am really excited to hear about. So, this is a graph showing the admissions and discharges in two different series during the beginning of the pandemic, and what we saw in the early days was all of our hospitals were emptying themselves out for the COVID wave that we knew was coming, and for a period of about six weeks, we would see the admissions exceeding the discharges on most days, and that really saw the COVID bubble develop to the point where we reached our peak in the first wave and had several weeks of two things happening. One is the discharges were now exceeding the admissions, and gradually, you saw the overall level of activity start to pick back up. We are still not back to pre-COVID levels of normal activity, but I think this chart

demonstrates the validity of using the kind of data that HIEs are collecting for this situational awareness assessment. Next slide.

So, one of the other interesting things that has come out of this work is we are engaged with several offices of emergency management, so they are usually a unit of the department of health or other county agency, but what they asked us to do was give them a real-time dashboard showing the level of activity in area hospitals, even on an hour-by-hour basis. So, there are a bunch of technical challenges around this, but what we have been able to do is, if you look at the next slide, what we see in this view is just the hospitals, and we are comparing their current volume with what is expected at that site at that time of day on that day of the week and whether they are seeing levels that are exceeding their normal activity, and that will make them go yellow or red.

Now, this view was not necessarily designed for COVID, which, of course, builds over time. This was more a function of other types of disasters that we have seen around here, whether it is a train derailment, chemical spill, or something like that that would happen suddenly. So, this dashboard is available to the Offices of Emergency Management for that purpose, and if you go to the next slide, there are other views in this dashboard that are looking more at trends over time that would relate more to COVID admissions. Next slide, please.

So, some of the challenges – I will not go into all these just in the interests of time, but there are some I will comment on. So, having properly coded data – and, I know the use of controlled vocabularies and all the coding systems that are required by the different regulations have all been a big help, and I think they have improved the overall level of data quality, but I will still say that we do still have people who are sending us local LOINC codes that we have to deal with and data that is not properly coded in one way or another.

With COVID in particular, it was really interesting in the early days – there are still people who are using the codes that CDC recommends not using to designate COVID-19. You have to meet people where they are for this kind of work. But, I really have to say the EHR developers really stepped up because in the early days of the pandemic, people did not have the necessary codes in their coding systems, and most of the hospitals rely on the vendors to keep those libraries up to date, and they very quickly pivoted and got that information in there, and that has been a big help, but it does highlight the reliance the health systems have on the vendors for perfecting the data in that way.

A general issue that we have is, of course, delays in coded diagnoses. We typically do not get these until days after an encounter, so there is sort of a lag in our ability to provide accurate data around any particular diagnosis. And, just as a policy issue, this committee might be in a position to help expand public health access under HIPAA. A lot of the things we are doing right now are possible because of the waiver of HIPAA enforcement during the COVID emergency, but once that COVID emergency period expires, we have to modify our public health use case to permit some of these things, which may require us to go back member by member to let us use their data for these public health purposes. It would be an extreme help to us in terms of efficiency to not have to go get and document the permissions from 450 different organizations to share some level of this information with the public health agencies, so anything that ONC or this committee could do in that respect would be helpful.

Another challenge has been around tracking nursing homes and other congregant living residents. So, we have many nursing homes that are members of HSX, but when you are looking at the ADT feed or you are looking at the CCDs, it is not always straightforward to identify who is a nursing home resident at that moment in time. I do not think that is a field within the ADT spec, but it might be something that you could look at to include in the USCDI. It would certainly be valuable to know people who are living in these special situations that they dictate how they are received or the care that they get. In fact, what we were left with as the best solution was to try to match on addresses. The person's address comes in on an ADT message, and if you compare that with a known list of addresses from nursing homes, you can make a lot of the matches that way, but as we heard in the project earlier with the US@ and addresses, that is certainly an imperfect process, so I am anxious to hear if that project will be able to help us with that. So, I think that was all we had, and I welcome discussion or any questions.

Denise Webb
All right. Thank you very much for the very informative presentations and all the work that you are doing. It looks like we just have one question in the queue – oh, here they come. The first one up is Sheryl Turney.

Sheryl Turney
Thank you, Denise. My question was for the HS – hold on, I have to get back to it because I wrote down my question so I would not forget it – the HSX group. So, you mentioned it verbally, but it was not on the slide about pushing data to payers. The slide only showed pushing data to providers, and of course, I represent a payer, so I am interested in this because with the interoperability rules that currently are being implemented, patients have the ability to come to payers to get information, and it is curious to me that we are not pushing to the payer the information that even patients would want to know, like ADTs and notifications that you had talked about from their COVID vaccines for monitoring and things of that nature. So, are you automatically pushing those out to payers as well as providers?

