

Transcript

PHARMACY INTEROPERABILITY AND EMERGING THERAPEUTIC TASK FORCE 2023 MEETING

July 19, 2023 10:30 AM – 12 PM ET

VIRTUAL



Speakers

Name	Organization	Role	
Hans Buitendijk	Oracle Health	Co-Chair	
Shelly Spiro	Pharmacy Health Information Technology Collaborative	Co-Chair	
Pooja Babbrah	Point-of-Care Partners	Member	
Chris Blackley	Prescryptive	Member	
Shila Blend	North Dakota Health Information Network	Member	
David Butler	Curatro, LLC	Member	
Steven Eichner	Texas Department of State Health Services	Member	
Rajesh Godavarthi	MCG Health, part of the Hearst Health network	Member	
Adi V. Gundlapalli	Centers for Disease Control and Prevention	Member	
Jim Jirjis	HCA Healthcare	Member	
Summerpal Kahlon	Rocket Health Care	Member	
Steven Lane	Health Gorilla	Member	
Meg Marshall	Department of Veterans Health Affairs	Member	
Anna McCollister	Individual	Member	
Deven McGraw	Invitae Corporation	Member	
Ketan Mehta	Micro Merchant Systems	Member	
Justin Neal	Noble Health Services	Member	
Eliel Oliveira	Dell Medical School, University of Texas at Austin	Member	
Naresh Sundar Rajan	CyncHealth	Member	
Scott Robertson	Bear Health Tech Consulting	Member	
Alexis Snyder	Individual	Member	
Fillipe Southerland	Yardi Systems, Inc.	Member	
Christian Tadrus	Community Pharmacy Owner	Member	
Sheryl Turney	Elevance Health	Member	
Afton Wagner	Walgreens	Member	
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer	
Tricia Lee Rolle	Office of the National Coordinator for Health Information Technology	ONC Program Lead	

ON		

Name	Organization	Role	
Laura Conn	Centers for Disease Control and	Presenter	
	Prevention		
Lynn Gibbs Scharf	Centers for Disease Control and	Presenter	
	Prevention		
Agha (Nabeel) Khan	Centers for Disease Control and	Presenter	
	Prevention		

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

Michael Berry

Good morning, everyone, and welcome to the Pharmacy Interoperability and Emerging Therapeutics Task Force. I am Mike Berry with ONC, and we are glad that you can join us. We also have several guest presenters with us today, and I would like to welcome them and thank them for joining us as well. This Task Force meeting is open to the public, and your comments are welcome in Zoom chat throughout the meeting or during the public comment period that will be held around 11:50 Eastern Time this morning. I would like to start rollcall of our Task Force members, so when I call your name, please indicate if you are here, and I will start with our cochairs. Hans Buitendijk?

Hans Buitendijk

Good morning.

Michael Berry

Shelly Spiro?

Shelly Spiro

Good morning.

Michael Berry

Pooja Babbrah?

Pooja Babbrah

Good morning, I am here.

Michael Berry

Chris Blackley?

Chris Blackley

Good morning.

Michael Berry

Shila Blend? David Butler?

David Butler

Good morning.

Michael Berry

Steve Eichner?

Steven Eichner

Present, good morning.

Michael Berry

Raj Godavarthi will be joining us a little later. Adi Gundlapalli?

Adi Gundlapalli

Good morning.

Michael Berry

Jim Jirjis? Summer Kahlon is on vacation this week. Steven Lane?

Steven Lane

Good morning.

Michael Berry

Meg Marshall? Anna McCollister? Deven McGraw?

Deven McGraw

Good morning.

Michael Berry

Ketan Mehta? Justin Neal?

Justin Neal

Good morning, everyone.

Michael Berry

Eliel Oliveira?

Eliel Oliveira

I am here, good morning.

Michael Berry

Naresh Sundar Rajan?

Naresh Sundar Rajan

I am here, good morning.

Michael Berry

Scott Robertson?

Scott Robertson

Good morning, I am here.

Michael Berry

Alexis Snyder is also on vacation this week. Fil Southerland? Christian Tadrus?

Christian Tadrus

I am present.

Michael Berry

Sheryl Turney?

Sheryl Turney

Good morning.

Michael Berry

Afton Wagner?

Afton Wagner

Good morning.

Michael Berry

Good morning and thank you, everyone. Now, please join me in welcoming Hans and Shelly for their opening remarks.

Opening Remarks (00:02:18)

Hans Buitendijk

Good morning, everybody. I will start. I am really looking forward to today's discussion on the long-term topics and how case reporting may address some of the areas as well, so I cannot wait to dive in. I want to thank everybody for joining on the Task Force, and to those from the public, I am looking forward to your comments as well. You can do that in the chat throughout the entire discussion, and at the end, surely, you will have an opportunity as well to further highlight that, so I cannot wait to dive in. Shelly?

Shelly Spiro

Thank you, everyone, for joining us today. We truly appreciate all of your insight and the great conversations. Continue to put information into the chat. We are so thankful to everyone for bringing pharmacy to the forefront on these very important issues. I want to thank our presenters from CDC in advance today for helping us get through all this. I so appreciate it. Thank you very much, and I am looking forward to our discussion today. Take it away, Hans.

Hans Buitendijk

All right. Sorry, I had to unblock my mute. So, what we are going to start out with today is a presentation by a number of guests. We will have Laura Conn with CDC talking about electronic case reporting and the role

that CDC has in that rolling out, as well as Lynn Gibbs Scharf, Chief of the Informatics and Data Analytics Branch of CDC, and Dr. Agha Nabeel Khan, also from the CDC. I am looking forward to hearing more about what has happened with case reporting over the last couple of years, where it is heading, and particularly also in that context and where our discussion is going to be looking as well at how we can apply that, take advantage of it, and what we need to do in advance from a pharmacy interoperability perspective and an overall perspective there during emergencies and otherwise. So, I am looking forward to that, and I am going to pass it to the first speaker. Laura, is that you, or is somebody else going to jump in?

Task 1 Guest Presentation (00:04:51)

Laura Conn

It looks like it is me, Hans, and thank you for the invitation. I will spend a few minutes talking about electronic case reporting, and then, I particularly look forward to the discussion of the pharmacy needs and any way that we can work together moving forward. On the next slide is some background. As was evident with the COVID-19 pandemic and really in routine times as well, timely and complete patient data is critical for public health to do its job, and reporting of a number of conditions of significance to public health is required in all states and territories in this country.

So, historically, that reporting has happened by manual process, sometimes by phone, fax, or even mail, unfortunately, so we have been working to automate that process and take advantage of data that now exists in electronic health records by automating the generation and transmission of case reports from health records in healthcare to public health agencies for review and action. There are currently 208 conditions that can be reported using this electronic opportunity now. Those include things like COVID and tuberculosis. Mostly, people think of reportable conditions in the infectious disease space, but we also cover a number of conditions that are reportable in chronic diseases, such as cancer, and noninfectious diseases, like Parkinson's, opioid overdose, birth defects, and elevated blood lead, as other examples. Next slide.

