Health Information Technology Advisory Committee

The Office of the National Coordinator for Health Information Technology

Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) MEETING

May 13, 2021, 9:00 a.m. – 5:00 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
James Ellzy	Defense Health Agency, Department of Defense	Federal Representative
Adi V. Gundlapalli	Centers for Disease Control and Prevention	Federal Representative
Ram Iyer	Food and Drug Administration	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
Avinash Shanbhag	Office of the National Coordinator for Health Information Technology	Acting Executive Director, Office of Technology
Mike Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Daniel Jernigan	Centers for Disease Control and Prevention	Acting Deputy Director for Public Health Science and Surveillance
Tom Frieden	Resolve to Save Lives	President and CEO
Mark McClellan	Duke-Robert J. Margolis Center for Health Policy	Presenter
Greg Singleton	HHS Office of the Chief Information Officer	Presenter
Michael Fraser	Association of State and Territorial Health Officials (ASTHO)	Presenter
Linda Rae Murray	University of Illinois School of Public Health	Presenter
Anne Zink	Alaska Department of Health and Social Services	Presenter
Ian Williams	Centers for Disease Control and Prevention	Presenter
Sarah Boateng	Health and Human Services (HHS)	Presenter
Lilly Kan	National Association of County & City Health Officials (NACCHO)	Presenter
Linda Thomas-Hemak	The Wright Center for Community Health and its	Presenter

	affiliated entity, The Wright Center for Graduate Medical Education	
Joseph Kanter	Louisiana Department of Health	Presenter
Jonathan Greene	Office of the Assistant Secretary for Preparedness and Response (ASPR), Health and Human Services (HHS)	Presenter
Sam Imbriale	Office of the Assistant Secretary for Preparedness and Response (ASPR), Health and Human Services (HHS)	Presenter
Annie Fine	New York City Department of Health and Mental Hygiene	Presenter
Terra Abrams Ankrah	District of Columbia Department of Health	Presenter
Karen DeSalvo	Google Health	Presenter
Hans Buitendijk	HIMSS Electronic Health Record Association & Cerner Corporation	Presenter
Mary Beth Kurilo	American Immunization Registry Association	Presenter
James Watt	California Department of Public Health	Presenter
Christopher Harrison	Georgia Department of Public Health	Presenter
Denise Chrysler	The Network for Public Health Law	Presenter
Nicholas Soulakis	Chicago Department of Public Health	Presenter
Lance Gable	Wayne State University Law School	Presenter
Joneigh Khaldun	Michigan Department of Health and Human Services	Presenter
Jim Daniel	Amazon Web Services	Presenter
Ken Mandl	Boston Children's Hospital & Harvard Medical School	Presenter
Eric Topol	Scripps Research Translational Institute & Scripps Research	Presenter
David McCallie	Individual	Presenter

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

Mike Berry
All right. Thank you very much. And good morning, everybody. Thank you for joining the May 2021 HITAC Meeting. We are really excited to have you here with us today. My name is Mike Berry, I'm with ONC, and I'm excited to kick off our meetings this morning.

First, I'd like to welcome ONC's executive leadership team to the meeting. And with us today is our National Coordinator, Micky Tripathi. Steve Posnack, our Deputy National Coordinator. Elise Sweeney Anthony, the Executive Director of the Office of Policy, and Avinash Shanbhag, the Acting Executive Director of the Office of Technology.

I'll now start the meeting to order and begin the roll call of the HITAC members and our federal representatives, starting with our co-chairs. Aaron Miri.

Aaron Miri
Good morning.

Mike Berry
Denise Webb.

Denise Webb
Good morning.

Mike Berry
Michael Adcock

Michael Adcock
Good morning.

Mike Berry
James Ellzy.

James Ellzy
Good morning.

Mike Berry
Cynthia Fisher.

Cynthia Fisher
Good morning.

Mike Berry
Lisa Frey.

Lisa Frey
Good morning.

Mike Berry
Valerie Grey

Valerie Grey
Good morning.

Mike Berry
Adi Gundlapalli. Steven Hester.

Steven Hester
Good morning.

Mike Berry
Ram Iyer.

Ram Iyer
Good morning.

Mike Berry
Jim Jirjis. John Kansky.

John Kansky
Good morning

Mike Berry
Ken Kawamoto.

Ken Kawamoto
Morning.

Mike Berry
Steven Lane.

Steven Lane
Good morning from the sunny West Coast.

Mike Berry
Leslie Lenert. Arien Malec.

Arien Malec
Good morning.

Mike Berry
Clem McDonald. Jonathan Nebeker.

Jonathan Nebeker
Good morning.

Mike Berry
Brett Oliver.

Brett Oliver
Good morning.

Mike Berry
James Pantelas. Carolyn Petersen.

Carolyn Petersen
Good morning.

Mike Berry
Raj Ratwani.

Raj Ratwani
Good morning, everybody.

Mike Berry
Michelle Schreiber.

Michelle Schreiber
Good morning.

Mike Berry
Abby Sears.

Abby Sears
Good morning.

Mike Berry
Ram Sriram.

Ram Sriram
Good morning.

Mike Berry
Sasha TerMaat.

Sasha TerMaat
Good morning.

Mike Berry
Andy Truscott.

Andrew Truscott
Present and good morning.

Mike Berry
Sheryl Turney.

Sheryl Turney
Good morning.

Mike Berry
And Robert Wah.

Robert Wah
Present. Good morning, everyone.

Mike Berry
Good morning to all, and thank you. And now, please join me in welcome our Deputy National Coordinator, Steve Posnack, for his opening remarks. Steve?

Steve Posnack
All right. Can you hear me?

Mike Berry
Yes.

Opening Remarks (00:02:19)

Steve Posnack
Very good. Well, I seem to have lost the video option, but the show must go on. So, pretend that I'm in a full tux, which is precisely what I'm wearing right now. And we will continue on.

So, thanks very much, everybody. Good morning. I'd like to welcome you again to join our May HITAC meeting. It is going to be an exciting day. We have a lot planned for you. Speaking of wardrobes, I debated on whether I should wear my sweatpants and workout gear because we are going to be busy today.

As you likely know, we plan to spend most of the day having a discussion with a variety of experts on their experiences, the performance of public health data systems during the COVID-19 pandemic response. We're going to look at gap areas in the current public health data systems infrastructure, talk about the future, a whole end to end related to public health.

We'll also hear some preliminary recommendations from the Interoperability Standards Priorities Task Force. So, thank you to our task force co-chairs, Arien and David, and the task force members for all of their hard work. We look forward to next month's meeting when those recommendations will be discussed and up for a vote.

We accepted membership updates. We had a transition with our FDA member, and I would like to welcome Ram Iyer as our new federal representative to the HITAC from FDA. Ram is the chief data officer at FDA, and today is his first meeting. So please join me in welcoming Ram, and I'm going to turn it over to Ram to introduce himself for a quick minute.

Ram Iyer
Yes, very good. Thank you, Steve, and I'm very honored to be part of this Excellent group. Dr. Amy Abernethy has said great things about the work you do. I must say that I have not caught up with all the materials that Mike has been sending, but I hope to do that, and I look forward to participation today and going forward.

Steve Posnack
Thank you very much. I also wanted to note that as of this morning, we kicked off a new effort called Health Interoperability Outcomes 2030. So, we're at the start of a new decade. We're at the start of a new administration. And we have a pretty good view of the pieces that are falling into place over the next couple of years. And without repeating too much, that's in the blog post that just went up. Later this fall, we intend to publish a prioritized set of interoperability outcomes for 2030. Either the outcomes that we want to achieve that we think would be possible, that we think should be possible before or by 2030. In other words, because of interoperability, these outcomes will be possible.

As part of this launch, we're looking for well-framed outcome statements, so a sentence or two. And the submission process for the public at large opened today with an end date of July 30th.

Because this is right up HITAC's alley, and I know many of you are itching to tell us what the future should look like, we also plan on putting aside some dedicated time at the June 9th HITAC meeting to have a discussion and specifically to get the HITAC's input on what you think 2030 outcomes from an interoperability perspective should look like. So please start giving some thought to your 2030 interoperability outcomes. Again, the blog post is up on our health IT buzz blog, where you can find the full narrative and plan for future work.

So, with that, we have a busy day ahead of us. Thank you to all of our HITAC members, as always, for your continued service. I want to thank in advance all of our guest speakers that have come today. Also appreciate your patience as the ONC plus CDC team worked on overdrive to pull together a fantastic lineup of guest speakers. I think it would be a great grab to have anyone of these people individually, and so we have assembled the Avengers here to get all the guest speakers lined up.

I realize that we've provided a lot of materials to review, as well as just inbound over the past few days, some coming in late yesterday, and there are plenty of metaphors and idioms that I could use. As many of you know, I like to use them. But we appreciate everybody's understanding in terms of the flow of inbound materials.

So that's a wrap from me. Next time I'll get myself on full view. But over to Denise and Aaron to take it away for the rest of the day.

Remarks, Review of Agenda and Approval of April 15, 2021 Meeting Minutes (00:07:08)

Aaron Miri
Sounds good. Thank you, Steve. And good morning to all of you. Welcome to our May HITAC, and as Steve just articulated, what a lineup. When I saw this final agenda, I just – I mean, talk about a powerhouse. We should really walk away with some Excellent knowledge, which is exactly what's important for us to inform us going forward on the HITAC and in other items that we're doing.

So, with that, also I wanted to introduce my co-chair, please. Denise, are you on the line?

Denise Webb
Yes, I am. And I want to thank all of the presenters in advance. I know this was a huge logistical effort for ONC to put this public hearing together today, and I appreciate all the efforts. I do want to apologize for a lot of the materials not getting out in advance, but this was a really huge effort. A very important day for us today, and I think it's going to provide us a valuable framework to work from as we go forward.

Aaron Miri
Absolutely. I totally agree, Denise. And thank you for calling out on your well-deserved PTO. So really appreciate you for being a leader and teaching us that we should take some time for ourselves, too. So, thank you for that.

All right. Let's go through the agenda really quickly, and then we'll go over the table of minutes and then turn it over to Micky Tripathi. So, our agenda for the day, after Micky speaks, Micky and Dan will be speaking. Dan will be talking about talking a holistic approach to public health data systems, plus public health systems performance during COVID-19, big picture perspectives, then more public health perspectives during COVID-19 around operational perspectives. We'll have lots of discussions.

And then this afternoon, we have data needs during high consequence public health threats, and technical infrastructure, current status and future status, and then legal and policy issues, and lots of discussions. And so, at the very end of the day, we've created the public health ecosystem of the future, then the ISP Task Force update with Arien, and we'll close out the day.

Denise Webb
I was just going to say, too. Very importantly, we will have two open periods for public comment to get comments from our public. Very important.

Aaron Miri
That's correct. Yes, we will. So really quick, let's go ahead and get the approval of the April 15th, 2021 meeting minutes. Do I hear a motion?

Unknown Speaker
Move for approval.

Aaron Miri
Second?

Andrew Truscott
I second.

Aaron Miri
Everybody in favor says aye.

All
Aye.

Aaron Miri
Everybody opposed saying nay. Okay. The meeting minutes passed, and with that, I'm going to transition it over to Micky and Dan.

Micky Tripathi
Okay, great. Thank you, Aaron and Denise. Can you hear me, okay?

Aaron Miri
Yes, sir.

Denise Webb
Yes, we can.

Welcome Remarks (00:10:06)

Micky Tripathi
Great. Well, good morning, everyone. I'm Micky Tripathi. I'm the National Coordinator for health IT, and I really just want to welcome everyone today. I'm really honored to help kickoff this really important hearing. It informs the work that the CDC and ONC are co-leading to respond to an executive order ensuring a data-driven response to COVID-19 and future high consequence public health threats.

I have the privilege of co-chairing the work group that's focused on the public health data systems portion of that with Dr. Dan Jernigan, who is going to speak right after me. And it really is a privilege to work directly with Dan and the CDC on this.

Interoperability, in particular, is specifically called out in that executive order as well. So that's a key component of what we're looking at as we look at public health data systems.

So, I think transparency is really important to ensure trust and confidence in our public health system. And the pandemic has certainly stress-tested our public health system and revealed what we've known to be true for a long time, which is that we don't have a single public health system. We have a patchwork of federal, state, tribal, local, and territorial public health systems, which are loosely strung together with higher

varied, often inconsistent jurisdictional policies, technical capacities, and processes for collecting, analyzing, sharing, and acting on real-world data.

And the results that we've seen were clear, and the country found the public health system infrastructure, unfortunately, was not as responsive as we needed it to be in terms of data accuracy, timeliness, reliability, and relevance. Not as connected with the clinical EHR systems that we as a country have spent $40 billion to put in place over the last decade, and not as interactive across all levels of the system as we would have liked it to be.

And the gaps that created these results have been pointed out by public health experts for a long time, and I think that we need to acknowledge that. But we've had historical underfunding of our public health systems for decades and a lack of urgency to solve these problems.

Now the current pandemic, of course, has changed that. I can't think of where the opportunity and importance for building back better are more vital than with our public health systems as we look at them now.

So, it's really important for us to learn and use the funding and the urgency and importance that we now have to get us past the current crisis and to prepare us for the prevention of and response to future crises. I see this effort as thinking about how we move from the concept of public health data systems, which is what's sort of stated in the executive order. But in a way, it is sort of the problem that we characterize them as public health data systems, rather than saying that we ought to move to a public health ecosystem or a public health internet that can help protect all of us in the future.

So, I want to thank Aaron and Denise, I want to thank the HITAC, and I want to thank all of our invited speakers. I've had the opportunity to read all of the testimony that's been submitted, and I know I just want to thank all of you in advance for the observations, insights, knowledge, and guidance you're going to provide to us today. So, thank you very much, and let me know to turn it over to Dr. Dan Jernigan.

Daniel Jernigan
Great. Thanks. Micky, are you able to hear me?

Micky Tripathi
Yes.

Daniel Jernigan
Great. I wanted to check. So, thanks again, just to follow along from Micky, thanks to all of you for the time that you're giving, the thoughts that you're giving, and for the important information that we'll get from this engagement. It's really important for us to achieve the purpose of the executive order, but from the CDC standpoint and the public health ecosystem standpoint, it's really important for us to get these kinds of information, data, guidance, recommendations for us as we move forward with our data modernization initiative.

The DMIs and activity that we have wanted to have for many years to address a really important need, but now it's actually becoming real. Funding has come through. It's momentum. It's money that allows us to do

some things that we have just never been able to do before. So, the information that you are able to provide us is going to be quite helpful for us to get better data, faster data, data for action, for us to do public health as fast as we can and as meaningfully as we can.

It's helpful for us to get this information so that we can get some short-term needs, address some things that need to be done now still for the pandemic, for the COVID response, but also to see how we can put this together in order to have a long last, a sustainable approach, to improve public health and public health data systems.

Many years ago, I was a board member of the HL7 with Clem, I think, and some people that were on the phone a long time ago. And so, there were a lot of issues that we were dealing with at that time, trying to work on interoperability, develop standards. It's where the electronic laboratory reporting standard first came out, and at that time, there were problems that we had with low resources and high complexity in public health. It made for a very difficult problem.

A lot of those problems have never changed. The complexity has stayed the same. The resources have stayed the same. But with COVID, it became quite clear to us with the pandemic, especially at the front-end, where I served as an incident manager, that we just didn't have these systems in place. We had components of it. We had a process that worked, but it was not incorporated, engaged, interoperable, and flexible, and scalable.

And so, for that reason, we really, now have that opportunity to try and address that. So, I appreciate the input that we will be getting from you about new technologies, about how we can use these new resources at the federal and the state level and use the momentum of the COVID response in order for us to address these short-term needs, but also these longer-term sustainable needs that won't really change the public health ecosystem.

So, appreciate that. Really, thanks to everyone for what you're about to go through here and through the rest of the meetings in order to give us this information. And we'll hand it back to Micky and to the chair.

Aaron Miri
All right. So, I know we have about ten minutes before we are ready for the next section, so I'm going to actually ask Micky and Dan if you don't mind taking one or two questions, maybe for the audience here. And so, the first question I have for you, and this is specific to Dan, is, first of all, let me first go out to the question, thank you for your agency or the FDA and the work you've been doing from a provider perspective here in Austin, Texas. So just want to say thank you for that. You guys have been Excellent partners, especially over the past year, but even way before that. So, thank you for all of that effort.

So, the question is, Dan, do you see further collaboration with the ONC and the FDA going forward in the next couple of years in the forms of either hackathons or leak type awards, or other types of hyper-accelerated data efforts, to really sort of innovating and spur the next generation of thought leadership and technology leadership?

Daniel Jernigan

Yes, absolutely. And so, I think just as part of the executive order, engagement, there are several things that we're working on with the ONC, but there's a whole list of things. Micky and I have actually gone through several of those in the last week to talk about what are the next steps where we need to have collaboration between CDC and ONC. And so, absolutely, we're looking forward to that.

In terms of hackathons, there is a planned activity over the summer where we will be looking at FHIR standards, how to use those to really jump start the needs for getting that public health information from electronic health records and from other sources, using FHIR standards through hackathon and through that activity. So those things are definitely planned and through a number of different engagements. So, we'll be working with Micky on those as well.

Aaron Miri
Great.

Micky Tripathi
Yes, and I would just add that certainly share that Dan and I have been collaborating closely on thinking about how ONC can best support the CDC in this. And there's. Also, I hope I'm not speaking too far ahead, but there's a lot of thought around sort of FHIR accelerator activities as well, specifically focused on public health. So that, I think, is another huge opportunity area for us. I think, as all of us appreciate, the opportunities for FHIR and the work that FHIR accelerators have already done to move all of this forward.

Aaron Miri
Excellent, Excellent. And so, the second question here is – and this one, Micky, is for you. Do you invasion for future USCDI or other standards-based work to really start focusing on public health and maybe even mental health as it relates to public health? There's a lot of data, a nebula of data standards that are out there that are still kind of together, and USCDI Version II, the draft one that was posted, made a great thing for the community to really spur that conversation around SDOH and others. Do you foresee future data standards really taking public health into account?

Micky Tripathi
Yes. I mean, yes. And so, we are looking really hard at the USCDI and all the various needs and opportunities to be able to use USCDI and ways to move the industry forward. And public health is obviously at the top of the list in terms of the immediate need of presented themselves and the part of the solution.

And so, we recognize from an ONC perspective, that's one of the important levers that we have in thinking very creatively with the CDC, with FDA and CMS and IHS about how we collectively use all of our levers to be able to push this forward. So absolutely, that's one of the things that we're looking really hard at for sure.

And I think, as you know, we do a lot of work supporting SDOH in particular and helping support the FHIR accelerators and the work in areas that are important ingredients to the data that we need for the future of the public health infrastructure and trying to accelerate the work in those areas so that we can get as much of that data standardized and available for the types of things that we'd like to be able to use it for from a public health perspective.

So, I know there were a couple of slides here that I was remiss in not covering. But some of those go over – if there are more questions in the queue, I'd much prefer to be responsive to people's questions. Otherwise, I'd be happy to go through these couple of slides. It's just a little bit of a table setting.

Aaron Miri
Yes, go for it. Please, just a few slides.

Micky Tripathi
Okay. All right. Great. Again, just to orient everyone, I think I did say this, but this is the executive order that we're working on. And Dan, I think, is working on all of them. Actually, this is Section 3 of the executive order, sorry, that's focused on public health data systems.

So, as you can see, there's a very clear focus in Section A on effectiveness, interoperability, and connectivity of public health data systems, and then the review of other systems as well, and then issuing a report and summarizing those findings. So next slide, please. And this is publicly available. If you Google that, this is an executive order that was publicly available.

We also, last week, for those who were able to follow it, we did launch a task force, which's in addition, sort of a supplement to this hearing, which will be working on a weekly basis to provide input to this process as well. So, we have this hearing, which is a really important milestone for a number of experts to provide input. But there is a task force that will be meeting weekly and will be gathering input in a variety of ways that they are working on now, and with the expectation that they will have some recommendations, I think, in July. And that's all publicly available as well, so please follow that if you're interested in that. Next slide, please.

And this is the Public Health Data Systems Task Force. I want to thank in advance all of the members of the task force, and especially Janet and Carolyn. Their interest, as I said with the launch of the task force, is going to be richly rewarded and a ton of hard work that we are going to be asking of them over the next weeks, from now through July. But we really appreciate their willingness to volunteer and give their time and expertise to thighs really important area.

I'm not sure if this is the last slide. It might be. So, this is the overall timeline, starting from – as I said, we kicked it off on May 6th, and then it goes through mid-July for a set of draft recommendations, with weekly task force meetings, as you can see there. Next slide.

Is that it? Okay. Great. Thank you again, and hopefully, that gives enough basic grounding on what we're about here. And let me turn it back to you, Aaron.

Aaron Miri
Sure. No problem at all, Micky. So, I think we are getting Tom on the line right now. And so, he is dialing in. We've got about **[inaudible] [00:23:46]**. Tom, are you there?

Tom Frieden
I'm here.

Aaron Miri
All right. Perfect. Great, perfect timing. All right, so I will turn it over to you then, Tom.

Taking a Holistic Approach to Public Health Data Systems (00:23:58)

Tom Frieden
Okay. So, I think we have some slides, and you asked me to give the big picture, kind of, how did public health do in COVID-19? That's a pretty tough question, and I'm going to give a pretty tough answer. So, if you go to the next slide.

We failed. Basically, globally and in the United States, public health failed the COVID test. Now on the next slide, I'll say that in the US, public health failed in part because it was undermined. And so blaming CDC for failing to implement effective COVID control in the year 2020 is kind of like blaming someone who was encased in cement for failing to swim. Public health was not allowed to succeed.

But I will also say that we shouldn't let public health off the hook. Public health had some very important preexisting conditions, some preexisting weaknesses. And I'll mention five of them here.

First, there are cases among federal, state, city, and local public health. And we see a big gap between the state and the feds, a big gap in most states between cities and states, and a big gap in most states between counties and states. And that is all down the line. That's not just about data. That's about perspectives, recommendations, communication, staffing, what's practical, what can be done, what's the local context.

Public health has been slow. In a pandemic, time is lives, and we are less used to the kind of urgency that communicable disease control requires of us in public health. And so, doing in minutes what is taking hours or days, doing in days what is taking weeks or months, is something we need to get used to doing.

We are underpowered and understaffed. We have decades of underinvestment. We have a loss of critical staff. We have underpowered in terms of not being able to connect well with political leaders, with media and social leaders, with healthcare leaders. And understaffed in areas ranging from data dissemination to data analysis to integration with healthcare.

We have detection, information, and response systems that are not robust, and we have healthcare and laboratory information systems that are neither standardized nor coordinated. So, when we look at a place like the United Kingdom where they've got terrific data on hundreds and thousands of patients, and other than the few examples of integrated health systems around the US, we don't have that. We have healthcare systems that are poorly coordinated within and among themselves and laboratory systems that are poorly coordinated and no standardized—next slide.

Though we failed for many reasons, we failed because of budget rigidity. At CDC, you have close to 200 budget lines, and even if you have examples of real progress, for example, electronic laboratory reporting, you have a real disincentive to have a platform-based approach to improving information systems. We have the failure of city, state, CDC, and county integration. We have nonstandard dashboards from day one, and I feel this could have been better.

My group, Resolve to Save Lives, reviewed this on two, three occasions. We found that we had 50 different ways to do it. Some of them were very creative. All of them represented hard work at the state level. There was no federal standardization. There was no facilitation. There was no provision of tools. And because of that, we were not literally on the same page. And that meant that we didn't have very simple information, such as week to week, what was the race, ethnic, age breakdown of cases. We had cumulatively, but not week to week, so you couldn't see what was changing.

You couldn't see the most important indicators of COVID control on virtually any of the dashboards in the country. We weren't focusing on the most important data. We weren't focusing on collecting it, managing to it. It was a lack of parsimonious actionable data. So big efforts to collect information that wasn't that important. Failure to collect crucially important information in almost all jurisdictions.

Lack of real-time data and user-orientated data systems. Lack of simple, practical, and clearly communicated guidance. Weak connection with healthcare, especially primary care. Insufficient infection control, including, most visibly, PPE, but the hierarchy of controls failed. Insufficient protection of workers in many industries. Meat packing got emphasis appropriately, but we failed. We failed to protect workers. No one should have to choose between their job and their health. Lack of incorporation of the fundamental concepts of risk alert levels into all thinking. And this continues to this day.

It's one thing to say what you can and can't do in terms of wearing a mask when you've been vaccinated. It's very different if you're in a high prevalence community from a low prevalence community, and that basic thinking needs to infuse our work.

Failed COVID support services. These were born as contact tracing, a term Americans don't understand and don't like. We should have learned from decades of work in HIV, STD, and others that what we really needed to do was support people who have COVID, might have COVID, might have been exposed to COVID. Make sure their employment was preserved, their food, their housing, their logistical mental health, and physical and medical needs were addressed insufficient learning from and support to global partners. So that's a pretty depressing list—last slide. Let's talk about what we do next.

We, I hope, will fix the budget rigidity. Having run CDC for eight years, having close to 200 budget lines where you can't move money between them, really is not any way to run an organization effectively. We need cross-cutting lines that can be used rapidly. When I was a health commissioner in New York City, I had literally 20 times more flexible funding than I did when I was CDC director.

We need to integrate CDC, state, city, and county systems, especially through embedded and rotating staff. And I think we should have thousands of staff on the federal payroll at each of these levels, state, city, county, and I think they should rotate back to CDC after two to five years. I'll give you a historical vignette.

Joseph Mountin, who founded the CDC, believed that all health officers at CDC should spend at least a year as a county health officer so they could see one budget through from proposal to approval. We need parsimonious real-time data based on case management information systems with agile user-centered design. I want to come back to this issue and focus on the issue of case management information now because it's a house of cards. The information that you have at the federal level roles up from what is done with the case investigation. And if that fails, all of the rest of the information is not working.

Now between homegrown systems, some commercial systems, some new systems, things have been cobbled together, but they're not agile. They're not user-centered—that actional real-time data with weekly data on equity. We still do not have, to this day – well, I don't know about to this day. But when we checked last a month ago, we did not have any state in the country providing on a weekly basis of who is getting vaccinated by race and ethnicity, so we can see if we're improving the race/ethnic disparity that is profound.

We have to keep recommendations clear, simple, and practical. Strengthen connections with primary care and help strengthen primary care. Primary care is the most important and most neglected part of our system. There are very important new reports out on it. It's the part of our healthcare system that will deliver health when we invest in it. We neglect it. We need to change the model of payment for that to happen.

We need to finalize and procure safely reusable N-93 Estimator respirators. There are respirators that can look like a facemask, not have an expiration valve, not like a gasmask, be easy to speak through, be easy to clean, and in regular use. There is no reason for people to be reusing nonreusable equipment.

We need to protect workers in all industries, incorporate risk alert levels in all thinking, relaunch COVID support services, engage with, learn from, and partner with countries around the world to step up preparedness because the pandemic will not be over until it's over globally. We're going to have an ethically unacceptable situation in the fall with Americans going to movies and body bags stacking up in other countries which do not have access to vaccines to the extent needed.

Now, to the topic of this meeting, to think about a public health informatic platform as a public good, built on data standards that promote interoperability, that mandate interoperability as opted for the EHRs, with a healthy relationship with contractors, with steadily improving functionality and usability. And I want to spend a couple of minutes on this.

So, a platform means something you can plug things into. Sometimes that's a public good. Something that's probably publicly funded. It is, if you will, the public option for public health informatics. Built with data standards that promote interoperability. So, you can have public or private entities putting APIs onto it that do important useful things and communicate seamlessly, with a healthy relationship with contractors.

So, the elephant in the room here is, or maybe I should say the gorilla in the room here, is the presence of IT contractors, some of whom do terrific work, some of whom scam public agencies, some of whom have lost leaders and then get government into large contracts, some of them do great work, user-focused, agile design. Some of them have systems that are cumbersome, so you're going to have to stick with them. You've got to basically set the standard as ONC did for health IT so that if you're going to use any federal dollars for health IT at the state, county, city, or federal level, you have to meet these standards and be interoperable in this way.

So, the contractor relationship is very complicated. Because basically, it's not simple to have contractors who are working effectively. At the same time, you can't build it all by the government. We tried that at CDC, we failed. You can try, and I would encourage you to try. I would encourage you to try to outcompete the private sector. If you can build a product that's good enough that people want to use it, that it's a joy to use,

it's helpful, it's easier than what they're using now, then they will use it, and you can, in a good way, let the private sector function on other functionalities. But you need to steadily improve functionality and usability.

And I want to talk about at least eight domains where public health informatics was tested and found wanting in this COVID pandemic. Communicable disease reporting, case investigation, contact tracing, electronic laboratory reporting, including negative tests, death reporting, syndromic surveilling, hospital bed capacity tracking, immunization registries. I'm sure I've left some out, but those are at least eight systems that really should be talking to each other and informing each other with full respect for confidentiality, understanding that there are exceptions to HIPAA in the public health space.

So that's what I have to say for now, and I think you wanted to ask some questions. I've been looking into a blank camera. I don't know how to turn it on. I haven't used this interface before.

Aaron Miri
So, Tom, thank you very much. I appreciate that presentation. What we're actually going to be asking the HITAC to do is to hold their questions until 10:15. We're going to be having discussion time. So, I'd really appreciate it if you hang on.

I would say just before we transition to the next group, from the provider community perspective, we really appreciate the comments you were saying and a lot of the opportunities. But I will give a lot of credit to the innovation that occurred throughout the healthcare continuum. In fact, here in Austin, we 3-D print our own N-95 masks that are reusable, exactly like that you were saying, so there's a lot of opportunities there.

All right.

Mike Berry
Aaron, excuse me, it's Mike. While Tom's here, it might be good to let the HITAC members ask questions. The 10:15 discussion is kind of marked for after the first panel gives their opening remarks. So, we could ask a couple questions from Tom while he's with us.

Aaron Miri
Perfect. All right. I just want to make sure we keep the running shows. All right. Then HITAC members that have raised their hand. I personally see Les Lenert in the queue.

Leslie Lenert
Hi, Tom. Thanks for a great talk. I really appreciate all the things that you've been able to bring up here about the importance of informatics at the CDC and moving forward with collaborations in an ecosystem with population health assets throughout the healthcare system and those things. Very important.

However, this reflects a huge change in the culture for public health. And as Peter Drucker has said, culture eats strategy for breakfast. The point is that most public health practitioners, including the EIS that is the leadership today, have been trained to think in information supply chains. In fact, that's the language used throughout the textbooks, and the other materials that people do that do this, which has this idea of data flowing up to the CDC and enabling policy decision making, rather than creating this network of people

working together collaboratively across the healthcare system and in the private sector and other areas to mutually advance population health.

How can we change the culture of the CDC so that it's ready to play in this information ecosystem rather than with supply chains?

Tom Frieden
All right. In this HITAC environment, I finally figured out how to make the camera work. So, I think behavior changes culture rather than the other way around. And I think data is the lifeblood of CDC and of public health. Informatics is not a language that public health speaks well, and if you go back in time to the golden era, we had EPI info 6.04 B for dos. And those of us who used that program kind of understand what it would be to have a platform, a platform that was used widely and effectively and simply.

And I think part of it has to do with revisioning how informatics is designed and implemented so that you really do have tools that are quite effective. The fact is that we're very cumbersome in how we do our informatics work in public health. We have systems that have been cobbled together that don't work very well, and having a system that's truly modern built is something that I don't think we've gotten to.

I will tell you that during COVID, my group, Resolve to Save Lives, worked in this area. And we have the – be modest for our group. We have a terrific digital team. Really terrific. We built a product called Simple. You can look at it, www.simple.org. It's got 700,000 patients on it around the world. It takes 18 seconds for a health worker to record follow-up information. It gives all of the information needed to manage a treatment program.

And when we deployed this team to the US, they really hit a grinding halt because the environment was so difficult. So, we were able to do things like creating a data ingestion flow that has worked well, improve locating information for patients. But what you've got is a very messy informatics environment.

It's as if, if you think about plugs for electrical outlets that are different all over the world, it's as if every state and many cities have different plugs. And you know, there's a big transition cost to standardizing those. Unless there's a real benefit to it, why bother?

So, I think part of the challenge is demonstrating that you can have tools that really are user-focused, that are agile designed, that are not contractor driven in a way that gets you inf or a dime, in for a dollar, and that can make a big difference in the work of public health. That's why I go back to the info because, ultimately, the info was well used because it worked. And what we have now are cumbersome systems.

And maybe with all of the IT advances in the last 30 years, we can get to the kind of simplicity and utility that at the info brought to public health.

Leslie Lenert
It can be pretty simple if you have no standards: backing interoperability and semantic interoperability. And what at the info provided was a platform that could do that, could make exactly what the epidemiologist wanted and make it unable to talk to anybody else, and make it unable to talk between each other for different problems.

So, I think the info is actually an example of what was wrong with public health. But at the info built on top of the platform that you say, where we have standardized standards for naming things. Standards for clinical vocabulary, interoperability, database design, those types of things, and then an at the info on top of those standards, I think that would be brilliant, and that it's just a matter of reengineering things from the dos era.

So, I guess the question I'd ask is it sounds to me as if you really believe that CDC needs to be raising the boat of informatics capacity. The tide needs to rise. If all public health departments need to be working together in concert, and that informatics needs to be a major activity for CDC in the future as it moves forward at a national level, supporting state and local governments and creating these sorts of a platform that we both agree is so important.

Tom Frieden
I think, as you know well, informatics has to be integrated with the program. It has to serve the needs. And there are certain things for which the juice isn't worth the squeeze. So, for example, when we did ELR, there are certain lab tests that you get hundreds of thousands of years. There's other that you get hundreds a year. It doesn't necessarily make sense to spend the same amount of effort on both of those things. But you have to think about functionality. I mean, fundamentally, you have to design systems to meet the use that people need them for, and then they'll be used. Then they'll be tweaked.

Aaron Miri
Les, I appreciate the comments very much. We need to go to other people in the queue. So next in the queue is Clem McDonald.

Clem McDonald
There's a couple of comments. First, I think you nailed it with the budget separation. And I think what you need to do early at CDC is to destroy all the walls built around diseases. That's what screwed everything. The budget's that way, the system's that way, everything's that way.

I think you under gave credit. The labs were doing very well standardizing and sending you stuff. All the public health services couldn't take it in. Some of the states had trouble taking it in. And I think you also under ignored IHEs, which provide – and we're not using them well enough to pull in all the data you could.

I think the biggest problem with this COVID was the doctrinaire approach through how it's caught. That whole story about droplets and contact was all wrong. But it was so embedded in doctrine air, and we've got to get rid of this kind of doctrinaire stuff. And we still don't see anybody monitoring air inside Walmart or places like that. Get the physicist was the only – medicine screwed it, public health screwed it, our research screwed it, the physicist is the one who detected this, found how we really were spreading it. And we still haven't set up monitoring systems to figure out what size room really gets you catching it. Anyway, that's my rant.

Aaron Miri
No problem. Thank you.

Tom Frieden

I will make a couple of quick comments. 1.) The essence of an effective response is to learn during the response and to adjust and adapt as you learn. There is still a lot of epidemiology that we don't know nearly as well as we should because we don't have good information systems.

