

Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) PUBLIC HEALTH DATA SYSTEMS TASK FORCE 2022 MEETING

September 9, 2022, 10:30 a.m. – 12:00 p.m. ET

VIRTUAL



Speakers

Name	Organization	Role
Gillian Haney	Council of State and Territorial Epidemiologists (CSTE)	Co-Chair
Arien Malec	Change Healthcare	Co-Chair
Rachelle Boulton	Utah Department of Health and Human Services	Member
Hans Buitendijk	Oracle Cerner	Member
Heather Cooks-Sinclair	Austin Public Health	Member
Charles Cross	Indian Health Service	Member
Steven Eichner	Texas Department of State Health Services	Member
Joe Gibson	CDC Foundation	Member
Rajesh Godavarthi	MCG Health, part of the Hearst Health network	Member
Erin Holt Coyne	Tennessee Department of Health, Office of Informatics and Analytics	Member
Jim Jirjis	HCA Healthcare	Member
John Kansky	Indiana Health Information Exchange	Member
Bryant Thomas Karras	Washington State Department of Health	Member
Steven Lane	Sutter Health	Member
Jennifer Layden	Centers for Disease Control and Prevention (CDC)	Member
Leslie Lenert	Medical University of South Carolina	Member
Hung S. Luu	Children's Health	Member
Mark Marostica	Conduent Government Health Solutions	Member
Aaron Miri	Baptist Health	Member
Alex Mugge	Centers for Medicare & Medicaid Service	Member
Stephen Murphy	Network for Public Health Law	Member
Eliel Oliveira	Dell Medical School, University of Texas at Austin	Member



Name	Organization	Role
Jamie Pina	Association of State and	Member
	Territorial Health Officials	
	(ASTHO)	
Abby Sears	OCHIN	Member
Vivian Singletary	Task Force for Global Health	Member
Fillipe Southerland	Yardi Systems, Inc.	Member
Sheryl Turney	Carelon Digital Platforms (an	Member
	Elevance Health company)	
Avinash Shanbhag	Office of the National	Executive Director of the Office
	Coordinator for Health	of Technology
	Information Technology	
Dan Jernigan	Centers for Disease Control and	Deputy Director for Public Health
	Prevention	Science and
		Surveillance
	Office of the National	
Michael Berry	Coordinator for Health	Designated Federal Officer
	Information Technology	
Ann Kayser	MN Department of	Presenter
	Health	
Laura Conn	CDC	Presenter

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

Michael Berry

And good morning, everyone. I am Mike Berry with ONC, and I would like to thank you for joining the Public Health Data Systems Taskforce. We have a couple guest presenters with us today, and I would like to thank them for joining us and participating in the discussion. All taskforce meetings are open to the public, and your feedback is always welcomed, either in the Zoom chat or during the public comment period that is scheduled at about 11:50 Eastern Time this morning. I am going to begin rollcall of our taskforce members, so when I call your name, please indicate that you are here, and I will start with our cochairs. Gillian Haney?

Gillian Haney

Here, good morning.

Michael Berry

Arien Malec?

Arien Malec

Good morning.

Michael Berry

Rachelle Boulton?

Rachelle Boulton

Here.

Michael Berry

Hans Buitendijk?

Hans Buitendijk

Present.

Michael Berry

Heather Cooks-Sinclair? Erin Holt Coyne? Charles Cross? Steve Eichner?

Steven Eichner

Good morning.

Michael Berry

Joe Gibson?

Joe Gibson

Good morning.

Michael Berry

Raj Godavarthi? Jim Jirjis? John Kansky?

ONC HITAC

John Kansky

Good morning.

Michael Berry

Bryant Thomas Karras?

Bryant Thomas Karras

Hello, everyone.

Michael Berry

I believe Steven Lane is not able to join us today.

Steven Lane

Actually, no, I am here, Mike.

Michael Berry

Oh, great. Welcome, Steven. Thank you. Jennifer Layden? Leslie Lenert?

Leslie Lenert

Good morning.

Michael Berry

Hung Luu I know is not able to join us today. Mark Marostica?

Mark Marostica

Good morning.

Michael Berry

Aaron Miri?

Aaron Miri

Here.

Michael Berry

Alex Mugge?

Alex Mugge

Here.

Michael Berry

Steven Murphy?

Steven Murphy

Good morning.

Michael Berry

Eliel Oliveira? Jamie Pina?

Jamie Pina

Present, good morning.

Michael Berry

Abby Sears?

Abby Sears

Good morning.

Michael Berry

Vivian Singletary?

Vivian Singletary

Good morning.

Michael Berry

Fil Southerland?

Fillipe Southerland

Good morning.

Michael Berry

And Sheryl Turney? All right, thank you so much, everyone, and now, please join me in welcoming Arien and Gillian for their opening remarks.

Arien Malec

Good morning. We have a pretty impactful topic today. As I think we experienced through the last three years, getting case information for a case investigation has been one of the workflows that has required the most effort. Starting early on, it was mostly accomplished through traditional means, filling out paper and digital equivalents of paper, sometimes faxing information back and forth, and case information is an essential part of the public health response. It starts off the process and helps us with contact tracing, helps us with understanding the course and progress of disease, helps us with assembling research summaries as to the progress of an outbreak, and the ability to get prompt and timely case information out of EHRs is a capability that would greatly serve the next public health crisis.

Fortunately, CDC had done preliminary work in putting together an ECR, electronic case reporting, standard. Unfortunately, by the start of the outbreak, we were not in a deployed state, but we very quickly transitioned from having a draft standard to a partially deployed standard rolled out across multiple jurisdictions, and the jurisdictions that had access to ECR often reported that the electronic case information was coming into the local public health authority faster than, for example, the positive lab information indicating COVID. And so, I think we have good indications that a broad, nationwide deployment of

electronic case tracking and case reporting would be key to improving the public health information ecosystem.

And so, today, we are going to talk about the F5 criteria. This is a set of criteria that, right now, does not have a set of standards and implementation guide, although use of ECR is an acceptable way of addressing the F5 criteria, and so, we are going to get a view from the ground from the Department of Health perspective as well as CDC perspective, and then we will sort of canvass the participants here for experience on the provider side of adopting ECR. We will go to our usual discussion, and then, hopefully, folks have been able to look at the tracking worksheet for topics. I did some work earlier this week in assembling the aftermath of the immunization hearing that we heard last week in formulating a set of observations and, in some cases, draft recommendations, so we will go in at the end of the session to the topics worksheet. That will be the course of today. Gillian, anything more you want to add before we start the panel?