Phil Beckett
This is Phil. Thank you for the question. Yes, we are pushing – typically, we are just pushing ADTs to health plans. We have been working hard with them to be able to send clinical data. Part of that has been they are used to getting a facsimile – and, I do not use the word to refer to a fax, but an actual, literal clinical record that their order system can go through, not a CCD, which is what we are all exchanging. So, we have done quite a lot of work around HEDIS, risk adjustment, and even some prior authorization using the CCDs. I think it is still early days on that, but I think both the health plans and certainly we are incentivized to want to do that so that they would have the clinical data too.

Bill Marella
I can weigh in from HSX. So, we are also sharing – most of our payers are receiving encounter notifications from us, so that is an automated process. Not all of them, but most of them are receiving what we call real-time results, so we are sending the raw ADT messages as well as the raw CCDs to them. It just depends on the payer whether they have the infrastructure to absorb information that is formatted in that way, and there is sort of a continuum of their readiness to do that, but we are sending all the data in real time to most of our payers.

Sheryl Turney
Thank you for that.

Elizabeth Scoles
Bill, this is Liz from HealthShare Exchange. I do just want to add one more thing, that the data that is being shared with health plans is filtered down to the eligibility roster of that health plan, so they only get data back from us on patients that are within their membership, just to clarify.

Bill Marella
That is a very important point, thank you.

Denise Webb
That is a good clarification. Let us see. We have Clem McDonald next in the queue.

Clem McDonald
First, I have – some of the mechanisms are not crystal clear, so I am going to make some assumptions and you can correct me. Do you collect the data centrally from multiple sources? The second thing is if you do, what message system do you get it in with? Is it your own hacked-up one, or are you using V2 or FHIR? I had a third one, too – oh, can providers at large get access to look it up, or is it just the big hospitals or even the big hospitals that can get at the data and look it up?

Phil Beckett
Again, this is Phil. These are all great questions. Typically, we get V2 and V3 – so, HL7 V2, the old-fashioned stuff, over a VPN terminal, so that is encrypted. We get CCDs via web services, but we also do get some FHIR, probably not so much from hospitals and electronic health records, but from other vendors a little further on with FHIR, but we do get it that way, and it is a bidirectional interface. So, again, to my earlier comment, we try to integrate it into the workflow so that physicians – anyone, as long as they have a relationship with that patient, we have the governance and paperwork in place so they can get that data back right into their workflow, either on a query base or we do try to set it up for automated push as well so that, for example, for transitions of care, you are the PCP for the patient and they just got discharged from the hospital. We will send you a notification and the clinical documentation so that you can follow up with them and get it within 14 days and prevent a readmission, for example.

Clem McDonald
Thank you. What about –

Eric Heflin
This is Eric. From the perspective of the SANER project in particular, that is all based on new standards for gathering the hospital capacity information, Clem.

Clem McDonald
Okay, well, thank you. It is gratifying to hear how well some HIEs are doing.

Denise Webb
Did any of our presenters have anything else to add from either presentation on Clem's question?

Bill Marella

This is Bill from HSX. It is the same story for us. So, the majority of our data is coming in through CCDs and HL7 V2 – I think we are on V2.5.1 – but we also have dedicated lab feeds coming in through ORUs. Radiology information can come in that way as well, so it is all entirely standards-based.

Clem McDonald
Good. Well, everybody decries V2, but it is actually the engine that works right now, I think. I am a fan of FHIR, but I think most systems are dependent on V2.

Bill Marella
We are using FHIR primarily to let people hit our database and pull information from HSX as opposed to putting information into it, but that is certainly coming.

Denise Webb
All right, thank you, Clem. Les Lenert, you are next.

Leslie Lenert
Thanks. This question is for Larry Jessup, and it is more on a policy level. I am really excited by the STAR program being able to get HIEs to have a core of five, and then to move on to an additional 16 or 17 HIEs in the second ground is great, so I am going to give you the softball question that every person who runs a program wants, and at the same time, alienate Micky forever by doing this. The question I have is based on the premise that we are no longer in a place where we need demonstration projects that show us the way. What we need to do is lift the capability of HIEs, so my question to you, Larry, is how much more money would you need to be able to fund all the HIEs who apply to the STAR program to communicate between their jurisdictional IIS systems and the HIEs – not just the subset that you have had, all the qualified applicants for that – and then, how much would you need to raise this capability for all functional HIEs – I think that we are at around 100 HIEs in the country – to be able to create this advanced infrastructure for this rather than demonstration projects as to how to go? I think we need to really focus on how to lift all boats at this point, not just demonstrate a few advanced projects – that all HIEs need to help.