Just yesterday, there was a really good study looking at the relative infectivity of different variants. This is the kind of information that a good information system with a good case investigation system would be able to give you at the drop of a hat. We still are just learning, if you have a higher viral load, are you more infectious? Why do we have variable infectivity? And there are no simple answers here to how it's being spread.

I would disagree about the laboratories. Having worked in states on this, you need a better catcher's mitt, but you also need better standardization. The labs are sending all different types of information. It's garbage in, garbage out. The patient's address is the lab address, the patient's phone number is the lab phone number. Lots of problems with this, but it's because you don't have a feedback loop, and the key is to have a feedback loop for learning.

Clem McDonald
Okay. All right. Thank you.

Aaron Miri
Thank you, Clem. Thank you, Tom. So, I want to remind the HITAC that we only have a couple more minutes left with Tom to be respectful of time. So, we have time for one more question. Mr. John Kansky, you're next in the queue, sir.

John Kansky
Thanks, Dr. Frieden, John Kansky from the Indiana Health Information Exchange. I understood you to call for a government option to create some form of public health information network. In some, but clearly not all states, not-for-profit statewide health information exchanges were pretty effective in aggregating and reporting and doing a lot of the things that were on your list as gaps. So, in this public health information network that you envision, you acknowledge, I think correctly, that contractors would have to play some role. Do you think it's possible, practical, that in states where the health information exchange is robust and capable for the government to contract with them to carry the water for that state? Thank you.

Tom Frieden
Thanks. And congratulations to Indiana. It's one of the real strong lights in terms of information management during this. I think so. I think we have to look at what's a standardized set of definitions? How is that going to work? How is it going to be implemented? What's the standard functionality? What parts of that overlap with HIEs, and what don't? But certainly, we have to look at what's out there.

I do have a bias here, and it may be wrong, but my bias is that if there is a public option, as it were, for some of the programs, if it is forced to function effectively, to be agile, to be useful, it's going to outcompete the private sector for a significant share of the market and its worth doing that.

Our goal is not to let contractors make money. Our goal is to improve health. And if we improve health by turning over some of the work to contractors, great. If we improve health rather by building something and

letting contractor's rand HIEs and others plug into it as a platform with APIs that may be publicly developed, or even sold or given from one HIE to another, result, we're all open source free, but our model philanthropy given, but so is Signal, for example. So, there are ways to establish public good.

And I would just challenge you and leave you with three thoughts. 1.) What can be built that's a truly public good. 2.) How can you get the functionalities that you need right? And 3.) How can you do it in a way so that it's easier and more pleasant and engaging and effective to use than what exists or what's being sold today?

So, thanks very much. Best wishes for the rest of your meeting.

Public Health Systems Performance During COVID-19: Big Picture Perspectives & Discussion (00:52:40)

Aaron Miri
Yes, absolutely. Appreciate that very much, Tom. The rest of the HITAC members, folks in a queue like Aaron and others, your questions are important. ONC has offered to be able to send those questions onward to Tom. So please email Mike Berry, and he'll happily get those collected and send those forwards for you all. So, I want to make sure everybody gets their questions answered even though we're on a tight schedule.

So, with that, we are ready for the next exciting group here—public health systems performance during COVID-19 in the big picture perspectives. I want to ask Group 1 to please make sure that you keep your comments and testimony to five minutes each so we can get to everybody, and that leaves time for discussion after that.

Right before, though, we do a transition. Just as a reminder to you all, I see a lot of questions about how I turn on the camera. There's a little icon right above probably my head here, where I'm speaking, that just says start, and then you hit share, and that should turn it on. If not, I know Accel is on the line too and probably can give some instructions as well, or if you want to reach out to them, they're happy to help you.

So, with that, I believe let's turn it over to Group 1. We'll start with Mark. You may be on mute, Mark.

Mark McClellan
I hope you can see me and hear me. Good morning.

Aaron Miri
Yes, we can.

Mark McClellan
I'm the Director of the Duke-Robert J. Margolis Center for Health Policy, and we spent a lot of time in the pandemic working with public health organizations. Our focus is on improving population health through healthcare reforms, and if you look at where healthcare is headed, a lot of steps towards more care in the community, more use of data and analytics to enable earlier interventions. We do a lot of work with

community-based organizations, social service organizations, and in the pandemic, public health organizations.

And I want to focus on – if you go to the next slide, three main messages. One is that the pandemic response, all of the challenges that Tom talked about were notable. We've also seemed some important progress. And in the pandemic response, public health and private healthcare organizations working together in unprecedented ways made a difference.

Unfortunately, our data systems haven't been consistently connected or integrated across public health and healthcare, which is a complicated timely, and coordinated response. And back when ONC was set up, I was at Service for Medicare and Medicare Services, and the first ONC director, we talked a lot about opportunities to make these connections. And I hope the pandemic is going to provide an additional push for practical ways to connect healthcare and public health more effectively.

Want to talk about for just the next few minutes are some use cases, I guess you could say, actions that are taking place right now that show how those kinds of connections can make a big difference, certainly for preparedness for future pandemics, but also in this one.

And the next slide talks about four main areas that are important for any pandemic response from a public health standpoint. One is surveillance and early detection. The second is being able to ramp up supplies to deal with the public health emergency and allocate them to where they're needed. The third is detecting and managing outbreaks within a public health emergency or activity within a public health emergency when it occurs for enabling fast response. And fourth, particularly for this case, vaccinations are really important, but getting treatments to the public, all areas for public health healthcare interaction matter.

The next slide is the first example of this. And I didn't have written testimony, but I'll leave these behind. Go on to the next slide.

One here is in surveillance. And right now, there's an effort underway to detect variants of concern early and track variants around the country that represent, I think, a really good example of CDC and public health working with private commercial labs around the country as well as public health labs to get much more availability of samples. We could build on that further by setting up payments that are integrated with healthcare payments or running the task and creating a more automatic data connection in connecting that real-time data back into a public health surveillance system. That's one example of where that we have the connections that are starting to make a difference.

Our next example is in – if we go to the next slide, it is in supply ramp-up. Here, I'd like to reference a report that our center did with the healthcare leadership council doing kind of an early lesson learned as cases where we've got existing data systems, for whether it's PPE, diagnostic test materials, vaccination materials, which work well for normal times. But when we have big increases in demand and a need to get it to certain places, the market's not set up to do that.

There are models, we discussed in this paper, where the federal government could serve as more of an air traffic control tower, getting timely electronic information in from suppliers, enabling much faster and more

effective allocation of responses and cessation of supply shortages and the like, really refer people to that paper.

The next slide talks about data sharing between healthcare and public health for diagnostic testing and also with the employers and the broader private sector community for screen testing. We don't have a reliable way to consistently toss hare that information or good examples for electronic record functionality can do it. Get information flowing both ways, both for protecting outbreaks and engaging healthcare providers in helping them manage them.

Finally, on the last slide, and there are several reports on that too. The last couple of slides deal with immunization systems. This is a challenge right now. In North Carolina, we do have good data on race and ethnicity, to Tom's point earlier, because there is the connection via electronic records into the IIS system for identifying race and ethnicity for patients so we can capture that in near real-time. Most states, though, have not set up ways for their IIS systems to connect back to the healthcare providers. So, since most vaccinations so far have occurred in public health settings, which means that healthcare providers, health plans who have established relationships and engaged patients, don't have good ways of connecting with them and doing more micro-targeted engagement and outreach to get vaccination rates up.

There are examples of states like Indiana that have HIEs that are done this. There are examples of states that have set up API portals for this. But it's still the minority, not the prevalence of the approaches of dealing with immunization data sharing. This is something where improvement right now can make a big difference in getting immunization rates up. Thanks very much.

Aaron Miri
Thank you, Mark. I appreciate the comments. All right. Next up is Greg Singleton.

Greg Singleton
Hello, can you hear me?

Aaron Miri
Yes, sir.

Greg Singleton
All right. Excellent. Just getting through on the platform here. So welcome, everyone. Good to see folks. So, my name's Greg Singleton, Senior Advisor for National Security and Advanced Research at the CIOs Office at the US Department of Health and Human Services.

In the COVID response, I served as a program manager for hospital data programs and CIO lead for the cross-agency data strategy and execution work group. And of course, first off, I want to thank Aaron, Micky, Dan, HITAC for inviting OCIO to take part in this forum. And why I represent the HSOCIO, I want to be clear that the platform I'm talking about today, HS Protect, is the result of hard work by a number of colleagues all across the government, from CDC, ASPR, USDS, White House, and really many, many others. I'm just the first one on the agenda today, but you'll hear from a number of my colleagues as well.

So, three things to start off with today. I want to talk about what's really possible, user engagement, and then also platform evolution. But big picture, I want everyone to go back 18 months. Go back to December 2019. Think about health data systems then, what was possible and what existed. If we, as the government, collected a report, when would the public get these insights? How many weeks? How many months? How many users could directly access the data, and how engaged were their folks in beating the systems. Think about that from 18 months ago and then think where we are now and consider where we've come through the COVID mission, through the HS Protect infrastructure that we spun up to support the response.

I can now tell you that we had 33,689 positive COVID cases across the nation yesterday. I can tell you there were 35,023 patients hospitalized with COVID yesterday. This system gets 500,000 data points reported every day and 200,004 records a month. It covers roughly 6,000 hospitals across the nation with next-day visibility.

But the technical systems don't exist in isolation. And you can think of them as like a sensor network, an intelligence net, maybe an immune system, but they require input engagement to function. As Tom Frieden said, they have to be a joy to use, I think, is the word he said.

On the data user side, on the output side, on the palatine platform side, we have 3,000 plus direct users from CDC, states, tribes, DOD, the White House, and frankly, tens of thousands more indirect users. These are folks working on a response, asking how things are looking in their community, and looking for information to guide their local decisions and mitigation measures. And all these individuals have access to the system to get real-time data.

But just as importantly, on the input side, and this is supported by the tele tracking platform, we have 17,000 users feeding data into the system, into the platform for those 6,000 hospitals, 2,000 therapeutic sites. And this feeding, this information, it's essential for the national response. Without that, we're nowhere. It's more than a one-way pipeline. This platform provides historical downloads, real-time compliance use, validation, authentication, help desk. We have automated uploads and integrations into EMR systems. At this point, we have 64% of users providing data through some sort of automated function, and the system continues to grow to accommodate users.

It's true that the unity of purpose behind the COVID mission allowed us to make great strides in public health data systems. As the platform capabilities underpinning these systems enabled an evolutionary response to developments on the ground to support the national response. Design systems meet the needs of the moment and engage the tens of thousands of users and adapt it as the pandemic has progressed. This has meant changing data elements, definitional clarification, reporting guidance, and really just continuous improvement in an organic manner. The data, the people, the systems have evolved to meet the needs of the analytic users and the needs of the input users.

So big picture, I don't think any of us are where we thought we'd be 18 months ago. If you'd told me we'd have this 18 months ago, I would have told you were nuts. We've far surpassed what we thought was possible at the time, and we now have the largest, most comprehensive public health data system the world has ever seen. In 97% of the hospitals report all data elements every day. We're engaging users on the input and the output side and in ways we haven't seen. These aren't just simple pipes.

We have an evolutionary platform that's dynamic and meets national needs. Systems are working. They're enabling a response. In many ways, we are the duck in the old saying, "calm on the surface, but paddling furiously underneath." There's clearly more to do, but I look forward to discussion and engagement to help us move forward. Thank you.

Aaron Miri
Thank you very much, Greg. Appreciate that. That was Excellent, Excellent commentary. Okay. So right on cue, and I appreciate, Greg, you are keeping right to time, is Michael Fraser. Michael, you there? You may be on mute. I can see you.

Mike Fraser
Thank you. It's only been for 18 months. Can you hear me now?

Aaron Miri
Yes, I can. Thank you.

Mike Fraser
As mentioned, I'm Mike Fraser. I'm the CEO of ASTHO, the Association of State and Territory Health Officials. And our organization works with every secretary or commissioner of public health across the country, including our US territories in the Atlantic and the Pacific. And I do want to thank the committee for allowing us to share our perspective and acknowledge our president-elect, Dr. Zink from Alaska, will also be presenting on this panel, and you have several other state health officials on your panels which we appreciate a great deal.

ASTHO has been identifying, tracking, developing, advocating for solutions and barriers that our members have faced over the past year, and data and technology are foundational to this response and critical to health departments on the front lines of everyday endeavoring to prevent illness and save lives.

First, I'd just like to offer a few comments on the challenges our members have experienced on the state level that are specific to COVID, but frankly, applicable to the entire public health enterprise. I also want to mention that data systems in healthcare, which we talk a lot about, are very different from public health data systems. It's extremely important that ONC prioritize both healthcare and public health interoperability but focus specifically on public health systems in addition to healthcare sector needs and priorities.

Most health policies, including data use policy and data agreements, are state and territorially specific, and they might be funded and government by federal program requirements, but also state and territorial legislative authority and regulations. And I would submit to the committee that a lot of the issues we face around data systems are political science problems, not computer science problems.

State and territorial health agency information systems are mentioned by Dr. Frieden earlier this morning are comprised of long-standing, often outdated, legacy systems, as well as newer technologies. Think silos or vertical streams of activity versus enterprise-wide or horizontal solutions. You can imagine this in really two ways. Imagine we had a separate interstate system developed for every type of car. Or imagine an electronic medical record for every specific body part or disease state. Sounds crazy, I know. Except that

is exactly how we've approached data system development in public health because funding is categorical and program-specific.

This is the result of categorical appropriations for a specific disease in the way these programs are managed federally and then how they flow down to states and territories. These are political science problems, not computer science problems. They are not the result of bad people, but bad policy.

It's also important to remember that federal to local systems, such as the IHS, Indian Health Service, and VA, Veterans Administration health data, often bypass all of the conversations we're talking about today and go straight to federal agencies for decision making.

So COVID investments have been used to support enterprise-wide solutions, but if they're not – that flexibility isn't really explicit, we're going to have the same problems in our next public health emergency. We need to close the chasms to paraphrase Dr. Frieden's comments earlier.

States are consumers of data. They're not just producers of data, and federal efforts should really tap this strength. The notion that the state's role is to just push data to CDC for decision making needs to be changed to a far more collaborative approach that acknowledges most of what our public health agencies at the federal level do is done with state partnership and sharing of information.

So certainly, we acknowledge that the private sector, especially healthcare systems, are often not part of the discussion that we're having around public health data systems, and they are expected to connect to those systems, so we have outreach to do there.

So, in sum, our state and territorial public health information technology infrastructure is notoriously characterized by a lack of interconnectivity. There have been stories of the use of faxes and fax machines from clinical partners to public health departments. A lot of the stories we also hear are about redundancy and ate collection methods such as both phone-based and online reporting and criticisms of lag time and lack of real-time data.

I'd like to remind the committee that these problems, again, aren't technical. They're political. We had two health officials who lost their jobs as a result of not being able to quickly solve some of these data issues to the satisfaction of their governors. So, the stakes are high here.

So, what's our solution? And I'll conclude with these points. For big picture transformation in the coming years, the public health community has been working in earnest over the last decade towards a comprehensive data modernization strategy. And it wasn't until last year that significant dollars were put into this effort. And through Congress's action, we now have more than a billion dollars to build public health data systems. But we stress that there needs to be a national approach to this planning, not a federal approach to this planning.

Our tenants of what that new system looks like include enterprise-level system planning, interoperability, a lot of which was shared earlier this morning, advanced security practices and policies, a workforce prepared to deliver these data and support these systems, and public-private partnerships that fuel innovation.

We've learned a lot in this response. There has been a lot of innovation, and I think there are some bright spots when we look at the vaccine program when we look at exposure notification. But certainly, have a long way to go. And we thank you all for your attention and your diligence to these issues by highlighting them this morning. And on behalf of all of our members, we thank you for the opportunity to share our feedback and for including us in these conversations.

Aaron Miri
Thank you, Michael. Appreciate that. Next up is Linda Rae Murray.

Linda Rae Murray
Well, good morning, everyone. I'm glad to join this panel. I have written a statement, so I won't bore you with reading it. Let me just say at the beginning, I want to second the comments made by Dr. Frieden and the last speaker, especially from ASTHO. It's easy to talk about the problems that we have. I'm going to be trying to focus on questions of health equity. But all the problems that they laid out, and frankly, public health, whether it's American Public Health Association, ASTHO, NACCHO, all of our organizations have been crying for decades on the lack of investment in infrastructure.

But let me suggest that if we look at the medical side of things, simply improving, and we certainly have improved electronic health records in my career. Simply improving the backend computer parts of it doesn't necessarily translate into major changes in how physicians practice. And simply improving all of these horrible problems that we have in public health doesn't automatically address health equity.

I was amused that Dr. Frieden actually brought up EPI Info. There aren't that many of us old people around that even remember what it is. But I will tell you one of the real strengths of EPI Info. I could take that software and give it to a college student, a high school student, a nursing student and have them work on a project and know that it would function, and they could learn it quickly and finish the project.

So, what are the problems that we have with health equity, and what are the issues that we face in public health? I agree that many of our problems, if not, in fact, most of our problems, are not computer problems. They really are political and organizational problems.

So, where I live and work, whether I work for the Chicago Department of Public Health or the Cook County Department of Public Health, I've worked for both, that information can't easily be shared across those jurisdictions, even though the communities that we serve clearly ignore those political boundaries. Why is it during COVID-19 that we have to resort to journalists, public advocacy organizations, some academic centers to get some kind of reading by race and ethnicity for all of the metrics that we're concerned about?

In Chicago and Cook County, we have political jurisdictions that are dedicated to addressing health inequities that we've seen in this pandemic. But still, much of the data, not just the fact that we're missing race and ethnicity, much of the data we need to do that isn't easily collected. We do not track where people work. We don't track outbreaks easily by the workplace. If it gets really bad, then we may notice it's a certain workplace. We're not set up to really do that. We ignore class as we capture our public health data.

We have lots of examples and long lists from CSTE and other organizations that say what we should be doing. I don't want to repeat that. I do think that Resolve to Save Lives has played a major role in really

advanced some suggestions about dashboards, etc. I want to take a minute and suggest that if we're going to address health equity, we have to start with who's in the room.

So, we have a data system with a hierarchy. Epidemiologists, computer folks, they are important. But the data people that we need go far beyond that and far beyond GIS experts. They include people like community health workers that are collecting the basic data or cooks setting in a medical office that's actually collecting that information. If we don't have a process to make sure that the whole line of people is well-trained, that they can understand what the dashboards mean, that they understand their role in contributing that information, then we're lost because we won't get the accurate information that we need. And if we don't listen to those people, we won't be collecting the information that we need.

So, the Urban Indian Health Institute, among others, has called forever for disaggregating racial and ethnic data. In a city like Chicago, a metropolitan like Chicago, it doesn't do me any good to simply say Asians have this metric, or Latinx have that metric. I need to know exactly what those disaggregated groups do so I can tailor my interventions and outreach specifically to those communities. It's not a simple matter of having data and thinking automatically health equity will resolve. It doesn't work like that.

So, the first step we have to do as public health people see and value people equally, not only by race and ethnicity, by gender preference, by where they work, by what socioeconomic status they have, and not just think we can create these indexes that show us high-risk community is the answer to it.

We also have to, and this is a real challenge, especially during something like COVID-19, but it's still a challenge we have to meet. We have to begin to integrate other data systems that do not pay attention to biomedical markers into public health. Public health is really everything. I need to know what under-resourced housing communities exist. I need to know where the workers are. I need to know where small plants are. I need to know where unemployment rates are going up a down. So, all of these economic systems, political systems, faith-based systems, where we have lots of data, we need to integrate that into public health.

If Google and Amazon can know what book I want to read next before it's even published and be correct, then we in public health trying to help people's health need to gather all of this information together. The most important component is the human component. Let's look at who we're training and who we're talking to. Thank you.

Aaron Miri
Dr. Murray, I'm giving you a virtual high five right now. Those are phenomenal comments and totally agreed across the entire committee, especially those out on the provider side. And those of us also, like myself, who are also Latino and others. So, I appreciate that. All right. Next up, Anne Zink.

Anne Zink
Hello. Thank you so much for having me. I would also like to give Dr. Murray a big old high five from over here. I agree with so many of those comments. I'm a practicing emergency medicine physician in the state of Alaska. I am also the state's chief medical officer, and I've been very fortunate to be the ASTHO president-elect.

I come to you as really a practicing emergency physician, where you see three bracelets on a patient, which taws the only way you could figure it out. They've been to three different hospitals with three different CTs. And the frustrations with IT systems really led me into this role. A saying in emergency medicine, I'm five clicks too crazy. And I have now joked with my healthcare professionals that if they thought EMRs were bad, they should try to state IT because it's taken it to a whole new level.

You can hop around the world, and you can put your credit card or ATM in any machine and get out in currency money from your bank. We have ways of doing secure data information exchange worldwide that cross boundaries, not only the state but internationally. Yet, I cannot get my state labs to be able to go over to my EPI team without significant effort.

As soon as we saw really what was happening as far as COVID, we put a ton of time and effort into continuing to try to boost our IT systems to really connect things within the state and without. Despite a ton of effort and time, we ended up having to place National Guard in our state lab just so they could enter a positive into the NBS system into our contact tracing system, as well as into our EPI system to use and the LYN system to be able to see what was happening. A tremendous amount of time and resources.

You know, I have three specific areas where I really feel like we need to focus with one large ask for you all at the end. You all have talked a lot about national data standards, my one clause analogy for plugs in different areas, and I could not agree more. Even on a state level with different IT vendors, and I think we need to look beyond just public health, but we need to have standard ways that we're talking across data systems. Just as mentioned, with race and ethnicity data, gender data, location data, and if we don't have those national standards, then we cannot even start to begin to have this conversation.

The second big request is streaming of IT funding, and this came up with a few of the other speakers before. We're a fairly small state and with a fairly small public health team, and we get funding opportunities from many different sources, be it CDC, CMS, ONC, but they all have a similar sort of goals, similar sort of initiatives, yet slightly different requirements and totally different federal rules. And so, we spend most of our time really just trying to meet each of those goals rather than having federal funding really being funded and collectively done together from an IT perspective. Sometimes the grants are almost identical with separate reporting requirements with similar dollar responses, and a federal cohesive leadership response is critical.

The third is really tools associated with funding. And I think there were some great examples of this earlier. But federal funding and federal reporting requirements need to come with tools that we can gather together. A great example that we've really been struggling with most recently is ELC funding. It's a lot of money, and it's great to be able to think about how to do testing and vaccine in our schools and what that looks like. But we spend most of our time just trying to figure out the reporting requirements around that. How to set up remote rural schools that don't have broadband access to even think about reporting that without doing it all on a piece of paper and an Excel spreadsheet that they're going to be able to send to us. So having a tool that is able to fit significant federal funding requirements is key.

I think HHS and just the hospital level reporting is an example of that. There was a huge demand for that during the pandemic. The federal government set up a response and worked with our hospitals, so we didn't have to in the public health sector, but then we were able to have access to that. I think another

example that's worked fairly well has been Tiberius and the real need to be able to see how many vaccines were allocated, where it was moving, and was able to be built over time.

So those are two examples that during the pandemic, there was really a federal tool to meet a need that we were all having, and we didn't have to spend a lot of time at the state to be able to scramble to figure out what that looks like.

I think there have been some real successes, such as the AIMS platform and the national thought file, and then the weekly calls, I think, have really helped. These real opportunities, like CDC Prime, have a lot of capacity and to fill a large existing gap, and other opportunities like NBS, where I think we could do a lot with National Disease Reporting Surveillance but have a long way to go along those lines.

We solved a lot of problems, but honestly, we've asked to make a highway, and we're driving on a gravel road. We could have funded over 100 IT positions in the state, but we don't have enough qualified personnel, let alone the bandwidth to be able to do it, and this continues to be a real challenge at the state level.

As mentioned previously, not being able to get good IT really builds inequities in our systems. And I would build on Tom's comment and then actually add to it. He talked about the gorilla in the room, and I would say potentially even the elephant. And I would challenge us to not only think about the IT dollars, but I would challenge us to think about all healthcare dollars.

When we saw emergency medicine, and we saw patients showing up to hospitals and not getting care, EMTALA was formed as a law that made every practice have to standardize, stabilize, and treat patients. And I think we need not only an EMTALA but as well as a commerce clause for IT. We need to make sure that anyone who receives healthcare dollars, be it Medicaid or Medicare, has a way to share that data that is benefiting patients. We need a system that serves patients instead of patients serving systems, which is what is happening now. And we need to cross jurisdictions. We can have people move, but we can't have data move. And people don't live in one spot. They move and cross, and we have got to think about this from the whole person's perspective.

The cost of inaction and inoperability has a moral billing as well as a challenge to our staff, our budget, and a cost of life. I've often felt like the pandemic, we were thrown into a river swimming upstream, and IT was our biggest failure, holding us back with weights on our legs, and I think we have a real chance to do this better moving forward. Thank you for the opportunity to speak.

Aaron Miri
Thank you so much. I really appreciate that. And for those of you following along, I just glanced at social media, and boy, that discussion with that first panel has already listened up on Twitter this fantastic comment about equity and public health data systems and transaction with data systems and things we need to do and think about. So, thank you, panelists.

So, with that, we will now transition to the next section here, which is our HITAC members being able to ask questions. So, we have a few minutes here, so I would ask the panelists if you could please hang on

for a few minutes while we get folks in the queue and in line to ask you guys questions. All right. First up is Arien Malec.

Arien Malec
All right. So, thank you. This has been a fantastic presentation. I'm basically going to ask the same question to every panel. And I'm sort of reminded by the last two presentations by Anne and Linda Rae on standards or standards for race/ethnicity. In many cases, we have the standards. For example, the OMB coding goes down to the usual classifications for race/ethnicity. But the ONC names the CDC enablement that actually goes down and is able to fine slice into Hmong versus Vietnamese verses etc., and not just at the broadish level, at Asian. And yet, in Alameda County, where I live, the race not specified is by far the largest vaccine recipient.

When we looked at the Duke Margolis workgroup that I was able to participate in under Dr. McClellan's leadership, when we looked at data sharing for lab information, we actually have all of the standards that we need. We may be able to improve them, but in many cases, our issue was not using them and not having data flowing.

So as an example, when we think about demographic information, address information for contact tracing, much of the issue was that the data was being lost between the hospital, the lab, and public health, in large part because the hospital and lab are incented to get reimbursement and not necessarily to have that data flow for public health. So, if I don't need the information to get paid, it's kind of a pain to set up my interoperability to flow that information. And so, when push comes to shove, I'm going to put in the information I require to get paid.

So, my question to the panel is really mindful that this notion is the political science problem, not an informatics problem. How do we think about incenting and funding the actors involved in this workflow where those actors are healthcare settings who are incented in many cases by fee for service and EMM coding, the labs, and other intermediaries, who again are incented to get paid? Public health, which, as I think folks have noted multiple times, sometimes is incented around strict programmatic and siloed requirements. And then how do we make sure that when we have the incentive structures, we actually have the funding to match.

So, you know, my favorite example here is that we had in many cases in meaningful use the public health measures but states who were unable to do the interoperability that was required in the public health measures in the EHRs. So how do we think about this as a systems problem, and how do we think about the incentives and the funding mechanisms to make sure that that systems problem actually is firing all of the cylinders that need to fire to exchange information. Thank you.

Aaron Miri
I don't know which panelist will take the question. There are several in there from Arien. I'll open it up to any of the panelists that wish to answer that.

Linda Rae Murray
Well, this is Linda Rae. Let me make a comment first before – because the heart of these questions was really incentives. Let me make a comment first about our racial and ethnic categories and recognize openly

that this is a message of our racist society. It makes no sense. Anybody, for example, immigrating to the United States when they are faced with our normal questionnaires thinks we're crazy because they don't think of themselves in that way.

So, I want to acknowledge that and point out that as we discuss race and ethnicity especially, it is a political and social construct, and we have to have – I don't even want to call it a feedback loop. We have to have constant conversations with our communities about how we identify people. So that's the first problem. And I want to suggest, just because OMB has a list of categories that solves our problem. That's the first thing.

In terms of the substance of what you're saying here, I really support what Dr. Frieden says. I support forcing certain things from the public, from the government's point of view. In other words, we can make it so that you can't get paid if you don't give us the patient's home address. You know, why do we allow labs to report information when everybody has the same lab address. It doesn't make any sense, and obviously, you can't do contact tracing or anything else with that kind of data.

So, this means having the political power to force certain kinds of information as mutable in order for people to get paid.

Aaron Miri
Thank you. Anne?

Anne Zink
This would go with Dr. Murray's comment. Yes, absolutely. And I would say that's really why, that kind of EMTALA comment at the end, I think that we have to think beyond public health sources of funding, and we need to think about Medicaid and Medicare dollars. Because that very much drives a lot of our fee for service. And if you are a hospital system, if you are a lab system, if you're not reporting race and ethnicity data, if you're not reporting syndromic surveillance, there's a cost to that from a public health perspective, from an IT perspective, from a Medicaid and Medicare dollars perspective.

You know, I get bills from our Medicaid department every day, telling me how expensive COVID was, and then I send them back preventive bills and show them how much we saved them. We are connected in this, and we need to connect it from a dollar's perspective. So, I think Medicaid and Medicare dollars have to be tied.

Aaron Miri
Good points. Mark? You may be on mute. We cannot hear you, Mark.

Mark McClellan
Yes, probably we don't have racial and ethnic categories, but the ones we do have and are using, it's hard to get that complete without the trust of the people who are getting vaccinated. And if you, as you said, linking this to payments, making it a requirement for participation in the program, and linking it to a real strategy on what's going to be done with the information to address equity, it really helps get that participation rates and enable us to target, engage providers a lot more, and groups a lot more in these equity issues.

Aaron Miri
All right. Thank you, sir. Greg or Michael, any comments you would like to make? And then Greg, any comments from you, sir? Nope? Okay, perfect. All right. Good deal. And I appreciate all of those questions.

Alright. So, the next question in the queue here is from Clem McDonald.

Clem McDonald
Can you hear me? These ones for Greg Singleton. As you describe the system, it seems to be the solution to a lot of things that other speakers were complaining about. But I just wondered first, what is the name of that and who runs it? And wouldn't that – if it really is working well, wouldn't that solve some of the issues that people want to build new systems for?

Greg Singleton
Sure. Thank you. And I'm sorry. I didn't catch your name.

Clem McDonald
Clem McDonald, like the hamburger.

Greg Singleton
Oh, okay. Fantastic. So, I think, again, thinking through the systems and what we have right now, recognizing that we didn't have these systems in place at the outset of the pandemic, and the systems weren't configured, and they weren't capable of addressing a number of those issues. So that is on us. That's on the federal government, and we weren't there at the time.

But through a lot of effort, we have stood up these systems, gotten them in place, and appreciate factors, recognizing kind of where Tiberius has worked well, where the hospital reporting systems have worked well, where they're now in a place where they are functional and providing the insights to decisionmakers and community leaders across the nation.

It addresses a number of the issues and a number of the challenges that folks have been looking at, but there's still a lot of work that needs to be done. There's a lot of areas where we can evolve and develop the platforms. I think it's key in what we have set up is that they're kind of this underlying platform technology, I think, as Dr. Frieden said, with the capability to evolve and meet the needs as we move forward. So, using guidance insights from this panel, from other bodies, from the users, figuring out how do we pivot? How do we adapt? How do we incorporate additional or different functionalities? Because right now, it's the unity of purpose around COVID. It's the COVID pandemic. It's COVID stuff. So, if you wanted to evolve that, what would you bring in at different times, and how would you adapt aligned with national leadership and guidance from other participants.

So, there is a lot of capability there, and I appreciate you recognizing what has been put in place. And then it's this broad discussion, again, folks on the people, not just the systems, focusing on the political problems, not just the technical problems. And I think it's just a fascinating discussion that we're going to take part in today.

Clem McDonald
So, I have another question for the last speaker about the **[inaudible] [01:33:29]**.

Mark McClellan
Can I respond to that first one first?

Clem McDonald
Sure.

Mark McClellan
I would have to react to your characterization of the conversation as complaining. I don't think that's accurate. We're describing a current state. It's not a complaint. It's accuracy.

Clem McDonald
I'm sorry. I didn't mean it that way, sorry.

Mark McClellan
Sure. The second thing I would say is I think we've learned a lot in COVID that we can apply, but a lot of the systems that were developed in COVID were facility to federal government reporting systems that I think a lot of states would want to talk about before we use that as the best practice. But certainly, shows a proof of concept that we all buy into and are supportive of. But it does require some post hoc tweaking to get the data back to the state, and then states are creating duplicative reporting systems with numbers that don't match, which creates communications challenges for state health officials and their governors.

So, I certainly appreciate the spirit of your comment, Clem, but I just wanted to clarify, from our perspective, there's a long way to go here, with some great bright spots from COVID for sure. And it shows exactly what Greg is saying. You need a purpose, and money and smart people combined can get this done. That's what we really learned in all of this, which is fantastic. So, thanks.

Clem McDonald
Well, I guess we're not at nirvana. That's what I was really trying to get to. The question for the last speaker about race capturing. Because I worked in an inner-city hospital in Indianapolis for 35 years. And we didn't get good race data. And what appeared to be either the clerks, who were mostly African American, wouldn't ask because it sounded funny or racist, and/or the patient wouldn't answer. And I'm not sure which it is. Do you know why it's happening? It's not that the hospital didn't want to collect it. It's just that it didn't get done.

Aaron Miri
So, Clem, is that for Dr. Murray?

Clem McDonald
Yeah.

Linda Rae Murray

I think that's an important question. And I spent much of my career in the Cook County Hospital System. We had similar – our clerks were predominantly black, with many Mexican American and Puerto Rican clerks too.

Plus, the way OMB sets up this question makes no sense. So first they ask you your race, you know, are you black, white, you know, and then they go separate, are you Hispanic? Well, I'm sorry. First, they say, are you Hispanic non-Hispanic. I mean, it's a crazy system.

If you ask people to ignore the computer screen and the little thing if you just talk to a person and ask them how they – once they're here and understand we think race is important and ask them how they self-identify, you got a coherent answer.

Now the problem is if you take that coherent answer, I'm Puerto Rican or whatever and put that into a set of definitions that go into a computer. So, I think you have to be respectful of people. I think you have to allow them to self-identify. I think you have to understand that new immigrants do not understand the role that race plays in our society, and it takes them a little while to get used to this crazy question that we ask.

We are able to get that information over time. It means training the clerical staff, but also everybody, physicians, the nurses, the entire system has trouble with this question. It's a question of asking people how they want to be self-identified and explaining in general why that's important. But we can have more Chinese interpreters if we know how many Chinese patients we have in our system.

Aaron Miri
Sorry, Clem, one second. I think Michael was going to respond, and Dr. Zink was going to respond, and then you can do a follow-up if you don't mind. So, Michael?

Mike Fraser
I yield my time to Dr. Zink, and then if I want to add, I'm happy to add.

Anne Zink
Yes, I would just build on Dr. Murray's comment. I think that this really needs to start with interactions with people. I think we need more training for healthcare providers and clerks on how to ask this question and the importance of it, and there's very little training in medical education on this. So, I think we need to move way upstream and work with our medical counterparts to be able to move in that direction.

I think we need to, as mentioned, have good questions that people feel comfortable answering and letting them answer themselves rather than been interpreted between people, and then we need systems. I'm embarrassed to say that Alaska has 32% of our race and ethnicity data for vaccines is unknown. We've done a deep dive into it. It's every single step of the way. There's data loss, and so you get the end point. We have 32% that is unknown. So, I think it's every single step that we need to look at. Thank you.