Gillian Haney

Yeah. I just want to say that electronic case reporting is in its relative infancy as compared to some of the other public health data streams of syndromic surveillance and electronic laboratory reporting, and I think that is really important as we talk about what types of certifications may be appropriate, and the other thing to add, just in terms of its relative time in this arena, is that public health really came together to determine what data elements would be appropriate for that initial case report, which turned into the electronic case report, and then has really established a centralized location for all of the data to flow and be routed. Laura Conn is going to be speaking more to that, and then, we also have Ann Kayser here from Minnesota, who will be talking about their experience with ECR. So, I think we can just go right ahead and get into the presentations. I am hoping also that Steve Lane will be able to speak a little bit to his experience as a provider as well. So, first up, we have Ann Kayser from Minnesota. Please, Ann, take it away.

(f)(5) Transmission to Public Health Agencies – Electronic Case Reporting Cures (00:07:42)

Ann Kayser

Thank you, Gillian. I just want to check. Do you need me to pull my slides up for this? Ah, perfect. Thank you so much. So, good morning. My name is Ann Kayser. I work as an electronic onboarding coordinator at the Minnesota Department of Health, and I would like to speak about our process and where we are at. So, Minnesota attested to ECR as an appropriate means for reporting cases in July of 2021. Presently, we are receiving for COVID-19 and some monkeypox ECRs from visits that are both in-state and in other states where the resident is Minnesota because we are utilizing the AIMS platform, which is a centralized hub for routing ECRs to the appropriate public health agency.

We have automated the consumption of ECRs into our surveillance system, MEDS, as of August of 2020. We are able to extract some patient and minimal visit information in order for the ECRs to route to the appropriate patient and disease in MEDS and attach each human-readable EICR to the investigation. This allows for cases to show up in workflows and not hand-enter in patient information, but does still require manual review of the EICR to extract clinically relevant information, essentially like an e-fax. We receive data from five major healthcare organizations and four federally qualified healthcare organizations within the state of Minnesota, and we continue to work with two healthcare organizations for COVID-19 onboarding and two more for all reportable conditions. Next slide.

So, the extraction of relevant clinical information from an EICR is quite burdensome, as it requires creating individual lookup tables for each disease and/or clinical information, which is why we have not done additional extraction of relevant clinical information. So, for example, for syphilis reporting, we would need to identify and extract treatment information relevant to syphilis, as well as, if the patient was on PrEP, HIV testing information and signs and symptoms related to neurosyphilis or ocular syphilis in order to meet the same case reporting requirements that we have on our paper syphilis reporting form.

If the burdensome buildup does not occur, public health program staff then still have to go into the case report and manually enter the information into the investigation in order to message relevant information to CDC. It is important that some information is not being utilized through national standards, such as lab data with LOINC codes, specifically where the tests are not public-health notifiable, but are part of a case definition and definitions of a case per CDC case definition. For example, the alanine aminotransferase, or ALT, testing, which is done under liver function panels, can be more commonly done in-house and at smaller labs. ALT results are included in the case definition for hepatitis A, B, and C, but on their own are not reportable to MDH.

Routine tests, like a liver function panel, are less likely to have the national standards into a system because the codes are not needed for public health reporting purposes. This is also true for specialized testing that gets sent out, as labs can utilize a general test order in their system for rare testing rather than building them out individually. When this is done, it is very difficult to add the appropriate test codes for their triggering for ECRs. Even if the lab findings do show up in an ECR, it then requires public health to mine and map local codes in order to extract appropriate information into our surveillance system. Next slide.

So, the recommendations that I would put forth to improve ECR would first be to include an ECR transmission standard into the regulations. For example, ELR will call out the usage of the HL7 2.5.1 implementation specifications, the addition of the standards to follow, also help public health in routing, extracting, and error handling on ECR messages. It is a blueprint for us to know where we can find relevant information to extract. The object IDs, or OIDs, are the unique facility ID that is used to identify facilities and systems sending ECR messages, yet there is not a registry or a lookup for this available publicly. Many public health agencies do require a unique ID for facilities to register for promoting interoperability. For lab reporting, this is the CLIA. These IDs allow us to route messages during onboarding, as most public health agencies will route production messages to a test environment to ensure issues are resolved prior to putting the production data into their production system.

Next, the downloading of the RCTC codes from the ESRD or trigger codes that are loaded into the EMR to identify encounters that are appropriate to report to public health do not have a timeline put in around how quickly they need to be implemented within the healthcare organization after an update is released. In reviewing ECRs submitted from July of 2022, some of the healthcare organizations submitting to MDH were still using RCTC codes from the previous summer. Lastly, there is a need for more direction or review on addressing codes and standards from feeder systems such as reference laboratories in how they integrate with EMRs in order to improve the national code usage. Next slide. And that is my contact information. Thank you.

Gillian Haney

Thanks, Ann. I think we will just hold for one second for questions. I just want to put a little bit of context into Ann's presentations in terms of how the public health investigation then follows. We heard the term "electronic case report," but what does that actually mean? That often is the initial piece of information that gets reported to public health in terms of a suspect case that is based on a trigger code. There may not actually be a case yet. And so, what public health then does is take those initial pieces of information, look through, and start an investigation to determine whether or not that individual requires an investigation, and then gathers clinical information, risk information, and so on and so forth that may be in the EHR, may be held in notes, maybe we need to contact the actual case themselves to get the further information.

And then, from there, we will actually synthesize all of that clinical information, that laboratory information that is coming from a variety of different spaces, to determine whether or not that individual's information will meet the actual case definition that then determines reportability to CDC. So, I just wanted to provide a little bit of context in terms of some of the things that Ann mentioned there. The other thing that I heard, again, is the challenges of working with unstandardized codings and the need for timely implementation of trigger sets that needs to be of consideration. So, I think I would like to turn it over to Laura right now so that she can provide the bigger context of ECR, and the AIMS platform, and RCKMS, and we will start with questions. So, Laura?

Laura Conn

Thank you, Gillian. Just checking audio. Can you hear me?

Gillian Haney

Yes, we can, go ahead.

Laura Conn

Great. Good morning, everyone. My name is Laura Conn. I am the ECR program lead at the CDC, and I appreciate the opportunity to talk with you this morning. You can go to the next slide, please. So, hospitals and healthcare providers reporting to public health using ECR within their EHR system became required as part of the Public Health and Clinical Data Exchange Measure under the CMS Promoting Interoperability Rules this year in 2022. However, the original ECR certification criteria shown here dates back to 2015. These criteria lack the specificity of standards that are needed to be implemented to optimize connections with public health. The public health community has been and continues to advocate for more stringent standards-based criteria to support the needs of public health agencies to rapidly use this critical clinical data provided in electronic case reports. Next slide.

Gillian mentioned this, but public health has agreed upon a single interface for ECR data to be exchanged between healthcare and public health agencies, and a single standard has been published for reporting of all conditions and is being used nationwide. The way public health has come together for this is an enormous accomplishment. We now need ECR standards to be required as part of EHR certifications. In addition to requiring the use of the standards, more consistent provision of the data must also be required to make it more easily consumed by public health systems. Next slide. The current version of the ECR standards is listed here and are available on HL7 websites. I will discuss these more in the next slide. Next slide.