So, how does it work? This is just broad strokes, but when a patient sees a provider in healthcare and a healthcare provider enters their patient information into a health record, there are a number of trigger codes that are provided by public health, and if those codes are entered into the patient's health record, like a diagnosis, laboratory order, or laboratory result, it would trigger the creation of a case report that would then be provided to public health to determine if it met reporting needs, and if it met reporting needs, that report would be provided to a specific public health agency where it met that reporting criteria.

Once the public health agency received that case report, a real-time response would go back to the healthcare organization or provider that sent it to say, "This is the condition that was reported, this is where it was reported to," and it could provide any additional information in the context of that condition back to the provider from the public health agency. And then, the public health agency could take that information in real time and start its public health action. In the early days of COVID, it was contact tracing. For other conditions, there are different actions that can be taken. Next slide.

This one is more of the architecture of how the system works itself. Starting on the left-hand side, we have a provider using their EHR, in the middle, we have a shared services platform, and on the right-hand side, we have public health agency. So, as I mentioned, across the top, public health provides a set of trigger codes based on those conditions that are reportable, and electronic health record products have a couple of ways to do electronic case reporting. Some vendors build that capacity into their product directly, and

some use what has been developed as an ECR NOW FHIR app that is freely available for providers to use. If those trigger codes are matched in electronic health records, a standard electronic case report is created, called the EICR. It is currently in a CDA format, but we also have a FHIR format as that standard advances. That is sent over to an intermediary platform.

On the intermediary platform is where public health agencies have provided their reporting rules so that, as case reports come over, those case reports can be compared to jurisdictional reporting requirements and, when reportable, can be sent on to the appropriate public health agency, and that can be either based on where care was provided, or based on where the patient lives, or both, so that cross-jurisdictional reporting can occur. There is a feedback loop in the reportability response, represented by RR on this slide, and that is the document that I mentioned that tells what was reportable, where it was reportable to, and any additional information. This is facilitated by a trust framework or policy pass that is built on top of existing public health information networks, like eHealth Exchange, Carequality, and CommonWell, that allows this platform to view the reporting on behalf of healthcare without any additional legal agreements needing to be put in place for those participants in those networks. Next slide.

So, I wanted to share with you the data elements. There are a lot on here that are included in a case report. This is Release 1.1 of the CDA, the FHIR is consistent with this, and this is what is operational now. I particularly wanted to point out for you and for this group the medications administered and immunization status and that you can see a broad swath of clinical data in addition to just demographics about the patient that are important for public health. Next slide. We have done an update to this standard as well, and you can see here additional information that has been added based on our lessons learned of implementation through COVID medication upon the mission, medications administered, historical medications, planned medications, and additional immunization status information. Next slide.

Just to give you a quick sense of our progress to date, we were in pilot stage at the beginning of COVID, and we really have ramped up nationwide during the pandemic. I looked earlier today, and we have over 27,000 facilities in production with ECR, 27% of hospitals, 25% of critical access hospitals, 10% of FQHCs, and about 10% of ambulatory facilities that are staffed by at least one MIPS provider, and this ECR is a required metric and public health measure in the CMS Promoting Interoperability program. Next slide.

So, what has made this successful? We use a shared, scalable infrastructure. It allows for a single connection point from healthcare organizations to that platform that the providers on board want and can report to all public health agencies. We established that single data standard that is used for all reportable conditions, and we have a policy framework that is built on existing health information networks, so those one-off data use agreements and data sharing agreements do not have to be put in place. We have a secure pathway for data exchange that supports all reportable conditions. It captures the data identified by public health as what is necessary for public health action and meets those jurisdictional reporting requirements for providers.

So, our ultimate goal is to move on past manual reporting to this electronic reporting and reduce the burden on both sides of public health and of healthcare, and it has proven flexible to allow reporting needs to change over time. We ramped up quickly for COVID. Almost a year ago, or a little bit more than that now, we added monkeypox as it became a condition of importance, and as I mentioned, we are at 208 conditions

now, but we really have a single target for healthcare providers to be able to report to public health for all conditions and to all jurisdictions.

One thing I will just wrap up here with, especially for this group to consider, is as we are working through and learning about this data, the data consistency and data quality, especially in data for public health purposes, to analyze needs to be coded is an area that we continue to work on. I suspect that will be an area in this space with medication codes and maybe immunization codes. I suspect that my colleagues that will follow may talk about that as well, but I would be happy to have some of those conversations in discussion and understand more of your needs. Thank you for the time, and I look forward to the discussion.

Shelly Spiro

Thank you, Laura.

Hans Buitendijk

Who will be going next? Shall we hold questions until the end, or should we entertain some questions? I see that Ike has his hand raised. Ike, can you hold the questions to the end, and then, we will have you first in the queue?

Steven Eichner

Absolutely.

Hans Buitendijk

Okay, let's do that, and let's go on to the next speaker. Thank you, Laura.

Lynn Gibbs Scharf

Good morning, everyone. This is Lynn Gibbs Scharf. Nabeel is on the line, but a little under the weather, and has lost his voice, so we are going to try to spare him for questions, but thank you for inviting us today. We are really excited to be able to share a little bit about our COVID-19 pharmacy program and the associated data. Go to the next slide, please. So, the Federal Retail Pharmacy Program is a public/private partnership that involves 21 national pharmacy partners, and that includes more than 41,000 pharmacy locations nationwide, representing a variety of different types of programs, including long-term care pharmacies. As of the beginning of this week, there were about 304 million COVID-19 vaccine doses administered through this retail pharmacy program. That represents about 44.5% of all COVID-19 vaccine doses administered through the federal program. Our pharmacy partners have supported efforts in a variety of ways, including providing onsite clinics to reach specific populations, such as teachers, colleges, schools, and long-term care. Next slide, please.

This is just a list of all of the different pharmacy partners participating in the COVID-19 program. On the left, you can see the chain partners, which consists of a number of different sites within a particular chain. There are 13 of those. We also have what we call network partners, which are coalitions of pharmacies, essentially, working together, and that makes up a total of 21. Next slide. This is just to give you a little bit of a flavor of what the Federal Retail Pharmacy Program administrations look like. On the left, you can see where those doses have been administered across the country. On the right, I know it is very hard to see, but the blue line is all administrations, and the orange line is pharmacies, so that you can see that they have been major contributors to the overall COVID-19 vaccination effort in the U.S. Next slide, please.

This is the administration data flow for pharmacies. Pharmacies have been early vaccine administration partners from the beginning of the COVID-19 program. As far as data goes, they send data directly to the COVID-19 data clearinghouse using what we call the COVID-19 Vaccine Reporting Specification, or CVRS. That specification is available on the CDC website, if that is of interest. In addition, pharmacies also send data to immunization information systems in many jurisdictions, and they use HL7 VXU-22 messages for that exchange. The HL7 base capabilities have increased over time and throughout the response.