Mike Fraser
I would echo that and suggest that what we've heard from other states as well is that the individuals that have an experience with our healthcare system and distrust it feels that by disclosing race, they may get

substandard care, and that's current as of yesterday. Not years and years ago. So, this legacy does need to be unpacked.

I also think we need to balance something like a vaccine campaign where we want to get vaccinations out quickly. There were a lot of people who said, why do I need to collect that, and what does that have to do with the delivery of healthcare to me. So, a lot to unpack here, as I think all of us can acknowledge.

Clem McDonald
So, the problem is deeper than just incenting, it sounds like. It's multifactored. I also comment that I worked at Cook County for a year, and I also was sick there for a year – not a year, 10 days when I was 10. So, I know Cook County.

Public Health Systems Performance During COVID-19: Operational Perspectives & Discussion (01:39:39)

Aaron Miri
Well, thank you very much, Clem, very much for the comments there, and thank you to the panelists. I will say that here in Texas, we also resemble a lot of the remarks Dr. Zink and others were making and really the need for fairness and community effect. And really partnering with people and treating people as humans, and not as a data standard. It's critical. So as Dr. Tripathi always says, health equity by design, even when you're doing surveys or whatever else. So, it's very, very important.

So, with that, I don't see any more hands in here from the HITAC. Let me just quickly ask, is anybody on the line? HITAC has a question? Okay. Hearing none, then we will go ahead and transition to the next panel, which again, I do remind the HITAC that there is a public comment period that we want to keep to at 11:50 a.m. But we'll have the discussion before that after this next panel. And then we'll have plenty of opportunity for more dialog and debate. But I want to make sure that we give enough time to every group here.

So, with that, thank you very much to that panel that just finished. That was fantastic. So, we will go to the next section here, public health systems performance during COVID-19, operational perspectives, which should be very interesting. And then first up is Dr. Ian Williams.

Ian Williams
Good morning, everybody, and thank you very much for the invitation to present to you today. I'll turn my camera on here. So, I am. Basically, my day job is the deputy director of the Center of Preparedness and Response, but I've been working on early response, COVID, for the last 15 months in a couple different positions. Been a deputy incident manager, I've been a chief data scientist, primarily working on the data strategy working group at the federal level. So, I'm going to explain a little bit more of that later.

But my remarks today are really informed by that perspective, working on the federal response, and thinking sort of how our public health systems performed to basically inform the larger federal response at an operational level.

And I'm going to echo what other speakers have said today. Overall, as a whole, the system did not perform well. Some individual systems worked well, others not so much at all. So, I'm going to delve in a little bit from an operational perspective, which ones I think did and didn't, and opportunities for improvement.

So, one of the things I think you've heard other speakers say is the COVID-19 pandemic exposed well-known weaknesses in our public health data systems. I think some of what happened is not a surprise to a lot of people. Some of our key systems rely on paper, manual entry of data. We have lots of data silos, most systems are not interconnected. Data is not easily shared. It's not a big surprise that, especially in some of the areas, we did not do so well in this pandemic. So there have been a lot of suggestions about how to fix it, and we'll get into it.

So, I've worked in emergency responses for more than 30 years, and what I see in every response historically and in this response is that when the pressure's on in the middle of a pandemic, and you need to get answers, people rely on spreadsheets and access databases to manage the basic data in outbreaks. As a matter of fact, that was the initial plan to count and manage and track places at CDC when the pandemic first started.

One of the challenges to layer on top of this is SARS-CoV-2 was something new—lots of unknown. We need lots of data to fill gaps. You've heard other speakers speak about that.

So, if you think from an operational perspective, what kind of data did we need at the federal level to basically try to solve this very complicated problem, a new thing, very quickly. And I would sort of say there are four general trenches or buckets of data that we focused on or needed to get our house in order in order to basically move things forward.

The first is national data on situational awareness to really track the trajectory of the pandemic across the US. This is down to a county level. This is stuff we need in real-time at a daily cadence. These are case trends, lab data, that sort of information.

There's also a second bucket. That's the national data to characterize the epi of the pandemic. There are things like line-level case data, mortality surveillance data, syndromic surveillance, hospital patient impact capacity data, nursing home data, we need these more or less in a timely way, but we need more data in depth.

The third general bucket is our sentinel surveillance systems. These are team surveillance data in selected populations that collect in-depth but less timely data. These are like hospitalization data through a system like COVID net.

Finally, there are the special studies we need to answer specific questions, and these can be done sort of on an ad hoc basis, large scale geographic **[inaudible] [01:44:14]** studies are a good example of those.

I think where we struggle…

Aaron Miri

Dr. Williams, really quick, your camera is not on if you were trying to turn it on, so I just wanted to let you know that. It's still in preview mode. You've got to hit the button one more time to share just so you know. Go ahead.

Ian Williams
There we go. Did that work?

So, I say a place where we struggle from an operation perspective is the first two around situational awareness and categorizing the epi of the pandemic.

So, one of the things to look at is what do we do to try to innovate, and I would sort of say there are two places where I see innovation stood out trying to address those first two. And some of this is going to build on the remarks of Greg Singleton.

The COVID-19 pandemic clearly demonstrated the need for a federal interagency coordination process to align ongoing data collection, analytics, and reporting efforts on key health indicators. The ultimate objective of these efforts is to produce essentially actional information for agencies that public health enterprise, the operator or common understanding of the pandemic and implement optimal response.

To address this urgent need, a group was set up called the Data Strategy and Execution Working Group, relatively late into this. This was last June. This was brought in as part of the HHS incident management structure, under the direction of the White House, and really was focused on those two first general buckets of data, integrating data from cases, laboratory testing, syndromic surveillance, hospitalizations, healthcare utilization, supply chain, vaccination. The idea here was really to try to give us a common operational system.

So, you've heard from Greg Singleton. Greg is part of the Data Strategy and Execution Working Group, part of the leadership team you're going to hear from later today from Sam Imbriale from ASPR, who's also this. So, they are part of this group that's trying to help us develop a new forward in this common operating platform.

The other thing I would say to build on some of Greg Singleton's comments, the second key to our success at the Data Strategy and Execution Working Group has been the establishment of HHS Protect. This is the secure web-based platform that serves as this core public health data management integration platform. This is really a common operating platform that gives us essentially a common sense of what's going on in the pandemic.

And I would sort of say, I see as a way forward that we really need to have an interagency level approach to data integration to ensure effective public health emergency responses. So, a lot of it's building on what we've started now, moving forward to make sure that we have more success in the next pandemic because it's not a question of if. It's just a question of when. So, with that, I'll conclude. Thank you.

Aaron Miri
Thank you very much. Appreciate that. And I agree with that. The more data sharing among agencies and the general public, the better. All right. Next up is Sarah Boateng.

Sarah Boateng

Hi. Good afternoon. Good morning. I want to thank Micky and the whole team at the Office of the National Coordinator for inviting me to participate on behalf of the Office of the Assistant Secretary for Health. It's also nice to be joined on this panel session with some old friends, including Dr. Linda Thomas from the Wright Center, who I know well from our time in Pennsylvania.

So, I'm Sarah Newman Boateng. I'm the Chief of Staff for the Assistant Secretary for Health, Dr. Rachel Levine. I recently joined OASH in February of this year after spending over five years at the Pennsylvania Department of Health, where I most recently served as the executive deputy secretary for health, working alongside Dr. Levine in that role as well.

We would often say in Pennsylvania during the COVID-19 pandemic response that we have never pushed out so much public health data so fast. Typically, public health data is presented in annual reports, summarized, and published in the subsequent year. But the needs of the pandemic response clearly would not allow for that approach. Public Health professionals, clinicians, public health leadership, government leaders, the media, the public all wanted this data, and they wanted it fast.

So, when I think back on that work, and I consider our task here at the Office of the Assistant Secretary for Health, I think of a few specific areas to consider as we look forward to continuing data-driven public health responses.

But first is the challenge that public health data, particularly during the COVID-19 pandemic, there were many different audiences who wanted that data for many different purposes. So, dashboards and visualizations were key to communicate with the public, the nonpublic health professionals, but it frustrated academics and researchers who wanted to do their own evaluation. But the inverse, complete datasets online, in Excel spreadsheets, didn't tell the story to the public on what the data means, and most importantly, what it meant to them.

Second, consistent data definitions are key in applying those definitions across datasets and across jurisdictions to allow for an accurate comparison. These data definitions must also be posted and easy to find to ensure that the public does not make incorrect comparisons because two data sets, two data points, seem the same.

Third, we must continue to expand the infrastructure in public health departments. I spend as much time in my role in PA with our state epidemiologist as I did with our CIO. The IT systems and the IT staff worked in overdrive, ensuring server space. They built bridges to exposure alert app, contact tracing management tools, and many other necessary IT structure changes and often built those to very old systems.

And one of the hospitals, nursing homes, academic centers. An increasingly with the advance of testing, care testing by non-clinicians and even the public. And to get the data, individuals understand why we are collecting it; the most difficult aspects of the pandemic were taking data that we had, sometimes building in case notes or free text fields, and pulling it and preparing it for public review.

Fourth, and I heard some discussion on this as I logged in, is that we only put out data as good as what we get in. And we, as a collective concept, as public health infrastructure doesn't own most of the input. Private labs, hospitals, nursing homes, academic centers all put data in. and increasingly, with the advent of at-home testing, point of care testing by non-clinicians, even the public may become reporters. And to get good data, individuals must understand why we are collecting it and trust the system to protect their information.

An example of this in the COVID-19 pandemic was the public's keen interest in contact tracing data, how many cases were tied to bars, how many cases were tied to gyms, how many cases were tied to this specific gym. And yet, a contact tracing process and the contact tracing task are not constructed for that purpose. It's constructed to stop and slow the spread of disease. And so, turning the tool to put out aggregated information that the public needed was difficult and incredibly time intensive.

And finally, the fifth and clearly the most important area is to collect more and better demographic data. The COVID-19 pandemic has highlighted stark disparities among Black, Hispanic, Native American, and Native Hawaiian, Pacific Islander populations in several areas, including infections, hospitalizations, death rates, vaccination rates. Recently my colleagues at ASPE published a brief, Health Disparities by Race and Ethnicity During the COVID Pandemic, Current Evidence, and Policy Approaches, which called for improving public health data infrastructure, data collection, and dissemination to inform evidence-based decision making.

But we must build this improved data infrastructure to capture the full diversity of the American public. We must consider and capture multi-raced individuals. We must allow data centers to capture gender identity and sexual orientation and account for the various identities that the American public has. And a barrier to this type of data collection is often not policy or political but rather structural. There are not fields built-in systems to capture it, nor standard operating procedures that embed it into a process.

For example, in PA, we began to capture sexual orientation and gender identity data during the pandemic. The policy decision to do this was easy. The operation of it was quite difficult. To capture the data required us to build new data fields into an old system during a pandemic. We needed to establish standard operating procedures and conduct training to effectively add this data to our response.

Given all of the above, I am a relentlessly optimistic person, and I am confident we will build back better. I found preparing for today's presentations brought up feelings of anxiety and stress, as data, data presentation, and the public's intense demand for data during the COVID-19 pandemic was quite difficult to manage from a leadership perspective. But I also found it therapeutic, as we must do just as we are doing today, learn from the pandemic and incorporate those learnings into the future.

So, I just want to thank ONC for hosting today's meetings and appreciate the opportunity to share my perspective.

Aaron Miri
Thank you very much. All right. Next up is Lilly, please. Thank you.

Lilly Kan

Great. Thanks so much. Good morning, everyone, and thanks for the opportunity to provide operational perspectives on the performance of the healthcare system during COVID-19. I'm Lilly Kan, and I'm the Director for Infectious Disease and Informatics at NACCHO, a National Association of County and City Health Officials. And NACCHO's the national association that represents the nation's nearly 3,000 local health departments, which has been on the frontlines of the public health response to the pandemic and protecting our local communities, in coordination with a multitude of partners.

And I have been at NACCHO for 13 and a half years, so I was at NACCHO supporting local health departments during H1N1, and it was just so remarkable to see the challenges we were facing back then and to compare them against the challenges and also successes that we are looking at today.

So, what I'm going to say is really going to reinforce some of the things you've already heard. This pandemic has really highlighted how infectious diseases impact every sector of our local communities. It's also revealed the improvements and investments that we as a nation have to make if we are going to sufficiently address that need for timely local data to inform people and guide public health action in our communities.

And so, as we determine what those efforts ahead must be, it's really important for us to acknowledge where our local data systems were as we entered into the pandemic. So next slide, please.

There's wide variability in local information technology systems. We had encouraging data from NACCHO 2019 national profile's health departments, showing that most respondents indicated they'd implemented immunization registries and electronic disease reporting systems. The low percentage of local health departments implementing health information exchanges is an important factor to consider when we think about the interoperability challenges that local health departments face.

If local health departments are not a part of an HIE within their state, then they're not able to access those data and are left to obtaining the data in other presumably more manual ways—next slide.

Also, in NACCHO's 2018 forces of change assessment, only three percent of local health departments we surveyed reported that all of their information systems were interoperable. And one-third of local health departments reported that none of their systems are interoperable. We're all well aware that lack of interoperability in many cases leads to inefficiencies and necessary risks that come with manual data entry and duplicate data entry and sharing. This lack of interoperability leads to substantial costs in local health department staff time and financial resources to both report and exchange data. And this can lead to delays in providing critical public health services.

Regardless of what our local health departments' information systems were in March 2020, it was clear that across the board, these systems were not designed to equip or to handle the data needs or flows or volume of data that eventually became available as testing and contact tracing efforts ramped up. Early on, as local health departments were navigating the management of data on cases and testing, they have also been asked for data on matters such as hospital capacity, including bed, ventilator, and supply availability. As COVID-19 vaccines initially became available, local health departments were being asked where vaccines were being available in their local community. And as health strategists for their entire communities, local health departments needed data on doses allocated within their local jurisdiction in addition to doses administered to inform approaches for fostering equitable COVID-19 vaccination uptake.

And local health departments that didn't have direct or timely access to those data that were being reported to the federal level were left seeking alternative approaches to obtaining those data, which again leads to duplicate and cumbersome reporting or not having granular. Ideally, zip code level data they needed to inform their response efforts.

So, throughout this pandemic, the unprecedented demands and expectations for real-time information and data have shown that our public health data infrastructure at local, state, and federal levels all need to be equipped, so that information going into these systems is securely accessible for those who appropriately need it. And as responses are executed at the local level, managed at the state, and are coordinated at the federal level, we need to involve local health departments in federal and state efforts so that the approaches to improving interoperability across health information systems reflect local needs and circumstances. And also, we need to invest in local health department capacity building, capability building, and modernization efforts that are necessary for supporting a robust public health data infrastructure.

And so, this includes, 1.) supporting a skilled workforce that can navigate their agencies to requiring and modifying information systems, including addressing data governance and data considerations. And 2.) ensuring that sufficient funds reach local health departments widely for maintaining and upgrading their systems to enable seamless data exchange.

COVID-19 has shown that we can't achieve our federal goals without a strong local foundation. And a public health data infrastructure that is inclusive of and equitably bolsters local health departments is critical to maximizing the use of available data from healthcare and other sources for a timely and effective public health action.

So, with that, I really thank you for the time to provide some perspectives, and I pass it back over.

Aaron Miri
Thank you very much, Lilly. Appreciate that very much. Excellent discussion. Okay, next up on the panel is Dr. Jim Jirjis, also a HITAC member.

Jim Jirjis
Yes, hey. I want to express thanks for being asked to present. Can you guys hear me, okay?

Aaron Miri
Yes, sir.

Jim Jirjis
Okay, great. Well, I'm Jim Jirjis. I'm the chief health information officer for HCA Healthcare. And one of the reasons I appreciate being able to talk about this is because we have, like many large organizations, have a unique vantage point, whereby during COVID, we experienced some of the challenges of the current state of the union, if you will, in public health.

HCA is in 20 different states, so we had the opportunity to interact with 20 different public health departments and got a sense of some of the variations. Six percent of all acute care is provided by an HCA hospital, so it's kind of a nice slice of sort of a biopsy, if you will, of the current state.

If we think about our experience with COVID, I'll go ahead and flip to the next slide here. If you think about our experience with COVID, I think about it sort of as afferent problems and efferent problems. And the afferent problems are everything we're trying to do with USCDI, with standard with TEFCA, etc., trying to standardize the data.

And what I'll start with is when COVID first became an issue. Even collecting the data on which patients, who hadn't been tested and who had tested positive, was a challenge. In many cases, the public health departments themselves were doing the testing. And the way they were reporting back to our hospitals was to make a telephone call and verbally let the infection prevention specialist know the result. And you can imagine how challenging that is to actually capture that data and then turn around and use it for federal and state reporting.

Many of our hospitals experienced where they were doing the testing themselves or were sending out the testing, had to pivot on a dime and use multiple different approaches because reagents would run out, etc. So, you had all this variation in terminology and semantics and capabilities for how lab testing would occur, and it created an enormous amount of work with value sets, trying to make sense of it all and map it so that we could then report it. So, there's a tremendous wind in the sails, I think, of going more rapidly and defining more clarity around complete and specific standards.

One of the challenges we have is the notion of the many to many problems, and it's sort of akin to TEFCA, where we're trying to have an easy one-way onramp for people to easily connect with a trusted intermediary or at least a system that everybody agreed upon, both technologies, contracting, processes, consents, etc. With public health dealing with 20 different states, we found there was a wide variety in public health interface readiness. I think somebody – Steven Lane in the chat was talking about meaningful use or promoting interoperability requiring you to say yes. Well, most of that was yes, we are working in good faith to get an interface set up, but we identified four or five states we were in that didn't yet have interfaces ready. They were months away, for example.

But there's contracting for every single public health department, interface testing, various technologies, approaches, and interpretations. If you've seen one, you've seen one, and that created a lot of costs, but more importantly, it created a lot of delay in state and federal governments getting the insights they needed to deliver the right care.

The difference in interpretation. If there was a field missing, some states would take the rest of the file, others would reject it. If the staff was on vacation, it was hard to know whether our submissions were received or not.

So, to summarize the issues, redundancy was an issue, IT variation, process variation, lack of standards, adherence, implementation variation, interpretation of how the interface had needed to work, resource constraints at the public health departments in particular, and lack of incentive to align. One of the questions

is if they build it, why will they come? And lack of specificity and completeness in the terminology standards I mentioned.

And from our perspective, it's sort of analogous to what we're trying to do as a county with TEFCA. If there was an easy onramp for providers to interact, all the hospitals to interact with a single system, not just from a technology standpoint, but also from a process standpoint, and interpretation, it would simplify this many to many problems that are in the way of getting the insights that were needed. Public health funding, alignment of incentives so that public health departments not only have the funding but align and adopt. Our belief would have made it much, much more efficient, and faster time to market for those insights.

So, from our perspective, we can attest to the enormous cost of not having a TEFCA like, if you will, approach public health reporting.

Aaron Miri
All right. Jim, thank you very much for that testimony. That was excellent, and I appreciate all the work that you and your colleagues are doing across the country. All right. Next up is Linda, please.

Linda Thomas-Hemak
Hi, everybody. Wow. This is an overwhelming but historically significant meeting testimony to what I see as an emerging collective genius. And honestly, I just want to say to all of you, this makes me really proud to be American, and it makes me proud to be a primary care physician, so thank you, everybody.

So, I am an anomaly, I guess. I'm a primary care, first-generation physician. I care for multiple generations of families in my hometown community, and that's a small borough of 2000 people, so it's incredible that I found my way here, and I'm really grateful. So, I practice in German, Pennsylvania, and I come with a glass-half-full, which is essential to tell you there is a huge success in the history of IT in America, and the meaningful use journey took that small blue house into what is now one of the largest teaching health centers in our country, and the biggest economic development project in my community.

And so, I have the privilege of practicing there, and EMR meaningful use really enabled us to become a patient-centered medical home, organized the way that we connect the care of individual patients to the way that we take care of whole populations. And that really positioned us to successful designation as a patient-centered medical home, but also to a recent designation as a federally qualified health center look-alike, which is essential, in our minds, an extension of the federal government to steward health.

And that essential community provider status landed us square in the middle of COVID. So, I'll share with you in this brief presentation how we saw the failures of the system, but also the opportunities.

We've spent the last 15 years trying to take all the lessons that we learned from meaningful use to become a medical home and an essential community provider, to really push the margins to connect a medical village and to cross all of the silos, be they funding streams or courts of our care delivery systems, or the sectors between the payers and the providers.

And so, when COVID hit us, we actually were very Intune with what was going on and how the system was going to fail because every system is perfectly designed to get the results it gets. And we really looked for

every opportunity to have these proximal conversations so that we could stay hopeful and be part of contributing to changing the narrative. So, you can move to the next slide.

So, I live in Pennsylvania, and I'm really sad that you stole our Secretary of Health, but we have a new up-and-coming, very competent Secretary of Health. And in Pennsylvania, we launched an honor system to deploy our resources to address COVID because of everything we'd learned with the opiate was. And we knew that we had a disconnect between the Pennsylvania Department of Health and the Health Information Exchange and DHS because we had lived through it.

And honestly, as an executive, I knew it because when I summated the data for a national presentation, I learned 17 people had died under my watch. And when I commissioned my team to find out why, they found out, not from vital statistics and healthcare delivery process metrics and outcomes that we could see, they found out on social media.

And so, I go back to Anne's comments about the technology opportunities in front of us, and we need to get away from the myths. We built interoperable systems at the PDMP, and it's been very powerful. And there are stories here about COVID that are for a different day, but it really highlights everything that's been highlighted already by different stakeholders in this meeting.

The last slide is really about we can really accelerate change through evidence-based strategies. And if you look to the Stanford social innovations and collective impact and how to get the government to be the backbone organization that the provider community needs them to be, and really look to Elinor Ostrom, who teaches us how to govern, common-pool resources, how we see it from the trenches is that we need to stop disconnecting resource investments and accountability from where care is actually provided, and all of the reporting needs to be integrated into the logistics workflow and data platforms of the healthcare delivery systems.

So, the external reporting is exhausting the people doing the work. And when we finally get it right and integrate it, we need to share metrics. They need to be non-modifiable. There need to be rules of engagement and sanctions for misbehaviors.

And so, we're very hopeful, and we really think that this is the opportunity and the platform to connect the country and to really transform American healthcare, not only for public health, catastrophe responses but for the daily way that we take care of patients and family.

Aaron Miri
Excellent. Thank you very much, Linda. So, I do see we have some time here for discussion amongst the HITAC to ask this panel any questions or thoughts or other items they want to further clarify or ask further of them. I will go ahead and seed the water with a first question to get the brain hurricane going around the HITAC members.

But the first thing I want to ask is, of Linda, of you. You brought up a really good suggestion regarding social media and other less commonly used data sets or data sites and other places to gather and sort of inferring what's going on with public goodwill. Do you feel that in a future state that potentially those kinds of data elements could be standardized and incorporated into electronic medical records or other avenues to

standardize so that we can further and rapidly exchange that data? And if so, how should we go about that engaging the various vendors to begin looking at those types of avenues?

Linda Thomas-Hemak
I think that that's a great question. And I do think that some of the capacity that we stress is absent in the current system. That capacity is in the patients and families to tell their story. And I think it gets back to hew wonderful comments earlier about the demographics of patients and families and to ask them how they would like to identify themselves rather than imposing on them metrics that don't make sense.

So, I do think it's possible. I think it's going to need to be centrally controlled because we saw from some of the adverse event reporting systems that are now being released, you know, men and menopausal women were reporting themselves as pregnant, and that doesn't help us in the scientific data assessments of adverse events related to the vaccine.

Aaron Miri
Excellent comment. Any other panel members? Okay. I will share an anecdotal story, on that point, about how we were using social media during the vaccination hub early days to make sure how was it going? Were people able to navigate our health system to come into the vaccine hub and get out quickly and whatnot? And so, we really adopted a lot of operational workflows and apply based on that exact social media scraping, understanding what's going on, and really engaging in the community, so I think it's an Excellent point.

A second question for you – actually, this is for Lilly regarding the infectious disease. One of the issues that we identified in the HITAC last year, particularly when COVID became a known variant and a known issue, was sort of the long timeline to a standardized code so that in the EMRs and others, we could appropriately diagnose this person has COVID-19, does not have COVID-19 whatnot, with the right ICD code. Do you think in the future that those codes, even if they are pending an official certification by the World Health Organization and others, should be something we should accelerate? Because there was a good month, month, and a half before that became an official code that most vendors were able to adopt. So, I'm curious from your perspective, how should we go about forcing that so there's not this lag time from when a pandemic is declared to when our systems can be modified and appropriately diagnose or code, say patient, Aaron walked in and is COVID-19 positive? Lilly? You might be on mute.

Lilly Kan
So, I think from a local perspective, we really have to take into account that – and I heard this mentioned earlier, when you've seen one local agency, and also, I know this is the same for state agencies too, you see one. And two, really ensure the timely progress to those efforts and thinking about the local health department roles that are involved, it really needs to be reflective of both those that are really deep in, addressing the solutions and approaches to modernization that really supports interoperability between the public health and healthcare systems and the other systems.

And so that looks very different across different local health departments. And so, there are different conversations and approaches to be taken for those that have relatively greater capacity and capability. It's also so critical when we think about that local health department serving a population size of less than 25,000 that is sitting in the most rural of local jurisdictions. And really, that actually is reflective of the majority

of local health departments and the jurisdictions they serve. And so, in order to think through those issues, you really need to be engaging and thinking through this from that capacity and level of thinking that each individual agency brings as much as possible.

Aaron Miri
Thank you. Any other panelists? Okay, the next question then is for – actually, I see one HITAC member with his hand raised. Clem McDonald, you're up.

Clem McDonald
I wanted to respond to the question about what could be done faster. I think it could be. And, you know, with the testing and the collaboration with the CDC and FDA, they were putting up the COs within three or four days, brand-new codes, but it's harder at a national level piazza to meet and collaborate and to get agreement, so maybe what was needed was some kind of a temporary code. I agree that a month shouldn't have been necessary except for international politics.

Aaron Miri
Good point. One of those things, but perhaps we can earn from that and blaze trails forward, be a forward mover. Okay. Any other HITAC member with their hand raised, please do so or speak up on the call. Otherwise, I have a list of questions here.

Okay. The next question, then, is for Ian Williams. First off, I'm going to give a lot of credit to CDC. There's a lot of work done last year around electronic case reporting and partnership with the various provider organizations. One of HITAC members, Dr. Steven Lane, did some phenomenal work with your team and even working with Texas and other states, trying to get a lot of folks to adopt eCR and those types of components. Are there better ways we could, as a provider community, or just a community at large, engage the CDC on those kinds of efforts to get away from – it was mentioned on an earlier panel, fax machines, the way to deal with case reporting? Are there other ways to do that, and if so, how can we go about that?

Ian Williams
Yes, so great question, and I really appreciate the collaboration early on. I think this really highlights a little bit of we were building the airplane while it was flying. We needed to do a little bit more of having the airplane more or less built before it took off the ground, and that's where I think we sort of failed in a lot of ways. Really, it's sort of that forward-thinking of what are the specific things we need, and Dr. Frieden mentioned this earlier in his opening remarks.

I think to me, one of the paths forwards is we haven't still quite solved all the bits and pieces for COVID. So, part of it is if we can use COVID as a model, do some innovation to look at what's happened. I think there's already been some progress here. Still push forward. The pandemic is not over yet. It's likely to go on for a period of time in the US. We still have an opportunity and impious to do this. And then use this as a lens to say to expand out to the other pieces that we need to do.

So, it's maybe self-obvious that we have to address the problem in front of us. But we also need to sort of think about this is setting some of the base pieces we need for the next go-round. So, it's a little bit of keep going, don't give up, iterate, and then think about how we're going to expand those over.

Aaron Miri
Thank you for that. Any other panelists want to comment on that? And others, that story of working with the CDC rapidly?

Linda Thomas-Hemak
This is Linda Thomas. I was aware of the CDC reporting capacity. I'm also aware of VAERS. I'm aware of the FDA's interest in adverse event reporting. And I can just tell you from the provider trenches and the primary care trenches, we hold the bag. So, if a patient got a vaccine in an alternative location and we can't see it, and then they went and got admitted to the hospital with a stroke or a pulmonary embolism and a serious complication, and then they come for a transition of care, we begin to connect the dots, and then it really is not available to us in our daily workflow to just jump in the EMR and report the event.

And so, it's another hassle, and not everyone in primary care has the level of visibility and infrastructure to support them doing one more thing before they go home. And so, it's exhausting our workforce, and it's diminishing the reporting capacity. And in the long range, that's going to dimmish our ability to really evaluate causality. And people know that we don't have the infrastructure to do that, and it's eroding the trust of both the provider community and the patient community, and that's going to be a huge hurdle for vaccine hesitancy.

Aaron Miri
A very interesting comment. Any other panelists? All right, the next in the queue, I see Sheryl Turney.

Sheryl Turney
Thank you, Aaron. I had to get off of mute. I'm so appreciative of all of the speakers that have come forward today. I really want to thank you for doing so.

One question I did have for the panelists because a lot of the recommendations that all of the stakeholders are making are very similar. What would be your highest priority initiative that really needs to come forward? And in addition to that, I also want to comment on what Linda just said, because again, I bring a personal consumer story forward. But in recent family situations where a COVID was provided at a public health space, and then the individual was having two surgeries, there was no place for the individual to providers in the EMR system that could record that information. And I thought that that would be important for the physicians to know in the event there were any adverse events while the patient was in the hospital the two times. And they're like, well, we don't know how to add it, and it's not information we can add. Put it in my chart and see if your PCP can add it. And now, three weeks later, it still has not been added. So that really speaks to, I think, the point that Linda was trying to bring up.

I think it also should be noted is that some payers are not getting this information because of the way that public health is working. I know in my case, I dropped my phone when I was filling out the little app, and then I could never get back to that space. It didn't allow me to put my insurance information in. So, if my insurer didn't provide an alternative way to put the info in, they would not know. And in the case of my family member, their payer has not provided that information. So again, there's no way for them to know that information.

So, there are all of these gaps that exist in the current system by real examples that are happening today. What would your priority be in terms of how do we address this going forward?

Jim Jirjis
I'll bite on that one just from the provider's peach. To me, it seems like the highest priority would be to get everybody to be incentivized to do it one way. Solve many to many problems. And I don't want to jump to a solution. It could be a learned intermediary, it could be technologies, but instead of all the different public health departments having different requirements, etc., if we made a move toward incentivizing people to be working on a national solution. Because, like Brent James used to say, it's more important that we're doing it the same way than that we're doing it right to start with. Because once we're doing it the same way, we can get better and better, increasing iterations of rightness. But right now, we can't even get to the right because everyone's doing it differently.

Aaron Miri
Any panelists?

Linda Thomas-Hemak
I think it's really a critical time to think about increasing our ability to track, collect accurate, and complete demographic data. So, I think there's no question we're going to be building new and better IT tools as a result of the pandemic and the investments that are being made. And even if not ready to make the policy decision to collect more demographic data or different demographic data, if we don't build the fields into the system when they're brand new, it makes making that policy decision down the road incredibly difficult.

So, building out more race fields, multiple race fields that can be chosen. Building out sexual orientation, gender identity, if necessary, the difference between gender and sex in the system now and then allow policy makers and decision-makers to make the decision at the time right for their organizations. But if we don't build it at the front, we've missed the opportunity.

Lilly Kan
This is Lilly here, and I think I'll just add – Linda. Thank you so much for those comments. And I think what you've highlighted also is layered on a foundation of needs and challenges that we've seen in the adult immunization data capture space. And so, there are a lot of conversations that have happened to acknowledge that and to think about how we can use the current COVID circumstance and some of the challenges we're seeing with systems not being able to capture that data or connect to the systems that may now have that information.

I know that Mary Beth Kurilo from AIRA is going to be talking later today and will certainly be touching upon those issues. But within this community, that includes both the health information technology and healthcare and health data space with the immunization stakeholder space. It's a huge, it thinks, opportunity and needs to leverage the momentum to this solution and problem solve.

Linda Thomas-Hemak
I can't resist, and I really appreciate it, and here's my punchline. Give me the information that I need to do my job and trust that I'm going to do the right thing for the patients and families, make it visible, make it real-time, make everybody engage in flowing it, put out the sanctions for information blocking, and please,

for the love of God, don't allow the people between the government and the provider community to modify the metrics and change the rules of engagement. We have a PDMP that's absolutely beautiful, and I can't see methadone in it as an addiction doctor. Okay, stop the exceptions.

Aaron Miri
Wow, Linda, I appreciate that. And actually, echoes the stuff that my medical staff tells me all the time. One of the biggest challenges we've seen, particularly since we've done an entire continuum here at public health with the contact tracing, case reporting, vaccines and what not, and the lack of a unique patient identifier and linking people across sites of care, and now even with pediatrics, linking mom and the baby, and those kinds of things because of a lack of a UPI and what we have to do behind the scenes. So, my physicians say the same thing.

Okay, next in the queue, we see Clem McDonald.

Clem McDonald
Yes, I wanted to comment sort of synchronizing with some of the other primary care physicians because I did that for 35 years. I think people forget that every time we ask for more data, it's more time. We did a study that shows with the existing computer systems, it's an hour and a half taken out of a physician's life, out of their free time. And primary care physicians are free for that reason. So, you've got to be very conscious of that.

And one of the ways I could capture – if the physician is supposed to be reporting the fact that he's found an infectious disease, most of that is going to the HIA in some of those states, let them report it. Plus, these labs are going to report it directly to public health anyway. And so, we really have to be careful of the burden we're putting on and driving these people out of practice.

Aaron Miri
Here, here. I wish there was an amen button, right. Okay. Any panelists want to respond to that to Clem? All right. Next in a queue then is Micky Tripathi.

Micky Tripathi
Great. Here let me grab my camera going so you can see my face. Great. This is a question. I think it's primarily for Linda and Jim, but I certainly welcome anyone's responses. It's really just following on Linda the comment that you and just made prior to Clem's comment, which was related to the information going back to you as providers.

I'd love it if both of you could elaborate a little bit more on that. We've talked a lot about the flow of information from provider organizations to public health, but we would love for you to elaborate more on what kind of information you'd like to get back that you see as informative and actionable.

Linda Thomas-Hemak
I'll give you a COVID example. I'm in the middle of a primary care workflow, and somebody shows up who broke his hip, went to a hospital, went to a nursing home, and there was a large federal contract to give him a COVID vaccine. And there was an honor system for whoever got the margin on that and the resources to do it to put it in a system or vaccine registry that's visible in my workflow. I jump in the registry. It isn't

there. He doesn't have a CDC card. He's not sure which one he got, and he doesn't know which pharmacy did it. And so, then I have to stop my workflow because even though you could have interchanged the vaccines, I want to be the do goader who gives him the right thing, and I don't have the information about the first shot, which is a really just fundamental, Level 101. If you give it, enter the data.