The very specific needs in including ECR certification that we will support are here. As we have seen just in the last two and a half years, but is a well-known phenomenon to the public health community, supporting the needs for public health to receive case reports for conditions and emerging outbreaks rapidly is key to public health action. For ECR, this means that healthcare needs to electronically receive and rapidly consume the codes used to trigger these reports. For example, during COVID, both the diagnosis codes and laboratory tests being used evolved over the course of the pandemic. These updates to codes needed to be taken and used within an EHR in order to identify patients that needed to have a case report submitted to public health for action. The HL7 standard that meet these emergency needs is the Electronic Reporting and Surveillance Distribution, or ERSD, transaction that is in the FHIR ECR implementation guide. This was most recently used to rapidly add monkeypox to ECR, but routine updates to codesets like LOINC and SNOMED occur on a regular release schedule and must also be accommodated.

After receiving ECR data from healthcare, public health agencies need to ingest the data into public health information systems. This makes the quality of the data coming from these electronic documents extremely important. Historically, data from EHRs have been irregularly structured and oftentimes not coded, even when code systems exist for specific data types. This is an area where USCDI does not yet go far enough. Public health needs EHRs to regularly store and provide coded data, not just be capable of handling it within their internal systems, and while we sympathize that not all data coming into EHRs from outside sources may be coded, the data is only useful when it can be used, shared, and consistently interpreted by those that need it.

For example, if lab results are not coded, identifying a bacterial culture result of salmonellosis stored only as text in the EHR could miss a report of this important foodborne illness not being sent to public health. Similarly, some conditions are reportable at the time of suspicion by a healthcare provider. For example, if an order of a measles test is done, it is an early indication of a possible measles case, and if it is not coded, then the EHR cannot trigger and send this possible case report, thus delaying public health action, so certifying the use of the full electronic initial case report, or EICR, both for structure and for content, will support these needs.

ECR was established to exchange information bidirectionally between healthcare and public health. The reportability response provides return information to healthcare, both to confirm that reporting has occurred, but also allow public health the opportunity to give information back to clinical personnel about the condition that was reported, such as treatment guidelines or potentially additional testing needs. This document also provides information to EHR system administrators in healthcare, such as indicating if they are using an outdated trigger set or if codes are in use, but have been deprecated from code systems. So, without a requirement for the use of these standards for both structure and content and ONC certification for ECR, it really takes a lot of work with EHR vendors to ensure that their products can provide data that is usable at the public health agency. The quality of the data from EHRs directly relates to public health's ability to process and use this data in their systems. Next slide, please.

So while I have focused on the EHR certifications so far, I know that this taskforce is also considering possible certification needs on the public health system side as well. As I shared earlier and as shown here on the left-hand side, all states, D.C., Puerto Rico, and 13 local public health agencies can receive electronic case reports. The ability for public health agencies to receive electronic case report data is not the barrier. In fact, at the start of COVID, less than half of these public health agencies could receive ECR data, and

within just a few months, because of the hub-and-spoke architecture, this capability was available nationwide, and ECR reports were flowing for COVID-19 from a growing number of healthcare organizations. Today, we are at just over 15,200 healthcare facilities using ECR, and similar to what you heard in the discussion last week on immunization, the use of the data is where the real challenge lies.

Data coming from different systems in different ways prevent public health from processing this data quickly and routinely. You can see on the right-hand side of the slide the use of ECR data in systems at public health agencies is a work in progress, with just over half using ECR data in either test or production systems. While public health system infrastructures vary, they need the data from EHRs that they can consistently rely on and is of high quality in order to process them in a timely way and make the data available for public health action. We have seen all of these challenges and needs manifest in the COVID-19 pandemic. It is time to ensure that data specificity that is needed can be addressed by enhancing certification for ECR. I would like to thank the taskforce and ONC for inviting me to share this with you today, and I look forward to the discussion.

Discussion (00:23:20)

Gillian Haney

Thank you, Laura. Our next speaker is going to be Steven Lane, and before we do that, I received a question in the chat that I would like to quickly address. The question made a comment about the specificity within the trigger codes and how that is applied to actual case counts within each jurisdiction, and I think depending upon the disease, the trigger codes are established to report a case as either a suspect based on a laboratory result or a probable or confirmed case, and it really depends on a disease. So, for example, for salmonellosis, you can have a confirmed case of salmonellosis with just a culture-confirmed laboratory report, but if you have a different type of laboratory result that comes in, such as a PCR for salmonellosis, that might go in as probable, and you need additional clinical information about symptoms to be able to actually confirm that case report.

And so, that is why public health needs to get the additional clinical information from either the EHR or the actual case in order to fill out that information and actually confirm that case. I think in terms of how that really applies to whether or not we are getting the true counts of jurisdiction, I think it really depends on the disease. We know, for example, for really high-volume diseases that cases are going to be missed unless there are automated systems in place to report those to us, but for smaller-volume diseases that may have required immediate disease response, like meningococcal disease, we feel pretty confident that we are catching the majority of this. I hope that addresses the question, and if not, I am happy to continue in the discussion. I do want to hand the floor over to Steven Lane, who is going to talk about his experience with ECR and from the provider provided. So, Steve, welcome. Steve, I am not sure if you are speaking, but we cannot hear you.

Arien Malec

I do not think I see him on the participant list.

Gillian Haney

Maybe he dropped.

Ann Kayser

It looks like he is here. Steven Lane? I see him up there.

Laura Conn

He put in the chat "bummer," so he is obviously here, but we might not be able to hear him.

Gillian Haney

He is going to try to call back.

Laura Conn

Gillian, while we are waiting, just one follow-up on the question you just asked, too, and I did not delve into the architecture in my comments, but one of the beauties of the single interface is to handle the complexity in the intermediary of the reporting variations for healthcare. So, the full architecture requires a two-step decision support process. The trigger is the first step, and then, on the intermediary, there is a decision support component that applies the jurisdiction's specific reporting requirements, so each jurisdiction authors their reporting requirements into the decision support tool, and the data in the case reports are then compared to their rules, and those reports go to the appropriate public health agency, and that is a very important step because you cannot use the RCTC alone. It is not specific enough to identify cases that meet a jurisdiction reporting rule, so those two steps have to occur in order to facilitate the appropriate reporting to public health agencies.

Gillian Haney

The other thing I want to just note is that the decision support tool also routes the case report to the appropriate agency automatically, which is critically important, I think, in terms of workflow. I think we have Steve back, so, Steve, can you...?

Steven Lane

How about now? Can you hear me now?

Gillian Haney

We can. Take it away, please.

Steven Lane

Wonderful, so sorry, and thanks for the opportunity to speak. You had asked me to prepare formal comments and slides, and my week just did not support that, but I a really glad to be here and to speak to this, and it was interesting, Gillian, you introduced this topic discussing that ECR was kind of in its infancy, which I think is the term you used, which is striking to me because I feel like we have been at this for years now, and we have made such tremendous progress.