Similarly, all COVID data in the IIS is submitted to the data clearinghouse using that same CVRS specification, so we really have, to some degree, dual pharmacy reporting going on here, directly to the data clearinghouse as well as into IISes in many cases. At CDC, we developed capability to receive, validate, and process this data, and later in the response, we added the capability to update and delete records that were previously submitted in bulk by jurisdictions, and a number of jurisdictions and pharmacy partners have taken advantage of that capability to make changes to their data over time as they get additional information as well.

All of the data is made available downstream for analysis and reporting by multiple systems, including the CDC COVID data tracker, which is a public website that includes a variety of metrics and visualizations of the COVID-19 vaccination data, as well as Tiberius and HHS Protect. The immunization data lake plays the role of the core data hub for all vaccine ordering and vaccine administration data. At CDC, we developed methods to deduplicate and link records that were reported by different entities in order to accurately determine dose counts, series completion rates, and follow-up administration of COVID vaccine. So, for advanced data linkage functions, privacy-preserving record linkage, or PPRL, services were utilized for linking doses in a manner that enables that linkage to happen while still preserving the privacy of the PII and PHI. I think we were going to stop there. Nabeel, is there anything that I missed that you would like to add?

Agha Nabeel Khan

No, thank you, Lynn, you covered it all. Thanks.

Lynn Gibbs Scharf

Okay, thank you all, and we would be happy to answer questions.

Shelly Spiro

Thank you very much. Ike, I believe you are first.

Steven Eichner

Thank you so much. I am just going to add a little additional information on ECR. Basically, each state health department or each state has laws that define what is reportable within that state. There is a core set that is used pretty much nationwide, but each state and each locality can add to that list about what is reportable in that particular jurisdiction, and what entities are required to report data. ECR is also a little bit different than electronic laboratory reporting. Laura, would you mind differentiating the two?

Laura Conn

Sure, thanks, Steve. Sorry, I was trying to get that double mute off. So, electronic case reporting covers the reporting required by healthcare providers in a state. Electronic lab reporting is a requirement of laboratories, and there is definitely overlap in the conditions that need to be reported from labs and from providers. Laboratories obviously do not have the detailed clinical information that is required of a provider to send through a case report, and really, both are used at the public health agency. Those are both very important data sources to be pulled together to see the complete picture, but there are also a number of conditions on the reportable condition list required by providers to report that do not necessarily have laboratory test or results associated with them, so they are very complementary and they are pulled together and matched when there are lab results for a condition at the public health agency to really pull that whole picture together for public health action.

Steven Eichner

Laura, I think you touched on it briefly, but can you just do a quick overview of the AIMS platform and the way that information gets from people submitting data to public health?

Laura Conn

Absolutely. So, the AIMS platform is an intermediary that sits between the healthcare organization and public health agencies. The relationship through the trust framework is that the AIMS platform is a business associate, essentially, of the healthcare organization to assist with reporting to the appropriate public health agency, so there are a number of services that sit on the AIMS platform, including validation, and I am not sure I called it by name, but the Reportable Conditions Knowledge Management System is that system that the public health agencies put their reporting requirements into so that, as Steve said, each jurisdiction can define their reporting requirements, so when Oregon wants elevated blood lead in only less-than-10-year-olds but Washington state wants it in less-than-15-year-olds, that platform can adjudicate those reporting requirements put in that system by the public health agency and send the appropriate case report on behalf of the healthcare organizations to the public health agency where it belongs. That is definitely an advantage for healthcare because you connect once to the AIMS platform, you send the case report there, and they get delivered to the appropriate health agency based on those reporting requirements.

Steven Eichner

Just to elaborate further, the AIMS acronym is about eight or 10 words long. Association for Public Health Laboratories Informatics Messaging Service is the full spell-out of it, but basically, what it allows providers to do is there are a bunch of different ways for providers to get data to the AIMS platform, and then it is distributed by patient ZIP code or other information to the appropriate health department, and the electronic case reporting components are part of Promoting Interoperability, with adopted standards that are included in certified electronic health record technology. I just put that up as a point so if we are looking at making a recommendation in this space down the line, again, it ties back around to certification as well.

Shelly Spiro

Thank you, Ike. I am going to ask a question. This is a topic that I am very interested in. We do have several pharmacy settings, such as hospitals and long-term care, that have to report in relationship to antibiotic stewardship. How does electronic case reporting mesh with electronic stewardship? We do know that the community pharmacies are being looked at by the CDC as a way to bring them into antibiotic stewardship. Do you have any thoughts on how these two processes, electronic case reporting and antibiotic stewardship

programs are different, and how can pharmacy merge these programs together and move it across the nation in all practice settings within pharmacy?

Laura Conn

Thanks, Shelly. I am not that familiar with the antibiotic stewardship, and maybe I will ask other colleagues from CDC if they want to comment. I suspect it is related and associated more with the National Healthcare Safety Network reporting, so ECR is reportable conditions to the jurisdictional state, local, tribal, and territorial based on their list of reportable conditions. NHSN reporting is made available to the public health agencies, but is generally reported directly to CDC on their behalf, so I think we would have to do some discussions here to determine how those two can mesh together. We have certainly had conversations with that program previously of if data can flow to multiple partners at the same time using some of these shared infrastructures, but unfortunately, I cannot say a whole lot more than that related to what gets reported through that antibiotic stewardship program, but others on the phone may be able to assist me.

Shelly Spiro

Does anybody else from the CDC want to respond to that? I guess not. Well, it is food for thought, maybe a parking lot item, Tricia Lee. Hans?

Hans Buitendijk

Thank you, and thank you for the presentations. I have a follow-up question that is possibly a combination of Laura and Ike in particular. In the context of pharmacists being more involved in the test-to-treat processes, where tests are being done at pharmacies as well, where do you see the potential or the need for either the use of case reporting by pharmacists and/or lab reporting for the test results? What is currently being used to report those test results, and what do you see as a need there to advance one, the other, or both? What are your perspectives on that?

Laura Conn

Steve, do you want to comment? Really, that is point-of-care test reporting related to jurisdictional law.

Steven Eichner

Just to elaborate on what Laura was starting to say, there may be jurisdictional law that applies to who needs to report and under what circumstance. For example, looking at Texas during the public health emergency, there was a governor's executive order that required any entity that was using an FDA-authorized test to detect COVID to report the results to the public health department. As a specific example, it is a little different than our usual course of business in terms of looking at reporting data, but I think part of it is that we are really seeing an evolution in the testing environment, prolonged, perhaps, by COVID, as kind of a first step as we are looking to newer testing environments and more at-home kinds of testing.

