Health Information Technology Advisory Committee

Pharmacy Interoperability and Emerging Therapeutics Task Force 2023 Virtual Meeting

Meeting Notes | July 19, 2023, 10:30 AM – 12 PM ET

Executive Summary

The Pharmacy Interoperability and Emerging Therapeutics (PhIET) Task Force met on July 19 for a guest presentation by members of the CDC team and to review Long Term Recommendations for Public Health, Emergency Use Authorizations, and Prescribing Authorities. A robust discussion followed the guest presentations.

Agenda

10:30 AM	Call to Order/Roll Call
10:35 AM	Opening Remarks
10:40 AM	Task 1 Guest Presentation
10:55 AM	Task 1 Long Term Recommendation for Public Health, Emergency Use Authorizations, and Prescribing Authorities
11:50 AM	Public Comment
11:55 AM	Task Force Work Planning
12:00 PM	Adjourn

Call to Order

Mike Berry, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC), called the meeting to order at 10:31 AM.

Roll Call

Members in Attendance

Hans Buitendijk, Oracle Health, Co-Chair
Shelly Spiro, Pharmacy Health Information Technology Collaborative, Co-Chair
Pooja Babbrah, Point-of-Care Partners
Shila Blend, North Dakota Health Information Network
Chris Blackley, Prescryptive
David Butler, Curatro, LLC
Steven Eichner, Texas Department of State Health Services
Rajesh Godavarthi, MCG Health, part of the Hearst Health Network
Adi Gundlapalli, Centers for Disease Control and Prevention (CDC)
Steven Lane, Health Gorilla
Deven McGraw, Invitae Corporation
Ketan Mehta, Micro Merchant Systems
Justin Neal, Noble Health Services

Eliel Oliveira, Dell Medical School, University of Texas at Austin
Naresh Sundar Rajan, CyncHealth
Scott Robertson, Bear Health Tech Consulting
Fillipe (Fil) Southerland, Yardi Systems, Inc.
Christian Tadrus, Community Pharmacy Owner
Sheryl Turney, Elevance Health
Afton Wagner, Walgreens

Members Not in Attendance

Jim Jirjis, HCA Healthcare
Summerpal (Summer) Kahlon, Rocket Health Care
Alexis Synder, Individual
Meg Marshall, Department of Veterans Health Affairs
Anna McCollister, Individual

ONC Staff

Mike Berry, Designated Federal Officer, ONC
Tricia Lee Rolle, ONC

Key Points of Discussion

Opening Remarks

PhIET Task Force Co-Chairs, Hans Buitendijk and Shelly Spiro, welcomed the Task Force, reviewed the Meeting Agenda, and recapped the Charge. Final PhIET Task Force recommendations are due to ONC on November 9, 2023.

Task 1 Guest Presentation

Laura Conn, MPH, eCR Program Lead, Public Health Data Transmission Branch, Detect and Monitor Division, Office of Public Health Data, Surveillance and Technology, CDC, Lynn Gibbs Scharf, MPH, Chief, Informatics and Data Analytics Branch, Immunization Services Division, National Center for Immunization and Respiratory Diseases, CDC, and Agha (Nabeel) Khan, MD, MPH, MBA, Senior Advisor for Informatics, Office of Informatics, National Center for Immunization & Respiratory Diseases, CDC provided a fruitful guest presentation on electronic case reporting (eCR). Laura reviewed the background of eCR and its architecture, as well as electronic initial case report (eICR) data elements and release. Lynn and Nabeel recapped the CDC COVID-19 Retail Pharmacy Program, its federal pharmacy retail partners, COVID-19 pharmacy administrations, and reporting.

Discussion:

- Steven Eichner noted each state health department has its own laws that define what is reportable. Each state and locality vary on what they report and what entities are required to report data.
    - Laura Conn said electronic case reporting covers the reporting required by healthcare providers. Electronic lab reporting is the reporting that is required to come from labs. Both are used at public health agencies and are complementary to each other.
- Shelly Spiro said various pharmacy settings, such as hospitals and long-ter mcare facilities, must report in relation to antibiotic stewardship. How does eCR mesh with antibiotic stewardship?
    - Laura admitted she is not familiar with antibiotic stewardship. She would assume it is based

on CDC National Healthcare Safety Network reporting.