Larry Jessup
Sure. I will give this a shot, but any time you are referring to federal dollars in funding, that is never a softball question, so we will start there, and I think we all recognize that the federal dollars do not go nearly as far as we would like. I do not think that there is any way to determine at this point how much money we would need, although I think with the supplemental program, we have found that with any amount of funding that we get, we are capable of designing and rolling out a program based on the needs of the country, based on what is going all to public health agencies, and based on the capabilities that exist with all the current HIEs.

So, no matter what that funding amount would be, as that funding became available, no matter the amount, I think that given what we have been able to do with the supplement and given the areas that we have been able to identify as gaps as it relates to improving the HIE infrastructure and also improving the public health infrastructure, I think we have a model here, but I think it is yet to be determined how – if we continue to be successful with this, I would say we would just continue to supplement this program in addition to – this is all unpredictable. We are all new to this, so I think we are identifying gaps as we go along. That would be my best answer. I think we would have to use this model again, and it is going to be very difficult at this

point in time to determine the exact amount that would be needed to go forward to fund all the HIEs to do what you had mentioned before.

Leslie Lenert
So, as a former fed who ran informatics at CDC, I am not going to let you off. How many applicants are there in the STAR program did you not fund or who remain unfunded, and what is the immediate need for the ones who were funded?

Larry Jessup
From a grant standpoint, I do not think we are at liberty to discuss how many were not funded. Bigger than a breadbasket as many as were funded, or…

Leslie Lenert
We are your supervising FACA here. I realize this is a public meeting, but would the needs be about the same as you just issued, or would it be larger? It seems to me that given the $1.98 trillion we are spending on the second stimulus for COVID, there might be a couple million dollars around.

Aaron Miri
Les, maybe we could take this conversation – I am not even apprised of how deep this is, and maybe there are a lot of conversations that need to happen, so if I could ask us to table this one and come back to it, we can definitely answer the question with more detail and information around it.

Leslie Lenert
Sounds good to me.

Denise Webb
I was going to suggest that maybe it is not just the federal government that might be a funder for this. There are a lot of foundations out there that, if they had insight into some of this and what it would mean for the nation, they might consider funding some of this.

Aaron Miri
Yeah, and I will add that on the Annual Report workgroup, we do also call this item of data exchange out – also for research purposes as well – even synthetic datasets and limited datasets, so I think there is a good opportunity to learn more here in this space, and Les, I think it goes to the heart of your question, and that will answer the funding question once we know what the landscape is and what those priorities are. But, you are right, this is a big issue, and I applaud these organizations and others, and I applaud the ONC for taking the first steps forward and helping us move this ball.

Denise Webb
So, next in the queue, we have John Kansky.

John Kansky
Thanks, Denise. One second, I will pop my camera on really fast. There it is, okay. Thanks, sorry. So, first of all, I just wanted to say thanks to the presenters from Texas and Pennsylvania for sharing what I think has become one of the key learnings of the pandemic response – the value of HIEs to support public health

in general. My neck is tired from nodding while you were presenting and from some of the shared experiences and challenges. There is a hearing specifically on the HITAC calendar for later in the year related to HIEs and public health, and I just wanted to point that out. Les, Valerie Grey, and I are HITAC members trying to help plan the content for that hearing, so I just wanted to plug that. I also wanted to comment on the reference to policy barriers that HIEs encounter, keeping in mind there is only so much ONC can do, and if they have a hammer and a screwdriver, we want to try and give them tasks to utilize those tools, so I think the policy barriers that ONC can work on are important.

Also – and, this might be a little surprising, and I do not want to get myself in hot water with my friend Les, but in terms of funding HIEs, I think there is some nuance that is needed in the policy there. I think there is a growing sentiment that HIEs need to – whatever they are now, each state needs to have a health data utility, and in some states, there are HIEs that are essentially functioning as statewide health data utilities, and in some states, there are not. I think just writing a check to every HIE out there is not necessarily the best path toward that future vision. So, it is not that money for HIEs is bad, but I think there needs to be some nuance around the funding policy to work toward this vision of HIEs as state health data utilities supporting public health. Thank you.