We at Sutter Health in northern California were well aware of ECR under the Digital Bridge. In our region, there were some organizations that were already engaged with Digital Bridge at the onset of the pandemic, and when the pandemic hit, it became very clear that there was an opportunity to pivot that effort to focus specifically on COVID-19 reporting, and literally, within two weeks, I think it was, Laura, we were able to organize one of the major EHR vendors and a number of healthcare organizations with Laura and the team from APHL, and we were able to get a COVID-19 specific ECR up and running nearly overnight. Literally, our implementation at Sutter Health took us, I think, three days.

And, what we saw in the early pandemic was a real enthusiasm for people to get on board with that. Engagement with providers, with EHR vendors, with public health agencies across the country, and those maps that Laura showed of the states where you have people reporting, where you have public health jurisdictions receiving and ingesting the data, are really a testament to the tremendous work that has gone into this. So, while this may be in its infancy compared to other things, it is such a tremendous example of how quickly things can move in the health IT world.

I think that there are great opportunities here to move this to the next level and really make it part of our established foundation for public health interoperability, and the prior speakers have spoken to that. I think it is critical that we support, incentivize, and eventually require public health jurisdictions to be able to access, ingest, and utilize this ECR data, and then to replace the manual reporting process that providers have been burdened with for so long. As I said, we in California got this up literally within a week, and only two weeks ago, finally, our state has said to us that they are now actually ingesting the data into the state system, two and a half years later. So, really, a remarkable timeline because one of the biggest challenges for provider organizations who need to invest a certain amount of energy to get this up and running and to maintain it is that they are still burdened with manual reporting, so it is really not until you can alleviate that manual reporting requirement that you are going to really see the traction, so I think being able to really push towards requirements for this is going to be important.

The other thing, as I think has been mentioned, is the benefit of including specific technical standards in EHR certification. Right now, EHR certification is rather lax about how this is to be done, simply that it is to be done, and the standards clearly exist, they have been battle tested, and I think we need to move forward on that as soon as possible. As Laura mentioned with the reportability response, this is really a model for bidirectional exchange between clinicians and public health. The clinicians send in the EICR and they get back the reportability response almost instantaneously, and it is great for now, it is simply an acknowledgement of receipt, but the opportunity that we have for this to carry much more valuable payloads back to the providers, specifically around antibiograms, about follow-up recommendations, about further testing, queries for additional clinical data to support case investigation, we can make so much more of this now that it is in place across the country.

This is also at tremendous model for customized interoperability. As we have heard, each condition, and oftentimes each jurisdiction, has its own requirements, and the ability to write these into rules at a central spot and then have everybody across the country benefit from that as the rules need to change is really a great model for how we can do a number of other pieces of public health exchange also. And also, as Arien, I, and others have discussed in prior workgroups, there is an opportunity to streamline some of the dataflows. I think what we have is we have thrown some data requirements into ELR and ECR, and they kind of overlap at this point, and I think once we have ECR as a requirement with technical standards, require to send, require to receive, then we can really streamline and rationalize some of the other data flows so that we are not sending duplicative information through multiple streams.

So, I thank you for the opportunity to discuss this here. This has just been a great project to be involved in, and the team that has been working on it has done a tremendous job. We now just need to push it over the line so that everyone is on board and utilization is going to be required. Thanks.

Gillian Haney

Thanks, Steve. I hope I did not imply that not a tremendous amount of work has not been done in a short period of time. It was merely comparing it to some of the longevity and time that we spent in getting electronic laboratories up and running, and syndromic surveillance, so, a tremendous amount of progress actually has been made. I think that as the data have started to flow, I think that one of the things that we are seeing is, again, the issues with data quality from the data that are coming from the EHRs and the need to really make sure that coding sets are being implemented in a timely way, and I see a question from Les Lenert in the chat about whether or not, Steve, you could comment about how it is to maintain those trigger codes and reporting data in the CCD to send to public health, so perhaps you could address that.

Steven Lane

Yeah. Again, we work with one of the larger EHR vendors, and all of that functionality has been automated. Basically, the vendor gets the updates for the trigger codes, and they just push that out to all of their customers who are sending the ECR, so there is no significant manual work on our part, and that is what I was talking about. That is the beauty of this centralized model, is that the rules come out, that determines the triggers, and the data simply flows. Our turnaround time for that is minutes. It really is a very light lift for us, so that is a great thing.

I did want to say one other thing. Sorry, Gillian. I did not want to throw the Department of Public Health in California under the bus because they had to do a system upgrade and get their act together, and now that they are receiving the data, my understanding is that they are working with a number of systems to check the data quality, to bring that data in, and what they have said to us is that now, they are hoping that in the coming year, we are going to be able to transition from ECR for COVID-19, exclusively COVID and orthopox, where we are today, to ECR for all conditions, so I am really hopeful that by the end of next year, we will be up and running with all conditions as well as being able to stop our manual reporting.

Gillian Haney

I think there definitely could be some lessons learned in terms of your timeline for implementation. I think the rapid turnaround for deployment of updated and current coded sets for the trigger codes has not necessarily been the experience across the rest of the country. I see, Les, you have your hand up.

Leslie Lenert

Yes, I do. I wanted to make a few comments, and first of all, I want to really than all the people working hard in public health about their dedication to ECR and to the task at hand of getting the data to all of us at a national level. Now, I am going to say some very hard things in response to this after acknowledging the great efforts in doing this, but I want to be very clear about it. Let's be factual about the real problem here. The real problem is that public health as a whole, at a state level, cannot agree on definitions of what reportable cases are, and as a result of that, we have to have unique authoring and unique reporting data requirements for each state that are continually evolving.

The advantage of the ECR centralized architecture is that it supports that, but the problem is the existence of this to start with. Until the states can come up with a unified approach, a standard for notifiable conditions that works across the country that we can rapidly add to at a national level when it is needed that is very specific, as specific as we need for case reporting, I think that this is a very difficult task. So, I want to push the responsibility back on public health because public health continually calls for the health system to do

more, but it cannot agree among itself as to what its data needs are and how to move forward, and this is an even older problem than ECR, and paving over the cowpath of the disagreements across states is possible. We can try to come up with a technical solution, but we have not addressed the core problem.

Gillian Haney

Can I just interject in there? Because I am not quite sure I agree with you that we cannot agree on what the cases are. The CSTE establishes the criteria for establishing what those case definitions are in terms of what makes a probable and confirmed case, and that consists of very specific laboratory criteria, as well as very specific clinical information. The challenge is for public health to be able to identify that clinical criteria to support meeting the case definition, and that is often embedded in notes within EHR systems and is not easily extractable and readable.