I think that, as well as pharmacy-based testing, are things that we are going to need to figure out how to adjust to, and it may very well be that as you are looking at conducting laboratory tests, the ELR requirements may apply in addition to anything about ECR, and again, that depends upon each state or what law applies in terms of who is defined to report or required to report data, whether it says any testing facility or facilities that are testing for X, Y, and Z, or there are a number of different permutations from a language perspective that could address who might be included in a reporting requirement.

Hans Buitendijk

And on that point, Ike, today, for reporting of the results of such tests being performed by the pharmacy, what is being used to communicate that to the appropriate public health authorities? Is it ELAR or something else? Is it a portal? What is generally used there?

Steven Eichner

Again, looking back to COVID-19 in particular, pharmacies had a number of different ways that they could report those test results to public health. Recognizing that many pharmacies did not or do not have the capabilities to generate HL7 messages, which is public health's preferred standard for the submission of ELR and indeed is consistent with Promoting Interoperability program requirements, again, due to the nature of the PHE, the public health emergency, we adapted our framework and worked nationally with the CDC to develop a comma-separated value format for submitting and ingesting data. We modified our systems so that we could then ingest a CSV file after it was securely transferred to us using secure FTP or a number of other different transport standards.

Hans Buitendijk

So, perhaps, maybe as part of the discussion that we are about to go into, we should consider if there is a need to further standardize that, explore the use of ELR, explore the use of FHIR, or stay with CSV files. Maybe one of the considerations in the discussion...

Steven Eichner

Sorry for interrupting, but I think a key piece is really understanding what tests or what laboratory tests are being performed in the pharmacy environment and whether they align to conditions that public health is interested in or needs to receive data on.

Hans Buitendijk

Right.

Steven Eichner

What is the best mechanism for doing that? In the chat, there was a discussion around looking at flu vaccines or testing for flu, and we also do run a flu surveillance program that operates a little bit differently than electronic lab reporting, using a Sentinel-based approach, so there are several different ways that things could fit in, depending on the particular condition or conditions that are being tested.

Hans Buitendijk

Great. Let's jot that down as a note that we need to talk a little bit further about to see what ONC may be able to do to help advance that or address something in that space.

Steven Eichner

I think part of that is the roadmap of what things are going to be available in the future and how they relate to public health concerns.

Hans Buitendijk

Right. Switching the topic a little bit, on the other discussion around the IZ Gateway data lake, are there any questions or comments that anybody has? I know I have one, but before asking that, does anybody

else? Lynn, the question that I had is you made a reference to PPRL, which then gets into the identification ability of deidentified patient records and still have some level of connection across them as they are being managed within the public health context.

What is generally the experience that as you have an IT gateway as an environment around that as data from different states and different jurisdictions come together on an individual of the use of PPRL or like mechanisms to actually get a more complete record of that person across all those different areas, or where are some of the challenges still to make that patient-matching opportunity better, particularly considering how we need to get everybody to then use the same kind of mechanism, algorithms, or whatever else to enable the same patient to be matched correctly however they are flowing through, and the challenges with reidentification depending on what data is being used to establish that more secure key, which, in the end, depending on what you put in, is not necessarily as secure, as you can start to reidentify? What experience do you have with the success or challenges on enabling patient matching, that being on of the topics in general as well?

Lynn Gibbs Scharf

Great question. I will start, and then invite Nabeel and, actually, Adi to weigh in here as well on some of the work that has been happening at CDC. I will just start by saying where we are in the implementation of PPRL. We have been using it at CDC for our pharmacy data feed in particular. We do not receive any of the identified data at CDC, so this occurs prior to data being put into the data lake so that we are only having access to redacted data at CDC. We have been using it with pharmacy. We are encouraging jurisdictions to onboard to PPRL and leverage that as a tool, not only to improve reporting at the national level, but to help them with their own deduplication and record linkage at the state level, and also to provide them with some additional opportunities to do data linkage between different data sets at the jurisdiction level. So, there is a lot happening, but the onboarding for jurisdictions is in the early phases, so we have not done as much work with that particular data set, but Adi or Nabeel, do you want to weigh in and share a little bit about what we have been doing with the pharmacy data?

Agha Nabeel Khan

Lynn, I can start, and Adi can chime in. So, with the pharmacy data, I think PPRL has been very helpful to us for deduplication of the pharmacy records that come in, and also, I think we were able to go across every person who received a COVID vaccine across multiple pharmacies. We were able to make that connection. As Lynn mentioned, we are expanding with the routine immunization data that is coming in, working with the jurisdictions. One challenge with PPRL has been slightly in the value add to the jurisdictions. What is the value add for them in the PPRL implementation? As Lynn mentioned, one of the areas is also that it is also very beneficial for them for their programs also, and I think we are still at the early stages of implementing PPRL, and we worked with Adi, which you can speak to, Adi, on the collaboration that we had looking at the PPRL immunization data and the other data center that you had in that research study.

Hans Buitendijk

Adi, any additional notes, or should we go to Shelly with a question? Why don't you jump in?

Shelly Spiro

I will go ahead, and maybe Adi can come in later. We know about the IZ data lake. How does this fit into this whole aspect of electronic case reporting and/or immunizations that pharmacy can leverage into this process? So, the IZ Gateway, I guess.

Lynn Gibbs Scharf

Oh, the IZ Gateway. Sorry, I thought you said the data lake. I think that is a great question. We currently do not have pharmacies onboarded to the IZ Gateway. We have focused in the last couple of years on trying to implement IIS-to-IIS data exchange, as well as federal agency data exchange with jurisdiction IISes, and that was based on a landscape analysis that we did at CDC that involved a lot of stakeholder engagement, and those are the things that were prioritized by all of our partners as highest priority, and particularly the federal agency connections, since, in many jurisdictions, those do not exist at all, and so, there is a significant gap in the data that they are receiving in their immunization information system because there is no connection to the federal agency.

So, we have prioritized that in the last couple of years. We have been able to successfully onboard the Department of Veterans Affairs so that data is flowing to, I believe, 42 jurisdictions who have VA facilities within them that are now receiving that federal data. Since pharmacies are, in many cases, largely connected to the jurisdiction IIS already, either directly or through a data exchange partner, that has not been as high of a focus. As we continue to implement the federal agency connections and, at some point, wrap those up, I think that would be an area looking at again to see if, even if they are connected, there are ways to streamline that and reduce the burden.

Shelly Spiro

Great, thank you. Pooja?

Pooja Babbrah

Thanks, Lynn, for that answer. I guess I am a little confused, and maybe I am confusing two different things. I have been sitting in on some of the early HELIOS calls, and I know HELIOS is working to take some of this information and use FHIR to be able to do some of this reporting. I thought that in some states, pharmacies were connected to the IZ Gateway, and I am specifically thinking of Minnesota, but maybe I am confusing two things. Lynn, do you know, or do they have their own state gateway?