And that's painful. And when you multiply it by the number of times it happens. It also has serious ramifications because I had a patient who was out of state, her, and her husband both went, windows down. He got a shot in the left arm, she got a shot in the right arm, they were told to pull over. Nobody took their information. They didn't know what shot they got. She comes home, and then she gets admitted, and I get called from the emergency room because she's had a stroke. The hospitalist didn't recognize that it was linked to potentially one of the shots. They certainly weren't going to go outside of their hospital-based EMR to get into theirs and report it. Right now, I'm doing a transition of care. I'm having a conversation about did the shot cause this. Okay. And I have the added burden, but professional responsibility and moral obligation to go to the CDC space and put that in VAERS.

It's painful, and I think not everybody will take that level of a workaround. The first slide that I didn't get to emphasize is the mathematical equation of a known error. It's to do root cause analysis into these problems. And then what we've been doing is we've been doing workarounds. That's our biggest coping skill in primary care. We work around the absence of this, and we're going to have to learn how not to do that to make the problems persistently visible and proximal to your decision-making.

Jim Jirjis
Micky, can I comment on that too? Jim Jirjis here. I want to echo what she's saying. To me, more of the clinical staff and physician's time today is spent either making decisions without complete information, which is dangerous or spending time trying to get the information. And if the information flowed as it should and followed the patient wherever it went, including in the workflow of the EMR, that would pivot the medical and clinical resources to a much higher value.

The second piece looks at HCA we were dealing with – nothing brought the community together like COVID because of ventilators. Some ICUs were full. So, we felt like we were giving a lot of information, but A.) we didn't get confirmation it was received sometimes, and B.) we wanted to benefit from being able to tell in our region what was happening, how many people have COVID, how many ventilators, who did we call. It was really hard to manage our resources, whether they be people, staffing, across the company, across the country, or resources like equipment, medicines, reagents, testing. We were on the dime trying to make decisions like that.

We had to build our own internal dashboard because we're sort of a micro chasm. If only we had access to a federal system that allowed us to collaborate and make resource decisions, it would have markedly improved.

So, there is sort of a workflow-centered answer to your question I concur with Linda on. But there's also management leadership around resources during a crisis. And the tools we built allowed us to do it within our walls, to the exclusion of other non-facilities.

Another one's a hurricane. When we have hurricanes, we have to transfer people, right. So, we built systems inside to determine which patients are on a ventilator, for transport reasons, which can walk out, which need an ambulance, who's on a drip. And our data systems capture all that. And so, when a hurricane hits, and we don't know when it's going to change paths, we're able to de-risk a hospital by planning transport and pivoting it. Imagine if the entire state of Florida had that, not just HCA.

I hope those are two good examples of what opportunities we're leaving on the table if we don't accelerate what you're trying to do, Micky.

Aaron Miri
We have a few more minutes left before public comment, is there any other member with a question or anyone online who can't raise their hand for a question?

Clem McDonald
This is Clem. I can't find my hand right this minute on the screen. And I'd like to really highlight and emphasize what Jim just said. What we really need – much of this would be solved if we got TEFCA running. I think that's what you're saying, Jim. What can we do to accelerate that so that the information flows without a lot of work and we have better care and less waste of people's time chasing data?

Linda Thomas-Hemak
It's Linda. You know I think that one piece of advice that is a simple and straightforward one is that I think when we look at the meaningful use campaign, there was a language challenge because what it was asking people is can you do this, but it wasn't asking them are you doing this, and it certainly wasn't telling them you must do this in terms of turning on the connection. So, everybody was claiming it was there, but the functionality was not released in daily practice, and the precluded iteratively enhancing it and making it agile.

Aaron Miri
Good point.

Clem McDonald
Actually, it was even worse because they declared – somehow, labs definitely weren't sending all their labs with codes on them properly. And the ONC decided they were. And the labs themselves said they weren't. We took it off the table. Said we don't have to worry about that anymore because it's being done, but it wasn't.

Aaron Miri
We learn from the past. Good comments there. But next in the queue, I see Arien Malec.

Arien Malec
Hey, thank you. This has been a fantastic presentation. I sort of summarizing the lessons from this presentation as every time we add burden reporting burden in the system, we reduce the fidelity of the data that's being reported up and down. And we reduce the opportunity for clinicians to operate at the top of their license.

One comment is that I think there was a perspective that we don't have, for example, standards for race/ethnicity. In almost all of these cases where we believe that the issue is lack of standardization, we're going to find that we have a more than adequate standard for representation, transport, etc., and the issue is that we, as I think we've noted multiple times, we haven't connected and wired the systems to use the standards that are available.

So, for example, the CDC race/ethnicity code goes down to the nth level of detail that we would want and need to track and manage. But if we haven't source normalized the data and if that data doesn't flow through our interoperability mechanisms, that information is not going to be available. So, I just encourage people not to look at lack of standards as the issue but instead ask where the incentives are and where the information flows are that allow those standards to get used.

But again, I think the key insight from this panel is that when we don't connect these flows, we're not actually reducing the burden. We're increasing burden. I think sometimes the talk on interoperability and interoperability requirements has been a burden add talk because we're forcing people to do stuff that may be unnatural. And I think sometimes we don't see the burden that we add on the other side of this when we ask people to do manual workarounds and hacks and shims and separate procedures for something where the information could just flow.

This has been a fantastic panel. I just thank the panelists.

Aaron Miri
Any panelists wish to respond to that?

Jim Jirjis
I just have one great point, Arien. I was just commenting in the chat. I think you're right, the standards, it's about connecting them. There's also – the reason I like the whole Sequoia approach, for example, is there's also variation in interpretation on how those things are used, and having a forum where people are getting the consensus around process, how you deal with rejections when there's a blank field, in addition to connecting, having some forum where we're all agreeing to interpret things the same way would be valuable.

Linda Thomas-Hemak
And this is Linda. I just want to say that it's going to auto accelerate when we get it right and learn from our accomplishments. And like so, how you've changed primary care and healthcare delivery with E-Prescribing and the PDMP is just absolutely amazing from the trenches. And we can iteratively improve it and put methadone and maybe even medical marijuana in there, so the addiction doctor can see what's going on. But we've done this as a country, and I think as we do it more and more, what you're going to recognize is that there is this whole untapped capacity of providers and patients and families and social media to help accelerate this change.

Aaron Miri
Great point, and again, the provider community has made a heroic effort of overcoming those challenges. I always tell people, a clinician will do whatever it takes to care for their patients, data be done, they will do it, and they will figure out a way to make it happen. So, you're exactly right. Hopefully, we can get there.

Okay. I will give one more opportunity to HITAC. Any other questions or comments or hand-raising or folks on the line? Okay. Otherwise, then for this panel, thank you all very, very much. This was a fantastic discussion. I recommended that everyone on social media look for the hashtag HITAC. You'll see tons of comments people made, juices going, thoughts going, it's great conversation, the whole point of this. So again, thank you to all the panelists for today.

So, with that, Mike Berry, are you on the line? Do you think we can go to public comment a few minutes early?

Public Comment Period (02:41:17)

Mike Berry
We can do so. Operator, can we open up the line for public comments?

Operator
Yes. If you would like to make a comment, please press star one on your telephone keypad. A confirmation tone will indicate your line is in the queue. You may press star two if you would like to remove your line from the queue. And for participants using speaker equipment, it may be necessary to pick up the handset before pressing the star keys.

Our first comment comes from Janet Hamilton with CSTE. Please proceed.

Janet Hamilton
Thank you so much. I just wanted to thank the panelists that just concluded as well as the ones from this morning. I am Janet Hamilton from the Council of State and Territorial Epidemiologists, and our epidemiologist is on the frontlines of the COVID response. I really wanted to harken back to a comment from Jim Jirjis on the last panel, where he said something along the lines of, and forgive me for the paraphrasing, that clinical staff time today is making decisions without all of the information in front of them, and if the information flow, we would have much better decision-making. And I think we could say the exact same thing for public health.

And I think it's crucial that as a community and as a group, we start bringing these conversations together so that it's less of decisions in healthcare and decisions in public health and then the best policy decisions that we can make to improve health for all. We're making decisions in public health, missing 50% of race and ethnicity information. We're not able to make the best decisions possible. And I think this is a good time for us to look at this in a new, different, holistic kind of way so that we can have better health for all. And just really appreciate the discussion.

Aaron Miri
Excellent, thank you for that. Are there other comments, operator?

Operator
There are no more comments.

Jim Jirjis

Aaron, Jim Jirjis, I can respond to that. There's a cute little catch phrase that may or may not be desirable, but when you don't have – somebody earlier mentioned give me the information I need when I need it, and I would add, and nothing more please, we've heard that before. Because if you don't have that, then you only have two choices, you either wing it or wait, and both of them have cost to the patient and to the system.

Aaron Miri
Well said, sir. I like that anecdote. Okay. So, I just want to make sure one more time that there's no one else on the line. Is that correct? Did I hear you right?

Operator
That is correct.

Aaron Miri
Okay. Good. All right. So, with that, if there are no other comments, then I believe we can give you a couple of extra minutes on your break. That way, maybe you can grab maybe a full sandwich or half a sandwich or whatever it may be. But we definitely need you to be back here at 12:30 prompt and sharp, and right on the money, so we can get started on the next half of the day.

But again, I want to thank all the panelists, the HITAC, all the listeners. I see a tremendous amount of people that are listening in and just thank all of you. Excellent discussion. That's exactly the point of this.

So, with that, I will let you all go. Again, 12:30 sharp, and we will see you then.

Mike Berry
All right. Thank you very much, and welcome back, everybody, to the second half of the May HITAC meeting. Just a reminder that we will have another public comment period towards the end of the program, and of course, the public can make comments in the public chat as we're speaking.

Also, all materials presented today can be found on the HITAC calendar on healthit.gov. And with that, I'd like to turn it over to our HITAC co-chairs, Aaron Miri and Denise Webb, to kick us off.

Data Needs During High-Consequence Public Health Threats & Discussion (02:44:34)

Aaron Miri
Thank you so much, Mike. I appreciate that. And so welcome back, everybody. Hopefully, you got some lunch and are ready for the next half-a-day session and presentations. Again, I think all the panelists from this morning. I thank the HITAC and all the community that's listening. What an amazing and robust dialog that we've had, really going into some very meaty topics. Also, some orientation for the public in the HITAC annual report every year that's sent to Congress. That's mandated by law. And a lot of public health items can also be found in there and suggestions, lots of tactical items around beta data standards and others if you're so inclined to learn some more about some of the topics we're talking about today.

All right, so with that, let's go into the next fun chat here. It's around beta needs around high consequence public health threats. And we're going to start off with Dr. Joseph Kanter.

Joseph Kanter

Thank you, Aaron. I really appreciate that. I need to apologize to you and the group for having some tech issues with the video, so I can't get the video feed to work, but hopefully, the audio is coming through. I'll go ahead and get started with my testimony.

Good afternoon, members of the Health Information Technology Advisory Committee. I think you for the privilege of addressing you today. I am the State Health Officer for the Louisiana Department of Health.

In the 14 months and four days since we identified our first case of COVID-19 in Louisiana, nearly 10,500 families have lost loved ones. All of us have made sacrifices of varying degrees. The team at the Louisiana Department of Health, I'll say some of the most committed and tireless public servants I've had the pleasure of working with, continues to work diligently to provide the data that informs decisions as large as state-wide mitigation measures and acute care capacity expansions, and as granular as when a family might feel comfortable coming together after months of distancing.

Our team benefited from strategic investments in public health data technology infrastructure in the years following Hurricanes Katrina and Gustav. We also identified our fair share of gaps and vulnerabilities and are eager to continue addressing these.

I would like to share some of our success, opportunities, and lessons with you. The experience of repeated severe weather invents, particularly large disruptive storms, such as Hurricanes Katrina and Gustav, led to strategic investments in health information infrastructure, which have bolstered responses to public health threats in the years since. One such example is the development and deployment of Louisiana's emergency support function 8 or ESF-8 portal. The ESF-8 portal, a homegrown communications system made possible through HHS, hospital preparedness program, or HPP grant funding, provides for bidirectional communication with all hospitals, nursing homes, assisted living facilities, intermediate care facilities, and other licensed facilities by the Department of Health.

Separate modules exist for bed availability at surge capacity, operating status, including generator and fuel status, security status, situational updates, and security updates.

Formal rulemaking in Louisiana has established a requirement for daily updates of most licensed facilities, of which about 1,500 are currently enrolled, comprising approximately 4,000 individual users. This portal has been instrumental in our ability to coordinate hospital and nursing home evacuations, as experienced most recently during Hurricane Laura, and route mass casualty incident patients to appropriate facilities.

During the COVID-19 response, Louisiana's ESF-8 portal proved invaluable in three key areas. First, as cases and hospitalizations rose exponentially in March of 2020, threatening the capacity of our acute care system, the real-time hospital census information available to us through the portal allowed for effective load leveling of patient volume throughout the state. It also allowed for predictive modeling of short-term hospital and ICU census spikes, which informed our critical investments in alternative care sites and auxiliary licensed care providers.

Second, the portal afforded real-time visibility on the usage and supply of ventilators throughout the state, allowing targeted redistribution and informing emergency procurement decisions.

And third, as the data request by HHS and hospitals evolved throughout the pandemic, we were able to integrate additional data fields into the portal, synch with the HHS tele tracking platform, and save hospitals the burden of dual reporting.

Identified areas for improvement in portal capability include interoperability with electronic medical records to alleviate the need for manual data entry by hospitals and other facilities and improved end product GIS mapping capability.

An additional success during the COVID-19 response for us has been our experience integrating disparate data sources to improve the completeness of racial and ethnic demographic data pertaining to testing and vaccinations. Similar to many other states, our first pass demographic data suffered from an unacceptable level of incompleteness. In a rush to launch the vaccine campaign, unoptimized electronic medical record linkages with our immunization information system, or IIS, incomplete entries by vaccine providers, and inconsistencies within our own IIS yield reliable demographic data in only about half of all instate vaccine administration.

We were able to mitigate this by cross-referencing our vaccine administration database with existing data sources, such as Medicaid logs, the hospital admits discharge transfer notifications, and Office of Motor Vehicle records. The ability to reference Medicaid records was particularly enabled by Louisiana's 2016 expansion of the Medicaid program and the housing of that expanded program within the Department of Health's umbrella structure. This cross-referencing improved Louisiana's racial demographic completion rate to 93% of all vaccine doses administered in the state.

Our biggest data challenge to date during the pandemic was seen in the need to rapidly scale up and staff up our information system operations. Years of defunding have trimmed public health departments like ours to leaner organizations, not easily able to surge when a crisis emerges. The data systems we relied on during the pandemic required significant staffing resources to onboard new users, troubleshoot technical problems, and conduct provider relations and quality assurance checks on incoming data.

We found the quality and timeliness of the data entered into our portal, lab management system, and IIS suffered when staff was not available to monitor user's inputs and quickly address insufficiencies. It is labor-intensive work for which our pandemic workforce was undersized.

Aaron Miri
I'm going to stop you right there. You've got about 10 seconds.

Joseph Kanter
I'll end there, and I appreciate your time and your attention. I look forward to having the discussion. Thank you, Aaron.

Aaron Miri
Fantastic. Thank you so much, Dr. Kanter. Really appreciate that. And I appreciate all speakers keeping it to about five minutes, so we can have a chance to get to a dialog afterward, so thank you again. Next up, we have Jonathan Greene.

Jonathan Greene

Thanks, Aaron. Appreciate it. Thank you for the opportunity to speak to all of you today, and thanks for bringing this group of data experts together. I'm pleased to speak with you a little bit about how ASPR leverages data from our response activities related to COVID and how we're taking lessons learned from COVID to be better prepared for future responses. Certainly, we could spend eight full hours talking about the data needs of the COVID response right here in ASPR, but I'm going to touch on just a few key areas and hopefully prompt some discussion.

In discussions about data, it's not just having access to data or information, but the ability to understand what it means, the analytics applied against it, and then trending over time to tell us whether the interventions that we've chosen are making a positive difference in the problem set.

There are several key questions that are most pertinent to ASPR in this space. One of them is how we can better use data for critical resource allocation, including medical personnel and supplies. And I want to focus on the personnel and supplies part of it today. Another question, how can we best leverage modeling and forecasting for response decision support? And what is needed to improve sharing data and analysis regionally to support state and local response personnel?

I think very early on, leaders in government were asking what seemed to be very simple questions, as we recognized that there were PPE shortfalls or a projection for more ventilators that would be required. And simple questions like, well, what does the supply situation look like right now? How much PPE do states, and then drilling down into individual health systems and facilities, how much do they have? And the questions soon became much more complex than they seem at the service, and it proved to be a critical blind spot for us early on because no such structure to ingest that kind of information and understand it. There was zero visibility into the commercial supply pipeline for medical supplies.

And therefore, when we have competing requests from 56 states and territories for a very, very small number of resources in the strategic national stockpile, for example, trying to weigh the criticality of one request versus another and understanding what the true supply chain looks like in that area and how best to ameliorate that spot shortage, is a real challenge without the type of data that I explained.

Operational timelines are really fast-paced, as we know from all kinds of responses, and that was certainly true with COVID-19. An offer requires modeling and analysis to be done with incomplete information. However, what we learned was the ability to have a discussion between the folks that are making requests or asking for data and modeling with the folks who are going to be doing that modeling greatly improves the process and reduces the opportunity for error or misinterpretation of data. At the end-user to a lot of the models and analysis, I recognize the need to have a dialog with the analyst to ensure that they understand the operational requirements that I was looking to meet, and at the same time, appreciate the challenges and try to work through other proxy measures for data elements that simply just did not exist.

And ASPR developed short-range forecasts to include an ensemble of hospitalization models, specifically designed to make critical resource allocation decisions for medical personnel, staffing, and augmentation. It was a tremendous demand signal for federal responders to help support medical surge operations across the country. And trying to understand the criticality in one jurisdiction and how an influx of personnel would

make a difference there, and what type of personnel and what numbers, and oftentimes making very, very difficult choices with very constrained resources.

Prior to COVID-19, there was very limited visibility to the medical supply chain within the United States, which I mentioned before. And it made really difficult, as I said, as a blind spot. And one of the end results was we developed a supply chain control tower in March of 2020. And it was transferred from FEMA to HHS in September. Now the control tower aims to provide the US government medical supply chain visibility for the current pandemic and future pandemics and medical events.

Now, because we're so close to the event, we still have a great deal of collaboration and cooperation across the spectrum, whether it's health systems, state and local government entities, suppliers, manufacturers. My hope is that over time the further we get away from the pandemic situation that we don't return back to the default where there's less information sharing. I think we are in a better place today and have more data sharing between agencies, whether the state, federal, local, and private sector, to enable us to make really good allocation decisions, and most of all, understand where we are in terms of personnel a supply that we may need for response operations.

And I'll feedback on my last 10 seconds. I hope I spawned some conversation topics, and I'm happy to answer any questions you have.

Aaron Miri
Jonathan, thank you. And yes, from the providers, I'm certain there will be a lot of questions and inquiries. But regardless of that, thank you for all the work that you and your division are doing. It's not easy at all to get your arms wrapped around that. So, thank you for that.

Okay. Next up, we have Sam.

Sam Imbriale
Yes, thank you: good afternoon and good morning to everybody. So, thank you for the opportunity to speak with you about this extremely important topic. It's been a long 17 months for all of us, the beginning of January of 2020, ASPR and CDC modeling and data groups began meeting regularly to discuss the modeling and then analysis needs from the evolving outbreak. We relied heavily on strong interagency relationships that were developed over multiple years of modeling and data analysis coordination activities. We identified the need for a common set of assumptions that could be used for modeling based on very limited data and known science at the time.

Without any real-time data sources, a pre-COVID static data source only captured reporting hospital bed availability on an annual basis without any indicators if limits were due to space, staff, or other issues, which resulted in a lot of difficulties estimating actual capacity across the country.

Within several months, the data landscape changed drastically, and we started to get very detailed and granular data at the facility level on capacity, staffing, and supplies. Data infrastructure was either built up or modernized to be able to keep up with the fast operational tempo. Existing capabilities such as the CDC's national NHSN system became essential, and new systems like HHS Protect had to be developed and implemented extremely quickly.

Critical resource decisions were made based on these data, ventilator allocations, PPE, and natural disaster medical teams were a scarce resource, and requests were coming from across the country, as John Greene stated already.

After more than a year of significant improvements in data collection and infrastructure, we've made tremendous progress in the data space, but we need to continue that momentum and not lose any of the ground gained during the COVID response. We need to continue to support tools such as HHS Protect or some other shared integrated data sharing and analytics environment and continue to modernize the data infrastructure across the public health space and ensure integration and coordination amongst these systems from the local level to the federal level.

This needs to be all hazards. We've identified the specific data elements needed for forecasting the trajectory of the COVID outbreak, but we need to identify the minimum data elements for a sustainable capability, as well as what's needed for other types of public health emergencies such as hurricanes and other natural disasters.

This last year has reiterated what many of us already knew about the importance of data, but the implications were far more significant as critically limited resources, including PPE, ventilators, and medical personnel, were a nationwide need.

In summary, data collection analysis must evolve as we learn more about the response and what decision-makers require. Collaboration and coordination are essential at all levels, both public and private. A common operating picture, centralized analytical environment, and integrated data collection tools are critical. And data limitations will always be a challenge, but we've learned a lot over the last year, and these lessons need to be remembered to ensure continued success in the disaster space. And I will give you back more than 10 seconds.

Aaron Miri
Thank you, Sam. Appreciate that, and I appreciate your succinctness. But right on the money with your presentation. Thank you for that. I'm sure there will be lots of questions for you after the fact. Okay. So, we're running about two minutes ahead. That's good. So next up is Dr. Fine.

Annie Fine
Hey, good morning, everybody. Or good afternoon, I guess. I am speaking from the perspective of a local epidemiologist for the New York City Department of Health, who was very much involved with the epidemiology data for the COVID-19 response. You can go to the next slide, please.

So, thank you so much for giving me the opportunity to speak with you today. As you all know, the need for rapid, accurate, and comparable data at local, state, and federal levels is enormous in an emergency such as this one and future emergencies.

Some of the challenges that were unique to this COVID response but will be seen in other responses in the future include the gigantic volume of data that local and state health departments had to deal with just to count cases and to calculate key metrics, which placed enormous stress on existing systems. We also had

to onboard new reporting sources, such as point of care testing and provider officers that had never reported to us electronically before. We also had to provide information that is very difficult for public health, traditionally, to get. Normally we rely on case investigation, a very manual process, individual case by case, but we were asked to report out on hospitalization and death outcome measures, which normally are quite difficult for us to get in real-time. Also, treatment information, race/ethnicity, occupation are just data points that we were not set up to have easily at our fingertips.

And then the need to quickly answer key epidemiologic questions about the virus itself, the clinical spectrum of disease, its transmission properties, and the response and effectiveness of all of our countermeasures and interventions. And then finally, the very appropriate focus on equity, which we had to do proactively in order to really eliminate and address the disparities across race/ethnicity, poverty, and other parts of our population. Enormous injustices that we had to highlight and address.

So, what do we need to effectively respond in situations like this? So, first of all, we do need a really strong partnership between the federal, state, and local levels in all phases. Preparation and during the response. And our data systems really need to be fortified, robust, tested, able to handle these large volumes. We need to keep the primary data points that are aggregated at the federal level as simple as possible so that they are easy to report and collect and aggregate and not waste a lot of time on very complex data systems that take a lot of time to develop and report out on.

We need to standardize and clarify definitions of these data points, including things just as simple as cases, hospitalizations, and deaths, which are not as simple as they seem. And use epidemiologically meaningful data. For example, not the date something is reported, but the date something occurs in real-time. This has been a major issue across many jurisdictions.

We need to develop and implement best practices for the collection of race/ethnicity at the point of care where the person presents for care. And that data needs to be standardized and then be able to be transmitted all the way up the chain.

And then for the key questions, we do need to have some kinds of very rapid ways to develop a simple but rigorous epidemiologic study that could be deployed to really collect vital information to inform the response—next slide.

So, this is kind, and if you build it and connect it, it will get used. And I've seen this happen in my own work so much that if you anticipate ahead and prepare ahead of time, being strategic and forward-thinking, and thinking what will be needed and how do we build these connections to be able to connect data sources and answer questions, they will get used. So, we need to connect up systems like surveillance systems with vital registries and with immunization registries. Connect laboratory data. Right now, we're having struggles connecting whole-genome sequencing systems with our surveillance systems, and we need to improve our ability to match people.

We need to connect public health systems with electronic health record data. This is critical. There's so much clinical data sitting electronic health records that we cannot currently really leverage. And we need to have standard data definitions, questions, question packages across jurisdictions, and then we need to focus on making the data public in formats that are easy to access and understand.

And I really look forward to a conversation about all of this important work. Thank you so much.

Aaron Miri
Excellent. Okay. Next up, we have Terra. Terra, are you there?

Terra Abrams Ankrah
Yes. I'm here. Can you hear me?

Aaron Miri
All right. Yes, ma'am.

Terra Abrams Ankrah
All right, good afternoon. Thank you for this opportunity to share information about one of the interoperability projects completed by the District of Colombia Department of Health last year. My name is Terra Abrams Ankrah, and I the State Registrar for Vital Records in DC Health and the district government. Next slide.

So, during 2020, the Department of Health completed a project to interface its electronic death registration system with the Office of the Chief Medical Examiner's case management system. The messaging between the two systems is FHIR-based, and this is a high-level workflow of how that project or that workflow works between the two systems.

Future development is that we're looking into interfacing the laboratory information management system with the OCME's case management system. Those plans are in discussion. Currently, in production, we have a system where the medical examiners enter their investigative report into their case management system. They click a button in their case management system to send the data into the electronic death registration system using FHIR messaging. And once the data are received in the electronic death registration system, the report of death is registered and automatically submitted to the National Center for Health Statistics. Next slide.

At a national level, through funding provided under the Offices of the National Vital Statistics Cooperative Program, we participated in this project with our Chief Medical Examiner's Office to support the modernization of national mortality reporting. FHIR messaging is used, as I mentioned on the previous slide, from CMS to EDRS to facilitate the timelier data transmission to local and federal partners.

Locally within the district, we've streamlined our process such that medical examiners are no longer required to enter data into two systems, so we've reduced the double data entry. And also, within the case management system, we have employed NCHS's death at its specifications so that data problems can be resolved at the point of entry before they enter the electronic death registration system. Next slide.

This is the first successful implementation between a medical examiner/coroner system and an electronic death registration system using FHIR messaging. We're very proud of that accomplishment. We're also proud of the fact that the two agencies were able to complete such a large undertaking of a project during the year 2020 as we all navigated pandemic response. Again, the direct impact was faster reporting of vital statistics, faster ability to participate in the National Vital Statistics System. Next slide.

So, part of this conversation of how we continue to modernize public health data flow within the country. And so, here in the district, we're exploring other opportunities for interoperability within the vital statistics system. We've also been in contact with many of our local hospitals to discuss how we might interface our EHRs with their systems and fully automate that data flow loop.

Thank you very much. I'll give you back a minute.

Aaron Miri
All right. Thank you very much, Terra. That was a fantastic presentation, and vital statistics is critical. That's one of the things that also wide-bearing, depending on the state to state. So, look forward to seeing some questions that the HITAC members are going to have.

Okay. So, with that, I think that's the entire panel. So, if all the panelists will turn their cameras on, we can get to the group Q&A component. And I would ask during that time, I would ask the HITAC to please raise your hand so we can see you with your questions, and I will call upon you in the order that you are. All right. First up in the queue is Mr. Les Lenert.

Leslie Lenert
Hi, thanks. I have two questions. 1.) How far did we get at able to predict where the pandemic was going next and linking that to both enhancing the commercial supply chain and dispensing resources from the stockpile? Were we really able to get two weeks in front, or are we still kind of driving in the rear-view mirror with that? And then my second question I'll get to after you answer that one, but it's more on FHIR and public health.

Sam Imbriale
So, this is Sam, and I'll respond and let John add on anything if he wants. But I think it really depended on the geographic area in some of the early data collection. Some areas were getting pretty robust reporting from state and local government, from healthcare systems, and then obviously, all of the testing data that was coming into the CDC. So, it did vary geographically. Some areas we were able to lean a lot further forward on.

We started to get a lot more of the commercial supply data in too. So, all of the distributer data for the main top PPE categories from the six big distributors and started to see areas that were getting increased orders, but also the inability to fill orders, which also indicated some significant challenges and the PPE burn, etc. in those areas.

So again, it really depended geographically, but as we got further along into the fall wave, we were able to lean further forward as well because reporting started to be at a much higher percentage. We were close to around 100% of facilities reporting across the country in the early fall. John, anything you want to add to that.

Jonathan Greene
Yes, yes. Just a couple points. Thanks, Sam. That's really great. A couple of things I want to add is that the information from the state and local collection, whether it be at the health department level or the health

system level, is really needed oftentimes to get context. So, you'd get week after week of facility reporting that they have less than two days' worth of PPE and 95 masks when we have visibility into the supply chain, and we understand that there is the availability of N-95 masks in the system. What does it really mean when somebody has less than two days' supply, and oftentimes what we're finding is that supply of that particular mask that that particular health system wants to use because it has all of its employees fit tested for that device, that particular one is not available in the quantities that are necessary when the overall availability of N-95 might be greater? That's one area.

And the other area, and I think we gained a lot of ground on this piece, was that the strategic national stockpile, we need to be more transparent about what's in it and what the purpose of it is. And, of course, many of us realize the purpose is to ameliorate spot shortages, but not to take the place of the supply chain. And so, gaining better visibility of what the medical distributors and what the supply chain is able to supply customers, and then understand where there are pinpoint spot shortages where we can use assets from the strategic national stockpile to build that bridge while we work with manufacturers and suppliers to remove the roadblock in the system that's designed to deliver a product to the health system in the first place. And we have much greater visibility on that than we had previously.

And I think moving forward, and I think I touched on it in my comments, and I'd note that Sam touched on it as well, that we need to somehow encourage and ensure that we have the same level of collaboration and cooperation in data sharing so that as we move away from this current pandemic into a day to day in preparation for the next event, that we have that similar transparency across the supply chain.

Joseph Kanter
I agree with that. To add a state's perspective, particularly one like Louisiana that had one of the earlier spikes. New Orleans spiked in the middle of March 2020. We were really good, I think, at predicting what the need was going to be on an **[inaudible] [03:16:46]**. We weren't that good at predicting what was going to happen after mitigation measures were entered because we had nothing to go on. So, we were predicting an unmitigated pandemic at that point, for example, to have a thousand extra patients that we had no beds for, and then another thousand each successive week. And so, we built out a thousand-bed field hospital in our convention center with an option for a second thousand beds. We weren't good at predicting what was going to happen after a stay at home, masking, and the other mitigation measures. We got a lot better at that as the spirit in this pandemic went on.

Jonathan Greene
Yes, I would agree and say that the wildcard, of course, is compliance. And one of the take-homes – it's not specifically a discussion about data, but it is about information and, probably, more importantly, misinformation. In all of my years of working in this field, I never in a million years dreamed of how social media and alternative sources of information would drive behavior in the population as opposed to following good solid, scientifically based guidance. And that's a challenge that I think that A.) Researchers are going to be doing a lot of work for many years on how social media and alternate sources of information affected our ability to respond to the pandemic.

But also, we as folks who work in this space need to have those discussions on how we work towards countering that message in moving forward. And making sure that as we make these scientifically valid

determinations of what should happen in a mitigation strategy, that the populous will take that information onboard and ask in their own best interest.

Leslie Lenert
I think that one of the things you may need to focus on also is taking your systems that are working at a federal level and making them available to state and local governments, so they don't have to replicate those and that they all – everyone can be working off the same playbook, basically. And then instead of allocating things based on population size, we're really focusing on allocating according to need and projected need, I think is really important. But to do that, you have to get your modeling infrastructure out to everybody and then have everybody be able to use that locally to have that kind of effect.

Aaron Miri
And I would also add to that, to be able to forecast out, John, you would need to know the case data, right, and what do we suspect is happening in the community. So, for epidemiologists like that, defining others who are an epi team to say we think this is what is happening. This is what the case volume looks like. This is what we think exposure has been for that week of the forecast, the demand, for, let's say N-95 or PPE, as necessary.

So, it's not just I would say material systems like Les is saying. I would say all systems, right. Contact data, materials management data, of course, EHR data and clinical data and whatnot, and getting that flowing.

I would also ask the question here; we have another question. This is for Terra, actually, around vital statistics and records from the communities that are particularly rural and that they're not on electronic systems. And this has been something plaguing a lot of states like Texas and others, where you have rural counties that are under counting, or they're still working on paper. How do your account for that? Are there ways to be able to extrapolate and expand in an electronic manner to get those records digital and then be able to react faster during a situation like this? What are your thoughts?

Terra Abrams Ankrah
Well, I would say in the district, we are fortunate to have had electronic death registration since 2004. WE, up until about 2018, were still collecting paper death records for events that occurred outside of an institution. And in 2018, we made it mandatory that all of our records be entered into our electronic death registration system, which did give us the ability to have the records entered into our system closer to the event and be able to drive the registration process a little bit faster, working with the funeral directors, working with the medical examiners and the hospitals.

So, I would say that while that's a hurdle that we recently overcame in 2018, that more states should work to adopt laws that would require their providers to participate in electronic registration of vital events so that again, the state's staff can work to drive registrations faster.

Aaron Miri
Interesting. And I would agree with that. I'll give you an example. We're still dealing with an opioid issue, a major issue, which didn't go away. In fact, it got worse as this pandemic occurred. And we actually, in partnership with Texas DHHS, built opioid syndromic surveillance platform because of this exact issue. So,

the point is the more states that can go electronic or mandate electronic submission, the faster the provider community can react and try to get in front of these epidemics.

Sam, from you, specific components in terms of data modeling or data visualization, maybe standards that could be adopted, a playbook, per se, in terms of the provider organizations out there making some of the public health efforts in partnership with their public health authority, like a UT Austin or similar. Is there a playbook to point folks to in terms of how to model and visualize and really develop that common language, that public trust, to understand what's going on? Do you have any recommendations for that?

Sam Imbriale
Yes. So, we try to do a lot of information sharing on best practices and a lot of our methodologies and codes for our models through HHS Protect and through COVID data tracker, which again, relying heavily on CDC to be that trusted source of public health data and public health modeling, especially with the ensemble model that they put together, which brings together all the different federal and private sector and academia models. So really leveraging those trust sources within CDC and the more robust kind of communication strategies that they have to get information out there.

But no, I mean, there's not a single one-stop-shop for kind of those modeling best practices and those modeling methodologies, but it's definitely something that I think would be beneficial. I know a lot of emphasis around the COVID data executive order is to kind of make sure we're enhancing that public/private partnership around data sharing and making data and information analysis more public. So, putting in the methodologies and the source code around how we got to those models so that other entities can not only do the modeling themselves but also kind of check our work, because a lot of times it's really beneficial to have multiple different groups looking at the same model so we can all validate the analysis, validate the data. So, I think that's definitely something that would be really beneficial, kind of a centralized repository or centralized location for modeling best practices, modeling source codes, modeling methodologies.

Aaron Miri
Got it. Any other comments from the panelists on that one? Okay. Dr. Fine, what about you. So, one of the things I've noticed, and I've had the pleasure of hearing you speak before in New York City in some of the early pandemic response and the phenomenal work you and your team did in sending both ways, multiple ways, of this crisis. Was there a key component in terms of data sharing or a key agency that was a low hanging fruit win early days that really allowed you to get that bidirectional data going and be able to model that from an epidemiology perspective, what's happening, where it's happening in the city, and how to react?