- Steven Eichner noted the lab testing environment is evolving. It is important to understand what tests are being performed in a pharmacy and if they are aligned to conditions that public health agencies need to receive data on.
- Lynn said the CDC encourages jurisdictions to leverage Privacy Protecting Record Linkage (PPRL) as a tool to increase reporting on a national level and to help with r duplication of pharmacy data and individuals who received multiple vaccines at different pharmacies and record linkage at the state level.
    - Nabeel said the CDC is in the early stages of implementing PPRL immunization data. One challenge with PPRL is the value it adds to different jurisdictions. It is used slightly differently throughout the US.
- Lynn noted the CDC currently does not have pharmacies onboarded to IZ gateways. There is a significant gap in the data received from the Immunization Information Systems (IIS) because there is no connection to the federal agencies.
    - Pooja Babbrah thought some pharmacies were connected to IZ gateways. For example in MN. She asked for clarification.
    - Lynn said some states may have other ways to facilitate data exchange within their jurisdiction. The IZ gateway and PPRL are not connected. They are separate services.
- Pooja noted the National Council for Prescription Drug Programs (NCPDP) is piloting a national facilitator model. It may be helpful to bring them into one of the Task Force meetings.
- Steven Eichner cautioned against reporting all data because some information is not useful. There is a delicate balance between sending too much and too little information. Data is helpful for individuals and in the aggregate. IIS needs comprehensive information on immunizations at the population-level.
    - Hans agreed.

Task 1 Long Term Recommendation for Public Health, Emergency Use Authorizations, and Prescribing Authorities

Hans Buitendijk reviewed the Task Force Recommendations spreadsheet. The recommendations provided in the spreadsheet are in draft form and are not finalized.

Discussion:

- Hans asked for clarification on the Task Force's recommendation on certification standards for 1. Software and interfaces; and 2. Implementation and real-world testing.
- Shelly Spiro noted pharmacies are often weary of "certification standards" because it creates additional burden on them.
- Steven Eichner said there are ongoing efforts at ONC to move towards certification of some public health systems. Public health agencies are currently onboarding providers for eCR. There is a lot of work and rework necessary for that space.
- Steven Lane noted implementing a certification program may be a huge financial cost and burden. It is important to have interoperability between systems, but the rework needs to be done in the context of the rest of the ecosystem. How can we get to the same goal otherwise?
    - Steven Eichner said if a certification program is implemented, there will be some assurance built in, and it would support standardized interfaces. It would reduce the time and effort it takes to exchange data while removing the need for a pharmacist to be an IT expert.
- Hans said the certification suggestion in the Recommendation spreadsheet should be more explicit regarding how it can impact data exchange to become more efficient.
- Afton Wagner noted one challenge with community pharmacies is being able to support current standards is getting data formatted correctly.
- Scott Robertson noted certification is costly. He asked how do we help small pharmacies?. Unclear to

what extent standards can be defined for human factors/ human interface criteria

- David Butler noted machine learning is impacting how data is exchanged. Time should be spent examining how humans will continue to be part of the information sharing and gathering workflow, especially in a certification program. He likes the idea of usability testing and noted usefulness is different than usability.
- Pooja Babbrah said part of this conversation should include how pharmacists and physicians are sharing information.
- Eliel Oliveira noted there are recommendations from ONC and the FDA that can potentially be leveraged. There may be other agencies such as FDA with an interest in the work of the task force.

QUESTIONS AND COMMENTS RECEIVED DURING PUBLIC COMMENT

No comments were received during the public comment period.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Shila Blend: I may have missed roll. Present

Ketan Mehta: I missed it as well... present

Michael Berry: Welcome to the Pharmacy Interoperability and Emerging Therapeutics Task Force. Please tag "Everyone" when using Zoom chat. Meeting materials can be found at https://www.healthit.gov/hitac/events/pharmacy-interoperability-and-emerging-therapeutics-task-force-2023-2

Pooja Babbrah: curious how you define "planned medications" - is that based on the order in the EHR?

Steven Lane: Clearly lots of room to scale this.

Pooja Babbrah: @steven - agree

Heidi Polek: I can see where adding pharmacy to this process will be so beneficial

Steven Lane: And finding a way to support and incentivize this using TEFCA.

Hans Buitendijk: What are potential use cases where we should consider that pharmacists are an appropriate source of a case report for public health?

Laura Conn (CDC): @pooja yes, planned medications would be medications prescribed

Pooja Babbrah: Thank you Laura

Pooja Babbrah: As a TF, we need to be thinking about the pharmacy management systems and their ability to support FHIR. I know this is a requirement for EHRs now, but not for PMS. This is definitely scalable as Steven pointed out, but not sure how many PMS systems are ready to support FHIR or a FHIR app. I look forward to having the discussion about that in the next few weeks

Heidi Polek: @hans pharmacies are participating in test to treat programs for flu and covid and would report positive test results

Pooja Babbrah: @steven Eichner - is that specific to Covid?

Heidi Polek: I'd have to see the list of the 208 conditions that can be reported for to outline additional use cases

Hans Buitendijk: @Heidi: what transactions are used for reporting the tests? ELR? other formats?

Shelly Spiro: @Pooja can an intermediary convert to FHIR for PMS not FHIR ready?