Lynn Gibbs Scharf

I do not know the specifics of Minnesota. They may have other ways to facilitate data exchange within the jurisdiction that they are leveraging. I can certainly look into that and see if I can get some additional information for you. One thing I did want to note in the chat is the IZ Gateway and PPRL are not connected. The PPRL service is not a part of what is provided through the IZ Gateway, so I just wanted to make that clear so there is no confusion there.

Hans Buitendijk

Thank you.

Shelly Spiro

Ike?

Steven Eichner

From a public health perspective, looking at states or other jurisdictional IISes, we can use data for a variety of purposes, certainly looking at coordinating care at the individual level, but we also use the data in aggregate to understand what immunization trends are at the jurisdictional level, so it is really rather important that when we think about a source of truth, really, one of the goals or hopes for many of the IISes is to have comprehensive information about immunizations at the population level. I think that is a factor as we are looking at routing and what the best connection options are for different entities, and what laws apply is also a consideration.

Shelly Spiro

Thank you, Ike. Pooja, you had another question.

Pooja Babbrah

Yes. I just wanted to thank Christian for pointing this out in the chat. NCPDP is piloting a national reporting model around this for pharmacies. I know SPC Health was on a couple weeks ago. We did not really talk about it then, but we may want to pull in some of those folks eventually just to talk about what that effort is going on as well, because I know those are using current HL7 and NCPDP standards, so it may be worth digging into that a little bit at one of these meetings.

Shelly Spiro

Great. Ike?

Steven Eichner

One of the other things that does occur for some jurisdictions with their IISes is that it may be tied to things like Medicaid programs, or vaccines, or children's programs, so that it goes beyond just an immunization information service, but actually may be part of a participating provider's reporting requirement for either a Medicaid or vaccines-for-children program, and submitting data to the IIS is part of the participant's requirements and influences reimbursement to some providers for payment for services for validating that a state-provided vaccine was actually administered to a qualified patient, so that is another factor that needs to get considered as we are thinking about how data is routed and what data is included in any submission.

Shelly Spiro

Thank you, Ike. I have a question in relationship to IIS and electronic case reporting. Is there any aspect of combining all of this information? We have so many different... I am not talking about now, but about the long term, especially to the CDC team, and I know that you are doing it through identifying the data elements that are important, but when we have all these different processes in place, it becomes so cumbersome to the workflow and to the productivity, especially in the pharmacy arena. Is there any thought of combining all of this into one standard type of exchange?

Laura Conn

This is Laura. I will start. I am not sure that we have had the discussion of whether it should be one reporting mechanism for the clinical provider condition reporting and immunization reporting. Certainly, at a public health agency level, the two reporting data sources are often used together in determining what public health actions, like ELR and ECR coming together, as I talked about, the integration of immunization data with case report data at a public health agency is an important component as well. Lynn, maybe you can

speak to some of the specific things that are in an immunization report that may not necessarily be reported, but need to be, that might be different in a case report.

Hans Buitendijk

It is an interesting topic, and in various discussions in HITAC before, the question has been when ELR, when case report, and when immunization, because there are some overlapping data needs. There might be some things that need to be optimized further. From the conversation, it sounds like having a better understanding of whether the source is the original ordering provider, the lab, or the pharmacy, what is really the appropriate set of reporting, and where can we use the same standards, where feasible as much as possible, so that there is consistency and we can route it to a variety of parties in the same way?

Going back to some of the comments that Ike made about the jurisdictional variations about what is reported at that point in time, and by whom, that sounds like an area in the context of the pharmacy topic and the expansion of test-to-treat where the conversation needs to be had as well. Where there is a need to report, should we progress, and how can we best optimize the data flows, whether to use an ELR, a case report, an immunization report, or something else to improve upon what we currently have? So, I am hoping that, as part of the discussion we are going to have, there might be some recommendation on what ONC could do there to help advance that in collaboration with the areas where we think that might be helpful, which we need to name.

Steven Eichner

Hans, really quickly, public health uses data for a wide variety of purposes, and the same data may or may not be necessary, or the same resolution of data, or additional detail may be required for the particular purpose. For example, if you are looking at a case investigation, it may be critical to know that a vaccine was administered, but not necessarily the way that that particular vaccine was delivered, where, if we are looking at immunization services for other purposes, the route, method, lot number, etc. become highly useful and highly necessary information. So, one of the concerns that needs to be addressed if you were to look to a single standard is how you address those data variation needs for the particular purpose, and if you went to all the required data for every potential need for that data to be reported, you would be looking at perhaps an awful lot of unnecessary detail, again, depending upon the particular need at the particular moment. So, I think that is part of the balance that needs to get addressed.

Hans Buitendijk

I completely agree that that is one of the aspects to look at. We do not want to send too much or too little, we do not want to send too many different variations, etc., and that is not an easy balance, as we are finding as we talk about ELR, ECR, immunizations, and related topics on how to do that. HELIOS Align and Optimize is working on that as well to figure out how we can better balance that need or if we are in a good spot today. I am looking at the hands raised, and we wanted to transition, Shelly, to long-term recommendations as well. Shall we ask Eliel and Lynn to be the last ones?

Shelly Spiro

Yes. Go ahead.

Eliel Oliveira

So, Hans and Shelly, the thought that has come into mind here is if we are seeking other agencies that need these pieces of information as well for the same purpose. I am thinking specifically here of the FDA and their surveillance systems of drugs, and I think they would be interested in knowing what we are putting together here, and there may be other interests as well, so we may learn more from them what they could leverage from this discussion. Thanks.

Shelly Spiro

Great, thank you. Lynn?

Lynn Gibbs Scharf

I wanted to quickly add to this conversation about how ECR and immunization reporting touch one another, and I think Laura touched on some of those, and others have as well, but I think one of the important things to highlight is that with the immunization reporting, those requirements are set by individual jurisdictions, and there is not the same kind of national reporting requirement or authorization for immunization reporting that there is for some of the ECR-type work, and so, that is why we have more variation on the immunization side with reporting, and that clearly impacts some of those reporting entities, like pharmacies, that deal with multiple jurisdictions, and I think that is something that maybe is a topic for another day, but I think the policy framework that supports that reporting has a significant impact on how it works and the variation that we see.

Shelly Spiro

Thank you, Lynn. Hans, we are going to transition into our recommendations. Hopefully, if we have any time after that, we can continue the discussion, but we have a little less than half an hour to do our recommendations.

Task 1 Long Term Recommendation for Public Health, Emergency Use Authorizations, and Prescribing Authorities (00:53:10)

Hans Buitendijk

Right. Thank you to all the speakers in the discussion. That was great, and I think that will also have some good material and thoughts on what to ingest into the long-term recommendations in particular, so I am looking forward to that. Again, thank you very much. Great presentations. I see that the spreadsheet has come up where we can see it. I have a couple of introductory comments there, and then we will go through it and start to further add to it. On the left-hand side, in Column A, you will see a couple of minor adjustments from the last time around that try to organize the comments a little bit more along the ones that are alike or together in different areas in that there is a line break in between. So, it is not precise, but that might also help focus in on where we could have a recommendation that covers multiple like comments together, but do not feel limited by that grouping in that sense.