Annie Fine
Well, I think we had done a lot of work already on especially electronic laboratory reporting and automated delivery of that to our surveillance system, which that's the bones of everything that we did. And then we had also established relationships with what are called regional health information organizations in New York City, which are aggregate stores of electronic health record data, so we were able to leverage those relationships, but we did have to build ways to query those aggregate data and match them with our surveillance system.

So, some elements were there that enabled us to deal with this massive influx of cases all at once, but there was still a lot of work and ongoing work, a team of analysts to maintain and run these things. But I think it could even be more seamlessly interoperable and automated than they currently are.

The electronic death registry data was critical. I mean, we did a daily match, and that really informed our ability to monitor deaths, including the confirmed deaths that we matched to our lab data, as well as the probable deaths that had COVID written on the death certificate.

So, there were a lot of components to what we did, but I can still foresee a lot of improvement that could be made with enough time, money, foresight, staff, qualified staff that could even make this work better. So, I think one of the challenges is really the issue of comparability across jurisdictions and interpretation of the data and sharing the data to the national level and how it gets aggregated, and these multiple streams that are going up. There are streams from hospitals. There are streams from lab data. There are streams through case data. And they never agree with each other. So, I think somehow harmonizing, that work really needs to be done, because I think the public was confused at times.

Aaron Miri
Got it. And we've also heard some phenomenal stories in the HITAC from Valerie Grey and others that are doing phenomenal work there in that state. So, credit to you and credit to states that have state-wide HIEs or HIEs of that calendar, like John Kansky in Indiana and others. That's fantastic.

Dr. Kanter, a question for you, sir. Louisiana obviously borders Mississippi and Texas and so forth and so on. Was state-level information across state lines critical? I saw us even as New Orleans and others were starting to become hot spots you are alluding to earlier, here in Texas, really looking closely at the data to kind of progress, where is the population going to be next, and where could a hot spot be? Could it be in Houston or Dallas or whatnot? How did that work for Louisiana? Is that a critical element that we should be looking at as data crosses state lines and those privacy and security components and maybe differentiation there that has to be worked through? What do you think are some of those bugaboos that we should be looking for?

Joseph Kanter
Yes, I think it was a real gap during our response. I'm glad you brought that up. There is a Louisiana that the closest referral center, you know, petitioner hospital, is probably in Texas, closer to there than it is to here, and we had lots of bleeds over, and not just for COVID. For hurricane evacuations, we need to rely on Texas and Mississippi as well.

It is a real gap, and there tends to be – the automation stops at the state border, and then it becomes a manual process as you go to another state, and it does really slow us down. And thinking back to Hurricane Laura and Charles, we had a lot of Louisiana residents sheltering, evacuating, being housed in Texas. The visibility on them and the **[inaudible] [03:27:10]** process was really complicated because, just like you kind of alluded to, the communication systems were not robust once you cross state lines, and I think that's something we need the feds to help us with. It's hard to do just state to state, I think.

Aaron Miri
Interesting. Any other comments on that? Across state lines?

Sam Imbriale
This is Sam. One thing we tried to do again with HHS Protect was allowing border states to have access to their other state's data. There have to be MOUs put into place to do that. We probably could have done a better job of socializing that and discussing that. However, we certainly did try to do that. There were several pilot programs that we tried to do that would give different state and local users different ways to view and access, and visualize their data in Protect, and it was called Project Greenlight at the time.

But a part of that was having a dialog with state users on what they would like and what they wouldn't like. And a lot of the states brought up that they would like to be able to, at least neighboring counties, if not the entire state, be able to share that data. And that gets into kind of the proprietary nature of some of the data sharing. But again, kind of breaking down those barriers and having those kinds of open data sharing agreements and talking more about data governance versus data ownership, I think is one of the things we need to take away from this moving forward, not just for the remainder of COVID but for the next response so that we can more easily share data between state, locals, private and public, and different states.

Aaron Miri
Got it. Any other comments on that one, folks? Okay. Next question, then. Terra, this is for you. Regarding some of the – making sure we have a level playing field from a racial/ethnicity/equality perspective, and that's equality by design which we keep alluding to here at HITAC, from a health IT design perspective.

Is there a better way that we should be thinking about as we forecast out and really work on things like USCDI, now beyond 2.0, 3.0, and now there's the future? And certain elements are vital from a statistics perspective that we really should be thinking about gathering. I'll give you a specific example.

If you look at the NHS in the UK, they did an excellent job of breaking down demographic information and orientation information, others, to allow people to really opt-in local choices. Are there certain things we should be looking at as low hanging fruit to consider as we look at data classes that would really help accelerate the leveling of the playing field from a health equity perspective and ensure that as we collect future datasets that we really are taking that into account by design?

Terra Abrams Ankrah
Well, certainly, the 57 vital record jurisdictions cooperatively participate and the Vital Statistics Cooperative Program, with the National Center for Health Statistics. And we adhere to standards in how we collect data. The tools that we use to collect data are shared with our data providers. So, if we're speaking to mortality reporting, of course, you have in the workflow hospitals, private practice physicians, medical examiners, funeral directors. And so, the data collection tool that we all use, there are standard reporting tools that are advised by National Center for Health Statistics, and in the district, we use those tools.

And so, I think that one of the earlier panelists earlier in the day spoke to allowing, and in this case, mortality statistics, the decedent's loved ones or persons who are caring for the **[inaudible] [03:31:04]** sort of self-reporting that race and ethnicity data to the funeral director. And so, it's very much about how the decedent identified and how it fits within those boxes. Or how their loved ones are reported that they identified within those boxes.

And so, allowing for a little bit of flexibility there in terms of how people communicate about how they identify from a race and ethnicity standpoint would be very helpful at the national level to have those discussions on how to update those standards at the state level.

Annie Fine
Yes. I really resonate with that comment. Because we just went through a process where I work to try to enable the people we interview, people we interact with to identify themselves the way that they do identify themselves as opposed to the way that we box people. And it's a challenge because you obviously have to deal with denominator data that are collected in a certain way too. But I do think that's a very important national conversation to be had and we – for example, just an example, are that people who identify as Latino, Hispanic often do not identify as a race. So, to enable people to say as I identify as Latino or Hispanic, but I don't identify with any of these other races, which should be a legitimate answer, and we should be able to take that information and analyze it that way too. So just as an example, I really think that's an important comment. Thank you.

Aaron Miri
Dr. Kanter, last question for you. In Louisiana, you have a very wide geography of individuals, and it goes back to that equity by design component. And obviously, large urban areas like New Orleans or Baton Rouge or others, and then, of course, suburban and very rural parts of the state as well. And you guys do a great job of accounting for that personnel.

Are there things in their datasets, systems, or design, which was really key in trying to encapsulate the rural parts of Louisiana related to urban, or was it really just data collection in mass, normalization, and extrapolation of analytics to that? What is the secret sauce there that Louisiana is doing that really is keeping you ahead of the curve? Like talking about the DMV. That's brilliant. Those kinds of sofa things, what should we be thinking about?

Joseph Kanter
That's a great question. I think it's investment and investment ahead of time. And I was thinking about this as Terra was answering, and I think your comments were great. I really agree with them.

One of the things about marginalized communities is that's where you tend to have poor quality data because there are not the resources to collect and analyze. And looking at the Louisiana experience, the resources, the infrastructure we had to use during COVID, we would not have had if we had not had the experience of the hurricanes. So that's what allowed a relatively poor state like Louisiana to make the investments. I don't think we would have made these investments if we hadn't had a Katrina and a Gustav experience.

I think other states can learn from that and the feds, but there's a lot of money coming down now. But prior to this, it's hard for states, particularly poor states, to make an investment in this. It helps to articulate the need and what we realize now is you can't build these systems on the fly. You have to have an infrastructure in place ahead of time, and when you don't, it ends up being, as you allude to, the marginalized communities that suffer the most because as you get poor descriptors for what's going on there.

Aaron Miri

Got it. Any other comments for the panelists about this? Making sure it's equality or all, inclusiveness? All right. So, I see we actually have one more question in the queue here, John. This one's for you.

Regarding materials management and the flow of information of HHS, is there a way for providers to reach out and so call a phone a friend? That's Aaron's words here when there's an urgent issue like that. I'll give you a specific example. In Austin, there were a lot of smaller providers. Rural providers didn't know where to reach out. They had an issue with N-95 or other PPE needs, and they ended up reaching out to us, and we sort of became this aggregator and tried to put together a community effort to source. Does anybody have any extra masks? Does anybody have any extra gowns and gloves and whatnot so that everybody could kind of have a level playing field? Is there a way in the future for folks to be able to share those inquiries or datasets ahead of time, even if they're not electronic? They're an individual community provider or rural practice provider, which we don't want to leave them out of this equation? What would your recommendation be?

Jonathan Greene
No, that's a very interesting problem area. As long as we're in a national response, we've all agreed that FEMA becomes the front door in an all of government response. And so, we rely on FEMA, and we partner with FEMA, the FEMA regional representation, as well as the ASPR Regional Emergency Coordinator CADRE. They're the first point of contact to gather that information and bring it back into a coordinated fashion. And between FEMA and HHS and during the height of the COVID response, it was more of a FEMA-centric operation, and as time moves on, it's handing back to ASPR.

But I think to the point of the question is moving forward, we need to have a standing way of doing business that we can collect information and monitor the supply chain as well as the shortage that is reported by individual facilities and jurisdictions without doing it on the fly. And I think that was a great point that Dr. Kanter made is that we all were developing systems on the fly because the systems simply didn't exist, and we were developing relationships that simply didn't exist.

So, we've charged our regional emergency coordinators ASPR side to engage more fully with not only state and local public health, which are their traditional partners, but also emergency management, to build those bonds with emergency management that goes down to every community in the country.

And I don't know if Sam has any additional points that he wants to put forward on that particular topic.

Sam Imbriale
No, thanks, John. I think you covered it.

Aaron Miri
Got it. And this question actually is for Dr. Kanter and Dr. Fine, asking you both. So now we're in the era of vaccination. CDC has approved the pediatric, teenage/pediatric administration of the Pfizer vaccine and others. And as this continues to go along and we're now deeper and deeper to pediatrics, what data elements or data sets should we be looking at maybe a little different in terms of reactions or allergic reactions or whatever else, that we should be paying attention to from a pediatric sense that we learned from the adult side? What has worked well both from the epidemiology and from just a general health perspective, Dr. Kanter, that we should be considering prioritizing again from data elements or data classes

as we look at things and just learning as we go along? So that agile methodology that we like to capitalize. What should we learn from what you two have experienced in the field?

Joseph Kanter
That's a great question. I think one thing, we don't yet have great data connections with private practices. They have small EMRs when they do have EMRs, not typically connected to anything, and that's where we're going to have to get a lot of adolescent vaccinations done because that's where folks are comfortable doing it.

And I think that's one area that we need to build up on is our inner connectivity, not with hospitals but with small practices that typically have not been connected well. Dr. Fine, what would you add to that?

Annie Fine
I think that kids can be different than adults in terms of how they express both disease and infection, as well as other potential reactions to vaccines. So, I think the Very system can capture any adverse events that are pretty obvious. But I do think that there just needs to be perhaps better ways to capture population-wide responses to the vaccine.

And you know, I'm not sure exactly because I'm not in the vaccine field what needs to be different about the pediatric vaccine, but probably not that much compared to really just trying to get it out there. I think that's probably the most important, as you said, to get it into the hands of the people who can give it to the kids.

Technical and Infrastructure Issues: Current Status and Future Needs & Discussion (03:40:23)

Aaron Miri
Absolutely. Well, good. Let me again query the HITAC and anybody on the call for any other questions. We've got about two and a half minutes left. Any HITAC members with any follow-up questions or thoughts for this panel? Or anybody on the call?

Okay. Well, with that, thank you very much to this panel. You all did fantastically. It's great. You're following lunch, and lunch is always the most popular thing of any long day of panels. But regardless, phenomenal job. Thank you so much for the insight. We really learned a lot from you, and we thank you so much for your time and for your testimony.

As a reminder to everybody listening, all of the presenter's testimony, as well as their PowerPoints, are available on the ONC website, and as Mike said earlier, will repeat here in a little bit. But with that, I think we are ready for the next panel.

So, the next panel coming up here is technical and infrastructure issues, current status, and future needs. This is starting to look really forward and really build upon the conversation we just had. And we're going to be talking to some true industry superstars that have literally helped us pave the way and really did a tremendous amount of work last year, and I can't thank them enough and their organizations, as with everybody that's on today.

So, with that, we have my great pleasure to introduce you to Dr. Karen DeSalvo, former ONC National Coordinator, and current Chief Health Officer at Google Health. Karen, your camera you want to hit start and display? Do you want to be on camera? If not, the floor is yours.

Karen DeSalvo
Great. Okay, fantastic. Thank you, Aaron. Good to see you, and I'm really delighted to be here today. I want to thank ONC and the CDC, as well as HITAC, for convening this group on what I think is one of the most important topics that we have coming up in our journey coming out of this pandemic. It's really imperative that we create a 21st Century public health infrastructure that can not only manage the crisis but help protect public health every day.

The scale and scope of the pandemic, I think, has really highlighted for us that not only do we have a great public health workforce, but they were also committed and really want to do the right thing. But on the other hand, that we have some weaknesses in the system due to decades of under investments that I believe the committee's heard about today. And it's a really important time for us to reflect on how we move from using 20th Century tools to manage 21st Century challenges and really get us into a modern public health system that can do what it needs to do. One that is not only vibrant but resilient over the course of the next many decades.

We have to get it right. I think we've learned certainly in the pandemic that there is wrought to do, but if we are not protected by the public health system, one that's got strong foundational capabilities and resilience, it's even more difficult for them in times of crisis.

But the good news is we don't need to start from scratch. And the public health community, as well as many others, including most recently the National Academy of Medicine, have been working to provide the right vision and framework. What we need now is to make sure that we work with due haste on a roadmap to effectuate the kinds of changes necessary broadly for public health, but very particularly for the data modernization, IT upgrades that are going to be necessary to serve the public.

When I was in the Obama Administration, serving as the assistant secretary for health, we had the opportunity to work with public health agencies all across the US and develop what we called Public Health 3.0, which was a vision for 21st Century public health systems. One that included five key pillars, leadership, partnership, data, and IT, structure, and funding. And that framework is still being used today, including by groups like ASTHO, to think about how to build a 21st Century system.

I want to talk about two of the pillars today because I think they're relevant, and they reflect on some of my experiences here at Google during the pandemic. One is about a strategic partnership, and the second is about access to timely, granular, actionable data.

In the space of partnership, I think there have been many good examples throughout the pandemic that have been lifesaving for a lot of people around the world. And the notion that IT and public health should work together, I think just as they are in this hearing, has been crystalized that certainly for me that in the time of the pandemic, what Google has been able to do is a partner with public health agencies like the CDC or state health officials like those in Louisiana, like Dr. Kanter, and work to make sure we can amplify

the public health message for them using our various digital platforms. We do that in search and maps and YouTube and build up opportunities for them to raise their authoritative content and see that the public has the information they need at the right time to save lives. But also address misinformation.

We also, though, find ways that we can work with them more discretely on providing data to help the decision-making. And some examples of work we've done in that space are things like the Community Mobility Reports, which used something we call the business factor on maps to get a sense of how much people were adhering to shelter in place orders early on when we were working to flatten the curve. We can work more globally with academics, public health, and enterprises to create tools like Global at Health, which is designed to enhance disease surveillance and track not only COVID but be useful epidemiologically into the future. And then, of course, we were doing a lot of work in forecasting and trying to be supportive and helpful in efforts like the release of the Search Symptoms Trends database, which is a three-year look at how people at the county level are thinking about health and what kind of challenges they are facing and can be used for forecasting for high consequence health threats.

So, there are some examples of ways that we have been working with public health throughout the pandemic. And as we look forward, and I think like many others as possible in the tech industry, we see that that kind of partnership needs to help with advancing the way that public health will move into a more 21st Century model.

I want to just make a few final comments where my hat as former national coordinator and reflect on some of the things we learned in HITAC as this committee is considering how it wants to go forward with this important work.

First, my recommendation is that we focus on interoperability from the get-go, which means using our standards that we can allow interoperability between public health, the medical system, and the social care infrastructure. We must make those open standards and not proprietary ones.

Second, let's do it with an eye on the ceiling and not just the floor. We have a great start because of all the progress we've made during the HITAC era. And as we move into this new world, let's make sure that we're leaving plenty of room for innovation but really working to advance and modernize the public health infrastructure quickly to meet up with medicine.

And finally, as we're thinking about moving into this new era, I want to encourage us to continue to build on partnerships across sectors. Yes, ONC should lead, but all of us have a role to play, and we should be at the table because public health is what we do together to create the conditions in which everyone can be healthy.

I have one final thought in response to Steve Posnack's tweet this morning, which is I had a fill-in-the-blank for their interoperability roadmap, and it is because of interoperability, by 2030, public health will have prevented the next pandemic.

Thank you again for the invitation to be part of the conversation. I look forward to questions, but more importantly, to working collaboratively with you all as we go forward to do this really, really important work. Thank you very much.

Aaron Miri
Thank you, Dr. DeSalvo. And always, thank you for your hyper-focus on public health even during our Health IT Policy Committee days, that was always a champion of mine, and it really paid off, and continues to pay off going forward, so thank you for that.

All right. Next up, we have Hans. Hans, are you there?

Hans Buitendijk
Can you hear me now?

Aaron Miri
Yes, sir. We can.

Hans Buitendijk
So, thank you very much for the time, and my name is Hans Buitendijk. I'm the current chair of the EHRA executive committee, and that's who I'm presenting today. While other times of the day, I'm with Cerner as Director of an Interoperability Strategy. I'm really pleased to be able to be here and appreciate the time to talk about this topic on looking forward in particular but looking back to identify based on what we have experienced, what we have learned, and where we are seeing some areas that we can improve upon and then work together. I could very many words in that regard of Dr. DeSalvo, this is going to be a team sport. We need to try to figure this out together. Interoperability is going to be important in that, but we're also looking at a number of other parts. Next slide, please.

EHRA is an organization of 2930 EHR vendors that addresses a variety of settings, ambulatory, hospitals, long-term care, and in that context, we have been interacting a lot over the last year with requests for information to enable analysis, data flow reporting, etc. around COVID in specific, but also demonstrated some of the larger needs in public health.

One of the things that we have noticed is that you can see it here, but if you go to the next slide in more detail that I will not go through all of them individually. There are many places where the provider systems, source systems, are an integral part and an important source for data to identify, manage, analyze, react, prevent, etc.

Anywhere from identifying patients all the way to, at this point in time, with a key focus on vaccinations, and everything in between; scheduling, triage, contact tracing, etc., etc. So, it has an important role in that, and we have noticed that with the kinds of requests, questions, and where we started to, as a result, identify gaps. If you go to the next slide.

That's where some of the areas that we have seen particularly increase data needs is around research. How do we get access to real-world data more easily? How do we enhance lab reporting or caser reporting to get the data to get awareness in public health beyond what's currently already available? What was more standard? What kind of operation statistics? That has been highlighted earlier as well. And through those, some of the challenges that we have run into in particular are around very quick turnaround time requests, very understandable, but challenging, particularly if we need to do that across 50 states, 64-plus

jurisdictions, with slight variations among them. So, state variations, jurisdictional variations in data, different interpretations, different requirements, all at the same time, have been challenging. So, these notions of preventative looking forward be ready are critically important in how we can improve from here. If we go to the next slide.

Some of the areas that we surely will talk a little bit more about being around then what our recommendations are? What are some areas that we believe are important? Under our national reporting structure, having a core dataset. Having a superset of data that we all can agree on is important, but not everybody may need it. But if that's defined well, if that's more in place, reacting to a next emergency or any other progression will make it easier to respond and address the delta.

So, reporting once, share widely. We have been dealing with a variety of areas where we needed to report many different places for a particular provider, different requirements, which makes it challenging. So how can we get to a report one, share widely? Standard tests were mentioned, incentives, funding, education, training have been mentioned, so no need to go further. But also, then, looking at the next one, what should be our search process and infrastructure? How do we react when it happens, and something unexpected is going to occur? How do we engage everybody?

We found ourselves frequently very late in the process, being engaged to help figure out what to do as opposed to perhaps earlier on or as soon as possible so that we can help figure that out. As you go down the line to the different areas, that collaboration, working through that is an important part, including privacy and consents.

So, with only ten seconds left on the clock that I can see in front of me, we'll stop here. And looking forward to any discussion on this topic in the rest of the discussion. Thank you.

Aaron Miri
Thank you very much, Hans. And you're exactly right about requirements changing in real-time. We're actually going through that and doing some cleanup right now because depending on the way some of the vaccine patients are being marked, our safe immunization registry would see them as deceased. So, a lot of changes, a lot of nuances that can really impact the numbers and the fidelity in data, so you're exactly right.

All right. Next up, Mary Beth.

Mary Beth Kurilo
Okay. Thank you so much. So really appreciate the opportunity to present today. Just for a little context before I jump in, AIRA, my organization, is a nonprofit association that collaborates closely with CDC and IF to, among other activities, develop guidance and standards, test IF regarding their alignment with those standards, and provide technical assistance to support improvement. So next slide.

I want to start with just a little level-setting information about IIS. There are 63 IIS's across the US, so there's an IIS in every state and some at the city, county, and territory level as well. They leverage broadly across public health to produce coverage rates and support program needs, but they're also heavily queried by private and public providers for clinical decision support at the point of care.

As with most public health functions, they're governed independently by state and local laws and policies. But one important thing to know is that IF adopted HL7 standards very early in their development, with the first immunization implementation guide coming out in 1997. So, for the most part, they all use the same well-adopted, albeit older, D2 standards of exchanging data with hospitals, ambulatory clinics, pharmacies, HIEs, and others.

A growing majority of these exchanges are bidirectional, meaning the clinician is able to submit data to the IIS and to access the consolidated lifespan record while staying within their EHR. Pre-COVID, each IIS on average responded to 32,000 queries a day, which is roughly double the average number administered daily to each IIS. We know these numbers are much higher now in light of COVID. Next slide.

So, although the response to COVID-19 hasn't been perfect, there's a lot that went right about this response across IIS. IIS's have been able to leverage the well over 100,000 interface connections with both private and public immunizers that they built out over the 25 years to allow data to flow quickly from EHRs and pharmacy systems into IFs, and it's really allowed them to process data on Day 1 when vaccine arrived. They've onboarded thousands of new immunizing sites, and for the first time ever, IFs are submitting comprehensive record level data to CDC daily, creating a nationwide picture of what's happening with the COVID vaccination response in near real-time, contributing heavily to the 264 million doses that you see in the CDC COVID vaccination tracker.

And we've also gotten to test out how immunizers respond to a nationwide mandate to report all administered doses to IIS. And although that hasn't been without challenges, public and private providers alike have stepped up to share data—next slide.

And I also wanted to just acknowledge some of the things that haven't gone so well with the COVID response. And I know you've heard a lot about these, as folks have been talking. Although IIS's have made amazing gains with standards adoption, as we all know, variations still exist. Some of which may be modifiable, while some have caught up on state law and policy. We found gaps in some data both in overall reporting and also specifically with key data elements like race and ethnicity. And as many have mentioned, this is a shared responsibility but critical to using these data to support health equity questions.

IIS's have also had to ramp up their capacity for the volume of reporting and querying that really exceeded our expectations. And on the next slide, I want to share some data that was shared by one of our member states. They reported that they received 577,000 reported doses in one day last month. 70,000 of these were routine immunizations, and 507,000 were COVID doses. So, the same IIS had to move from 26 servers to 98 servers just to manage the incoming data and huge demand for queries from exchange partners that need access to those data. So next slide.

Looking forward, where do we go from here? There are three immediate steps that I think are worth talking about. And actually, if you flip to the next slide. Guidance on pressing emerging topics, like vaccine credentials, to ensure some level of standardization in implementing new functionality. Expanding support for third-party testing, and CDC funds AIRA to test IIS's for measurement and improve initiative, so we know where much of the variation exists across our systems. And now, we need to prioritize and fund IF programs and vendors to make those improvements and close those variation gaps.

And then, from a health IT systems standpoint, it'd be helpful to explore where incentive programs can help across the system.

And then, some longer steps might include a national policy and operational framework that supports increased standardization. Ideally, that would address opt-in, opt-out differences. We need to consider where emerging standards like FHIR could support problematic or new areas of messaging and for the long-term strategy on a transition to FHIR. And finally, underpinning all of this, IIS needs sustainable, dedicated funding to allow for long-term planning to both modernize and maintain our systems going forward, for COVID and for routine immunizations.

So, with that, thank you so much for your time. I look forward to your questions.

Aaron Miri
Thank you very much, Mary Beth. Appreciate that. Excellent presentation and excellent suggestions too, I can tell you. Okay. Next up is Dr. James Watt.

James Watt
Good morning from California, can you hear me?

Aaron Miri
Yes, sir.

James Watt
Great. Let me see if I can get my webcam going. All right. Thanks very much for the opportunity to speak with you. It looks like the webcam may not be working, but I'll forge ahead. I, as part of my role, oversee the infectious disease surveillance system, including our California disease reporting system known as CalREDIE. Can I have the next slide, please?

That is the California Reportable Disease Information Exchange. I'd like to share with you a little bit about this system, talk with you about our experience during COVID and then tell you about some of our plans for upgrading this system as we're moving forward.

So, the major components of CalREDIE are a reportable disease database with a secure, web-based user interface that's used by both local health departments and state users in California. We have an automated portal for HL7 message consumption, primarily for electronic laboratory reporting. And then, we have a secure data warehouse that can also be accessed through the internet by a state and local user.

Our system is based on proprietary software that's produced by Sun Quest, and it went live in 2010. We depend a lot on national standards for data definitions and data transmission standards. The system serves both infectious and non-infectious conditions. And it's funded by both state and federal funds. And I do want to give a shoutout to the epidemiology and laboratory capacity cooperative agreement from CDC, the Public Health Emergency Preparedness Cooperative Agreement, and Medicaid HITEC and Medicaid Enterprise System funding. Next slide, please.

During the pandemic, we have had some significant challenges. I'm going to echo a lot of the things that Dr. Fine said earlier. Some of our challenges have been dealing with a large increase in data volume that has gone up by 40-fold, a substantial increase in the number of reporting laboratories that have increased by 10-fold, dramatically increased reporting expectations, and we are now reporting publicly on a daily basis that means we have very limited tolerance for any disruptions in the system. And also needs new functionality, particularly for contact tracing.

And so, in response, we've implemented a number of enhancements quickly. We have launched a new system for managing laboratory reports and interacting with a large number of new laboratory submitters. We've launched a new data warehouse that can process data much more quickly. We have developed a separate contact tracing and case investigation system. We have expanded our human resources dramatically. And we have implemented a number of data matches across different systems, particularly with our immunization information system, to link vaccination data up with our case data. Next slide, please.

As we look towards the future, we have already begun planning for an upgrade to our system, and we are looking for a number of key characteristics, particularly interoperability. We need a system that is able to interoperate effectively with our internal state systems as well as with healthcare system data and local health department systems. We need a system that is more flexible. That can add new functionality. We need a system that is more scalable. We need tools for partner engagement and quality monitoring of incoming data and providing data feedback about incoming data. And we also need expanded human resources, particularly in the area of informatics.

To be successful, we will need stable funding. We will need a trained workforce. And we will definitely need national coordination. And so, any opportunities for having data standards that we can leverage, having information exchanges that we can connect to, having tools and resources like identify matching that we can adopt will be very much appreciated and will help us build a new system more effectively.

So, thanks for your attention, and I look forward to a discussion afterward.

Aaron Miri
All right. Thank you very much. Okay. Next up, Christopher Harrison.

Christopher Harrison
Good afternoon from Georgia, can you hear me?

Aaron Miri
Yes, we can, welcome.

Christopher Harrison
Well, thank you very much. My name is Chris Harrison, and I serve as the State Registrar for the Georgia Office of Vital Records. So, some of this may be similar to what Terra Abrams Ankrah reported earlier, and some of it may be quite different. Georgia has some different populations and different groups that we serve, different settings.

So, Georgia has had an electronic death registration system since 2010. And death records are filed by the funeral home and the medical provider in the county in which death occurred. And then those counties report the death record to the State Office of Vital records into my system. If you've ever been to Georgia or seen it, you may know that we have 159 counties. So that's a lot of different people that can have a hand in reporting death records. But luckily for us, all 159 of those counties use the electronic system, and so do nearly all of Georgia's approximately 900 funeral homes.

We have participation from 80% of our medical examiners and coroners in the electronic system, and about 30% of physician deaths are filed electronically. The remaining death records may be filed on paper, at least partially, and then they're put in the electronic system by the others involved at the county level.

The systems that we had done largely perform well during the early days of COVID-19. We found that our vital record staff was able to work remotely to register deaths if a county office had to be closed temporarily, either due to a COVID exposure, due to the people in the county being pulled onto other duties, staff could be virtually reassigned to cover for each other in neighboring counties. This was the first time we'd largely implemented that in the system.

We also received regular guidance that we were able to push out to our users within the electronic system, guidance from the CDC, National Center for Health Statistics, and support and best practices that we learned from other partner jurisdictions and from NAPHSIS, the National Association for Public Health Statistics and Information Systems.

Prior to COVID, we had already implemented automatic data transfers to our public health partners for surveillance and epidemiology purposes, and we were able to continue using those same mechanisms to share death information daily regarding COVID-19 deaths. And we were also able to use that information with our partners to improve the demographic and race/ethnicity reporting on COVID-19 case data. We were able to assist some that were tracking COVID-19 positive tests to see if those could be linked to vital records, vital statistics data to improve areas where certain demographic variables were unknown or missing.

Georgia, also like DC, has been working on HL7 interoperability, and we were able to make significant progress on this in 2020 despite all of the work that went into COVID-19. We just went live with our first medical examiner partner to use this new HL7 FHIR interface on May 3rd. So, it's brand new for us after many months of development and testing. We're very excited to see that in action. It allows the medical examiner office, once they've completed a death record in their death management system, to send that electronically to the death record with a press of a button. It eliminates a lot of the duplicative data entry, entering a death record two or three times, the same information over.

We look forward to expanding that to some additional medical examiner and coroner sites later this year and more and more as the years progress. As we do this, we're trying to document the standard that we will use so that this can be expanded to other facilities as well.

Some of the challenges we did have with data from COVID-19, the same people in the hospitals who have to report death records to us, had some other things on their mind, as you can imagine within a hospital. Physicians and the support staff who report those records were doing everything they could to serve

patients in the community and in the hospital. So, if we can continue to expand this HL7 FHIR mechanism, we think that will greatly improve timeliness and electronic reporting throughout the state. So, we really look forward to expanding that over the coming months and years. Thank you very much.

Aaron Miri
Excellent. Thank you very much. And thank you to our entire panel on that testimony. I would ask all the panelists if you will please turn your cameras on so we can get to the Q&A component here. And simultaneously, HITAC members, will you please get in the queue with hands raised. And I see them getting lit up right now, fantastic.

All right. So first up is Les Lenert.

Leslie Lenert
I'm not sure I'm used to being first this often. I've never been this fast on the button before. This question is for Dr. DeSalvo. One of the applications that Google's been heavily involved in, and that I had the opportunity to participate in as well that I thought you might have mentioned, was exposure notification. Or this idea of infrastructure to be able to inform persons confidentially when they've been exposed to someone who might have a disease. I'm wondering if you would comment on your conclusions on Google's efforts after a year or so of intensive engagement on that. And what do you think that this is an essential public health infrastructure that is patient-driven and needs to be part of our regular public health practice?

Karen DeSalvo
Great. Thank you for the question. You know, what you're referring to is what we call our exposure notification system, which is essentially an interoperable API that we created with Apple to enable the use of Bluetooth low energy to let one phone know if it was within six feet for more than 15 minutes of another phone basically, and another phone that may have reported to an anonymous encryption key server that the phone owner, if you will, had a positive test.

So, it's a very technical solution to this idea that could we create a way that people could know if the I've been exposed to COVID and do that in the most privacy promoting path possible. So, using BLE and using both Android and Apple, with these interoperable APIs, we worked with the public health community around the world actually. We have stood up for exposure notifications in about 40 regions and countries. In the US, about half the states are using exposure notifications today. And that system, just to say it again, is one where we created an API, but the states themselves built an app, or they can take advantage of the way the system is built into the operating system at this point.

And the data itself goes to encrypted T-servers that are hosted by APHL. And also, there is a test server that's hosted by APHL, so none of the data comes to the technology companies.

Here's what I learned in that journey. First of all, we've learned from the analytics work done in places like the UK that there probably thousands of deaths averted and hundreds of thousands of infections averted. We don't know on a global scale what the impact of the technology has been because, as I said, we don't have the data, so we're reliant on the public health agencies to do the analytics and looking forward to more of that happening in the US context.

So, what we learned in addition to whether it's useful is also that it's – the vocabulary and openness of the public health infrastructure, particularly in the US, has some gaps in it. And I think that with all due respect, since I come from both technologies and I served as a local health commissioner in New Orleans, I'm saying this with a full heart. But I think we're so busy sometimes thinking about public health that it's hard to even just have the conversation. And so, this is a reminder to us, we can't just build APIs or technology. We have to also build the capacity and capability in the workforce itself to be able to receive or build or act on the technology tools that may come available.

But I will say more broadly, though, is that the challenges facing the typical health challenges that we face in a place like the US are not about communicable disease-causing morbidity and mortality, but a rather chronic disease and the social determinants of health as big drivers of morbidity and mortality, even before the pandemic.

So, as we're thinking about tools that we need into the future, of course, we need good forecasting and epidemiologic surveillance tools, but we also need to get the basics right, if you will, about sort of the everyday opportunity to do surveillance with chronic disease and understand not just for people's healthcare experiences, but also be able to understand and interpret the lives that they lead, meaning how are communities living, learning, working, and playing? What are environmental and built environment drivers of health?

So, exposure notification is a great example of interoperability and partnership with public health, highlighted that there are a lot of gaps that we need to fill, and not just in technology but also in building out a better workforce that has got skills for the 21st Century. And then a reminder that though we're in the midst of a pandemic, the big drivers of morbidity and mortality for people in the US are likely to go back to being things that are not infectious. And so, we need to build systems that can help us address the surveillance and support the public's health in those areas as well.

Aaron Miri
Thank you, Dr. DeSalvo. Anybody else wants to respond to maybe more of an arrogation about platforms at large and those sorts of things? Maybe Hans, any comments there, or anybody else on the panel?

Mary Beth Kurilo
This is Mary Beth, and I was just going to say, I really support Dr. DeSalvo's comments about the workforce and really needing to invest in the workforce and make sure that there's not only time and space for those conversations, but that the public health workforce has the right people around the table, and they're well-trained and well-staffed and well-resourced to be able to have those conversations.

Karen DeSalvo
I want to add two things. One is to say, yes, you're exactly right, Mary Beth. And it's about the pipeline and the incumbent workforce. And this is something else we thought about in HITAC. The funding, I think, dropped off too quickly. But we really – there are new skills that need to be built up. And I'm not trying to knock the public health infrastructure at all. It's people that I admire. But the reality is that there's a lot of tech people know-how that we're going to have to make sure that we amp up. And we want to keep the people in the workforce now, and so we have to focus also on some incumbent support.