Denise Webb
Thank you, John. Micky Tripathi is in the queue next to talk.

Micky Tripathi
Great, thanks. I did not hear Les' question – my phone was breaking up – so I cannot respond to that.

Leslie Lenert
You are good!

Micky Tripathi
Scalability – I think these initial ones that are funded are certainly basic research, and then the question of scalability from the lessons that we learned there are the next set of questions, obviously. But, the question I have is actually not a question, and I think it is more for Eric and Phil – Eric, nice to see you again. It is related to something that you had just touched on, and I would love to just know a little bit more about what you are encountering on the ground, and that is a number of the data elements that we need for the situational awareness and supply chain kind of status do not reside in EHRs, and Phil, I think one of your slides pointed to that.

There are ERP systems, PeopleSoft, RCM systems, and all of that that are a part of the hospital constellation, and I just wonder what your experience has been in getting information out of those other systems which are not certified technology, so it is a little bit of a Wild West there. The second part of the question is whether any opportunity has come up to think about the EHR perhaps as a conduit for information from those other systems that does not naturally get documented in the EHR system.

Eric Heflin
Very good, thank you, and good to see you again as well. Congratulations and welcome to this role. We are here to support you in that. So, to your first question, we actually did anticipate the scenario you described, and so, the fundamental design of SANER is to collect data from any applicable data source,

which is likely going to vary depending on the hospital or facility, so that is accommodated in the fundamental design, and it does that by – if you will, let us say SANER is right here. It collects data, and there are a number of adapters that plug into SANER to actually allow the data to be captured from whatever system it happens to reside in with any given organization.

To your second question, that could certainly be the EMR. It could be others as well, such as health information exchanges. So, really, it is largely a data contract between the consumer of the hospital capacity, planning, and situational awareness data in the hospital's inner systems, and the hospital is in control of the deployment of those adapters, so they are the authoritative source, and they also get to have provenance over the data collection from those authoritative sources so that they are very comfortable with them and they also have the authoritative perspective on which is the best source of given information. Thank you for the great question.

Phil Beckett
Thanks, Micky. If I could just add to that, it is great to meet you. As I said, our first perspective is to make life easier for our physicians and hospitals, not to add extra burden, so if they can write a report out of their ERP that dumps once a night to a comma-delimited file, we will pick that up. Our first goal is to make it easy for the hospital to do this, but with the appropriate safeguards in place, too, so that errors do not get transmitted.

Micky Tripathi
Great, thank you.

Denise Webb
All right. We have Clem McDonald in the queue next.

Clem McDonald
I wanted to comment on a couple things. Can you hear me? I am never sure when a button is on.

Denise Webb
Yes, we can, Clem.

Clem McDonald
Okay. So, one of the ways to deal with cost is – so, I think we built the first one in Indiana, and John Kansky can say more about what the current state is, but it took about a day for software developers to hook a VPN, which I think we got up to 1,500-1,800, but I do not know where it stands now, to fix the message a little bit, and we had to tweak this and tweak that. But, the codes killed you. If we wanted to code a lab, it took three to six months.

So, the coding and the cost of the coding are the barrier, and I think once the ONC rules take hold and if the codes are really in the right place – they are often hidden in many mapping tables, and I know researchers cannot find them half the time – then I think the cost would be much easier. You could just flow them in. I hope people do not dump V2 because it is mostly working in these places, and you do not want to start all over. Again, I am a fan of FHIR. It is great. So, those are the two thoughts. If we could get the

cost down, that could help a lot, and I think part of it is that the darn codes are just difficult to map from the local codes that labs or whomever sends you.

Eric Heflin
I want to acknowledge that very relevant concern. The way we have addressed this so far is actually shining light on a shared vocabulary. So, the SANER project refers to these as measures, and there is an opportunity to actually curate those measures together as a country and as a world under, in this case, the HL7 umbrella, and so, there is actually an opportunity to, indeed, resolve that issue by collaborating together on what are the important measures, vocabularies, and value sets.

Phil Beckett
I agree, Eric. I definitely agree that the codes are the problem. It is really hard to map all those, and I see private opportunities out there, too. We do not all have to map all the codes. If there is someone who hosts, for example, lab codes for hospitals in Texas that we could all bounce an API against and get them, we do not all need to maintain that one central source of truth for some of these things.

Denise Webb
All right. I do not see any other hands up in the queue. I will just hold a second to see if there are any others.

Aaron Miri
Is there anybody on the phone?