Leslie Lenert

One standard for reporting. Let's start with that. One national standard for notifiable conditions in reporting. I appreciate all the CSTE's efforts to try to do this, but clearly, there is not one target there yet. Once you have one target, and then a national routing system to the right place, it seems like the job will be a lot easier, but on the public health side is one target that all the states agree on and meets legal requirements. I am sure the intellectual effort by CTSE is super important, but really, ECRs' architecture is designed to support the diversity rather than eliminate it, and it is unnecessary diversity. As you say, you have already done all the work to prove that there is only one definition of it. Why do we have all this unnecessary diversity among states as to what actually has to be in a case report form? That is the place we need to start.

I am going to continue on here because I have an important point to make about the architecture of ECR. It is wrong. As you said, the issue is getting a notification of an event worth investigation. That is fantastic. We know how good ELR is about notifications, and whatever the trigger event is, that is fantastic, but after the trigger event, it is not about a static, onetime pull from an EHR to go into a onetime transmission to public health. It is about giving public health the access to the EHR to investigate the case, as you lay out so well, Gillian. The point is that we need to use standards to allow public health to investigate cases. That means querying via FHIR, and expansion, and ensuring that USCDI data area available, and making bulk FHIR routinely available for public health for queries.

If we focus on those things, then public health can ask for the data that they want from either HIEs or from health systems on a regular basis, and it can be seamless with all the other data requests that are present for population health and other things there. It does not have to be a unique channel for public health. The reason you want to do this is that cases, as you say, go from probable to certain, but it is not actually categorized, it is a probability, and you are going to want to use AI methods and data science to actually figure out which are the right cases rather than having a hard, rule-based definition, which is some kind of weird AI from the '80s. Time to move forward on all this. We need to build back better rather than paving over the cowpath, which we have already shown does not work very well in really severe national emergencies.

Gillian Haney

Thank you, Les. Bryant, I see your hand is up next.

Bryant Thomas Karras

So, I both agree and disagree with Les. I think that there is a tremendous value in supporting state flexibility. Our health officers, state epidemiologists, and our governors have keen awareness of what is happening on the ground and need to be able to adjust as needed in a response, especially during an emergency. So, having a locked-in national standard case definition that does not allow any kind of state flexibility would have proven ineffective in our response to COVID-19, so I just want to remind folks that predetermination and standardization is absolutely great as a goal, but we need to go beyond that.

Where I do agree with Les is that I think that the "I" in EICR is "initial." It was never intended to be the end of the report or the end of the investigation. It is the initial component, and there is a hope that we would evolve and build in that capability to reach back to electronic medical records systems to retrieve the missing data elements, or if it is not something that can be queried via a data element, full access to the record, or a survey to the provider or patient themselves about what transpired. That is not part of the whole ecosystem yet, but I think that is where we will need to go next.

In terms of our local experience, Washington state has been receiving EICRs since 2020. We got 140 facilities onboarded in the first year of the pandemic; we got 315 onboarded in the second year of the pandemic. It has slowed down in 2022. We have only gotten seven new facilities on this year. There are still a ton more to go, and I think what we may be seeing and what we may be hearing from on this committee are the low-hanging fruit, those capable institutions that have the resources that can do this work or have a really strong, supporting vendor that can pull this off. It is the rest of our clinical community that are going to be lagging, and I think we need to remember that for public health to have a true, all-inclusive surveillance system that eliminates the need for reporting from our clinicians, we are going to need to bring along the remainder of those clinical parties.

Gillian Haney

Thank you, Bryant. Arien?

Arien Malec

Yeah. I am going to start off, first of all, just with a little bit of floor-setting, and then I actually have some substantive questions. As we started out our journey with this taskforce, because this topic of public health local autonomy versus nationwide interoperability is an evergreen topic and we could spiral on this topic, I really proposed the frame of making sure that we have a common nationwide floor and that we enable upward use to raise the ceiling in local jurisdictions supported by the provider organizations that are in those jurisdictions, and so, in this topic particularly, I would really encourage us to think about low-regret common floor.

As I mentioned in comments, having the ability to push a standardized, trigger-based case report to public health does not prevent public health from asking for more, it does not prevent public health from querying subsequently, it does not prevent organizations from pushing updated case reports. All it does is establish a common nationwide floor to receive triggers and push out initial case reports, and that feels like a set of capabilities that we can build upon to raise the national floor, but again, that is the framework that I would have, is as we think about standard and certification criteria rather than dream on perfection, let's just make sure that what we are doing is enabling a common floor. The substantive questions really are about the limitations that were mentioned in terms of coding and maintaining our trigger conditions.

Just to make sure I am understanding this correctly, it feels like the coding issues are secondary, No. 1, to order sets and lab results not being encoded via LOINC, that we get proprietary codes in some cases that are getting in the way. The triggers could fire if we got the standardized data, but we are not getting the standardized data that enables the trigger hooks. Is that a correct statement?

Gillian Haney

I think that is fair to say. Laura, do you want to comment?

Laura Conn

Yeah. I think that is fair, Arien, and I think that a lot of it is around the labs, although I will tell you that we are active with some vendors that are not using SNOMED codes and problem lists, for example, and things where we think there is basic coding that was established in certification prior that are not there now. So, I think it is a lot in the lab space, but there are other coding set issues as well.

Arien Malec

Got it, cool. And then, the second one is a theme we heard in immunizations, the need to make sure our certification criteria are inclusive of the ability to update terminology sets, and then, in the administrative networks, we call these operating rules. I am hearing that we have underlying certification for standards and implementation guidance, but we do not have the operating rules, the SLAs, the latency of data refresh for codesets, etc., and that that might be an important portion of establishing the nationwide interoperability flow. Is that a fair statement?

Gillian Haney

Yes.

Laura Conn

Yeah, I think that is very fair, especially if it supports the emergency response use cases when there is something that needs to be pushed out there quickly and see that rapid uptake, we need to certify against that.

Arien Malec

Cool, thank you. I appreciate that.

Gillian Haney

Rachelle?

Rachelle Boulton

Yeah, thank you. I just wanted to provide some thoughts from another state about implementation and challenges we have had. We have been working on ECR in Utah since 2015. Our first implementation was prior to the EICR standard, but it was really just a pilot to see if this was valuable and what data we could get out of it, so we have been looking at ECR for quite a while, and when I look at it, I kind of think of breaking it down into three pieces. One is just an initial notification. Is there a case that we need to know about? And, we have relied on labs and lab reporting ELR in the past to really be that initial source, and with ECR, where we have really found a benefit is rapid testing that does not go through a lab, diagnoses, so, conditions that do not have routine diagnostic tests, such as chicken pox, and then syndromes like toxic

shock syndrome and hemolytic uremic syndrome. So, that is where that clinical information really is the key piece to reporting, and so, ECR has been fantastic with that. The other is that demographic information to even be able to know how to contact a case or what state they live in.