Hans Buitendijk
And perhaps to add is that I would agree that technology is essential, but it's not sufficient. There are many other layers around it to ensure that policy agreements otherwise are in play to be able to act and react quickly. But having technology in place, if we compare a scenario, an example, where there is a need for additional data rapidly, what's available, not being connected to a network, not having CCAs or FHIR APIs or other capabilities in play, makes it much hard to respond and react. So, it's not sufficient, but it's certainly essential.

Aaron Miri
Got it. Dr. Watt, what about you? I know that California's done a phenomena l job there in really trying to link the state and really look at areas that and high positivity rate and now a high vaccination rate. And I even saw something there today. I saw that LA County had zero cases for the first time in many, many, many months. Congrats to you. What is it about that communication, that platform-level syndromic surveillance that really makes it successful for California?

James Watt
One of the things that we have worked on is, as I mentioned, bringing together different data streams and doing that at very small geography. And this has been important for looking at our cases, our immunization delivery, our healthcare utilization, and trying to understand that at county and sub-county levels so that we can direct our responses. And a big part of that has had high-quality data, and we have struggled with that. And then also looking at ways to display those data and overlay different data sources so that people can think strategically about what needs to happen.

And also to think about how equity is playing out geographically. And we focused a lot on the healthy places index as a tool for thinking about service delivery through an equity lens. So those are some of the things that we've used to try to organize the data to guide our response.

Aaron Miri
Excellent. Thank you. Okay, so next in the queue, I see Robert Wah. Dr. Wah.

Robert Wah
Thanks, Aaron, and thanks to the entire panel. This has been a great day and a great panel. I want to expand on this concept that we've talked a lot about public health data systems and health IT and how they can help people like physicians, health organizations, governments, public health agencies. But I think where we are right now in this particular discussion is the interface between those systems and our patients and the public.

And so, I want to think a little bit about that, and part of that's driven by my role as chair of the board in the Commons Project. Most of the committee knows that we've been working on how we empower individuals to privately and securely access their information and use that as they see fit. So, during the pandemic, we released CommonHealth, which is the Android equivalent of the Apple Health system, so that patients can download their information from electronic health records, labs, systems, and others onto their devices. We built COVID Check, which was a risk assessment tool that we deployed in nine languages. And then lastly, we deployed CommonPass, which allows patients to give authority to display their health status for plane travel, international border travel, and other venues.

And what we're seeing now, particularly with the IIS, is the patients want to have access to their vaccination status. And so, vaccination credentials, I think was mentioned by Mary Beth. I now serve on the steering committee for VCI, the Vaccine Credentials Initiative. But we're bringing together people to figure out how we can use technology to help our public and our citizens access the electronic information that's out there on their vaccine status in a way that's secure and is not proprietary.

And the health equity part of that is we want to make sure that despite the technology part of this, we want to also be able to provide it in a very low-tech ability, so they can get a QR code that they can print out and use to display their vaccine status.

So, my question to the panel, particularly for Karen and Mary Beth, is how do we go about this really new area of connecting our public health system with the public? Not necessarily with the physicians and the medical and the public health agencies, but the individual citizens? And Karen talked a little bit about that with the contact tracing. But I really want to think more about how we expand this because there's a new appetite on behalf of our patients and our citizens to start accessing this. But thank you for this great conversation and this great session.

Karen DeSalvo
This is Karen. I can start. Robert, it's good to see you. And Robert, having been around for the origins of the Office of the National Coordinator and one of the instigators, in a good way, of seeing that this will come to fruition, we'll remember that too many people that the Office of the National Coordinator grew from people who were at the CDC and were thinking about population health and the importance of public health and how we needed to use data in those ways. So, this coming together again, by the way, of the two agencies thinking about how they can work collaboratively to improve not only access to data that informs the care experience but to Robert's point, really tells us about the health journey of people and of communities. Because there are two issues here. One is using anonymized data to really begin to understand and forecast not only communicable diseases but challenges like opioid epidemics, as an example.

So, I think that's our most important change, and the way and the breaking of that, we've already started. I mean, not to repeat history, but going back to my time as National Coordinator, our strategic plan in 2015 called on putting the person at the center and thinking about all of the data sources that tell that story of their health journey, the EHR being one of the inputs, but there are other sources of data.

It's also a journey that the country is on to think about creating a longitudinal health record so that people can control and access their health data. And stack those on top of each other for people, anonymize it, and you begin to have a better look at the population's health.

And there are models where this is already being done and works, like in New York City with Microscope. We know that you can use EHR data as a proxy, but it's for surveillance coupled with other sources of data that gives us much better insights into how to target and address a public health need.

So, I think some of this, Robert is just – it's not just, but it's language. We have got to get away from talking about how the data is in service to healthcare because it's in service to the public. And we've got to get away from this notion that the rich and best source of data is the EHR and rather begin to respect and

understand the other sources of data there are. And if they're not of the same caliber of EHR data yet, let's bring them there through the data modernization work that has to get done.

So, it's also about focus. If we use all of our energy to focus on interoperability with the healthcare systems and all of the resources that we have, I think we're going to miss a really important part of the public's health that we would otherwise have access to.

Mary Beth Kurilo
I just wanted to add that I think that the vaccine credential initiatives that are out there are really important. And I agree with you that consumers need access to their data, and IF has these rich sources of data, and we want to make it accessible.

But one of the things that I think that we need to just think carefully about is the need for standardization there. And ideally, we want one common method for accessing and one that both protects privacy but also provides that access. And one of our stumbling blocks there is around authentication.

IIS's really had been set up to work with hospitals and clinics where there may be a patient on the other side, but that patient is authenticated by the system that's querying the IIS. So, thinking about who authenticates that that patient is who they say they are and has access to that record is important. And then standardizing the way that these ancillary systems interact with IFs so that we can have more of a uniform approach, and not 63 or 64 different ways, I think is really important.

And I appreciate a lot of the work that's come out of the CommonPass Project and the Vaccine Credentialling Initiative, where it's open-source and very much accessible. But I think some federal guidance and leadership on how IFs should be interacting with these systems would really be helpful as well.

Hans Buitendijk
That's an important question because there are many systems in play. And clearly, this is an indication there are many more than we perhaps already thought. There is the source system, where the initial data is being collected at the time of administration or medication or treatment or otherwise. The patient is across different systems interacting with different providers. The IS has information. So, there's a variety of different systems that we need to try to get together from a patient's perspective, from a consumer perspective, to pull that in one place.

So, I think we're going to see that a combination of when do I go through an EHR or when do I go through a network? When do I go through an IIS? When do I go somewhere else because the same data is accessible there? It's going to be a question of importance to make it as easy as possible for the patient. That it's not confusing to them, I need to go to five, ten different places, but how can I go to one place and have access to everything. Or how can I go to different places, but I still get access to everything as well so that the choice is not as critical in that regard.

Because the data will live in different places. Patients will interact with their provider where they got administered the vaccine, and that's where the logical place is to get the data. And how do we make sure that that environment from a provider and a patient perspective, they have the vaccines available from

across the multiple IIS's where they may have had vaccines over time if we use that as an example. The patient identification then immediately comes back into play. How do we know it's the same patient across systems?

So, I think there are many different questions still to be addressed on that path towards having a single virtual record from a patient's perspective, no matter where the data has been. And there's still a little bit of a way to go, but for public health in particular, in that context, that's also an important aspect to achieve.

We've seen with the efforts to date, and we see with the progression of the CURES Act, of CMS, of proposed rules coming up that this is being strengthened every time, and we'll need to make sure that as part of that, the data that is relevant from a public health perspective is included as well and in the right way. So still a few ways to go there.

Aaron Miri
Sounds good. Thank you very much, Hans. Thank you for the question, Robert. Appreciate that. The next question in the queue here is actually for Chris. Chris, the question for you is a lot of states are struggling with a lot of organizations within states are struggling with how to return to normality in the next several months. And querying various state registries or immunization registries for Aaron has gotten vaccinated? Has he gotten vaccinated somewhere else versus what we know of? And trying to get a level set baseline of what percentage of my population is actually vaccinated or not without really revealing any identifiable information other than that.

What strategy did Georgia take, or are you taking strategies or looking at to be able to query these different datasets, standardize, normalize, present back to businesses the ability to ask that question? Or is that something that is too far to reach right now?

Christopher Harrison
Thank you. Yes, that's a great question. Georgia does have publicly available information at a certain level that's deidentified. But at this point, it's not quarriable in a single place, depending on what someone is looking for.

We have our COVID-19 case counts and dashboards that we put out from the Department of Public Health, but it's somewhat you get what is presented. It's not so quarriable for a user to choose. And similar is true for our public health statistics at this point. That is a great suggestion and something we have talked about.

From what I've learned of the FHIR standard, it certainly can be used for querying a public-facing API. That's probably getting above my paygrade as the registrar, but our technical people tell me that's possible. Great possibilities for the future there to have a public API and then provide documentation of how that could be used.

Aaron Miri
Interesting. Turning to DeSalvo. One of the things that Google really made a lot of tremendous progress with was utilizing some of the publicly available consumer tools, like Google Maps and others, showing people where they could get testing, where to get vaccines now, and sort of that easy to follow along, like pops up when you're driving to McDonald's here, there's a vaccine shop right here, now, right. It shows up

on Google Maps. Are there components like that that Chris and James and others that are leading their state effort should look at to try to incorporate? And do you see consumer technology having more of a side-by-side with EHRs in the future where you would be looking at a Google Map side by side, with, say, your Epic EMR?

Karen DeSalvo
Well, let me start just with the communication responsibility of public health, which is the maps and certain YouTube. And we are a megaphone for public health. That's how we see our opportunity to be a good partner.

And having been in the local seat, I can say, you know you're really trying to get the word out about where your vaccine sites, popup sites are, etc., or what the new expectations are in non-COVID times, like is the water safe to drink or not safe to drink, and that's a push. What we have the opportunity to help with is the pull. Because on a surface like a search, people are coming and asking the question, and if we can get them directly to the right place for public health.

And I think that goes back to the partnership issue, Aaron, who is – I think I've said this before. That sometimes, when you have that first meeting between tech and public health, it's like a middle school dance, everyone's standing in the side and not sure who's going to talk first. And it's a little awkward, is the point. And I think if we can get over that because we've got these – or let me just say where we are in terms of the partnership that we've developed all the way to the ground and build on those into future health challenges, that's the communication responsibility public health that again, a company like ours is a megaphone.

I think the other thing that we've been learning as a company is that we have novel signals that are useful to public health. And that, I think, is just the critical thing as you all are thinking about, say, building forecasting tools. Can search symptoms trends, 400 kinds of symptoms that people are asking about, we've got three years of rolling data. It's publicly available. It's anonymized. It's at the county level. We are learning with our researchers that it can forecast challenges into the future and not just be cross-sectional information.

So, are those novel signals helpful? We also have a lot to learn, but we should be thinking about that, basically. It's real-time information about what's on the public's mind in the way that you're describing the map data, the business—the business factor.

One more comment, I think, in general, about the surfaces, which is something I didn't realize until I came to Google. But the data needs to be put into the system if you're going to show up on maps, essentially. So, we have to be really intentional at the company when we think about equity and ensure that the federally qualified health centers or some of the rural sites are thinking about making sure that they've got their information updated so that it is accurate on maps when people are looking and searching. It goes back to the partnership. Making sure that we're intentional in thinking about inclusion and equity. We're reaching out to those parts of the ecosystem, whether it's public health or it's a safety net, and thinking about how they're going to show up as an option. And then helping to build that capacity where we can as partners going forward.

I think we're just beginning the journey of what is all the way that we can better communicate, use novel signals, and make sure that we're working towards driving equity across the community.

Aaron Miri
Makes sense. Thank you very much. All right. In queue, I see Arien Malec. I want to make sure I get to you before we run out of time here. Arien?

Arien Malec
Thank you. So, a question might be to James Watt, but also the rest of the panel. There's a bunch of things that are scattering around my head, in particular the earlier comment on political science versus computer science. And where we can solve a problem with computer science and where we need at the policy levers, orient to the right way. But maybe we must think about how we get the data to flow in order to enable the policy. And then I think it was Jim Jirjis's comment on afferent and efferent flows in public health.

I live in the Bay Area, the San Francisco, Bay Area, where I think generally, we did a fine job in our COVID response, but we missed signal – and in particular, we missed signal relating to primarily Latino based essential workers who were the disease burden of COVID heavily hit, particularly in the fall, and drove some of the caseloads that we had in the fall.

And so, I think California has generally had pretty brilliant policy frameworks in terms of thinking about ramping up and ramping down MPIs, with a nice and easy-to-understand color system. But if you look at how that played out in practice in serving Latin based communities in the Bay Area who are the front line and essential workers, or the same population in the Central Valley and San Joaquin Valley where there's a disproportionate burden, what are the right – if we're thinking about this from a health IT policy perspective. What are the right policy levels that we need to have to make sure that the data's flowing up so that we get those early signals? And then how do we collect those policies – a much broader conversation, essentially, on how we connect those data signals to the policy levers to make sure that we're taking the right action. But based on the context of this committee meeting. Maybe we could focus on how we make sure we've got the right signals going up so that we can identify in real-time when we have a disproportionate impact on, whether in Karen's perspective, Social Determinants of Health, but in the context of COVID-19 disproportionate impact on disease outbreaks. Thank you.

Aaron Miri
I think, James, that question was for you initially.

James Watt
Sure, thanks. That's a great question. I'll comment on a couple things, and I'm sure others may have thoughts as well. One is the data completeness is an important point. And so, you particularly talked about the increased disease burden that we've seen in Latin communities, and particularly amongst essential workers. We struggled early on with gaps in our reporting around race/ethnicity. And we needed to establish new regulations, actually, and work with our laboratory submitters to get more timely and more complete data around race/ethnicity. So that was a key feature that we needed to be able to pick up that signal.

We have significant gaps related to occupation, and that's been a challenge for us. Really the only good data we have on occupation are for fatalities, and that's really just not enough to help us understand some of the key places, worksite risks that might be out there. So that's a challenge for us.

And then the other thing I would mention is just tools for communication. I think we really struggled initially with having effective data flows from our system, our surveillance systems, and we had a surveillance system. We had people to analyze data, but we didn't have great visualizations and took some time to get those in place and make them available to our state policy makers and also have tools that we could flow data back more locally. And I mentioned earlier that we've been working hard on that, but it's something we didn't have in place in the beginning and took some time to ramp up. And so, I think that was partly why we were a step behind in picking up some of those signals that you mentioned.

Aaron Miri
Interesting. Other comments on the panel? It was a good question. Mary Beth?

Mary Beth Kurilo
Yes. I think that the real-time and the near real-time conversation is really important. And then being able to have time to really dig in and analyze the data and do the analytics. And then look at what it's telling you. And I think so much of public health because they've been under-reinforced, has been reactive, and haven't had the time in the midst of the COVID response to really do the analytics and move from data to information and then good decision making.

And I think that that's one of the big lessons that has come out of COVID and the need to – I think a lot of this does come back to the workforce and adequately funding our systems, so we have time to do both sides of that, to collect the data, to send the data up, but also, analyze the data and make sense of it, and have good enough data around things like race and ethnicity to be able to use it to answer some of those really critical health equity questions.

So, I think the analytics piece and really diving into the data and being able to look at it in real-time and make good program decisions on the state level and the federal level is critical. So completely agree.

Aaron Miri
Excellent. Anybody else?

Karen DeSalvo
Yes, I do. I want to refer to something I went through quickly in my remarks, and that's we just released a report via the National Academy of Medicine on the 21st Century public health, which speaks to some of these issues that are being raised here and some recommendations, including the notion that if capacity and capability could be shared between public health departments, they don't all have to build out a data science capability or a data visualization.

And one of the things to think through is what are the ways that there could be better-shared services, including those that are able to make sure that the data is as complete as possible so we can understand where there are inequities and where there are disparities that have to be tackled.

Hans Buitendijk
One additional comment in response to Arien's question is that I think it's another good example that EHRs have a critical role, but they are clearly not the only ones, and that's also indicated that. It is a collective set of sources where we need to pull the data from, pull it together to get the insight that we're looking for. And understand better the respective roles of those different systems and how we can best access them.

And I think in moving forward, having a better understanding of the kinds of questions that we need to ask of these different systems and how to explore that will help us understand how to best engage with interact with those systems, what kind of access we need to enable that more quickly than what we have seen over the last year.

Aaron Miri
Sounds good to me. Hopefully, we can get away from fax machines once and for all. So, all right. With that, thank you so much to his panel. Greatly appreciate these insights. It is truly invaluable to our work and the efforts going on across the country. And we applaud you and all of your efforts at the state and national, international level in some cases, really making a difference out there. Thank you so, so very much.

So, with that, I am going to divert us quickly into a two-minute little curb here, so we can get Mr. Steve Posnack on the line to make a quick announcement to all of you. Hopefully, you're still paying attention, and here's some exciting stuff. Steve, turn it over to you, sir.

Steve Posnack
All right. Thanks' Aaron. Appreciate the opportunity for a quick commercial break, but we couldn't have scripted this any better with the HITAC meeting today on public health, Karen's comments on the workforce, and the other panelists. I did want to let folks know, and I will drop it in the chat as soon as I'm done talking, that the administration today put out an announcement regarding $7 billion from the American Rescue Plan that will be devoted towards hiring and training public health workers in response to COVID-19. So, there are a number of different investments that are being made.

ONC is fortunate to have received $80 million in order to focus with our CDC colleagues on training and recruiting public health leaders. So more to come related to the informatic space and public health workforce related to health information technology. But since it came out today and this is what the hearing is all about, we wanted to make sure that everyone is aware of the great news and exciting work that we have ahead of us. Back over to you, Aaron.

Legal and Policy Issues: Current Status and Future Needs & Discussion (04:43:00)

Aaron Miri
Wow. That is amazing. Phenomenal news. And hopefully, the beginning of many more planning activities and efforts to come. And what an amazing opportunity. Thank you for that announcement. All right. There you go. Everyone that's listening has a scoop today, so hopefully, you're furiously tweeting that and retweeting that and saying, Steve said. No, I'm kidding. That's fantastic.

So next up, we have a really good topic, one of my favorites here. So legal and policy issues, current status, and future needs. This is going to be interesting because I think we've touched upon it all day long regarding some of the variety of state laws versus federal laws. We talked about definitely at the HITAC numerous

times, the intersection points of HIPAA and where the FTC is and all these other components, and looking at third parties, and how do we do this in a way that really empowers the patient safely and securely. So, look forward to this group to talk to us and educate us on what we really should be thinking about as we blaze forward. So first up is Denise Chrysler.

Denise Chrysler

Fantastic, thanks. Could I get my next slide, please? Thank you for asking me to speak today. That's a really difficult announcement to follow, but I will try my best. As you said, I'm Denise Chrysler. I'm with the Network for Public Health Law. The network was launched over 10 years ago by the Robert Wood Johnson Foundation, and our purpose is to promote and support the use of law to solve public health problems.

So, when we're talking about modernizing our public health data system, it's essential to address law since the law governs every aspect of data. And the law may be a friend. For example, the law establishes public health agencies, and it grants them the power to collect data to protect the public, both during routine times and during an emergency. And that includes the power to decide what data is collected, what data elements, the formatting that's needed, whether data needs to be reported in machine-readable form, etc., etc., and public health also has the power to require reporting of data by race and ethnicity, including by subgroups that better reflect industry, language, and culture populations. And that is captured by the OMB classifications.

Often the law is cited as a barrier to data sharing, sometimes it is. Sometimes it's perceived that way because, as we know, the law establishes lots of requirements about what can be shared and with whom it can be shared. And we always need to ask, is this a legal barrier, or is the law being used as an excuse for political disagreement?

Just as an aside, in the early 1990s, an integrated national immunization registry was proposed as part of caveats as the Child Immunization Initiative Act. But this had to be dropped to get the law passed because of the protest that the federal government would be tracking our children. So today, as Mary Beth talked about, we have 63 jurisdictions with their own IIS based on their own laws and policies.

Mark Fraser also mentioned the biggest barrier, and that's for most data reporting. We have a decentralized system with state laws establishing reporting requirements. This decentralized system is based on our US Constitution, which generally does police powers, including public health powers at the state level. And so, the resulting variation among states and territories makes it difficult to coordinate, combine and compare data. And then, in addition to variation amongst states, you often have a different law within the state that applies with each different type of data. Next slide, please.

In modernizing public health data systems, remember to consult with your attorney. One reason is to facilitate legal compliance. For example, you want to design systems to make it easy for you to separate data that must be provided in response to a Freedom of Information request and to separate the data that must be provided from the data that are confidential or exempt from disclosure.

The legal landscape around data can be scary. There's ambiguity, and when there is ambiguity, there's the tendency of lawyers to promote data lockdown. And to promote data sharing goals, it is important to include your lawyers in the big picture discussions so that they recognize that while there are risks in sharing data,

there are also risks in not sharing data. Not sharing data to inform the public and to provide communities with the data they need to address social and economic factors that affect health. Next slide, please.

In collecting and sharing data, health departments need to juggle multiple roles and competing interests. As we know, first, they must protect the public. And they also have the responsibility of informing the public, which includes the release of data and information needed to inform and empower communities, their leaders, and the public in general.

At the same time, they have the responsibility to protect individual privacy, and the more useful the data, the greater the risk of an individual being identified from the data or when data are linked with other available information, even though personal identifiers have been removed. We know that our zip code can be more important than our genetic code, but privacy concerns and risk of identification of individuals increase when data are provided by smaller geographic areas when we separate data for a population by components or characteristics such as race or ethnicity, those subgroups for smaller geographic areas.

So finally, in modernizing public health systems, the policy, as well as technology, needs to be – is crucial and is one of the most difficult issues is the release of these with usable data while minimizing the risk of identification of individuals. Thank you, everybody.

Aaron Miri
Thank you very much, Denise. And I completely agree and echo those comments. You've got to put the patient first and the individual first, and that privacy and security around that. So, thank you for that.

All right. Next up is Nick.

Nicholas Soulakis
Great. Hello, everyone. Go ahead to the next slide. Good afternoon. My name is Nicholas Soulakis. I serve as the Chief Public Health informatics advisor to the Chicago Department of Public Health. My qualifications are briefly listed in Slide 2 for your review, but first, allow me to express my gratitude for this opportunity to offer public testimony. Next slide, please.

In my time as CDPH, I have grown accustomed to the laser focus on equity in all things, referred to as our hyper-local approach, and communicated end mass to the public as Protect Chicago. Where equity is not only part of our COVID-19 strategy but also our strategy. This is proudly illustrated in this slide from our vaccine operations center, recognizing the hard work of our staff to provide the most equitable vaccine distribution in the United States for April 2021.

I'll now speak to the following question offered by the committee for our consideration. What real and/or perceived barriers exist that continue to inhibit progress in integrating public health and clinical data sources while responding to public health emergencies. Next slide, please.

On April 6th, 2020, Dr. Allison Arwady, commissioner of health for the city of Chicago, issued Public Health Order No. 2020-4. Medical Data Sharing Requirements. This order requires hospitals within the city of Chicago to provide CDPH with access to electronic health records while taking steps to protect patient confidentiality to help CDPH in its efforts to stop COVID-19.

In brief, this order layer the policy foundation for city-wide reporting from hospitals. In practice, we received continuity of care documents from 18 of 28 Chicago hospitals for all individuals tested, positive or negative, through secure file transfer, HL7 messages, or the FHIR standard. Slide 4 summarizes this executive order and its basic components.

While this timely policy allowed Chicago unprecedented access to clinical records, it has shown an early light on the challenges of an equitable move towards standards-based reporting, such as the imminent nationwide rollout of electronic case reporting.

If your lens is equity in Chicago, you must first consider community hospitals, large FQHCs, and neighborhood healthcare providers. In a pandemic, time, resources, and sanity all grow scarce. We know this. The lure of building single-purpose applications, which are often overfit to the problem at hand and disposable, offers an attractive alternative to building new integrated systems and learning new workflows. If an innovation like e-case reporting is to succeed, we must recognize that not all hospitals are equally capable of architecting sophisticated, sustainable solutions. This is reflected in this slide, which plots the connection status of our Chicago area hospitals, overlayed with our Chicago COVID-19 community vulnerability index.

It's easy to see that the connections have not been realized in the most vulnerable neighborhoods, as revealed by the hatched red line. A simple example of how inequality frustrates progress is catching the attention of your EMR vendor to kick off such an innovation. Large academic medical centers often enjoy the highest tier of support, with instant or two-hour support service level agreements. Lessor resource providers enjoy Musak on hold while they languish in a queue. This would not be so bad if it were not for the workarounds, like manual reporting on paper forms that must be sustained in the meantime by the same staff. It is a simple example, but one that we all try and avoid.

In closing, I would summarize our hard-fought progress, which has evolved into the particular brand of informatics we practice in Chicago and uphold three fundamental principles. 1.) Informatics for everyone. We owe our entire Chicago community the opportunity to participate in informatics innovations. By measuring our impact, not only in-depth but breathe, we arrive at the most robust solutions, which stem from requirements born out of the most challenging working environments.

2.) People are essential ingredients of informatics. This falls under the rubric of don't monitor what you can't respond to. The information does not exist in a vacuum. To measurably improve a public health intervention with informatics, users must be better able to achieve their objectives.

And 3.) The basic unit of informatics is the task, which rolls up to a job. Breakthrough informatics, by definition, requires job redesign and process engineering. Equity by design reflects the practice whereby we fortify, not replace, experienced staff. By developing a more informatics capable workforce in the community, we create professional depth and opportunities for growth.

And with that, I will close, and I thank you for your time and attention.

Aaron Miri

Nicholas, thank you very much. Appreciate that and good diagrams there. Okay. So next up, we are actually going to go to Lance Gable. We're waiting on one other panelist, but we'll go to Lance Gable, please. So, Lance, you're up.

Lance Gable
Hello. Can you hear me?

Aaron Miri
Yes, sir.

Lance Gable
Okay. Great. So, just starting my camera here. Okay. There I am. Excellent. Thank you all again for the opportunity to participate today. This has been such an invigorating conversation. I feel like I've learned so much from so many of the other panelists. And I also think one thing that's really gratifying to hear is that there are so many people who I think are thinking along the same lines.

A log of the comments that I prepared for today overlap with some of the major themes that some of the other people have been talking about in previous panels and on this panel as well. So, focusing on the importance of public health surveillance in achieving successful public health interventions, especially during a pandemic, but really, during all periods of time.

The focus on equity and the focus on the importance of making sure that when we're collecting information, we're doing so in a way that is detailed and comprehensive and can lead to multiple responses that can really help improve public health. And so, I think just to focus on the slide here, I just have a couple of key overarching themes. So, I'll talk a little bit about how the law intersects with these as well.

The first theme, of course, is that public health surveillance is integral to public health responses. We saw early on in the pandemic that there was a lot of difficulty in collecting information about the spread of COVID-19 initially, in part because of limited access to testing, and some of that was the actual tests themselves being in short supply. Some of that was related to the capacity of health departments and other institutions to either do the testing or to share the data quickly enough to track the disease as it was initially spreading out of control.

And I think one of the things that became really obvious in that early stage was how important it was not only to have an expansion to the access of the capabilities of testing and to collect the data in a robust way from multiple sources but also making sure that that data was being collected in a way that was sufficiently robust, sufficiently detailed.

As Denise was talking about earlier, just a few minutes ago, each state, each jurisdiction has different requirements in terms of disease reporting and also different requirements about the kinds of data that are collected. And so, in jurisdictions where reports were not including demographic information, they're not including information about race/ethnicity, even sufficiently precise geographic information, which made it much harder to take that data and track the spread of the disease. It made public health interventions less targeted, and as a result, and this is something that I think often goes unremarked on.

One of the reasons that we had to make so many efforts to use the law to restrict interaction early on in the pandemic. The widespread restrictions on movement and gathering and closures that had to be put into place to really stop the out-of-control spread of the disease were in part necessary because we didn't have sufficient information to use more targeted interventions.

And so, that's one big takeaway here. Better information yields better public health interventions, targeted public health interventions. And it also can help us achieve better equity because if we know that certain groups of people are more affected, as they were, by COVID-19, especially poor communities, communities of color, indigenous communities, then resources can be targeted, not only testing resources to gather more data but also treatment support and other kinds of public health intervention strategies can be targeted to the communities that are most effected, improving the equity in our response.

Just to touch on a couple more points quickly. I think that when we're thinking about the legal aspects of the response, it's important to note that law does give both the state and federal governments quite a lot of flexibility in how they structure these systems. And so, to the extent that systems are not permitting the kinds of collection or sharing of data that's necessary to have an effective public health response. We can modify those laws and regulations to be more expansive, to allow sharing in more clear and explicit ways.

At the same time, if we're doing that, we need to be keeping in mind the privacy implications of collecting a greater amount of data. One thing that's important to always keep in mind whenever thinking about sharing data that's collected through public health surveillance or other sources is that if the data can be aggregated and deidentified and still be usable for the public health purpose, that's definitely preferable because that reduces the change that there's going to be privacy implications to the use of that data.

And just to wrap things up, I think as we go forward, we need to remember that the dissemination of this data to the public is one of the key important roles we're playing in collecting the data in the first place. Because having transparent, available information for the public, like many people, as many entities and jurisdictions did during the pandemic, that's the kind of transparency that allows the public to trust what we're doing when we're asking them to make changes to try to protect the public's health. And so, transparency is key, and we can continue to improve our systems.

I've been really impressed with so many of the suggestions today. I look forward to hearing more about our discussion and our questions.

Aaron Miri
Lance, thank you. Excellent. An excellent testimony from everybody here. So, if I would ask the panelists to either come on camera or sort of assembling here while we get the questions set to go. So, the HITAC members, please raise your hands using the hand raise function on your Adobe Connect, or I'll call on you here in a minute through our audio-only.

So, the first thing here, I see Mr. John Kansky.

John Kansky
Thanks. I have a question for Dr. Soulakis. I want to applaud the – if I understand the activity in Chicago, I want to applaud the aggressive connection of hospitals to share standardized data to benefit public health.

But I can't help pointing out that as the largest metropolitan area in the country that doesn't have a health information exchange serving it, can we seize on this opportunity to use these connections that are being built as a basis of a health information exchange in Chicago? Thank you.

Nicholas Soulakis
Hello. Sorry, I was on mute there. No, I agree with you. And I look for inspiration all the time. North Carolina, Washington, our neighbors in Indiana, fantastic. And we greatly benefit from their successes, their use cases. We use those standards, and we will – if you're familiar with the Chicago area, you're also familiar with our Illinois Health Information Exchange and its untimely demise, I guess you could call it.

And so, we're public health first. And a public health information exchange is certainly not out of the question. It's just a question of whether you need to call it that or not. But we absolutely look forward to using standards to exchange healthcare data.

And one example I gave was e-case reporting, which not everyone would consider health information exchange per se, but it's the same pipes. It's the same teams. It's the same standards. And most often, it's the same people at the hospital end that are connecting all of those pipes.

And so, our network is our network. I didn't plan this workforce development announcement. I really didn't. But we really focus on our partners. And today, we're asking our partners to start thinking about e-case reporting. Soon we'll be talking to them about other things and other use cases around clinical records. But for us, we start with the program first and the program needs, and then we move to how do we define success and how do we measure success?

And so, our health information exchange plans are largely dependent on our community's needs for health information exchange. And as we evolve into this, as we recover from Chicago, one of the things that I wanted to talk about but didn't have time to is I would love social services on health information exchange and greater integration of social services, which I think is an area of huge growth as we dig out of COVID and all the implications of COVID for Chicagoans.

Aaron Miri
Excellent. Any other panelists? Okay. All right. We'll go to the next question in the queue, then, was from Sheryl Tourney.

Sheryl Turney
Thank you again, Aaron. Again, I really appreciate everyone who's come forward to speak today. I think this has been a fabulous discussion. And the one point that I wanted to bring up since we're talking about the ecosystem is that there are some things that are still lacking. And although maybe I'm looking at public health reporting too broadly, I painted a picture after we had the intersection of the clinical, administrative data task force last year internally for an executive at my company to sort of look at this in a parallel to maybe the financial systems.

And in financial systems today, consumers have the ability to go out and look at, you know, Experian and a number of other companies to see where all their data has been reported and how it's being used. We don't have that today in health data systems. Maybe we need to have that from the consumer perspective.

Also, although we're making strides and making data available in third-party apps, maybe it's not necessarily always the way that a consumer would want to have the data. Today, you can go out to your bank, and you can use different tools to attach different accounts together. A member or a patient still does not have that capability within their ecosystem today, and how that may then find itself into public health reporting.

So, I do think that looking at the ecosystem overall, the things that have been talked about today relative to using the technology that already exists for EMR systems to talk together or payers and EMR systems to talk together. We need to build upon that so that we build out the ecosystem and not just look at public health reporting as a separate entity. But what needs to be there for the infrastructure so that the consumer, the payers, the providers, and the public health reporting, which includes federal and state.

States today, payers are sending millions of dollars of work to many different states for all kinds of health reporting. In looking at that ecosystem and understanding how we can improve those data connections so that they have data that's timelier, that's more consistent, and it isn't custom developed for every single entity that's asking for it. I think that's the way we need to look at this system as we're looking at prioritization moving forward. And I think then that's going to enable us to move forward more quickly, similar to what's happened on the financial side.

Because a lot more happened when financial firms decided on the backend to be able to communicate and share things, so then all of a sudden, you could move money faster. People who were having accounts could link accounts together. We still don't have that. And to me, I think that that needs to be in our line of sight. That needs to be the model or the goal that we need to go after here. Thank you.

Aaron Miri
Good point, Sheryl. Comments from the panelists?

Lance Gable
Well, I don't have any particular insight into what the appropriate mechanism would be to achieve that goal. But I do think it's a really important goal to pursue. And I think that from a legal perspective, there might be a couple of ways to think about how that could be accomplished.

Obviously, it would be possible to have either legislation, or some kind of legal requirement put in place at the federal level that would facilitate or authorize the development of that kind of system. It could happen outside of explicit authorization, but it would still probably be subject to existing federal regulations that attach to health information privacy.

And it sounds like, from what you were just describing, that you are envisioning this as being a variety of sources of information. Some of that information might be covered under a kind of existing HIPAA privacy regulations, but other information might not be.

So, part of thinking about creating more interconnected health information ecosystems needs to – there needs to be an evaluation of how both the existing and potential future legal regulation of that information

attaches to that ecosystem. And what we need to think about, obviously, is continuing to protect privacy in a robust way. But without unnecessarily impeding the kind of useful sharing that you're talking about.

And so, I think it's a complicated balance, and I think it's something, though, that we should absolutely keep talking about.

Aaron Miri
Any other comments?

Denise Chrysler
Sure. Lance spoke my mind. I was thinking in terms of a lawyer. I was thinking in terms of a consumer. I'm a person who uses every patient portal possible to monitor my own test results and all my information, but I have refused to use an app that would bring together all that information to facilitate me having access to it because I know that depending on by the app, often it's not governed by privacy protection laws. And so concerned about what data policies and privacy policies there are and how the data will be used and how it will be protected, and all those sorts of things I've found as an impediment.