Denise Webb
Oh, yes. Is there anybody on the phone? No? Aaron, it looks like we will move on, then. I would like to thank our presenters for their time. We really appreciate all the information you provided us, and we look forward to hearing more about your work.

Eric Heflin
Thank you for having us.

Phil Beckett
Yes, thank you for having us.

Bill Marella
Thank you.

Denise Webb
You are very welcome. All right, we are on to our final presentation before public comment. Public comment will be at 12:50, so we are right on schedule. This final presentation is on the priority uses of HIT and the annual standards process and overview, and we have Chris Muir, and I believe Wanda Govan-Jenkins is also on.

Interoperability Standards Priorities (02:43:21)

Chris Muir
Hi, I am just doing a sound check. Can you hear me all right?

Denise Webb
Yes, we can.

Chris Muir
Okay, great. Thank you. Hello, everyone. My name is Chris Muir, and I am the Standards Division Director in the Office of Technology at ONC. With me is my colleague Wanda Govan-Jenkins, who is a Nurse Informaticist and the person leading the Interoperability Standards Priorities task force efforts. We are here to discuss launching the ISP Task Force, and also to talk about the process for how we envision the work will go forward on an annual basis. This important work will meet the requirements of the 21st Century CURES Act, which says that the HITAC will prioritize the uses of health IT and also identify the standards and implementation specifications to support those uses. Our goal is to more closely integrate this responsibility of the HITAC with the work of ONC by convening the task force to help us further advance the Interoperability Standards Advisory, what we affectionately call the ISA, and ensure that the HITAC's priority uses are reflected in the ISA, along with the identified and related standards and implementation specifications.

As you know, the ISA is a list that ONC curates and publishes on an annual basis, which contains the standards and implementation specifications available to address specific interoperability needs. Through our online ISA system, we work with our stakeholders to identify and publish an ever-growing list of standards supporting those interoperability needs. The ISA also contains helpful information about the standards. I help the ISA users determine which among the competing standards may be most helpful for specific uses. The ISA is meant to be a first stop for federal and state policymakers to select among health IT standards when writing policy and regulations or developing programs. It supports such things as the ONC's health IT certification program. Additionally, health IT implementers can also go there, and it will help them determine which standards they should use for their projects, and overall, ISA is an important organizing factor for ONC standards work.

So, in summary, we are asking the HITAC ISP Task Force to help us build out the ISA to ensure that the HITAC's priority uses are reflected in the interoperability needs, and that the related standards and implementation specifications are identified and published there as well. Again, we see this as an important linking of HITAC's responsibility with ONC's work. And, with that, I will turn the time over to Wanda, and she will go through the slides, explain the charges of the task force, and also discuss how the annual process will work, and then we will take questions. Wanda?

Wanda Govan-Jenkins
Hi, can everyone hear me okay?

Aaron Miri
Yup, we can hear you.

Wanda Govan-Jenkins
Okay, great. It is a pleasure to speak to you all again. I worked with you all closely back in 2019 on the ISP Task Force. Next slide. I am Wanda Govan-Jenkins, and as Chris said, I am a Nurse Informaticist, and I have been with the ONC for about 10 years. So, the charge that we are hoping will take place: The ISP

Task Force shall identify the opportunity to update the ISA, the interoperability sections to address the HITAC priority uses of health IT, including new priority uses for health IT if necessary. The ISP Task Force shall also recommend additional or modified interoperability sections for consideration and updates to the ISA, including related standards and implementation specifications.

Last year – in 2019, rather – the HITAC report priority uses of health IT from the report – there were four domains. Those domains consist of – next slide, please. Those domains consisted of cross-domain orders and results, closed-loop referrals and care coordination, medication, and pharmacy data. Next slide. The HITAC ISP Task Force – the ONC charges HITAC to reconvene the ISP Task Force starting this month. The ISP Task Force shall launch and begin meetings starting this month. The ISP Task Force shall review ISA starting in March to review ISA and identify opportunities to update the ISA section to address HITAC priority uses of health IT. The ISP Task Force shall develop draft recommendations to add/modify the interoperability needs section for consideration and updates to the ISA, including related standards implementation specifications.

The ISP Task Force shall consider public feedback in developing those recommendations. During that process in March and April, HITAC shall review the ISP Task Force progress during that time. Lastly, in May and June, the ISP Task Force shall submit final recommendations to the HITAC for approval, and the HITAC shall review and approve those recommendations from the ISP Task Force. Next slide. This is just a chart that will just show you the ISA annual reference edition cycle that will happen after HITAC reviews and approves the recommendations after June.