And then, the harder one, which I think we have talked about, is all that clinical information that can give us either that full picture or to really begin to implement some sort of intervention in a timely way, and that is what we are still trying to figure out, just because of the complexity and just the variability of the implementation needed across the different conditions. So, kind of from our perspective, that is kind of where we are, the big challenges that we have seen, and as far as just consuming that data, but just being able to parse through, and what to expect, and what is realistic, and what is good enough, and how we need to change our processes on the public health side to take advantage of this opportunity. So, lots of challenges, but we have also seen a lot of really significant benefits, and so, I just wanted to throw that out there, that we have seen some really great things in production, in real life, and again, just grateful for our providers who have been engaged with us. So, I will leave it at that.

Gillian Haney

Thanks, Rachelle. I think Utah's perspective is really important because you have long been engaged in this world and have a lot of, as you said, real-world experience with moving this forward, so, thank you for that. John?

John Kansky

Thanks. I wanted to make a comment that I think is cross-cutting across the whole discussion today, and it is the need to accommodate both the direct-from-EHR path and the via-an-HIE or HIN intermediary path that we can accomplish the same thing, and I certainly understand those who come to this taskforce with the perspective that we want national homogeneity, meaning every EHR and every provider conforming to the same standard and reporting consistently across the country, but I started with listening to people of a short list of challenges, and that list keeps getting longer, and just real quickly, I want to highlight some of the potential advantages of those places in the country where you are going to do better relying on an intermediary approach and acknowledging there are places in the country where a direct-from-EHR approach will work better, but we have reducing burden on providers, we have hospital systems reaching out to the HIE organization that we operate, asking us if we can please do this for them.

One of the drivers for that is lower cost because their EHR vendors are charging them for this capability, and they are asking us if we can do it instead. There is a danger in bypassing the health information exchanges because of this value, for example, with public health, of having a statewide HIE able to have population-wide data, so bypassing them is bad. And then, the things that have been highlighted by Ann Kayser's presentation, and Laura raised some challenges, the HIE intermediaries are in a position to overcome some of the challenges like local coding because we are recoding data to standards as it comes in in real time. And then, also some of the data quality challenges. I do not want to go on any longer, but I just want the theme to be mentioned, probably in every call, that we have to acknowledge that we can implement these standards and achieve these goals via an intermediary or direct from the EHR. Thank you.

Arien Malec

Gillian, just a request that we go through the remaining two hands raised and then transition over to the spreadsheet.

Gillian Haney

Sure. I just wanted to point out that Laura did mention that there is ECR flowing through several HIEs, so maybe, Laura, you could speak more to John's comment in the chat. Hans?

Hans Buitendijk

Yes, thank you. I want to support particularly Bryant and John's comments in two parts. One, refining John's comments a little bit more, there are not only two methods, there are three methods, a couple of different methods. They should be all feasible because depending on the context and trying to get that long tail that Bryant was talking about, they may be suitable as well to help address and solve that, so it can be embedded in the EHR, you can use a FHIR-based app approach, you can use an intermediary, but it is key to have the common standards of the knowledge that you can share to have access to it, the output of the report, and an accepted set of transport. Currently, we see one use of APHL, it is XDR and direct, but there is a predictability of that and the small set, but there is consistency there. And then, whether the path is best in the EHR itself, using an app, or using an intermediary, it is then, at that point in time, more an appropriate decision based on the context and what is available, so I think it really needs to be standards-based with that level of flexibility to approach that.

Another aspect of it is that as we go through this and we look at what is being reported, as we are thinking about querying some of the comments back and forth, we have to be careful not to go too far to a query-only approach. It is a balanced approach, where at the time something happens, there is a need to share that it happens and to share information that is already known to be of interest with public health, but there also needs to be that ability to get more information because that becomes of interest or was otherwise not known yet and was of interest, so I think the work that Helios is doing in its optimization and alignment track where it is looking at those kinds of questions as well, case reporting sits very much smack in the middle of that from our perspective since that has the opportunity to get all that additional data as well at an appropriate time, so you have to not only look at case reporting and the querying for more, you also have to start to look at lab reporting and syndromic surveillance and say, "How does that all tie together?" At the time that there is a trigger of something of interest with all the challenges around the coding and the granularity available, but in principle, at the time of the triggering, case reporting is a substantial element and a key element to optimize and stream that, and then allow for lots of querying beyond.

Gillian Haney

Thank you, all good points. Arien, do we have time for one more comment, or shall I turn it over?

Arien Malec

No, let's please do.

Gillian Haney

Okay. Steve?

Arien Malec

Ike. We disambiguate the Stevens by calling Ike "Ike."

Steven Eichner

Thank you. This has been a very useful discussion in a lot of ways. Going back to a little bit of the earlier comments, looking at the data quality pieces and consistency, it is not just about the trigger codes, although those are certainly important, it is really looking at data all the way through, as well as looking at what is satisfactory or how the different local health departments or state health departments are validating the data that is coming across and how we address that component from a quality standpoint, as well as having potentially standards across public health so that providers are not in a position of having to meet three, four, five, or 10 different health departments' quality standards that potentially are in conflict.

Gillian Hanev

Also a good point. I just want to remind everybody that all of the comments in the chat are recorded as well, so please get your thoughts down there where we may not have had time for a verbal comment. Excellent discussion today. I think I am going to ruminate a little bit before some final remarks, so I will turn it over to Arien to talk about the spreadsheet.

Topics Worksheet (00:59:37)

Arien Malec

All right, thank you. So, if we can display the current version of the spreadsheet... All right. So, some little monkey named Arien Malec has done a fair amount of update to the spreadsheet, so again, just as a review, we want to use the discussion and deliberation that we have here. It would be very helpful to make sure the taskforce members go into the spreadsheet and update with observations and with the draft recommendations wherever possible. Can we scroll down? I have not looked since a couple of days ago to see whether anybody else has done any updates. Hans is always on the case, so, fantastic. This is great, a little stone soup in progress.

So, what I would like to do here is just establish a cadence of doing regular reviews of this material to see if we can get to a common set of recommendations, perhaps unify some of our comments into recommendations text, and then, that will serve us well as we go into crunch time to prepare recommendations, so maybe we can filter first to the immunization registry comments. Rather than do this on the fly, we will just do it manually by scrolling down. So, the first one should not have been "immunization registries," it should have been "other," so I apologize for that. If we go into the next one, so, first comment was that we have certification standards for the content, but not for the transport, and that we have a well-established transport specification for immunization.

So, first of all, just noting that there is a widely adopted immunization guide for immunization transport, and then, making a recommendation that ONC coordinate with yada yada yada to establish certification criteria for transport. I need to get the actual error report text, but there is some variation in immunization reporting that is jurisdictional. Based on the AIRA investigation, most of that was down to the need to track specific requirements for inventory, track jurisdictional variation in consent, and then, sort of an increasing trend in local jurisdictions looking for a broader set for race and ethnicity, and so, I drafted that to two requirements.