Nicholas Soulakis
And I would just add that we've all learned in the last 18 months or so, agile application development, for better or for worse. Health departments have had to turn into software shops. And when we talk about personal health records and personal data, we're talking about health departments designing apps for their constituents. For the public. And this is something we could all be better at.

I think that we've learned, we've been surprised with areas that we've been successful in, but I think we've also been shocked that it's not as easy as we think it is. And just even if we have fantastic vendors that are producing technology for us and using all of our standards, the translation of our programs to requirements to those vendors in a 24-hour cycle where anything can change has taught some of us that we're good at it and others that we need to become a lot more competent in delivering applications to consumers. And I think we've learned that in COVID.

So, where we've succeeded, I think that we'll double down, but there's still a lot of areas where we need to grow. And not the least of which is, in a state like Illinois, we have 103 counties, 97 health departments. So, when you stand up a – even if you are coordinated enough to stand up a statewide, consumer-facing application, a lot of times, jurisdiction will interfere with the ability for data to flow in an effective way.

So, I know that we'll never be -- I shouldn't say never. But hopefully, not in the near future, we won't be in a compressed time period like we are now, so we'll have time to thoughtfully plan these things out. But I've seen – it's not necessarily the connections to the data itself, right. We still have to go that last mile of health departments getting better at mobile applications consumer-facing applications. Some of us have done it, some that haven't, we should share our successes. And Number 2, when it's thwarted by jurisdiction, we need to make sure that we're working together to understand what all the use cases are. I can't tell you how many times I throw cases over the fence to Indiana or other states, and they do the same, and it's always different in everything we do. And I think we'd all like to see a little bit smoother exchange of data as we move forward. Yeah, that's all. Thank you.

Lance Gable
Could I make one follow-up point as well?

Aaron Miri
Please.

Lance Gable
This is just a point on Nicholas's point about the desire to have more time. And it'll be nice when there's a little bit less pressure from the impending response to the pandemic. But I also would encourage all of us not to let any of these issues languish and to keep pushing full steam ahead. I mean, the announcement about the new funding right before this panel is, I think, a great motivator for that. Because we've seen in the past that after a major crisis, resources become available to react to what just happened. But memories are short, and people will move on from this more quickly than we can imagine right now. And so, I think we need to keep our focus on making sure that we're using the public support as well as the financial support that we have available in a very focused and deliberate way to make these changes.

Aaron Miri
Got it. All right. So, I would also invite other HITAC members that have questions or comments to please raise their hand. Otherwise, I do have a couple questions from you guys also, sort of canvas from the group prior.

And the first question for you, and it can be either three of you to answer this, or all of you, is related to public health and data, sort of segmentation for privacy, and the ability for folks to have granular consent on different data elements. Are there certain things that we should be thinking about as a group, as a HITAC, as we look at USCDI standards in the future around privacy and security that help sort of regaining that trust with the public that their data is not being used for any other purpose other than public health and response purposes? Is there a thing that we can do? Is it a better definition of the data? How being the data used? Data provenance being all the different elements surrounding it. Are there things legally, from a legal compliance perspective, that we should be thinking about around these data elements as we further continue this journey of evolution? Lance, I'll start with you.

Lance Gable
Okay. I was going to see if somebody else wanted to jump in on that. That's obviously a great question, and it's one that I think is a little bit complicated to answer. But I think I would approach this with a few things in mind.

The first is that obviously, there are already existing privacy regulations that apply to some of the data that we're talking about. And so, making clear to consumers, to members of the public, to people whose data is going to be in these systems, how the exiting protections keep it private to the extent that it does. And also, making sure that the downstream recipients of that data, whether it be a public health department or it is some other entity, are making very clear the protections that they're using to protect the security of that information.

I think that right now, there's a lot of inertia in the existing HIPAA privacy consent process. Patients go in, and they sign the form, or they're emailed the form. And I think oftentimes, there isn't a lot of meaningful

dialog about what it really means for the protection of information, especially for downstream uses like public health reporting and things like that.

Now that being said, I think there's also – and again, this maybe is not a legal suggestion, per se, but I think it's important that we keep making the case as to why public health surveillance is really important for protecting our health. And that the collection of this information is really vital to responding effectively to the kinds of threats like we've just been facing.

And to the extent that the public is not feeling comfortable about participating in sharing information because they're worried about those privacy effects, making sure that there are laws in place that protect against discrimination based on health information being revealed. And overall, trying to increase those kinds of protections.

There's a separate discussion that I think we can have about sort of the role of non-governmental entities in the downstream, either in the collection of the data or the downstream use of this data. Because I think so much of the data falls outside of what would traditionally be protected by the HIPAA privacy rule, that increasingly more and more, especially data picked up by apps and other non-healthcare entities, thinking about how privacy protections apply to that data. We might need to rethink how our health privacy laws are applicable.

Aaron Miri
Got it. Other comments? Denise or Nicholas?

Denise Chrysler
Sure. Often there is hesitancy in releasing data because of the risk of reidentification, and that risk is hard to measure. And so, whether a health department is subject to the HIPAA privacy rule or not, often the health department uses the HIPAA safe harbor provision for deidentifying data. And that means when data is released, it's often at the state level. It often lacks dates and important demographic information.

There are a couple approaches. During COVID, I know at least one legislature that passed a law not only requiring that certain data be collected, including race and ethnicity, but that that data be posted on the state's website by municipality and county. And that's often something you don't get in a lot of data when it comes to, especially small numbers, because of that hesitancy.

The other thing is really developing robust data release policies that really carefully look at the risk of reidentification, and when you have laws passed, you've got a legislature that's made a decision, has looked at the balance between maximum support of privacy and the importance of informing the public and sharing important information, for policy. And so, I would encourage more effort for decisions that do that balance.

Nicholas Soulakis
And I can go ahead and give my two cents. I'm not an attorney. But I do work very closely with our general counsel, our department of law, our chief information security officer, our CIO. And I wish it was as easy as checking off HIPAA. One of our attorneys says that all the time, like we just check off HIPAA, and we're good, right? And it's just simply not true.

Of course, it's part of health data sharing, but we have an entire web of privacy laws. I'm here as an end-user. I benefit from good policy and good legal protections, both for consumers and for us. But when I build a system, I'm often thinking of Illinois STD Control Acting Code. Illinois Communicable Disease Acting Code. Illinois AIDS Confidentiality Act. Illinois Immunization Data Registry Act. Illinois HIV Registry Act. I think you guys get it, right? The LED Code, the Substance Abuse Disorders Records. Mental Health and Developmental Disabilities Confidentiality Act.

Right. I wish there was one place where I can see where my biggest headache is, but chances are I'm operating in multi-layered, multi-disciplinary programs that have a broad scope. And so, it's hard for me to interpret my own laws, and so that takes time and effort, and we work very diligently. But the informatics guys and the legal guys, or persons, I should say, we've got to grind it out, and there's a lot of translation between the two. We work together very regularly.

This is played out, I think, again in the compressed timeframe. We've been able to do – how many of us have made contracts in two weeks that used to take a year or even two years sometimes to hammer these things out, and we've gotten contracts through in light speed because we've been able to intensely focus on the task at hand, and a lot of times we have distractions in our day-to-day work.

Not to mention, other states are doing fantastic things. California and Virginia are passing state laws. There are ambiguities in HIPAA. We are authorized by law to collect information; it does not say how specific that authority must be. And so, even within HIPAA, there are still clarifications that we would benefit from.

So, I'm not a lawyer, but I benefit from it, and I keep these things in mind as practice informatics for the health department.

Aaron Miri
Great comments. Thank you for that. The next question I have for you is the intersection point of FERPA and HIPAA as it relates to public health. And universities, academic universities, universities like myself, UT Austin, and trying to navigate that. I mean, obviously, the catch-all answer could be here, consult your general counsel, your compliance team, and your distance may vary. But I would say looking forward, as we look at this from a public health response and making sure that there is a level set of just how much of this population's vaccinated, for what, what the risk points are, what could you advise us, again, looking at data classes, data elements, sort of that equity by design and trying to keep transparent, which I've heard from all three of you, is a key component, a key tenant in maintaining that trust with data. Are there other things that we should be doing because FERPA does allow for a limited release of information? HIPAA does not, with the consent or nonconsenting. So, to the degree of it, are there things we should be thinking about moving forward?

Denise Chrysler
First, make sure I understand. FERPA's much more restrictive when it comes to providing information to a public health agency than HIPAA is. And HIPAA says that if FERPA applies, which FERPA applies to student records, then HIPAA doesn't apply. And then there are all sorts of nuances when it comes to, say, university health centers and those sorts of things that I won't go into.

So, HIPAA has very broad provisions about sharing identifiable information with public health agencies for public health purposes. And this is for routine purposes. This is for emergency purposes. It doesn't have to be mandated by law. The health department has to be authorized to collect the information. However, with FERPA, it doesn't contain such a provision, and its equivalent is there having to be a health or safety emergency, and then it has lots of criteria about how you meet that standard. So routine vaccination information is typically not provided to health department IIS unless a parent consent. However, during an emergency, such as COVID-19, it's been a different situation because of that health and safety exception.

There are all sorts of provisions that do permit data sharing, and one of them I always talk about is if you're a public health agency, see how you can be a partner to a school district. And so, you can share data for the purpose of improving, making sure that students are in school, are able to learn, are able to be successful, and be partners in improving student performance, and that has the underline of health. Of course, that means the data's the school's data. It's not public health data. But there are ways to partner up and find ways to work together, notwithstanding law.

Aaron Miri
Great comment. Thank you—any other comments on that.

Lance Gable
I think Denise covered that very well. The only thing I'll add is that on that last point about partnerships, I think there's going to be a lot of opportunity for partnerships going forward between public health departments and schools, especially looking a couple weeks down the road when there is going to be hopefully more mindful approval of the vaccines. And using the academic institutions as a way to achieve outreach, to get more people vaccinated, get younger people vaccinated.

But I think this is also going to come up in the fall with schools talking about they are going to require vaccination for students to return? The legal precedent says that states have the authority to require a vaccination, although there's some ambiguity about one that's only been approved through emergency use authorization. I think, though, that there are some states where legislatures have come out and said explicitly that they won't allow businesses or schools to require a COVID vaccination.

And so, I think this is an area where the law's a bit in flux. And so again, consult your lawyers, and we'll try to sort it out as best we can.

Aaron Miri
Absolutely. Yeah, I meant to say it does not allow for the limited release of information. You're right, Denise. I went back and read my transcript. I misspoke there, so yes. Sorry for confusing you, but I meant FERPA, and HIPAA so thank you for that. Nicholas, anything you want to add about that.

Nicholas Soulakis
Not my wheelhouse. Thank you.

Aaron Miri
Okay. Sounds good. I see Clem McDonald with his hand raised?

Clem McDonald
Yes. And we all heard the earlier kind of discussions about why we aren't faster and how we're sort of slow, and suddenly, we're getting stuff done. But here in this discussion, it sounds like there's sand along the road everywhere. We've got all these different laws. They're different all over the place. Everywhere we've got agonizing, and it struck me, I'm a physician. 500,000 people died, and we're playing violins over all this stuff. I think that speed is important. We've got to fix something, so we don't have to agonize so darn much.

And I don't know, the privacy thing, it shouldn't trump everything. Not 500,000 dead people, in my mind. I don't know.

Denise Chrysler
I'll comment on that. Usually, the privacy thing, at least in my world, comes up when it comes to sharing data with nonpublic health organizations, with your community leaders, and with the public. And when it comes to accepting things like FERPA, you can usually find some ways to work with it. And I saw Denise Love mentioned 42CFR Part II, which is probably the most difficult laws to work with, which governs the substance use disorder data.

I've found in my work that it's usually providing information out of a public health system and out of a public health department and more generally to inform the public where the problems come up.

Clem McDonald
Well, I'm happy to hear that. But all the business of trying to combine data to make right decisions, a lot of it has to do with – as best I can tell, CDC can't avoid duplicates. I may be wrong on that. They just get counts. And shit. We've really got ourselves, I think, tied into knots. But somebody should figure out a way to loosen up a few of the knots and make it good for everybody, but not so darn complicated.

Lance Gable
Could I respond to that one?

Aaron Miri
Please.

Lance Gable
I really appreciate the comment. I really do. But the one thing I just have to say is that, for instance, a lot of the health departments have spent the last 6, 8, 10, 12 weeks trying to increase vaccination rates, operationalize vaccination points of dispensing, and we've been moving with great speed. And yet, so we have to do our RPs, we have to do our due diligence and have our operators come on. We all need help. And it's very easy if you're moving too fast to make decisions that come back on you later, and maybe that vendor doesn't protect their data as well as they should. Maybe they're flawed operations. They haven't thought, oh, what do I do when the software breaks down, and now, I have a stack of paper at the end of the day?

There are a million of these instances where we at least owe it to ourselves and to our partners to make sure all the protections are all in place. Because of the answer of while we were just moving so quickly, we didn't have time to do X, Y, or Z, sure. To your person in the foxhole next to you you've been living with for

a year, yeah, they get it. To your inspector general or state attorney's office or whatever it is, in hindsight, two years from now, it's going to look really bad.

So, I think that, unfortunately, we do have to take the time because it isn't just as simple as interesting an innovative idea about personal health records and things like this. It's our operations. And since we are specifically addressing public health emergencies, it's always going to be a compressed timeframe, and we're always going to have to do this very fast, very rapid decision making and risk assessment.

Clem McDonald
If I can comment on one more. You know, it's the talk about things, people watching their dad die. People are watching the nursing homes. They can't even get in to see the nurse. I mean, it was absolute misery for a lot of humans in this country and of other countries. And then we have -- the FDA took, I think, three weeks to approve the vaccine. England did it in five days. Why do we have to screw around for three weeks? I counted the number of deaths. Is it in the order of 4,000 for two weeks?

Creating the Public Health Ecosystem of the Future & Discussion (05:31:25)

Aaron Miri
So, Clem, thank you. I appreciate the comments. I apologize. We are at the time. I've got to keep us on track here. This is a really good discussion. As much as I love the privacy and dirty discussion, we've got to keep the calendar.

So, I want to thank our esteemed panelists, thank you so very much for participating, and for your testimony today. Very helpful, and again, thank you for all of your work. And Nicholas, thank you for the work you're doing here in Chicago. Great job.

Okay. So, we will transition to the next panel here. Creating a public health ecosystem of the future. I wish I could have a DeLorean go across the screen here. Some old-school PowerPoint presentation. But let's go ahead and introduce our first speaker here, Dr. Khaldun. Did I say it correctly?

Joneigh Khaldun
Yes.

Aaron Miri
Perfect.

Joneigh Khaldun
All right. Such a good afternoon. I want to especially thank the Office of National Health Coordinator for Health IT for having me on this panel today to share a little bit about Michigan's experience.

So as the Chief Medical Executive for the State of Michigan, I've had the honor of leading a team of dedicated public health professionals who have worked tirelessly for over 15 months now to fight this pandemic back. And I want to take a moment to acknowledge their efforts as well as the leaders and the staff of the over 45 local health departments across the state.

So, Michigan was really one of the hardest-hit states early in the pandemic and, more recently, as I'm sure everyone's aware, in our spring surge of this year. And we, like other states, have worked really hard to fight this virus back in spite of largely outdated, disconnected, and underfunded public health data systems.

And while Michigan is certainly pleased to have received recent federal funding to support public health preparedness and response efforts, it's really important to note that prior to this pandemic, national funding from the CDC for public health preparedness and response had been cut by over 50% in the previous decade. And in fact, in the fiscal year '16, Michigan's per capita state funding from the CDC was just $18.80. And that placed Michigan at 43rd in the country for CDC funding.

So, I'll be honest with you, I know it's a theme for the day, but this lack of investment is simply appalling. And to think that a country as rich as ours has to fight back a global pandemic with Excel spreadsheets, fax machines, and Survey Monkey tools is just simply unacceptable.

So, while Michigan does have a disease surveillance system. It's been in place since 2004. Many of our data prophecies throughout the pandemic were outdated. They were manual. They had to be built throughout the response, as I know we've talked about today.

For example, in the early days of the pandemic, when there was limited testing capacity, only our state lab was able to complete testing, and we were limited by a lack of an electronic lab infrastructure. So, we relied on paper forms. Those forms had limited to no demographic information on them. And they were physically being shipped from hospitals and clinics across the state to our lab. And this really did impede the speed of our response and our ability to get a robust understanding of where the virus was spreading.

So, Michigan was also one of the first states, and I'm very proud of this, to release COVID-19 data by race and ethnicity. And, of course, we identified appalling disparities. However, we were very limited in our ability to fully understand the scope and the breadth of the problem due to a lack of completeness of the data. So, while we've been able to close the gap in our missing data on race and ethnicity, there are still many providers who are not including this information in their reporting. There's still an unacceptable amount of data that are reported in this category of others, and who knows what that means? And there is a lack of more granular reporting within racial and ethnic groups.

There's also no reporting of data on religion, disability, veteran status, employment status, gender identity, sexual orientation. And these gaps really do limit the ability to disaggregate data. That's so important. Disaggregate data so it can be shared publicly and inform a more strategic and targeted response.

Marginalized and minoritized groups are not homogeneous. They have different experiences. They have different concerns. And really, this lack of ability to understand these nuances of how COVID-19 has impacted different communities really does limit our ability to focus and to guide our response.

So, I'll say that there needs to be mandated standardized and robust reporting, so all health systems, clinics, and labs, and currently, only minimal demographic data is collected from our hospitals and laboratories, and that limits our ability to more robustly understand virus spread or quite frankly vaccine accessibility and uptake.

So, in Michigan, my state vaccine information system, we're not receiving vaccination data from federal programs or from residents who may have gotten the vaccine out of the state. Systems across Medicaid, disability programs, EMF, federal programs, and health systems really should be updated so they can track and share data in a granular way. And they also need to be interoperable and integrated into public health data systems so this information can be analyzed and understood on a population level.

So, I'll just say I'm very pleased and proud of our response in Michigan. We've brought our curve down in the past. We're bringing our surge down now. But my hope is that we can really learn from this pandemic and focus on more robust surveillance data collection and reporting, not just so we can respond to this pandemic but current and future health inequities and pandemics. So, thank you.

Aaron Miri
Thank you very much. Great presentation, and yes, the work you're doing there in Michigan is fantastic and really a model for the country as we look to learn from it. So, thank you for all you're doing there. Okay. Next up, we have Mr. Jim Daniel.

Jim Daniel
I just wanted to say thank you to ONC and CDC to present today. I'm Jim Daniel, the Public Health Lead for Amazon Web Services with our state and local government group. And previously, I spent about a decade on the other side of the table working in public health innovation with the US Department of Health and Human Services for both ONC and CTO.

I want to just start by saying we support all the great work of all the public health organizations that we've heard from today, ASTHO, NACCHO, AIRA, CST, as well as the efforts of the data modernization effort. But from my role at AWS, I wanted to take the opportunity of the importance of cloud services as we start to think about the modernization of public health data systems.

One of the really important things we've heard about today has been the inability of many of our core public health systems, including electronic lab reporting, disease surveillance, and immunization information systems, to scale appropriately during the pandemic response. Many of our EOR and disease surveillance systems were receiving more results in just a few days than they would have normally received over the course of the entire year during the peak of the pandemic. And unfortunately, some of these systems were not able to scale to handle that type of volume and failed. We started to see the same type of performance issues with immunization information systems, as the scale of immunizations being reported and queries coming into vaccination information systems soared as vaccination campaigns started in late 2020.

And one of the key advantages of using cloud technology is that when you're running on the cloud, these systems can actually automatically scale as the demand for these systems increases. The public health departments don't have to spend the initial capital on building out a huge infrastructure that can handle peak volume. But instead, when they're using cloud services, they can actually have a system and an infrastructure that scales as needed and scales back when it's not needed. And that way, public health departments only have to pay for the infrastructure as they use it. They don't have huge capital investments for large infrastructure, but they can scale as needed. And in the long-term, I really think that helps with long-term sustainability and ends up saving dollars in the long term.

There are a couple of ways that I want to talk about that public health departments can really start to think about cloud strategies as we move forward. During the pandemic, we started working with many customers to actually implement what I like to call just a lift and shift strategy, where we were able to take their legacy systems and migrate them to the cloud in a really short period of time, that then enabled them to quickly have a scalable system and operate their core public health systems without the performance issues and failures that had been happening. And we weren't actually having to ask them to implement new systems in the middle of a pandemic, which is the last thing that you want to do.

Looking forward, though, as we have time to start thinking about really building out our new modern health systems and we think about what our needs are, what is the cloud strategy there? And one of the things besides just the lift and shift strategy, as we look at developing new applications, think about developing more cloud-native applications, things that actually run in the cloud better and can end up costing even less to operate.

One of the things that we did in the beginning when we didn't have any systems in the face for the large-scale contact tracing, we were able to implement cloud-native solutions implemented for contact tracing with many different states and jurisdictions.

I also wanted to talk just briefly about some of the other issues we saw with the COVID-19 response, specifically around mass vaccination campaigns. In the beginning, the seniors and other at-risk populations really had a difficult time scheduling an appointment on the web-based applications that were out there. Cloud-based call centers were actually able to come in and be quickly deployed to help handle the huge volumes of calls to help citizens schedule their appointment.

I also think one of the really exciting things that are happening that ONC and USDS are doing is opening up those APIs for open vaccine appointments to make it easier for citizens to schedule their appointments. I think that's a great first step, and I can't wait for the day that it's as easy to schedule a vaccine appointment as it is to book an airline ticket with additional API work.

And finally, I just wanted to quickly touch base on consumer access immunization data. Now we've heard in previous testimony, vaccine administration records are spread out across multiple systems and employ health records, mass vaccination applications, pharmacies, provider EHRs, and as a consumer, you don't even know where your original vaccination record might be stored. It's really important that we have the standards in place to make it possible for citizens to go to that one place where all that data resides, and that's the state and jurisdictional immunization information systems. Thank you.

Aaron Miri
Thank you, Jim, for the testimony. Appreciate that. And from the provider community side, and we use all the major cloud service providers, as do many people. So, appreciate the work of AWS and all the CSPs partnering with the provider community to help us get through a lot of what we needed to get done. Okay. Next up, we have Ken Mandl from Boston Children's. How about Ken? Good seeing you again.

Ken Mandl
Good afternoon, everybody. Thank you for the opportunity to present my testimony to HITAC for the public health ecosystem future is an honor. Thank you kindly.

I will succinctly propose an interplay and intersection between two technologies I spent much effort developing, virus surveillance systems and application programming interfaces, which turn EHRs into platforms for running apps and exchanging standardized data on populations.

Here on the first slide, if you could advance a slide, when planes struck the Twin Towers on 9/11, shortly thereafter, the US Postal Service found itself handling envelopes filled with weaponized anthrax. At that point, I was running a biosurveillance system leveraging health system data to generate public health intelligence. That system, which I designed, was one of a small handful of federal-funded syndromic surveillance systems.

We rely on chief complaints to identify patients who presented a symptom of flu-like illness consistent with anthrax exposure. Chief complaints are the staccato descriptions of why patients have come to the emergency department. The triage nurses type into ADT, or admission, discharge, and transfer systems at every ER in the country, spelling errors and all. Shown in the upper left are some of the more than 300 ways vomiting was spelled in a New York City ER for the chief complaints. We used Baize and natural language processing methods to parse them. Our system, called EGUS, which Jim Daniel was highly supportive of as our public health partner in Massachusetts, was one of the very early syndromic surveillance systems, which we described in a now-classic 2004 paper, shown in the slide.

And we squeezed so much information out from these little strings of text. In fact, do you think chief complaints about a region, we modeled the spread of flu, demonstrating that it begins in three and four-year-old and then spreads up to the age groups, receding mortality peaks in the elderly by a few weeks. Based in part on these ADT data and our analysis, the CDC added three- and four-year-old to the universal flu vaccination recommendation.

The opportunity at hand is to upgrade from chief complaints to the full content of the EHR as specified in the US Core Data for Interoperability. I estimate that this will include two billion full text notes a year, in addition to a wealth of structured data. Next slide, please.

How will public health get access to these data? Well, one way is via the 21st Century Cures Act regulated APIs. I don't do much lobbying, but after brief meetings with senators and staff, one sentence was inserted into the Cures Act, such that all EHR must have published application programming interfaces, that without special effort, give access to all elements of a patient's record. Under ONC funding, our smart health IT team produced two of these APIs, one that enables an app to connect to EHRs to handle data one patient at a time and one for extracting data on populations. These are called the Smart on FHIR API and the Smart HL7 Bulk FHIR Access API, respectively.

Thanks to Micky Tripathi's leadership of the Argonaut Project, whereby these two APIs were built into the EHR products, and the standardization of these APIs by HL7, the ONC rule implementing the Cures Act API provision requires support for both by December 2022. Next Slide.

To conclude succinctly, much richer standardized electronic health record data will soon be available nationwide to meet multiple needs. Public health can leverage required federal health IT standards and other broadly adopted capabilities. The EHR infrastructure, both siloed by institutions, can be leveraged as

a federated network providing intelligence. And the Smart on FHIR and Smart HL7 Bulk FHIR Access APIs together can underpin bidirectional communication between public health and clinical care. Thank you.

Aaron Miri
And again, appreciate the testimony. Next up is Dr. Eric Topol.

Eric Topol
Aaron, okay. Hello, Aaron. I have no slides. I'm here to participate in the panel discussion. So happy to do that.

Aaron Miri
Okay. Sounds good to me. And we will then proceed to Q&A for this group. So, let's go ahead and get HITAC to weigh in please and raise your hands please, and I will be able to call upon you in the order in which you raise your hand. All right. First up, I see Clem McDonald.

Clem McDonald
So, this is an aside, but the comparison makes it as fast as scheduling an airline reservation. I don't think it is a good goal. I don't think I finished one in less than half an hour in a couple years, so let's aim for something faster.

Jim Daniel
All right, Clem. You write the APIs; we'll make it happen.

Aaron Miri
He will. All right. Sheryl Turney.

Jim Daniel
I know he will.

Sheryl Turney
Thank you. Again, love these discussion topics. I have a question, probably primarily for these gentlemen who presented from Amazon. In terms of that cloud technology strategy, Jim Daniel, that you were talking about, I was just interested in terms of because of the way the cloud technology strategy would work, how could that be implemented in a way that states, federal, and multiple constituents could all access the same technology in that type of solution? Like I'm just trying to envision it, and I'm looking for you to solutionism it, but if you could just talk a little bit more about how that would come together and be connected, that would be helpful for additional discussions that I'm sure we're all going to have.

Jim Daniel
Yes. That's a great question, and there are a couple of great examples of that. And it does, I think, need to involve a third-party convener to make things happen between the state and local government. And luckily, we do have the Association of Public Health Labs that is running what we call the AIMS platform. And there are two examples of a shared federal-state infrastructure running on the AIMS platform. The first is for what syndromic surveillance has evolved into, where each state has its own private part of AIMS where they

have their own syndromic surveillance systems. But then that also shares data with the CDC on the same platform. So, I think that's one great example.

And another example is a project I started back when I was at ONC called the Immunization Gateway, which promotes sharing immunization data between states, sharing data with consumers, but then also has a tie-in for the federal government to have access to data as appropriate as well. So, I think there are some great ways to do that, and there are good examples with AIMS that we could follow to develop other shared infrastructure. And actually, electronic case reporting is another example of a shared infrastructure that is running on AIMS.

Aaron Miri
Any other comments from the panelists on providing cloud technology, being able to deploy at a side scale? All right. We have a question here for Dr. Eric Topol, actually, for you, sir. One of the things that you speak about a lot and do a great job of is giving examples of things like artificial intelligent devices plan tables, other technology stocks, wearables that we should be looking at that really generate a tremendous amount of personally held generated data to really give us a complete picture. Are there things the HITAC should be considered in terms of data standards, elements, other things we should think about that maybe we should accelerate, that are not so far off on the horizon, we may be thinking they are, they should become a part of a new USCDI standard of the near future? Can you educate us, given some of the research that you have done, in sort of that futurist role?

Eric Topol
Right. Well, I think the difficulty is integrating multidimensional data. So, if we just take the COVID example, we will want to have data at many levels, such as the data that Ken is reviewing on EHRs, but also the genomic data from genomic surveillance, the wastewater data, the mobility data, all these different layers of data and in real-time, to have that integrated, and then ideally, to feed that ack to all users.

So, this is a challenge. The idea of multidimensional data and AI is still a work in progress. But it's the kind of thing that it's doable, and if we work to that end, it would be a great service. It would be a great way to control or prevent outbreaks now that we're starting to get a handle on the case burden and getting containment in this country.

So, we're not ready at all for that yet, but the field is ready, and we could seize the opportunity.

Aaron Miri
Thank you. Any other comments from the panelists regarding things for the future we should be considering? Ken? Were you saying something?

Ken Mandl
Yes. I agree that the opportunity to merge multiple types of data, including genomic data, including viral genomic data, is something that public health should be able to take advantage of. APIs are one approach to bringing multiple data types and systems together. And we are in a position to move to a much richer fabric of information coming from multiple sources to inform public health decision-making.

I think right now, we remain limited to some very tried and true data sources. But we can move past that in the 21st Century.

Eric Topol
Yes. One thing I might add, and I'll admit it's just the one that we have the most experience with, is sensors. So just using a smartwatch or a fitness band, a Fitbit, with things like resting heart rate and steps, can not only pick up important things like a COVID case but also can be used as in other countries. For example, in German, where over 700,000 people are donating their data to have the total country surveillance.

So that's an important layer—passive collection of data from sensors that we already are wearing. There are almost 100 million Americans that have either a smartwatch or a fitness band that they could use to have this data be part of this multi-dimensional analytics.

Aaron Miri
Good deal. Dr. Khaldun, are there areas of mass data merging or mass data elements that could help accelerate discovering new trends and new things going on with the various cohort of patients? Or, from a public health perspective, are there tools unavailable today that we should be thinking about designing for the future to enable your job and the heroic job of others across the country to do what you're doing to be able to get in front of future pandemics?

Joneigh Khaldun
Yes, absolutely. I'm proud of my team again, but it's been a struggle. I mean, literally, I mentioned Survey Monkey tools, Excel spreadsheets. And I think that there's a way that we feel throughout the pandemic, pulling in Medicaid data, disability data, using EMS. But it shouldn't mean that we have to take three, four months to try to see if we can match and link and where's the person? And I think there are certainly opportunities to be able to do that. But I think to some of the previous points, my challenge throughout this pandemic has been – vendors, for example, have come to us and said, we've got an app. We could do this really cool thing. But when you're just hardly getting off the Excel spreadsheet, it's really hard to think about a cool app, and you can hardly just get your basic case investigation and contact tracing done.

So, I think if we do it now, for the next pandemic, we can be ready and pull in that data from all those various sources.

Aaron Miri
Got it. It's almost like a public health platform, connected via multiple APIs, secure APIs, and OAUTH, that connect with sensors across the entire country, sort of aggregating and allow you to respond. Something to that effect. Okay.

Jim, I'm curious from the Amazon Web Services perspective, are there components here that have been learned from data elements that are missing or data specification or classes as you've worked in various health systems going? Man, we've got to stand up something different as national infrastructure, or use standards as we've been thinking about to accelerate for Caesar providers or other vendors to be able to rock with Dr. Khaldun and others, to turn her Excel sheet into something with a bang that can be worked with?

Jim Daniel
Yes. I think the missing data elements that were mentioned all throughout the day, just basic address, phone information from lab reports, then all the social determinants of health, comorbidities, all of that was so critical in the early stages of COVID response and continue to be important. It's still a challenge to get that information.

And one of the approaches that we've done with some of our customers is to actually help build data lakes, which is sort of another cloud-based way to bring together data from multiple sources, put it together, and pull in the data, so it's actually available for public health. It's not necessarily an API-based approach but another way to bring that data together. And that's some of the things that we've been helping some states do.

Aaron Miri
Got it—Dr. Topol, curious about your perspective. One of the things, obviously, as we start pushing the envelope on looking at things like fences and others, this goes to a previous panel with cybersecurity and other considerations of other things we haven't even thought of yet. In all of your research a looking at this from a future perspective, are there dimensions of cybersecurity or privacy that we should be thinking about that maybe Germany or others have overcome, Israel or others that you've spoken about in prior discussions, that really, we should look at and learn some as we build out data classes and elements here from a secure perspective, and keeping privacy in the forefront?

Eric Topol
Well, I mean, there are a lot of things that we can take advantage of there that we have barely scratched the surface. Particularly federated AI, so that we could get the data from health systems across the country without having to actually remove the data from their rightful place. But in addition to that, we can do far better with homomorphic encryption and the tools that we have available so that we are not compromising the potential for security or privacy.

So, we haven't done enough there. We're in a difficult position. Israel, the entire country, is digital for their health records. And so that made it a whole lot easier to do a mass vaccination campaign, which was, of course, remarkably successful. Because we're vulcanized, and we don't have this cooperativity, even with the tools that we have, the federated AI and homomorphic encryption, and others, we are at a disadvantage. If we and teeth, in terms of the information systems, and that it was truly seamless, rather than somewhat operable, interoperable, that would help a great deal, but we've never really been that in this country.

We've let these IT companies' kind of rule the roost, and that's not ideal. We're not going to be able to simulate countries that have gone all-digital, whether it's Estonia or Israel or other places until we do that.

Aaron Miri
Got it. Does anybody else want to comment on cybersecurity and privacy considerations?

Ken Mandl
Yes. I agree. The opportunity that Dr. Topol points to that we could have universally available digital data is upon us. The 21st Century Cures Act, plus the ONC rule implementing the API and the information

blocking provision, will make data on populations available from every single site of care, whether it's a Kaiser Permanente or whether it's a federally qualified health center.

And not only available but available in a standardized FHIR format that should be the same everywhere. There is no doubt in my mind that there will be hiccups on the way there. When we turn this thing on in the summer of 2022, the data will not be in as good shape as we would like. That said, we can get it into better shape, and because we're going to be using those data across multiple use cases, their visibility will be so much higher than they are now, where they basically remain inside the electronic health record, generally not accessed in computational processes.

So, there's an opportunity to prepare for that December 2022 date. To anticipate the hiccups that we will have to try to head as many off at the path as we can. But to not underestimate the power of having data in the same format easily exportable from every site of care in the country. I hope we don't lose sight of that opportunity.

Jim Daniel
I just want to really echo Ken's thoughts there. I mean, FHIR Bulk Extract is a potentially huge game-changer for public health, and we all need to start, I think, preparing for that as we modernize our public health systems.

Aaron Miri
Dr. Khaldun, I'm curious, from a public health perspective, again, you spoke towards the duct tape and baling wire that's holding a lot of the public health infrastructure today, but there's a promise on the horizon, I think as Dr. Topol and others have articulated. Do you see it that way? As a near-term success, should we really be starting to incorporate machine learning and AI? Those have been topics that the HITAC has talked about. We've looked at that annual report we've talked about, but we know that's kind of on the horizon, right. There's a lot of things we need to do to get to that promise. But it is something that we should look at and bring forward and say, you know what, now is really the time to really double click on AI and what that means and those algorithms. From a practitioner perspective, what is your take on that?