So, starting late summer, the annual review and comment period will open for 60 days, and then, starting late fall – middle fall, rather – ONC and HHS staff will review those public comments they receive and the HITAC recommendations, make site updates, and prepare the following year's reference edition for publication by early January. And then, late winter/spring/summer of the next year, changes may be made to the web version of the ISA throughout the year, including changes considering HITAC recommendations while the ISA reference edition remains static. That concludes my presentation. Are there any questions?

Aaron Miri
Let us see here. Steven Lane, first question.

Steven Lane
Thank you. I really appreciate this presentation by both of you and really applaud the fact that ONC is going to be restarting this task force. I had the pleasure of co-chairing the prior ISP Task Force with Dr. Kawamoto, and we really had a marvelous group, very engaged, very active, and I think produced a useful bit of feedback for the ONC. I think this is a very important process to keep moving forward on an annual basis. It certainly has been called out in our Annual Report, and I think it is critical to the work of ONC, so I applaud the team for getting this going. I think realistically, given my role now with USCDI, I am not going to be able to continue to co-chair the task force, but I certainly want to do everything that I can to support this work as it goes forward.

Aaron Miri
All righty. Next is Clem McDonald.

Clem McDonald
I am a little confused, and maybe that is my current state, but there is ISA and there is USCDI, and it seems like there is a big overlap, so it would be good to get some clarification about the boundaries. Second, ISA is great and grand, but the problem is it is hard to know where the line is where this is what you have to do because you read about this, and then there is a comment, and it is hard to know what is really required. I think that is in USCDI, but the boundaries need to be clarified a little bit in those web pages because we really have to remember that if everybody does what they want, we are going to be in the same state. The only coding system that has been super successful is Medicare's because you have to do it. You have to use the three or four code systems they say to. If there is not some strength on this, we are going to be doing all kinds of extra work and battling for a long time. That is the end of my soap box.

Chris Muir
Thank you, Clem. Let me take a stab at answering it. I think the best way is to think of the ISA as pre-regulatory – well, it is not regulatory. So, there is no requirement within the ISA itself that it has to be used. We list a lot of standards in there that are required by regulation, but just by virtue of being listed in the ISA, there are no requirements that those standards need to be used. We require standards through the regulatory process, which shows up in the certification, and also, over time, when USCDI goes through the process of being adopted by regulation, those will also – what is in the USCDI will be required. And so, I think that is really the difference. It is through those other methods that standards get adopted.

The ISA is really like a big catalog of all the standards that are available. We include them all. We try to provide helpful information about each of the standards and the implementation specifications – it has both – and then, as policymakers want to add requirements to the certification or CMS wants to add some standards to their regulations, they can go to ISA, take a look at what is there, and because of all the notes and things listed there that you are mentioning, Clem, we hope and we think it will help them determine which standards they should include in their programs.

Clem McDonald
I agree, it is very helpful and very informative, but you got to that page to get USCDI, so I think some clarification of what world you are in when going there might be helpful.

Chris Muir
That is really good feedback, and I understand where you are coming from there. We are using the same platform for both, and that may be a little confusing.

Aaron Miri
All right. There is some good conversation here. Any other questions from folks on the line or on the phone as well? Jonathan?

Jonathan Nebeker
Hey, thanks. So, I think this is – I appreciate Clem's comment. I was going to make a comment on the USCDI presentation earlier. I think this is an area where there is some regulatory perversity – I will not go into how all this works now – that makes it difficult for us to advance standards, stick to standards, and focus work in the healthcare system and the vendors on moving the interoperability agenda forward. This

overlap is maybe indicative, but is a minor issue. I think there is an opportunity now – I think the last administration really did a lot of good in this space, but I am sorry that some of these conflicts came out.

For example, USCDI requires free sharing of information, so it disincentivizes some of the participants for really robustly advancing standards because by doing so, they cost themselves more money and maybe forego other financial opportunities. This is just one of the issues that we have. So, I am hoping, Micky, that we can take a step back and think about given where we are and all the advancements we have had, what is the best way to move this forward.

Aaron Miri
All right. Ken, I see your hand raised.

Kensaku Kawamoto
Thanks. Maybe just echoing a little bit of what Jonathan is saying as well, I feel like right now, a lot of the focus is rightfully on USCDI. There is a clear notion specified here that you must implement this. At the same time, there are a lot of issues around it, like the fact that there are not currently any federal initiatives. to try to promote and mature things that are lower down on the list, and I think that is one place to look. Maybe this is a scenario that the ISP Task Force can really focus on to try to use their efforts to look at things that are further down the list and work out what the right standards are and things like that as well. In general, it would be good to see if there are ways we can improve the incentive structure.