One is that we update the immunization implementation specification to better address how to handle specific variation in inventory tracking, better handle variation in consent, and then, separately, make a recommendation that we establish a common subset for race/ethnicity tracking. Again, just to give everybody the lay of the land, in the EHR certification program, there is a minimum OMB subset, which is the standard, very narrow OMB race/ethnicity subset, but the allowed codeset is the full CDC codeset, and

so, as long as you are using the CDC codeset, the PHIN VADS codeset, you should be able to capture more granular race/ethnicity, and so, the implementation specifications should already allow for the capture of more granular information, but we do not yet have a common, more granular than OMB, but chunkier than the full, pretty overwhelming CDC subset.

Next one is that we currently have two certification criteria for immunization. AIRA and HIMSS got together and created the IIP certification criteria, which is now listed as an alternate test method as opposed to the primary test method, and so, it feels like a pretty easy recommendation to align to the IIP test method as the standard certification criteria. We will skip over the overarching, but go to Hans, so, Hans, why don't you go through your comments?

Hans Buitendijk

Okeydoke. So, I included two sets of comments. The first, Lines 7 through 11, are effectively taking the discussion from last week and the presentation and putting them into an observation recommendation for it, so I do not think we need to go through them perhaps right now, just so that is the context where that sits. The second set that you see in there that has Steve Eichner's name and myself to it, as many probably know, there has been a HITAC Adopted Standards Taskforce working over the last couple of months to provide recommendations on certification. Its standards are referenced in certification.

So, what you see in Line 17 through 22, while those recommendations are about to be reviewed and finalized with potential updates, perhaps next week, already put in the pending HITAC approval notes related to the public health-related standards. So, in there, you will see the rationales as to why to maintain or phase out and replace a currently referenced standard with an upcoming or an already available version of that standard to advance it. So, I am determined to put that in because for this discussion on certification criteria, the discussion also would be around potentially what kind of standards are available to make the advancement we are looking for. Just a general comment to make.

Arien Malec

Hans, when you say "available," there are two flavors of available. One is included in the ISA, and the second is endorsed by the secretary through regulation.

Hans Buitendijk

So, the statements that are made here are based on the standards that are currently in regulation or in SVAP, but particularly in regulation, and then, the available new standards, new versions, or other standards, perhaps, are ones that are either already referenced in SVAP, so, indirectly, or that they are listed in ISA, or that they are known to have been published. So, it is the range of what is out there that has been worked on to advance the standards and implementation guides.

Arien Malec

Got it, and for the rest of the taskforce members, who may not be as intimately familiar, and I do not think anybody is as intimately familiar with all this stuff as Hans is, except for ONC, the lay of the land right now is that ONC names standards and implementation guidance in regulation, and then, the current set is the 2015 criteria amended at some point, so the set of criteria that are named in regulation are fairly old at this point. There is some speculation that there will be an update in regulation.

And then, ONC has established SVAP, a voluntary standards advancement process, and the theory there for the SVAP is that there is voluntary acceptance of upwardly compatible versions of standards over the floor that is established in regulation, and the intent there is to establish a more flexible means to update standards that is not keyed back to regulation, so, as the SVAP works, the standard named in reg serves as the mandatory floor, and the SVAP standard is the ceiling that most organizations are updating to, and then, at some point, ONC flips the switch on deprecating the older version of the standard that is named in regulation and goes to a later version of the standard named in regulation, so the back-and-forth that Hans and I were having is just related to the status of the relevant F criteria with respect to both the named-in-regulation standards as well as the SVAP-available standards.

And then, above SVAP, there is the ISA, the Interoperability Standards Advisory, which is a catalogue of potential standards where it is useful to make that standard available for reference, and so, functionally, the SVAP will draw from the ISA, and over time, certification will draw from the SVAP to deprecate the older version of the floor, so hopefully that is clear, and I am more than happy to provide clarity, or perhaps we can have ONC provide some additional clarity for how that machinery works. But, what I am hearing you say, Hans, is that we need to make sure that machinery is revved to ensure that we have the latest versions of all these pieces.

Hans Buitendijk

Yeah, and depending on which one you look at, the recommendations are in the direction of "There is a newer version, looks like that is appropriate to do." There are ones that indicate that there might be a newer version out there, but is the community ready to start to adopt it because it is work on a variety of sides of the equation, and then, in the case of, for example, case reporting, not directly referenced as a standard today in regulation for EICR, it is being raised in two cases as a potential augmentation or alternative, a blend of lab reporting or syndromic surveillance, and better balancing it with what case reporting can do. So, those are the contexts in which these recommendations are made to look at, and then, for this taskforce, perhaps, more specifically recommend what the right direction is.

Steven Eichner

This is Steve Eichner. I want to add that I appreciate both Hans's work on the taskforce and all of the work on the Interoperability Standards Taskforce's efforts, but I also want to emphasize, particularly in the discussion in the report regarding public health-related exchange standards, that there is an ongoing emphasis, especially because public health systems are not currently referenced or not currently certified. There is specific attention paid to ensuring that public health's needs are being met and that there is synergy between the standards that might be adopted for the existing regulations with public health needs to ensure that public health data needs are met, both in terms of content and timeliness and, of course, quality as well. So, the goal is to float all boats. There are just a lot of boats that we need to float simultaneously.

Arien Malec

Yeah, and again, just to repeat the preamble from the opener, as we contemplate certification criteria for public health data systems, we should be contemplating that those certification criteria come with appropriate means to update public health data systems. It would be illogical and folly if we assume that there is no funding to update public health data systems, and yet a requirement to certify to later standards. I think we know how that adventure would work out in practice. Are there any other comments in the

spreadsheet on immunization registry standards that the taskforce members have made that we should be reviewing?

Vivian Singletary

I have made a couple. I think I have made one on IIS and one overarching. I do not think it necessarily has to be reviewed. I think it may have already been discussed.

Arien Malec

So, Vivian, maybe you can look at the recommendation that I made above because it really is intended to get at the variation and practice for interoperability, and maybe we can harmonize those two recommendations.

Vivian Singletary

Yeah, makes total sense to me.

Arien Malec

Cool, thank you. Let's pick up on a couple of repeated comments that have come through. Jamie and I both noted variation in collection of race and ethnicity data. So, again, as I said, the way the machinery works right now is that the certification program and USCDI call for the collection of data to at least the OMB standard, which is the five race and ethnicity codes, including Hispanic and non-Hispanic Caucasian, and then, there is a full CDC PHIN VADS list that is incredibly granular.

So, Jamie, just to respond to some of your comments, as USCDI advances, part of the issue right now is that USCDI is still pinned to Version 1, as we advance to Version 2 and Version 3, we are going to get the updates that we have done for, for example, SOGI data as a matter of course. Clearly, the biggest issue right now is that we are still pinned to the OMB race and ethnicity codeset, and it would be helpful to get a list that is less granular than the full CDC list and more granular than the OMB list in order to unify nationwide standards. Gillian, is CSTE doing anything here? What is the lay of the land in terms of getting to, at least from the public health side, a minimally useful set to better track disease burden and surveillance?