Joneigh Khaldun
I know I sound somewhat negative because It's been a rough year. But absolutely, I am optimistic. I think we need to be looking at that information now. And I think we're all talking about the pandemic response, but I used to be the Detroit health commissioner, and we were just talking about lead. And can we, at every opportunity that someone is going into someone's home, or it's a social worker, or maybe it's a child that's getting immunization for something else. We really should be able to understand at any point in time what a particular family's needs are. Whether it's LED, it's Medicaid, it's WIC, do they get a COVID vaccine. I think there absolutely is an opportunity for us to use some of that information now to be able to guide not just pandemic response but other public health issues.

Aaron Miri
Got it. Does anybody else want to comment on that? On the power of artificial intelligence today? Ken? I know you're doing a lot of work with machine learning and others in Boston Children's so, I don't know if there's something you want to say there.

Ken Mandl
Yes. You know, I think there's an enormous opportunity, and I think we need to both work on machine learning for public health surveillance in parallel to being sure that we can move the basic data around. And so, we have to therefore pick our use cases accordingly.

One area where artificial intelligence will almost certainly be useful early on in our experience of having large data is in simply defining, for example, the case definition of an emerging disease. If you have some gold standard cases, you can begin to train against them and understand, therefore, the variation in case presentations. And this is something that we were not particularly good at the beginning of this pandemic, were just having enough clinical data to understand the range of presentations of COVID, we're still learning the range of presentations of COVID, and now moving on to the range of presentations of long haul COVID or post COVID syndrome. The opportunity there, I think, is one that's particularly well suited. And clearly also in the molecular diagnostics as well.

Aaron Miri
That is true. It's almost like a COVID second opinion. How do we really analyze the things with data to understand what variations are plaguing and try to help you?

I see two other people in the queue. I want to make sure I get to them, though. Clem McDonald, you have another question, sir?

Clem McDonald
Well, it's a question and a comment. We're talking about new kinds of data, and we're measuring wastewater which I think is a great idea. But we aren't measuring air, and if we had been measuring it earlier, we wouldn't be chasing handwashing so hard, and we might have controlled this stuff better. And it took physicists to find out it's really moving in the air. The medical field, I think, kind of blew it. But there are machines that can monitor the air, and I think they were really seriously looked at back in the time of biowarfare.

I'd also like to do a shout-out to Jim Daniel for AIMS. AIMS is a really good system. I hope that it's the basis for a lot of what's going to evolve in public health. And I want to also do a shoutout for Ken's good work on FHIR and all that because I fear with all the billions of dollars going into public health, they'll build their own thing instead of building it on the same kind of communication thing and taking advantage of the healthcare standards.

Jim Daniel
Yes, Clem, I couldn't agree more. The way that public health money is given out is often to states. And states are where it happens. There's no question about it. And so, it's totally appropriate. But at the same time, I think the challenge is how do you give money to the states to spend it as they see best and they know best for many issues, but still have an interoperable system that scales to US capacity. And therein lies some really interesting questions, not only about technology, but also about the sociology of being independent and self-sufficient, and also participating in an interoperable system where the whole is greater than the sum of its parts, and the parts work together.

Aaron Miri

Good points. Okay. Let's go to the next person in the queue, which is Robert Wah.

Robert Wah
Thanks, Aaron. Again, since we're talking about the future here in public health. We've talked a lot about how the future of public health against pandemics has been discussed a great deal. I want to bring up another aspect, and that is how we can use technology in public health to combat chronic diseases? Because just as the pandemic has killed a lot of people, our chronic disease burden in this country is huge. So, hypertension and obesity, and prediabetes are huge health burdens on society.

And I'm just interested to hear the panel talk about what are some of the opportunities we have to fight those chronic diseases. Maybe not the same as an acute pandemic.

And one of the things that I wanted to bring up was I've served on the board of a company called Heggie that has 10,000 of these stations that sit in pharmacies and grocery stores across the country, and they get like 3 million measurements per month across these stations of pressure and weight of people that come in. and if somebody wants to have a system record and keep track of it for them, they just put in their cellphone number and their email. And some nine million patients have registered, so now we have nine million registered users.

But just as an example, in Chicago, there are 286 of these stations, and they've done about a million sessions in 12 months. And from those million measurements, 62% of them indicated hypertension in the patients that were measured. 32% had obesity, and 39% had a high risk for type II diabetes. In the cores of that, two percent were found to have a hypertensive crisis during their blood pressure measurement.

Aaron Miri
If I got the question right, Dr. Wah, it's leveraging existing modalities to grab the data off of them to then infer other things like you would be able to infer from those devices. Is that what you're saying?

Robert Wah
Yes. I mean, we're talking a lot about artificial intelligence and where is the data come from for all that. And I think sometimes we focus on, as I said, the latest and greatest shiniest high-tech things, but there are some things that have been out there for a long time that maybe we ought to reexamine and see whether or not there's data that can be very useful.

Aaron Miri
Shiny toys are fun. Okay. So, panelists, anything about existing data from leveraging sensors that are right out there right now in the field that perhaps we haven't fully taken advantage of?

Joneigh Khaldun
So, I think that's a really important point. Again, when I was in Detroit, we were working on a project where literally you could understand air quality. And we connected air quality to people who already had asthma in the community and be able to let them know, okay, air quality is poor today, so you may want to take two puffs of your inhaler before you go out today.

So, I think there is a way. We did that with sensors that were out in the community. So, I think there absolutely is a way to scale that type of work to be able to address asthma, lead, high blood pressure. There's some work in Michigan around high blood pressure data coming from emergency departments. I think there's absolutely an opportunity.

And I'll say, I'm concerned because I think that we all know that many chronic conditions are more poorly controlled just because of the pandemic. People being stressed, not seeking general medical care. So, I think we need to, right now, not just build up our infectious disease surveillance but put out more surveillance specifically about those chronic diseases as well.

Eric Topol
And just to echo what Dr. Khaldun mentioned, Air Louisville was an incredibly successful project whereby the geolocation of hot spots which were causing wheezing and asthma was cashiered in everyone in the region. It decreased asthma attacks by over 60%, emergency room visits, use of inhalers. Why haven't we done that across the country? That's easy stuff, and we haven't. It's only in Louisville.

Aaron Miri
Interesting. Very interesting.

Lance Gable
I do want to put a plugin quickly for the environmental public health tracking network at CDC, where they are trying to build that infrastructure across the country. I think some states are still a little challenged. It's an underfunded program, but there are some folks working hard on that.

Aaron Miri
Sounds good. Ken, anything to add really quick.

Ken Mandl
The opportunity to begin to engage patients and giving permission for the data they generate using even sensors that are already in their phones or sensors that are connected to the pones, plus data that they may generate through active response to, for example, surveys or promise measures or other outreach, is almost as Eric points out, almost untapped compared to where we could be even today. I have no doubt that we will begin to move in a direction as these platforms become more consumer-centric and engaging.

Aaron Miri
Sounds good, Ken. I think we're all fans of case report outcomes and the SDOH elements like that, which I'm sure you're a fan of the new USCDI standard.

So, with that, I do want to turn it over to Micky Tripathi, who does have his hand up, and to give us some comments, please.

Micky Tripathi
Okay, great. Thanks. I have another question, so thank you first off to the panel. This has been terrific. I have a question specifically for Topol, but for anyone. But I know, Eric, you've been very involved in

innovation and thinking about innovation certainly as it relates to various types of technology, certainly discovery and life sciences.

We heard I think it might have been from Dr. McDonald earlier, sort of a little bit of a criticism of the FDA took three weeks to sort of approve the EUA for a vaccine. Whether that's a long time or a short time, I don't want to debate that. But it was more about your thoughts about how can we harness public health data systems, real-world evidence to shorten whatever that time cycle is from discovery and the bench to the patient as we think about the future here?

Eric Topol
Yes, well, firstly, Micky, thank you. I do want to comment on that point about the three weeks versus eight days in the UK because I think that was really a reckless critique. And the reason I say that is because the FDA tightened the EUA criteria considerably. We actually faced a situation where we could have seen the first vaccine, Pfizer's, being approved in October upon 32 participants in their trial in the first analysis. And thank goodness the FDA tightened things, where they said, no. You've got to finish the trial before we review the EUA.

And secondly, as opposed to the UK, it was done all publicly. Anyone could watch the entire review session and verb back at AEsa. So, I take issue with the fact that the difference in days that person claimed about all these lost lives. I get pretty upset to hear that.

Now. With respect to innovation, we're watching it. The pandemic is the most hyper-accelerated life science we've ever seen in our generation ever. And I think what's extraordinary here a lot of people are talking about mRNA as a platform that was being developed over three decades. That's true. But in order to go from sequence to a template to animal studies, preclinical, and then to have the largest clinical trial in the history of vaccines perform, all in ten months, with the results harvested and then, of course, rolling it out, we've never seen anything like that. The average time for a successful vaccine was eight and a half years. Now what we're looking at is to get a full license for the vaccines.

Now there, you're bringing up what is how can we innovate for the FDA to go fast because we have a BLA now pending at FDA. And the approval of that BLA would be transformative because the military, health systems, companies all over the country are waiting for this to say vaccine would be required.

So, part of the innovation here is not just the life science per se, but the regulatory science. And I hope that we can accelerate this BLA because that would really have a huge impact on the velocity of getting more people vaccinated in this country.

Aaron Miri
Any other comments from the panelists on that topic? All right. I love talking about the future. I guess I'm a Back to the Future fan, though. I keep thinking set a time machine for this. Set the DeLorean to this. But it's great to think about how close we actually are and the work that can be realized. That's super, super exciting.

Micky, is there anything else you wanted to say? All right. I thought I heard somebody talking. All right.

Micky Tripathi
Sorry, I've got the phone and the video, and you know. No, hold on one a second. I wanted to say I know we're going to be sort of ending here soon, but I just wanted to thank all of the panelists on this panel as well as all the panelists for a fantastic day. I know it's a non-trivial amount of time that people spend on this, and we really appreciate everyone's insights and guidance here.

And also, I want to thank you, Aaron, for just a terrific job facilitating this. It's been quite a marathon day, and you seem to have as much energy now as you did at 9:00 a.m.

Interoperability Standards Priorities (ISP) Task Force Update (06:20:46)

Aaron Miri
It's sparkling water. The secret is sparkling water. Just lots of sparkling water. All right. Well, thank you for that.

So, we do have one more exciting thing still up our sleeve, we don't want to lose it, and that is the ISP Task Force. And with that, if you'll permit me, we will transition. So, thank you to the panelists, thank you very much, and we will go to the next group here, which is our interoperability standards priority task force, Arien and David. The floor is yours. And good luck following that future panel that we just had. So, there you go.

Arien Malec
I am carefully orienting my camera in between the shelves in my studio to get the rugged elegant background in the back here. I know it's been a long day, and I'm tired too. But we have an exciting close for you, really thinking about standards prioritization and designing for the future. And in fact, we have some exciting recommendations on building a learning health system and assembling real-world evidence to accelerate pragmatic trials and accelerate even sponsored trials, among other exciting activities we're going to talk about to you today.

So really appreciate your patience after a long day. These are draft recommendations, but the HITAC feedback is going to be incredibly important as we work through the next month to assemble the full recommendation of the task force for the HITAC consideration. So, if we go to the next slide.

There we go, boom, boom, boom. Okay. So, we skipped over the timeline and the task force roster. I think that's fine. So, we've got a fantastic task force that's been heavily engaged in helping us work through our recommendations. We've got an overall timeline if we go to the next slide, which is marching towards our June HITAC meeting for finalized requirements, which is why it's so important that we got draft recommendations over to the task force today, so if we go on to the next slide.

Today we're presenting our draft high-level recommendations for HITAC input, so we really want to get your feedback on whether we're going in the right direction. And then we're going to be working feverishly over our next four meetings preparing for the June 10th meeting for final recommendations, and then a HITAC vote and transmittal level to Micky as formal recommendations to the National Coordinator. So, if we go to the next slide.

All right. So just as are a reminder of our mission, the ISP Task Force is part of the requirement of 21st Century Cures to be able to provide annual recommendations on the evolution of standards and

implementation guidance. And we took a pretty broad filter, and then we narrowed it in pretty carefully to make sure that we have the right set of recommendations. So, we prioritized interoperability needs based on ONC priority areas and assessing the standards landscape. We differed recommendations for public health to the Public Health Data Systems Task Force, and I'm glad we did. We heard so much today that's going to inform the roadmap for the Public Health Data Systems Task Force, and we just would not have done ourselves a service by recommending a public health standard out of the ISP Task Force.

So, we heard good amounts of testimony on health equity, EHR data use for the learning health system, and learn reduction in clinical, administrative data, and standards harmonization, all sort of about public health situational awareness. And then we believe there's feature work warranted outside of the public health and related activities like adverse event reporting, outside of the public health work on care plans, pharmacies, management, data sharing, and with federal and commercial entities. I'm going to go rapidly through this upfront preamble so we can spend time on the actual draft recommendations. So, if we go onto the next slide.

Here we are with draft recommendations. So, if we go to the next slide, here we are with draft recommendations. And David, maybe I'll trade-off with you on each of our areas, and we'll just go random order through each of the recommendation sections, and then we'll collect committee feedback at the end of our presentation on recommendations. So, if we go onto the next slide, I've done all the talking, so I'll turn it over to you for the FHIR foundational standards.

David McCallie
Great. Thanks, Arien. What we approached – our sort of cataloging of what we would focus on by categorizing the topics as to whether they were foundational or whether they were more narrowly targeted. And we tried to put as much emphasis as we could on interoperability priorities that would affect many domains. So, we've got a couple of specific things here that are emerging foundational standards based on FHIR that we think to warrant close monitoring by ONC through the ISA and through their investment in pushing these standards forward.

And in particular, there are four that we call out here that are not new but are emerging and are beginning to see uptake, and therefore, we think it should be tracked carefully on the ISA website so that people can follow and quickly learn how to engage with them.

And in particular, No. 1 on our bullet list here is triggers and hooks in the substrate for clinical decision support, capturing additional information through questionnaires that could address emerging data needs with respect to public health, social determinants of health, prior authorization, routine run of the mill decision support and so forth.

The two standards that we focused on for that category are CDS Hooks, or probably better called FHIR Hooks because they can be used for more than just traditional CDS, and then FHIR subscription, which is an emerging bit of work that I believe the Argonaut group is doing implementation guide development for to allow triggering providers to know about things that they might not have encountered in their routine workflow. It's a publish and subscribe kind of approach.

Secondly, many of the topics that we've discussed in today's meeting and in our work on the task force were driven by the need to capture additional data that is not already being captured in a routine care episode. Sometimes it's situationally apparent what you should capture. Sometimes it's something that probably ought to be built into routine workflows but isn't there yet. But an emerging interface standard to do that is the FHIR questionnaire, which allows for a standard-based way to push a standard question and answer responses right into an EHR workflow. A number of vendors are implanting that.

And then finally, the ever-challenging problem of capturing consent, particularly as we capture some data now that has newly sensitive reasons for or newly sensitive use cases for when it should be shared and when it shouldn't be shared, such as some of the social determinants of health, race/ethnicity, sexual preference, etc. So, the emerging work to strengthen FHIR consent directives, we think, is worthy of additional attention.

So, we are recommending – we will recommend in much more detail when we flush out our final letter, that ONC should invest in development, testing, and production usage of these standards and related implementation guides for broader adoption and incorporation into EHR certification criteria. Arien, did I leave anything out?

Arien Malec
Let's go into the next slide. Thank you, David. Such common data models. We heard from the research community, really looking at using EHR data use for broader scale research. And also heard from reconciling – reducing administrative burden by reconciling clinical and administrative data. And that really underlies the need to have common data models that back the underlying dataset for interoperability.

So USCDI really forms the foundational dataset for interoperability, the ground truth for the information that we exchange. That USCDI's obviously mapped to HL7 FHIR as well as older standards like B2 and CDA. We believe, and we will recommend that ONC should build a clear and rapid roadmap to expand the USCDI, which should incorporate research as well as administrative needs. I think we're making additional recommendations related to social determinants and health equity that are in line with the USCDI Task Force recommendations.

We recommend that ONC work with industry stakeholders and across the US federal government to align on a common research data model, and then map that data model to USCDI as well as exiting broadly disseminated research data models, including OMOP and PCORNET. The PCORNET, in turn, is based on the FDA Sentinel model, which is why getting alignment between ONC, the FDA, and CDC, as well as NIH, is important.

And then, we also make recommendations in the research and real-world evidence section and the administrative burden reduction section on some of the particulars of model alignment and USCDI alignment that's necessary in order to make EHR data use more broadly available for administrative efficiency as well as research use. So, David, on to you for the next slide.

David McCallie
We have two slides here focusing on terminology aspects of these foundational standards. Obviously, much work has already been done through the Meaningful Use Program and its successors and then the USCDI

to address foundational standards for terminology. We will see some specific recommendations about pushing this work both upstream and broader. On the upstream side, we will recommend – I'm pretty sure, when we finish our work, that ONC works with the FDA to push the capture of laboratory coded values as far upstream as to the analyte machine itself. So that the data, when it emerges from the get-go and doesn't have to go through potentially lossy mappings from a laboratory's proprietary standard to a site's proprietary or at least idiosyncratic standard, and then finally be mapped to something like LOINC for export, if we can push that upstream we'll reduce both the loss of data and the work that's required to take advantage of that data. And then CMS, through their authority over CLIA, will have to work on that as well.

And then the third bullet point I'm going to read because it's carefully worded. ONC should directly and through coordination with CMS harmonize procedural coding standards to open and freely available standards that are either international or clearly cross-mapped to international standards and that are optimized for clinical care, research, as well as, of course, administrative data use.

We heard quite a bit of testimony from our guests when we invited the clinical research community, the way they related the struggle to deal with the current procedural code standards, both through a lack of internationalization, so it made it hard to compare US research on COVID to international research, for example. As well as the cumbersome and expensive licensing models. Next slide.

In the transition eventually to ICD-11, ONC should work with CMS and the National Library of Medicine to make sure that SNOMED and ICD-11 are harmonized so that we can eventually have a single source of captured clinical data that can drive both clinical care/research, as well as the administrative workloads. And on the nomenclature for medications, the committee – or the task force I believe that Rx-Norm is working well as a standard that can harmonize across both the administrative domains that require NDC as well as international uses where the drugs of interest for research can fairly readily be mapped to Rx-Norm. So, we will recommend pushing forward in using Rx-Norm as a single source for clinical data, clinical use research, and administrative workflows. Arien, anything I left out?

Arien Malec
Nope. Fantastic. And it's hard to get more exciting than terminology standards, so it's all downhill from here, but if we go onto the next slide.

Health equity. So, we endorse the USCDI Task Force recommendation that ONC should incorporate Gravity Project standards into USCDI. We looked at USCDI standards for sex, race, ethnicity, and address. We endorse USCDI's recommendation to expand additions for gender identity and sexual preference. We believe that they're sufficient to assess demographics, to identify social disparities. But that data does not currently flow, as I think we heard copiously today, transparently through interoperability specifications.

So, therefore, I think if I were to modify this out of learning today, I think the comment on occupational standards would be something to add to this mix. But we should – ONC should ensure that associated interoperability standards meet our certification requirements prioritize the capture and exchange of this data for multiple purposes.

So, although glossed on this one, the standards themselves are designed to be pragmatic. Many of the standards have required, if available, tags on them in case that you don't collect the information upfront and

are basically out of compliance with the interoperability specification. And then, in the real world, many people take that flexibility and drive a truck through it and optimize the data interchange standards according to what they absolutely need to get built.

And the thrust of this recommendation is let's make sure that we're doubling down on interoperability requirements that require that information be flowed through upstream and downstream. So, we're not losing demographic information, for example, when we collect it in the EHR, do a lab order for COVID, and then have that lab order flow through an integration engine into the clinical lab, but then drop the resolution on contact information.

Likewise, there was some great testimony on at home initiative. We're looking at how we better Harmonize address information and collect address information and drive the requirements and other information, task force believes that's crucially important, and we recommend that they continue the work so we can better resolve social disparities in real-time and correlate like we just heard in the last session, correlate that information with the center data and other data for health. So that is our health equity recommendations on to the next exciting recommendations, which I think is the most exciting of the group. So, David over to you.

David McCallie

So, we heard a fascinating day of presentation from three large us research projects to address, in particular COVID, data in search of understanding COVID in the early stages of the pandemic. Really work was done by the efforts. Much of the world's breaking news, knowledge actually came from. The UK and their recovery trial, which we would describe as A prospective pragmatic clinical trial through the routine care in the delivery setting, not in delivery research centers.

Patients, as most of you probably know, would be randomized to sufficient data to capture it quickly to discover if the treatment was more or less effective compared to the other choice that's the patient was randomized to. And what we'll make our recommendations based on is that we believe that we should be able to do a better job of that in the U.S.

So, one of the barriers to doing that was the difficult work of aggregating data from the hrs. Due to the requirement of so much cross-mapping and let them fit the researcher's need. And we heard that there were numerous quasi-standard models that were sometimes to be mapped through each other through cumbersome standards. Sometimes they were relevant to specific use cases. What we'll put together and we have a bit of work to do here, we'll put together some bullet points around re-enforcing our belief that source normalization, getting the data coded upstream is the key and data loss reducer that administration gives standard divergence causes much frustration particularly understanding the procedures. They have a tremendous amount going on with the clinical effectiveness.

So, we made that recommendation on a previous slide about standardizing the procedure codes around a license-free and international standard because they are working on mapping themselves to the data, they should catalog and work with the stakeholders to evaluate, develop, and Harmonize to a research model that is mapped and across mapped to fire. Bits and pieces of this work are underway, and we think it should be supported and encouraged. Did I leave anything out?

Arien Malec

No. That is fantastic. When you look at the work that the UK did, they -- we are really machining at sponsor is clinical trials. But. The UK clearly had the work for running the college in clinical trials and the steroids and now the emergency use for moves and for acute patients with COVID. Sort of in the negative rollout gave the research as well as other broad pragmatic trials on the use of medication. They have a more broadly deployed system on health records and much more data. But we're missing out on the systems that are required to perform that level of work, and these recommendations are the foundational recommendations for addressing that capability gap that we believe will help build in if the health system.

Sorry, David. I forgot we have this divided into two slides—the next slide. There we go. So, in particular, in support of the ability to do the pragmatic recover-like trials, we cataloged a couple of important areas for standards development. One in our list, there is consent. We mentioned that in a previous slide. Two, prospective randomization, allowing for both enrollment and reenroll am. Some way to partition when necessary, research data from clinical data. Four, terminology for investigation material that doesn't yet have an official code assigned to them because they are not yet a standard product and five, recommend kick that they are assessing other functionality gaps and we also reiterate that the federal health care providers is a large swath of health care providers and they can lead the way in Harmonizing data models and avoid the proprietary burden standards that we mentioned earlier.

Next slide. I think we got one set of recommendations after that. So, we're almost there. These are recommendations on the harmonization for burden reduction. I think the level of burden on clinicians is a topic of great concern. We endorse the recommendations that were all about building a path to Harmonize clinical and administrative standards with the notion that the EHR collected data should be the system of record for the data record that drives it downstream and the administrative needs and the architect and design in a completely separate system relative to our other recommendations for the ISP. Odic, so track items.

And other add motive standards and across catalog using the fantastic resource. With respect to our previous recommendation on modeling there, it is implied, not a formalized administrative data model. The task force did their work at data modeling and mapping to the ustic. And we recommend that they should permanentize it. And we need to make sure that we can EHR collect the data and return it into documentation and be the source data and flow the administrative requirements. And we made recommendations relative to terminology standard. This is an area where the research community noted that the administrative requirements for the documentation are the ones that are absolutely required and going to get done. Researcher needs are often a secondary need. So, we can normalize and capture the information correctly upfront, and it also is a secondary effect on improving secondary use for the use and the last, but not least, recommendation. David back over to you.

David McCallie

Here we go. Back one. Before we transitioned our public health-related focus to the public health task force, we did hear a presentation on situational awareness from the saner project that we felt was an interesting and worthwhile project to track and to study through some pilot implementations. The goal of the project is to standardize fire and coded data and the kind of reporting necessary for the situational awareness during the pandemics and other emergencies, as we heard earlier today. That is the reporting challenge and getting up to date with the old-time data is a challenge, and it is a burden to the systems. Can we automate

that? Can we standardize the data? That is the task of the project. And they appear to be off to a good start. So, test it in the real world and pursue it if it works in the real world.

Aaron Miri
All right. Fantastic, gentlemen. Thank you very much for that. Is that the conclusion of your presentation?

Arien Malec
That is the conclusion of our presentation, and we are very excited to open it up and get further comments from the committee.

Aaron Miri
Absolutely. We've already got multiple hands raised, so absolutely. I just want to remind everybody, we do have public comment at 4:45, so I do want to keep the time and be precise. So, we've got a little less than nine minutes. Then we can come back after public comment if questions remain. We want to make sure folks get heard. So first up in the queue is Sheryl Turney.

Sheryl Turney
Thank you so much, Aaron. And this was a great presentation. Thank you to the task force for bringing it forward. One thing, I don't know if it is within the scope of the ISP work, but what I would like to suggest is that there is some recommendation to break down the proprietary roles of the patient portals. I know I have heard from a number of patients that have a similar challenge to what was brought forward earlier on this call during the public health hearing, who've indicated that they have multiple health systems that they have to deal with, and those systems don't allow their patient portals to be brought together in the same place. And there are some vendors that do allow some versions of their software. If the EMR system is what that particular health system has, to bring them together, but not even all of the same installations allow all versions to be brought together.

So, I do think that is one thing that would increase interoperability. Because at the end of the day, we want to provide the data to the consumer in the form that they would be comfortable with. And if they like that interaction included in their portal, then they should be able to attach their other portals to an API or some type of interaction, so they get the data in the same place.

And the other thing that is old like to thank the task force for making the recommendation around the Gravity Project and the social determinants of health. Especially with the pandemic, payers have basically been studying and also see such a huge disparity in terms of vaccine distribution and vaccine testing. And having a greater standard related to social determinants of health is going to help everyone because we're all capturing the data anyway. We're just doing it in a nonstandard way. So, allowing those standards to come forward and be part of the ecosystem is just going to improve everyone's ability to use that data.

So again, thank you.

Arien Malec
Thanks, Sheryl. Appreciate the later comment on Gravity, which, as we noted, really re-endorse the USCDI task force recommendation. On the former, it's an important topic, one that we didn't consider in depth. Clearly, we've done a lot of work around FHIR based API access and OAUTH2 based access. I think the

last piece of this, just from my experience, is making it easier for patients to use the credentials of their choice to link their own information across multiple portals and discover where their portal information is. Right now, we put the burden on the patient to log in with all of their credentials across all of their different health systems. I note that my oncology records, my primary care records, and my former primary care records are actually contained in three different Epic instances, and I've got three different portals that I use, even though it's the same underlying vendor.

So, I think we should carry that forward with our list of three things that we want to carry to ACT or ISP3. That might be one of the activities that we carry forward to an ISP3. David, I don't know if you have any additional comments on that topic.

David McCallie
No. I think that's a good suggestion. I think the goal, obviously, of the APIs that are now required of the EHRs is to enable an aggregator function. But Sheryl's point is if you already have a portal, why can't you use that as an aggregator? And that's an interesting twist. I think the APIs could play a critical part in that role, but you have to know where to go look, and that's missing information.

Aaron Miri
Good deal. I think we can take one more question before public comment, and we can come back after that. So next in the queue is Robert Wah, and I will just remind you that we have a 12:45 hard stop for public comment.

Robert Wah
Thanks, Aaron. I'll try to get this done in less than four minutes. Today we had a long discussion about public health data, and as we're talking about code sets, traditionally, they're often considered for administration purposes only. But I think it's important to remember they also play an important role in capturing data for public health purposes.

And many of you know I have a long history with the AMA, served on the board for 11 years, served as board chair, and president and the CPT code set was created by the American Medical Association because we felt it was important that we create this code set by physicians for physicians use. And it's also been important in meeting the needs of the CDC and CMS in creating COVID product and administration codes that are currently being used to track cases and vaccines administered.

And because it was already a very robust process, this work was done very quickly and efficiently because their CPT editorial panel, again, is a well-established, rigorous, and evidence-based process.

I think I saw a note in your slideshow about the NSP, interest in international harmonization. CPT has also been used in over 40 countries and has a close relationship with Snowman. And as the ISP finishes up its recommendations, I might recommend that ISP invite experts from the administrative coding side. I know you heard a lot of discussion from research and clinical perspectives, but maybe not as much from the administrative side.

Arien Malec

Thank you for that comment, and we appreciate your perspective. We did hear from the administrative side of the house. The comment made reflects the recommendation also of the ICAD Task Force. I don't think making it we're saying pro or anti-one coding set or another. It looks like attributes of a common coding standard in the same way that ONC has licensed international standards for use across the U.S. to have the same level of licensing flexibility and optimize our needs. So, I appreciate your feedback and the feedback from the AMA, and I think that is important as we look at the topic going forward.

Aaron Miri
Perfect. Right on the money. I love it. We have one more question. We'll say that till after public comments. Mike, if you're good with it?

Public Comment (06:57:23)

Mike Berry
Operator, open up the lines for public comment.

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

Mike Berry
While we're waiting for the operator, I want to remind you that all the materials presented today can be found on the HITAC calendar on healthit.gov. And also, our next HITAC meeting will be held on June 9th, where the HITAC will vote on the ISP Task Force recommendations that Arien and David reviewed just a few minutes ago.

Do we have any comments?

Operator
There are currently no comments.

Mike Berry
Great. Thank you very much. Aaron, Denise?

Aaron Miri
Fantastic. Let's good the last question in—the last question of the day. Looks like in the queue is Mr. Clem McDonald.

Clem McDonald
Thank you. I have a whole bunch of them. And I, unfortunately, missed the one meeting of the committee that David and Aaron did that talked about vocabulary. It's a high interest of mine. But just a couple of cautions.

Firstly, I love research. It's very important. But I wouldn't want to burden clinical practice with all of the detail that researchers would prefer to have. So I'm reviewing the DB gap table. There are 210,000 distinct variable names in that table. Some of them really are just variations of the same thing. But they are much more specific, very often, than what you need in clinical practice, and I think we're already burdened with that.

Also, of the interest of one of our committees, I think you're on it, David. One of the leaders, who's also a clinician, was saying they just use the billing code to make their problem list because it's easier and it works fine for them, and most people do that. So that's another thing. Just be aware of. But anyway, just wanted to make you aware of that.

And the third one is that procedures – no, I won't do that one. The third one is that there's already something called Livid, which is a mapping between instrument codes between IVD instruments and LOINC codes and SNOMED for when they don't have numeric answers. And that's been aggressively used. It actually has every single COVID test in it and had it within like three days after they were approved.

But the problem is that it can't be automated to any instrument in a lot of cases. Because the instrument doesn't know enough – some of the instruments can take orders and know what they're really ordering, but a lot of them can't. So just be aware. I'm fully behind what you're wanting, but it'll take a while before all of the instruments screw up enough to be able to do that automatically. The big ones can do it right now.

Arien Malec
Thank you. Those are fantastic comments. Just clarify, we probably should make this clear in the final recommendations' transmittal. We're not suggesting that we design clinical data capture for clinical care around the needs of research. Rather, what we're suggesting is that we do the work that's required to source normalize. So that when we do work for clinical research, we're not renormalizing data.

The testimony that we heard from the research community is that much of the work that's involved both in prospective as well as retrospective analysis is actually recoding work and renormalization work. Where if we were able to source normalize, we would be able to speed that work and use data for research.

Secondly, making sure that we've got the mechanisms for collecting additional information if it's warranted and desired by clinicians. But definitely not driving the need for clinical care around the need for research. So definitely appreciate that comment.

Clem McDonald
That all sounds good.

Arien Malec
Thank you.

David McCallie
I think we heard -- I could be wrong about this. I think we heard that certain data of high interest to researchers is not being exported like ventilator settings. It's already captured. It is in the systems, but it is

not part of USCDI. If ventilator systems were in place, it could have spread some of the learnings for treatment for COVID. So, it can be stuff like that's not new data. It's just not being exported.

Clem McDonald
So I'd like to also comment on the standardized, harmonize models. You know, they tried that already, and I don't think you got that one survived and do it, and then you've got to use it. But I think that HL7 and OMOP are already agreeing to a deal to marry, and two or three of the other ones are very close to OMOP, so it shouldn't be a huge thing.

David McCallie
Yeah, we heard that too.

Aaron Miri
Yes, you're right. You're right. OMOP and I2B2 and have other mechanisms share that data around is the way to go. But go ahead. Sorry, everyone.

David McCallie
The Odyssey that manages OMOP is working directly with Graham Grieve for HL7 on the beginnings of a harmonization. But there are other data models like I2B2 and PCORNET that are in wide enough spread use. They can't just be ignored. So we think it needs more study. There's not a simple answer. But something that should definitely be studied.

Clem McDonald
I'm confident that the PCORNET people are close. They just need funding to be able to make the conversion.

Arien Malec
I think that's generally our recommendation. Rather than have three underlying data models, we probably should at least have a common data model. There may be needs for additional data in particular circumstances. But what we heard was that many people who'd adopted, for example, OMOP, were taking secondary and sometimes lossy work to record for PCORNET and vice versa. And so anytime we've got effectively the same data model twice, we're actually driving administrative work that's getting in the way of research, and we're driving potentially lossy transforms. So that's really the incentive. Let's do the hard work to get aligned on one and then get aligned one. We believe that the reason, for example, that PCORNET went in the direction they did is they wanted to align with FDA Sentinel, which was the reason why making the recommendation that ONC align with other federal agencies and departments because we believe that that's – NIH and FDA and CDC have a high leverage ability to help standardize and align.

Clem McDonald
But on the Sentinel, one, we can't get to. It's private. It's a secret.

Aaron Miri
Guys. All right, Clem. Well, then.

David McCallie

We're not in favor of secrets. We don't like secrets.

Final Remarks and Adjourn (07:05:14)

Aaron Miri
Yes, no secrets. No secrets here. Okay. So, keeping the time, and I appreciate all the comments of everybody today. I'm going to go ahead and move us, Michael, unless you're concerned about this, to the final portion here, which is closing remarks and adjournment. Are we good with that?

Mike Berry
I am good with that. Take it away.

Aaron Miri
All right. So first, I want to turn it over to Denise Webb. I think she can help me close it out, and then I'll say a final couple of things.

Denise Webb
Thank you, Aaron. And I know I've been very quiet through this meeting, I've been trying to stay connected as we've been driving through Vermont and New York, and now we've arrived in New Jersey. And what a day. I want to say thank you to all of the presenters. I know the committee really appreciates the time you took to speak with us and give us some really great input.

And I also want to thank ONC and the Accel team because this took a lot of effort to put this together today. And then finally, I want to thank my colleague Aaron for doing a yeoman's job, a fantastic job facilitating this meeting today, and getting a lot of good discussions going. So, we have a lot to think about, and thanks, everyone. Appreciate it.

Aaron Miri
Yes, we definitely do. And so, for final remarks, thank you all for the long day, the fantastic dialog, the great discussions, one of the best HITAC meetings I can remember in a while, especially on a day of great joy, also with some of the news that's going on around us about vaccinations and the positive efforts coming around for that.

So, for all of you on the front lines, for all of you working every single day to help us through this and get to the next chapter as we move forward and learn from this, thank you. Those efforts are definitely noticed. You've noticed them today. We're building upon them, and we will move forward together as one team. As one family. So be safe. Please get your shot if you didn't grab your shot and take care.