In Column B, you will start to see a little bit more red markup coming up as well, and if you scroll down to about Row 5 and beyond, you will see the word "placeholder" dropping in. You will see it behind the name. That is where we are looking for the follow-up discussions that various members of the Task Force signed up to discuss, and then we will drop in hands toward the proposed recommendation in that area. So, you see a number of placeholders in there that we are looking forward to seeing pop up in the next week or so. So, have a look at that, but today, we are going to focus on the long-term question, and if you go to the first

one at the top, we will generally look at the different themes that we have had, standards of data exchange, etc., and we want to get a sense of whether there are possibly other recommendations to insert or if there is a concern with how the direction of the recommendation is currently going. Again, this is not to get to the final wording, but to go through that.

So, under the standards and data exchange, we see one, two, three, four, five recommendations in long-term that have started to be drafted. The first one is around working together between CDC and the public health community to create a set of metrics and outcomes. The second one is the opportunity for an information system to be certified and consistent, and also to provide consistent access to electronic health information. The third one looks at ONC working with CMS to develop model regulatory language for integrating pharmacy and public health for state adoption. The next one is around certification criteria of key functionality. Perhaps there is an opportunity to combine it with the prior one, which is also talking about certification, and create a general one around that. And then, the last one is ongoing process for evaluating, rating, and certifying human-computer interoperability. I think that one was meant more on the actual interactions, not the software going into it. Currently, that is a place where we may want to clarify a little bit to see if that combines with a couple of the other ones or stands alone.

So, looking there for thoughts, are we comfortable with the direction that is heading? After that, we will particularly be looking a little bit at the certification. Do we have two recommendations, or do we have one where we could merge them together? Any thoughts on that? Are we generally going in the right direction with these recommendations? If I do not hear anybody jump up... I need to make sure I can see the chat as well. It disappeared from my screen.

Okay, I have a question on the certification, a question for Steven and David in particular. It seemed from the discussion that we might have two types of focus when we talk about certification. One would be on the software itself, whether it can do certain things and support interoperability, but the other one is focusing on the actual interactions that are out in practice, and I am not sure whether that might relate to what ONC currently looks at as real-world testing, where the actual implementations are subject to some level of review all the way up to certification, or reporting in some fashion to understand how it actually is working. Can you clarify a little bit whether we are talking about one, the other, or both?

Shelly Spiro

I just wanted to jump in and set the pace for what Hans is talking about, Ike, if that is okay. So, when we talk about certification, especially using IIS or some of the other processes that are out there for pharmacy to exchange information, we do not really call it certification. It is sort of a testing mode that we go through to ensure that the systems can talk to each other. Most pharmacies and pharmacy system vendors get a little weary of the word "certification" because it can be very expensive for them, and these then become more unfunded mandates for some of the pharmacy vendors and their customers. So, I want to be wary of the term "certification" in pharmacy because of the implications that it can take. Pharmacies do follow state laws, and if it does become part of a state requirement, then they move forward with that, but I just want to be cautious of how we approach this topic. Go ahead, Ike. I know I interrupted you, and I apologize for that.

Steven Eichner

Not at all. I very much appreciate your comments and your concerns, I really do. One of the ongoing efforts at ONC right now is looking at potentially moving towards certification of at least some public health systems

for interoperability on the public health side of the equation for looking at receiving data. Just to give you a little bit of history, one of the things that came out of HITECH was certification of electronic health records systems really focused initially on electronic health records systems and their ability to both perform certain functions as well as generate messages in nationally adopted, standardized formats. In the last several years, there has been an interest on ONC's part in potentially exploring how to work on the public health side to look at potentially certifying public health systems, at least at the interoperability level, to validate that the public health system can successfully receive a message that is sent in the nationally adopted, standardized format.

So, one of the thoughts in this space is looking at ensuring that the system or a system that is sending data is indeed doing so in a manner that is consistent with the national standard or nationally adopted format, and the system that is receiving it can also receive the data in the national standard format to help avoid issues during implementation about whether a message is indeed compliant with those requirements to try to minimize the amount of extra effort required to actually establish an interface.

Currently, for example, as public health is onboarding a provider for things like electronic case reporting, we spend and the provider spends quite a lot of time validating the data that is being transmitted because the provider is using local codes that may be very appropriate for their system, but are not consistent with the nationally adopted standards, so there is a lot of work and rework necessary in that space. If we were to look at potentially certifying the interface capabilities, that helps reduce that extra work by having a system that, indeed, generates things that people are expecting to catch, and, again, validates that the folks that are catching can receive things that are consistent with the framework on the sending side of it.

Shelly Spiro

Thank you, Ike. Steven?

Steven Lane

Thanks, Shelly, and I know there are a lot of hands up, so I will be brief. I really appreciate your comments. Putting in a program of certification for a certain segment of the health IT ecosystem is a huge cost and potential burden, but the question is how can we get to the point we want to get to otherwise. As a physician, I really support the idea of leveraging pharmacists to provide appropriate spectrum of care to our shared patients, but as we discussed earlier, we have to do that in the context of assuring that that care is supported by all the appropriate tools, data, and functionality that it needs to be safe and effective and coordinated with the rest of the care going on in the ecosystem.

If there is a way to do that without assuring that pharmacists are using an appropriately connected health IT system or a way to do that without certification, I will be really interested in exploring that, but it seems that given the success that given the success we have seen with exploring certification on the EHR side and the consistency and standards that have been developed, it is hard for me to imagine a way to really bring pharmacists into the treatment process fully and appropriately without such support.

Shelly Spiro

Thank you, Steven. Pooja?

Pooja Babbrah

I think Steven pretty much summed up what I was going to say, but I do want to add to that. I know that in HTI-1, there was an RFI about pharmacy workflows and interoperability in that proposed rule. I know they were really focused on EHRs, but I think I would just have this Task Force really consider... I agree with Steven. I think we need to figure out a way, and it does not have to be full certification, but somehow ensuring that we can exchange the data with the pharmacists, so I really have nothing more to add, but I want to keep that in mind. Thank you.

Shelly Spiro

Eliel?

Eliel Oliveira

I have a different topic here, going back to that PPRL discussion that we had, and as you can see, CDC has made some great strides there to get data, preserving the privacy at the same time as linking and providing results. At the same time, you see other groups and agencies doing the same thing. PCORnet is one. NC3, the COVID collaborative, uses a different setup. The FDA considers different things. So, it seems to me like ONC would be well placed here to work a standardization on how these hash tokens are generated, shared, and matched. That could benefit all the agencies and all the organizations that are also providing data, like the pharmacies in this case here. So, that might be an important recommendation for ONC in terms of its standards definition for that.