Laura Conn (CDC): https://www.rckms.org/wp-content/uploads/2023/03/Conditions-available-in-RCKMS-March-2023.pdf

Pooja Babbrah: @shelly - possibly.

Shila Blend: We also need to think about pharmacies that may not be a part of a national chain and how some of our recommendations may impact them.

Laura Conn (CDC): AIMS = Association of Public Health Laboratories Informatics Messaging Services Platform

Pooja Babbrah: @shila - agreed. And we have some representatives from independent pharmacies on the TF who can speak to that

Ketan Mehta: Most PMS do support all reporting standards including FHIR

Ketan Mehta: if a mandate is provided, I am sure all would certify

Laura Conn (CDC): https://www.simplereport.gov/

David Butler: How is data gathered from pharmacist-recommended OTC and self-care therapy and combined with prescription medications data in order to measure the impact of these influences on outcomes?

Ketan Mehta: universal patient identification

Hans Buitendijk: Does the IZ Gateway PPRL approach use one service across all participating jurisdictions or each has their own?

Laura Conn (CDC): I think we might have lost Adi.

Christian Tadrus: NCPDP is piloting a national reporting model for pharmacies.

Eliel Oliveira: @Hans, they would have to use the same service and hash seed or PPRL would not work

Christian Tadrus: Would be helpful to have one flexible tandard for reporting

Christian Tadrus: Workflow burden and provider burnout seems quite directly related to the number of tools / websites / standards / similarly duplicative requirements that must be accommodated on any given day in healthcare.

Ketan Mehta: @pooja, while appreciate it if you could copy me on reporting standards as well

Deven McGraw: Apologies, but I'll need to excuse myself early for this meeting due to an unavoidable conflict.

Hans Buitendijk: The authorized scope of ONC appears to be HIT, not just EHRs. The incentive programs that would enable adoption of certified software has focused on EHRs, e.g., the CMS MU/PI programs. The question has always been whether the current process of certification is the most efficient way to ensure that HIT implements certain capabilities consistently to enable interoperability without special effort.

Ketan Mehta: @Pooja, I was referring to the pilot project by NCPDP

Christian Tadrus: Need standards bodies to work closer together. Maybe ONC can work on ensuring standards bodies are not developing in silos but co-developing public health data standards.

Ketan Mehta: Agree with Steven in regard to getting the PMS vendor certify and provide solutions to all the pharmacies... this is where mandates and certifications would help and all PMS vendors would support ir

Pooja Babbrah: +1 Christian

Christian Tadrus: Development costs (mandated or just necessary) do get passed onto pharmacies in the forms of higher fees (or additional fees from intermediaries). Pharmacies aren't exactly in the best financial situation right now to share that cost so would hope that any certification recommendations come with access to funding for that development.

Hans Buitendijk: @David: The current certification program includes the need for including certain user focused design and various standards. Would those be appropriate here?

Pooja Babbrah: Good points @christian and @scott. I think we need to consider both of these points related to costs. It's almost as if we are going back to the early days of EHR certification. There was funding for EHRs in the early days. I think this needs to be part of our recommendations

Chris Blackley: Interoperability standards are necessary and appropriate. However, one of the greatest barriers to information sharing is the fact that business models for systems vendors and HIEs continue to shift away from monetizing the capabilities of the system for the user, and instead monetizing the data and access to the same. If we do not address the issue of financial incentives that encourage information blocking, interoperability will struggle to achieve its stated goals.

Suzanne Gonzales-Webb, CPhT: @Pooja could you please add me to the eCare meeting later this week? Thank you! Suzanne.gonzales-webb@va.gov

David Butler: Physician-Pharmacist Collaborative Practice Agreements, authorized by states and reimbursed by third-parties, should be encouraged in order to move toward a generalist specializing in diagnostic processes and a generalist specializing in therapeutic processes available to every community in America. This would reduce the significant cost burden caused by the need to channel patients to so many specialists, commonly creating a 4-5 physician team involved in a single patient's care.

Christian Tadrus: David, more likely statewide protocols would be more functional and appropriate for Public health needs. Most states require separate CPAs by pharmacist / physician which is too narrow and practically impossible to manage.

Ketan Mehta: I would be interested

David Butler: Christian, I agree. My hope is that the technology, legal, and jurisdictional processes could be better coordinated and improved.

Christian Tadrus: Discussion with statewide health departments re: technical capabilities would be good

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

No comments were received via email.

Task Force Work Planning

This topic was not discussed.

Resources

Pharmacy Interoperability and Emerging Therapeutics 2023 Webpage
Pharmacy Interoperability and Emerging Therapeutics 2023 – July 19, 2023 Meeting Webpage
HITAC Calendar Webpage

Adjournment

The meeting adjourned at 12:00 PM.