Gillian Haney

What do you mean? For race and ethnicity specifically?

Arien Malec

For race and ethnicity, yeah.

Gillian Haney

I do not know the answer to that question. I will have to circle back.

Arien Malec

And then, Bryant, if I recall, you have been working on creating more expansive code sets for race and ethnicity. Do I have that right?

Gillian Haney

Bryant? I can try to speak for this because I chatted with him about this. Washington has passed regulation, I believe, that has expanded the list of what is included in the race and ethnicity dataset.

Arien Malec

Yeah. Bryant, if you are available, can you post to chat or to the taskforce members the update to the Washington subset list? But again, that is the structural issue that we are faced with right now, which is that USCDI calls for the OMB list, which is very, very small. It allows for a much more expansive list. It would probably not be a very good idea if every jurisdiction established a slightly different subset list for race and ethnicity that picked from the CDC list. It would be useful if there was a nationwide floor that was more expansive than the OMB list, but actually useful for tracking disease burden/disproportionate impact and serving the public health response needs. Okay, I see a couple more comments on race and ethnicity, so I appreciate the updates. Again, it feels like a useful thing to contemplate. Are there other common topics that people have put in that they want to discuss in the next five minutes? And then, at some point, we need to transition to public comment. All right. Maybe, then, unless there is anything else the taskforce members want to comment on, we should transition to public comment.

Gillian Haney

Before we do that, I had my five minutes of rumination, so I wanted to provide a few thoughts about the discussion today, which I thought was incredibly diverse and useful, and one of the things that I am really hearing is that there is an opportunity for perhaps tightening the standards within ECR and adoption. I think that there is common agreement within public health for what the ECR standard is, both in terms of transport and in terms of the data elements that we would like to be reported to us, so I think that there is an opportunity there to discuss meaningful certification, and I think that something to consider, for which there is precedence, is perhaps a phased approach to certification. As ECR matures, maybe we should consider strengthening or tightening certification requirements over time, so I just wanted to put that out there for people to think about.

Arien Malec

Yup, and Gillian, my biggest observation out of this is that ECR is only as good as the data in the EHRs that drive the triggers, and so, being thoughtful about vocabulary in practice and making sure that we are upgrading USCDI, upgrading associated vocabularies, and being thoughtful about data flows that capture the source vocabulary, that hit the triggers, is going to be critical to make the investment in ECR actually work.

Gillian Haney

I could not agree more.

Arien Malec

Maybe we should do a quick preview of coming attractions.

Gillian Haney

I think Joe has his hand up.

Joe Gibson

The ECR development that has gone on has primarily been at the state level. There have been some cities involved, but there are a lot of local health departments that are not involved, so when we talk about public health coming together on a certain standard, there are still a lot of stakeholders that need to be at the table, and if we are talking about certifying systems, are we just talking about certifying state systems, or are we talking about getting it down to the local level? I was the director of Indianapolis. We do not have a system that would be certified by this, although we do a lot of work with ECR and we have a lot of struggles getting data now in a population level around ECR with the state. There are always challenges getting data back and forth between locals and states. So, just to bring that up.

Arien Malec

That is right. So, by and large, when we are talking about certification, we are talking about certifying systems, and then, the way this often works, at least as work on the CMS side, is that ONC establishes certification criteria for systems. Those certification criteria are voluntary. And then, CMS, in this case, establishes programmatic requirements for participation in a variety of CMS programs and ties certification requirements to those programmatics. One could imagine that the national infrastructure for where certification would tie in is that CDC, for example, would establish programmatics, funding opportunities, and other kinds of policy goals, and then tie certification criteria and use of certified systems to those programmatics, which is why I noted that these are going to be voluntary.

There will be ways for local jurisdictions to not participate. There may well be funding ties. As you contemplate how all this works, there may be funding ties that require certification, so the exact mechanism of how a local jurisdiction uses a certified system will likely be tied to whatever programmatic CDC chooses to attach certification to. But, we do have to go to public comment.

Public Comment (01:24:16)

Michael Berry

All right, thanks, Arien. We are going to open up our meeting for public comment. If you are on Zoom and would like to make a comment, please use the hand raise function, which is located on the Zoom toolbar at the bottom of your screen. If you are on the phone only, press *9 to raise your hand, and once called upon, press *6 to mute and unmute your line. Let's pause for a moment to see if anyone raises their hand. I am not seeing any hands raised, Arien and Gillian, so I will turn it back to you. Thank you.

Next Steps (01:24:43)

Arien Malec

Awesome. Can we just go look at our preview of coming attractions? Back to where we are relative to the calendar. Gillian, remind me. I think our next hearing is either on lab or...

Gillian Haney

Lab, electronic laboratory reporting.

Arien Malec

Yeah, so be prepared for another thought-provoking, engaging, incredibly challenging, and informative presentation on where we are with lab. This challenge is not getting easier, so, fantastic uptake for the spreadsheet. A plea, when you draft proposed recommendations, to follow the rubric of "We recommend that ONC..." because it is very easy to establish recommendations; it is much harder to have

recommendations to ONC that ONC do something, and you will see that I have been provided some template examples in the draft recommendations that I have done, but I really appreciate all the work to engage in the spreadsheet, and this will be the material that we will use to turn into our final recommendation text.

Steven Eichner

Arien, can you or Mike address Jim Sinclair's question regarding meetings that is in the chat?

Arien Malec

Which comment?

Steven Eichner

"I believe this is the last public meeting." It is Jim Sinclair's comment.

Arien Malec

No, it is not. All of our meetings are public. We are following federal advisory rules for all of our meetings, and as you can see, this whole series lines up until our final recommendations for the HITAC.

Michael Berry

And Arien, I see that Jim has raised his hand, so, Jim, if you would like to go, you have three minutes.

Jim Sinclair

Oh, thank you. I was just following up on that, and I am always happy to admit that I am just doing something wrong, but in looking at the schedule as it is on the ONC website, this was available for registration. Maybe as the next meeting goes closer, they will open it up for public registration, but it just did not appear that way as it is currently listed.

Michael Berry

Right. The registration links are posted one week in advance of each meeting, so if you log on after basically each taskforce meeting, then the next meeting will be up.

Jim Sinclair

Excellent. Thank you, Mike. I appreciate that guidance.

Michael Berry

Absolutely. Arien?

Arien Malec

All right. Well, with that, we will close this meeting. Again, just a plea to go into the spreadsheet and get the recommendation juices and observations flowing. We have made tremendous progress in just three meetings, and fortunately, we have a lot more work to go.

Gillian Haney

Thank you, everyone. Great participation.

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Arien Malec

Thanks, everybody.

Adjourn (01:28:00)