Hans Buitendijk

Eliel, would you be able to write something up in whichever theme makes the most sense to address that? Because pace matching and ability to streamline that is certainly a key point that we want to have a recommendation for on how to further advance that.

Eliel Oliveira

Definitely. Do you want that on the short-term one, to be more like an evaluation of **[inaudible – crosstalk] [01:07:06]**?

Hans Buitendijk

If you feel that there is an opportunity in the short term already, then we should put it in one of the short-term categories.

Shelly Spiro

I would think both.

Eliel Oliveira

Excellent, will do. Thank you.

Shelly Spiro

Thank you. Afton?

Afton Wagner

Thanks, Shelly. I will be quick. I just wanted to mention that Pooja had talked about the HTI-1 comments. That would be really important to look at from a pharmacy workflow perspective, what we had suggested

in those, and then, I just wanted to reiterate that one of our biggest challenges for community pharmacies in being able to support current standards like HL7 and FHIR is getting the data formatted correctly. We have really talked about that at length, but somehow, we need to ensure we can exchange the data with pharmacists and really keep that top of mind.

Shelly Spiro

Thank you, Afton. Scott?

Scott Robertson

I think I am going to repeat a lot of things that have been said, so I will be very brief. Certification does involve a lot of cost, and I find that difficult to put into the very small users. Especially in pharmacies, there are the small users for whom it might be rather burdensome to address in some manner, but I think it is within ONC's purview to work across the HIT spectrum, and that does include pharmacy. The other point, on the technology and interfaces with humans... I am really not sure of the extent to which ONC or that standards can really be defined. There are a lot of psychosocial and human factors that come into play. Standards tend to want to be one thing, even if you have 15 or 20 variations. It is going to be extremely difficult to come up with strict criteria. I am not sure if that is something that would be accomplished. Thank you.

Shelly Spiro

Thanks, Scott. Ike?

Steven Eichner

I just wanted to add in that when we are talking about certification here, especially if we are looking at the interface certification, at least traditionally, the certification has not been provider-specific. In other words, it has not been a particular hospital getting certified, it is certification of the technology, really looking at the vendor or the HIT developer getting the technology certified on behalf of all of their customer base so that each individual pharmacy would not have to go seek individual certification. It is a shared resource or a shared tool that may help individual pharmacies actually have an easier time of implementing interfaces because they have a tool.

If they go down a certification route, if they are getting a piece of certified technology, they have some assurance built in and supported by their vendor that would support standardized interfaces, and that can reduce the time, effort, and angst about actually being able to exchange data and remove the pharmacist from having to be an IT expert or work with their particular implementation of a system to resolve an interface problem. I think the real-world testing, again, is looking at the vendor side of it to validate that whatever is developed actually works in the real world, connecting to real-world providers, not just a lab environment or a simulated environment, again, trying to remove future burdens from actual users of the systems so they have an easier time in actually putting the tools to work, and they can focus on the practice of their profession, not the practice of technology.

Shelly Spiro

Ike, I totally agree with you in the sense of the provider, but what we have in pharmacy, especially in the community setting, are multiple smaller vendors, unlike what we see in the consolidation of the larger EHR vendors out there. So, it is a different environment. Hans?

Hans Buitendijk

I would like to pick up on a couple of comments that have been made, and then I want to pass it to David Butler to provide some perspective on his comments, and then we need to start to look at time a little bit as well.

Shelly Spiro

We have seven minutes.

Hans Buitendijk

I have a couple thoughts, and part of it is based on experience with the certification program as it currently exists and what that means, and I completely agree with a number of the sentiments that certification is more involved because it provides a level of rigor of testing and ensuring that data can be accessed and shared consistently, particularly around interoperability, which is the main topic here. So, the question is how can we make a program that effectively is aiming to establish that consistency, whether you call it certification or otherwise? How can we make that more efficient, because that is in the best interests of everybody? And in the provider EHR space, there are small vendors, large vendors, and everything in between that have those same challenges, yet I will look at some comments that Steven Lane made as well that the value proposition is the consistency, but how can we do that better and more efficiently so that is not burden as it is at times? So, I think that is part of it.

Where we make suggestions around certification, we probably need to be more explicit that it need not mean the exact same thing as it means today in terms of how it is being executed, but how can we make it more efficient? The other part ties a little bit into Scott's comments and where I am curious from David's perspective. Indeed, certification has typically been looking at the capabilities that are in common and where it is critical that the data is being shared. So, vocabularies and using the same terminology in the vocabularies, the same coding system, is typically that area of focus. User/human interfaces are not, beyond general design guidelines, as you can see in the current certification program. Indeed, we have to be very careful there that as we move from the data and the design practices overall to get into the details, so I would be having some concerns around No. 2 that David raised, but that is where I would like to pass it for a little bit more information and context and target the real-world testing.

Shelly Spiro

Before you do that, Hans, I do want to comment on what you are talking about. Pharmacy has had a historical aspect, especially with DEA and electronic controlled substances, on going through a rigid certification process for that that was very costly to the vendors and has been very difficult, and I think we need to learn from those experiences as we move toward standardization and certification. Pharmacies are beginning to standardize the terminology quite extensively. That is one of the roles that the pharmacy profession has taken on. Now we can move to David.

Hans Buitendijk

Just to indicate, I completely agree on efficiency and certification of testing. How you can do that with the least amount of burden is absolutely critical. David?

David Butler

Thank you. Those are great comments, and I will just lead into my thoughts here by commenting on what you are talking about. In my statements, I am definitely creating a different paradigm, but the problem is we have had the paradigm that has developed over the last 50 years, which has been that we view system and system design as computers, engineering, and the component of a computer system, where systems design is really the overall organizational system.

So, it has to include the human-computer interaction, or it is not a full system design, and the issue that we have had is that because it has been so expensive, we have focused much more on just the computer aspect of it, and it has functioned because the discrepancies may have been minor, but now we are moving into a different world, particularly with the machine learning that is being developed and the concept of AI being part of that, and I think we need to at least devote some group to start thinking about the human part of systems. Humans are part of the system of information sharing/information gathering, and in effect, they are an extension or a partner with the computer, and that is going to be increasing and growing. We need to be thinking about that.

My first thought in proposing that was what you see when I mentioned the work that was done by Jacob Nielsen and others, pushing the idea of usability testing. Usefulness is different from usability. Usefulness means you pack everything possible on the screen in every form to capture everything, and useful is not usable. No one could read the whole screen because your font size would be too small to get all the data on there. So, we need to think about the usability testing that many of these researchers have used to see if humans are actually bringing the correct data to the system and if they are retrieving and applying the correct information from the system, and I think exploring usability testing as part of the certification process would be a good consideration, and the example I offer is Example No. 2.

Shelly Spiro

David, I do not want to interrupt you, but we only have a few seconds left before public comment.