As I think Jonathan was alluding to, there are really perverse incentives now where we have enshrined in regulation that if you make it to USCDI as an EHR vendor, you may not make money off of it, and some major vendors have taken that and said, "Okay, if it is there, we are just going to make it available for free," and there are obvious issues there when you are saying the moment something enters it, if you were making any money off of it, you may no longer make any money off of it.

So, I think it is what it is now, but we should really be looking at it and maybe taking a step back. What do we fundamentally need to do to make standards that make sense to implement and are implemented widely? I do feel like the current approach will basically result in the current status quo staying relatively unmoved for five to 10 years. Thanks.

Aaron Miri
Ken, this is Aaron. To my understanding, when you are saying "make money off a standard," are you referring to a specific registry, like a clinical registry of some sort, or a specific data class?

Kensaku Kawamoto
In the regulations for the US Core Data Interoperability, it says you may not make a profit off of it. It says you can only do cost recovery, which is also tricky and also gets to the point where it leads some major vendors to say, "Okay, it is not worth it for us to figure out exactly how much we can charge without running afoul of regulations. We are just going to make that available for free." Because then, you have every incentive to leave as much as possible in the not-USCDI bucket because then you can actually charge for it.

Aaron Miri

I see your point, okay. Thank you for the clarification. Any other questions from the committee or folks on the phone? I do think this is a critical topic, and I echo what Dr. Lane was saying. I am glad this is being restarted. It was a great committee. Okay, I do not see or hear any, so Denise, what do you think about asking for general questions from the committee? I know we are about 15 minutes from time. We can always do public comment early, but the closer we are, the easier it is for the public.

Lauren Richie
Aaron –

Denise Webb
I was going to suggest – sorry.

Aaron Miri
Go ahead, Lauren.

Denise Webb
I was going to suggest that since we do have, if there is any discussion or questions on any of the topics we had today from the committee, we could open the floor for that, or Lauren, if you would prefer to go to public comment early, we can certainly to that too.

Lauren Richie
Sure, we can do that. We will ask the contractor to pull up the public comment phone number. In the meantime, for those that served on the prior ISP Task Force, we will just assume that you are indeed interested in remaining. If you are not, I know that we just started the USCDI task force, so we want to be respectful of your time and bandwidth, so if you want to just shoot me a note to let me know of your preference. Also, if you are interested in serving as co-chair for the ISP, please let me know as well. I want to thank Steven Lane for previously co-chairing, though we are tasking him with the USCDI task force for now. We will certainly be back in touch in terms of the kickoff date for that task force.

Denise Webb
It looks like Steve Posnack has his hand up if we want to hear from Steve before we go to public comment.

Steve Posnack
Thanks, I appreciate it. Just to follow up quickly on Ken's comment and in reaction to Jonathan as well – and, I am sure this is probably an offline conversation – we went to great lengths to make sure that there was an opportunity for cost recovery, both in terms of the certification program parameters for the condition of certification so that the research and development engine for our regulated entities – in this case, health IT developers – were able to recoup costs that would allow them to continue to make changes and update their technology over time. And so, while there are particular policies that focus on usage costs that have certain limits from a financial perspective for certified APIs, the information-blocking side as well had included the opportunity for – I believe we put "reasonable profit" or something along those lines in the terminology. Let me go back over to the website, which was loading slow for me in terms of the fees area. But, I did just want to note that to set the record straight, the cost prohibitions were not as they were represented. I am happy to talk about that further.

Denise Webb
Thank you for making that clarification. Lauren, I think we can go to public comment. I do not see any other hands up at this moment. I think you are on mute.

Public Comment (03:03:42)

Lauren Richie
Thank you. At this time, we will ask the operator to open the public line.

Operator
Thank you. If you would like to make a public comment, please press *1 on your telephone keypad. A confirmation tone will indicate your line is in the queue. You may press *2 if you would like to remove your line from the queue, and for participants using speaker equipment, it may be necessary to pick up your handset before pressing *. Our first question or comment is from Shelly Spiro with Pharmacy HIT Collaborative. Please proceed.

Shelly Spiro
Hello, can you hear me?

Operator
Yes.