David Butler

All right, well then, I will just point out that we still ask if you have drug allergies. We do not really capture everything that applies when you talk about adverse drug reactions because people do not understand that, so we have done a poor job so far of catching that, and I think we need to improve on that.

Shelly Spiro

Thank you, David. Mike, I am going to turn it over to you for public comment.

Public Comment (01:19:03)

Michael Berry

Sure, that would be great. If we could put up the public comment slide, we are going to open up our meeting for verbal public comments. If you are on Zoom and would like to make a comment, please use the hand raise function located on the Zoom toolbar at the bottom of your screen. If you happen to be on the phone only, press *9 to raise your hand, and once called upon, press *6 to mute and unmute your line. So, let's pause just for a moment to see if any members of the public raise their hand. I am not seeing any hands raised at this time, so I will turn it back to our cochairs.

Hans Buitendijk

Thank you. Shelly?

Shelly Spiro

David, do you want to continue your discussion? I apologize for that, but we do have a strict time stop for public comment.

David Butler

Yes. So, are you saying I can jump back in?

Shelly Spiro

Yes, you can jump back in.

David Butler

Okay. Hans has already put a good point in the chat. I just think it is important that we start thinking about that human-computer interaction in the certification process, and we need to expand that area, and you can see my example. We should not be asking if people have any drug allergies on the forms that are on the computer screen. We should be breaking those down into what really needs to be captured, which is which adverse drug events occurred in that patient over that length of time and what the surroundings or cause of an adverse effect were, as an example. We do not do that today because of poor design.

Hans Buitendijk

Thank you. So, certainly, in this area, there is a little bit more work to be done to align the various comments and determine how far we can have consensus as a Task Force on the extent to which we address certification, so I invite everybody to look at that further. Based on the conversation, we are going to see whether we can have some alignment of the different components here that we might be able to run by next week. Can you go to the spreadsheet again?

Shelly Spiro

While you are doing that, Hans, I do want to make a comment in relationship to how we might be able to help, and I think I put this in my recommendations in the certification process. If we link certification to quality measures, such as measuring which pharmacies are some type of measurement on electronic case reporting, or IIS, or immunization reporting, if we bring those measures forward, it might help us show the industry that we need to go through the certification process, and that is what I meant by that recommendation.

Hans Buitendijk

Thank you, that is helpful. That is great. Okeydoke, let's go to the pharmacist/physician collaboration. Next topic, which is Row 8, if you can scroll down just a little bit. When we look at the long-term, that would actually be Row 10, where we have long-term, we currently have a placeholder for Shelly. We have a number of different comments on the left-hand side that identify potential recommendations. Based on the conversation, has anybody identified other recommendations that you are thinking of or working on for long-term, particularly on the pharmacist/physician collaboration?

Shelly Spiro

Go ahead, Pooja.

Pooja Babbrah

Maybe I am a little confused because I know we are having a small taskgroup meeting later this week to talk about the Pharmacist eCare Plan. I think that was one of the items that we wanted to include with this, so I think part of the conversation needs to be how pharmacists and physicians are sharing information, and I know we have that as a tool. I think there have been some comments about possibly looking at how we add additional codified data elements. Hans, I am assuming that is what you are referring to.

Hans Buitendiik

Yes, unless anyone else already had that sort of [inaudible – crosstalk] [01:23:50].

Shelly Spiro

I will jump in on this. Hans, even through the certification process, especially through electronic prescribing, what we have historically had in the past is this push, this one-way exchange. What we need to do is to really promote, especially through the physician certification side, this bidirectional push of information so that the pharmacy does have information to share with the prescriber in the e-prescribing model, but they are reluctant to take that other type of information, such as a changing prescription or different types of recommendations. In the way that the certification process is now for the physician side, it is usually a push, but it is more difficult to get that information back to the physician. Pharmacies are used to receiving data from other sources, but have more difficulty in that bidirectional exchange of information. I think we have a question. Go ahead.

Hans Buitendijk

Eliel?

Eliel Oliveira

Not a question, but I was just going to say that maybe the long-term box here would be a good place for the recommendation I had earlier in terms that, in my opinion, the FDA surveillance systems for medication is still public health, so, in addition to having that recommendation for the CDC, maybe for the FDA also. In an emergency situation like we experienced with COVID, developing and rolling out a new drug was critical, as you all know, but also, monitoring the side effects and what was taking place would also be key, and FDA is the one doing that.

Hans Buitendijk

Great, thank you. There was also a comment that Adi made on Row 7, pharmacist/physician collaboration. Is there anything you would like to add there, or can we just incorporate that as we progress with the recommendations? Any additional thoughts there, Adi? Okay. In that case, with just a couple of minutes left, rather than jumping just to the next, are there any other areas from today that have jumped out where we can consider recommendations that seem to be areas? One is around patient matching. There probably should be some areas where we can identify how we can advance that further and understand how techniques, such as PPRL, can help. How would that work and where would that fit to achieve more complete records?

So, I suggest that we find a spot in our listing somewhere. Ike, I am curious whether you in particular have some thoughts at this time about this balancing act we have been going back and forth on in other contexts

as well on ELR, ECR, and other data feeds. How do you see that in the pharmacist/public health collaboration in particular, but perhaps some other areas as well, on what this Task Force should look at to recommend how to address or advance that? Is like still on the line?

Steven Eichner

I am very much here. I was not sure if you were looking for a real-time response.

Hans Buitendijk

If you have one, great, or otherwise, this may be where, with a couple of people, we could collaborate on coming up with a recommendation around that over the next number of days for next week to draft something.

Steven Eichner

I think it is something that we can look at. I think one of the challenges in this space in particular is that each jurisdiction does have the flexibility to identify what is reportable and who needs to report what kind of data, and again, looking at tests, if you are looking at pharmacy-based testing as to whether it is actually the pharmacy doing the test or the pharmacy as an intake location for a test that is subsequently performed by an offsite testing facility, which would already be reported, if that makes any sense.

Hans Buitendijk

Yes. It sounds like you would be willing to work on that. I am certainly happy to work with you on that. Is there anybody else who would be interested in that? Put that in the chat so we can pull a couple folks together on that.

Task Force Work Planning (01:29:06)

Shelly Spiro

I think we need to stop the discussion at this point and get ready to close. It is at the top of the hour. I do want to remind everyone that we will be moving to Task 2 on our next meeting, which will be on July 26, and we have several presenters coming in. Thank you, everyone, for all your time today. I appreciate it, Hans. Anything in the last few seconds?

Hans Buitendijk

In the last couple of seconds, while we are shifting over to the next task, we can and will continue to work on these recommendations, so, as individual groups have feedback and suggestions, drop them into the sheet, and if there are other ones that you think of, please drop them in as well so that we can start to move them into a set of recommendations down the road. Thank you very much, and thanks again to the presenters as well for today.

Shelly Spiro

Thank you to the ONC team. Thank you.

Adjourn (01:30:09)