Shelly Spiro
Okay, thank you. My name is Shelly Spiro. I am the Executive Director of the Pharmacy HIT Collaborative, representing over 250,000 members of the majority national pharmacy associations, including pharmacy education and accreditation in 13 associate members. A major focus of the Pharmacy HIT Collaborative is to ensure pharmacists in all practice settings – community health system, hospital, managed care, behavioral health, and long-term post-acute care – are integrated into the national health IT infrastructure. With the wide adoption of the Pharmacists' Electronic Care Plan effort using the FHIR standards, Pharmacy HIT Collaborative commented on USCDI Version 2 with additional data elements needed to be included in USCDI Version 2 to assure nontraditional EHR vendors are able to certify for interoperable exchange of clinical information.

This includes pharmacy system vendors that are sharing over a million pharmacist-provided electronic care plans. Pharmacy HIT Collaborative is a steward of over 650 SNOMED CT codes and over 100 value sets within the National Library of Medicine's Value Set Authority Center to standardize the collection, documentation, and sharing of medication-related pharmacist-provided clinical services, with standards such as the Pharmacists' Electronic Care Plan. The Pharmacy HIT Collaborative made comments, including two new data points under the new class, for a payer coverage data point to be included and are being used within the Pharmacists' Electronic Care plan. Thank you.

Aaron Miri
Thank you.

Denise Webb
Yes, thank you for those comments.

Aaron Miri
Okay. We are seeing no further comments in the public, so we do have about nine minutes – well, no, actually, we have about 15 minutes, to be honest with you, but we can always give time back to folks. To pick up what Denise was saying, are there any questions from the HITAC on any of the topics today needing further elaboration just because we were running out of time on a certain section? Do we want to give the committee plenty of ample opportunity here with this group? I see Steven Lane.

Steven Lane
I actually just wanted to follow up on the comment from the Pharmacy HIT Collaborative that we just heard regarding the comment submitted regarding USCDI Version 2, and it strikes me – I have not seen those comments yet, I have not tripped on them. We have discussed with the ONC team that navigating the site can be a little challenging. I will keep looking for them, but if someone wants to send me a link to show me where those comments got posted, that would be really helpful, but it would also be nice on that site if we could create some sort of a search function to allow one to find comments, either by keyword or topic area, et cetera, because I think as we get more and more comments on the site, it is going to be increasingly challenging for people to find them all and sort through them.

Aaron Miri
That is a good point, Steven. It is a great point, and I have seen a lot of comments here about information being readily disseminated out there and all the good work that is going on. To your point about maybe trying to help coalesce questions, inquiries, or comments, that is always helpful, so that makes a lot of sense. Okay, other questions or topics from folks? All right. Well, this is a great discussion, Denise. I think we can move to closing remarks here and close out the day. Lauren, any objection?

Final Remarks and Adjourn (03:08:22)

Lauren Richie
No objection, just a quick reminder that our next meeting is actually a month from today, on March 10th. All the materials from today's meeting can be found on our HITAC calendar at HealthIT.gov. Again, shoot me a note and let me know your preference on the ISP Task Force, and if you have any follow-up questions regarding USCDI, feel free to contact Steven, Terry, or Al from ONC. Otherwise, that is all I have for today.

Aaron Miri
Wonderful. For closing comments – go ahead, Denise.

Denise Webb
I just wanted to mention – and, Aaron, you and I are both on the USCDI task force – just to let the entire committee know that we are meeting on Tuesdays, and I believe it is from 10:30 to noon Eastern Time, in case you want to listen in or join any of those meetings. I want to thank everybody today for the very thoughtful comments and questions, and for engaging in the topics today. I thought we had a really excellent dialogue, particularly around the USCDI and around public health information exchange. So, thank you.

Aaron Miri
Absolutely, great. Let me just echo this for all the folks on the front lines and the provider organizations – those that are in the middle of treating COVID-19 patients as well as the vaccination efforts that are going

on – hats off to you. It is not easy, and taking time out of your morning to do this is critical because it is helping advancement from a national perspective. So, I wish the best of health to all of you. Enjoy the Valentine's weekend. It is freezing here in Austin, Texas, but that is okay. Hopefully, it is warmer where you are, and we will definitely see you at the next meeting. Micky, did you want to make any closing comments?

Micky Tripathi
Nope. I just wanted to thank everyone and thank both of you for leading a great discussion.

Aaron Miri
Thank you, sir. Thank you for your attendance. Everybody have a great day. Be safe.

Lauren Richie
Bye, everyone.

Denise Webb
Thank you. Bye-bye.