Health Information Technology Advisory Committee

Pharmacy Interoperability and Emerging Therapeutics Task Force 2023 Virtual Meeting

Meeting Notes | September 20, 2023, 10:30 AM – 12 PM ET

Executive Summary

The goal of the Pharmacy Interoperability and Emerging Therapeutics Task Force (PhIET) meeting on September 20 was to continue the review of the final recommendation draft wording and structure. Two guest speakers joined the meeting and presented information to further discussions around Topic 3. A robust discussion followed.

Agenda

10:30 AM	Call to Order/Roll Call
10:35 AM	Opening Remarks
10:40 AM	Task 3 Guest Presentations
11:10 AM	Task 1 Review of Recommendations
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 10:30 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
Chris Blackley, Prescryptive
Shila Blend, North Dakota Health Information Network
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)
Jim Jirjis, HCA Healthcare
Steven Lane, Health Gorilla
Anna McCollister, Individual
Eliel Oliveira, Dell Medical School, University of Texas at Austin
Naresh Sundar Rajan, CyncHealth

Scott Robertson, Bear Health Tech Consulting
Alexis Snyder, Individual
Fillipe (Fil) Southerland, Yardi Systems, Inc.
Christian Tadrus, Community Pharmacy Owner
Sheryl Turney, Elevance Health
Afton Wagner, Walgreens

Members Not in Attendance

Meg Marshall, Department of Veterans Health Affairs
Summerpal (Summer) Kahlon, Rocket Health Care
Deven McGraw, Invitae Corporation
Ketan Mehta, Micro Merchant Systems
Justin Neal, Noble Health Services

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 and reviewed the Meeting Agenda. PhIET Task Force continued the Task 1 draft recommendations review.

Task 3 Guest Presentations

Shelly introduced guest speakers Stephanie Garcia, Branch Chief, ONC, and Mark Dunnenberger, Assistant Vice President, Personalized Medicine and Pharmacogenomics, NorthShore University Health System.

Stephanie gave a presentation regarding Sync for Genes, a program with a mission of standardizing genomic information sharing between key stakeholders. She gave an overview of the initiative and shared primary goals and objectives. She also reviewed methods of implementation, project phases, themes, and a summary of findings.

Mark gave a presentation on germline pharmacogenomics detailing the interpretation process and its impact on the quality of clinical care. He also discussed challenges between laboratory communication, allele nomenclature, and variations in lab reporting and emphasized the need for standardization of lab reporting to minimize these difficulties.

Discussion:

- Pooja Babbrah noted that PGX is relevant for pharmacy workflow and referred the group to the link she submitted in the chat regarding a white paper published by the National Council for Prescription Drug Programs (NCPDP) regarding lab information standardization.
- Christian Tadrus said this requires a large pool of information. He asked a few questions:
    - Where would standardization best occur for lab results? Through a self-directed learning working group?

    - Where would this apply?
    - Where can that work be done?
        - Mark said stakeholders need to collaborate with laboratory reporting organizations, advocate for the need for standardization, or develop the standards themselves.
- Shelly asked Stephanie for comments on some of the issues Mark addressed.
    - Stephanie said clinical standardization should be left to a group that has a majority of clinicians represented. Once standards have been developed, it is a matter of transporting that information in a standardized way. She noted that they have confirmed the ability of Health Level 7 (HL7) to parse out different parts of the genetic test report and send it using Fast Healthcare Interoperability Resources (FHIR), as well as embedding test results within the report. She cannot speak on the clinical interpretation of the report.
- Anna McCollister asked if the data needs to be complex or if it can be simplified.
    - Mark said simplified data could suffice if information regarding the methodology behind the results is also shared. Metadata is needed to render the information viable and to enable effective and correct clinical care. There is no universal agreement on laboratory result translation.
    - Anna sought to clarify whether Mark is referring to polygenic trait scores or polygenic pharmacogenomic risk scoring.
    - Mark said the focus in on a single gene. What is known now will only get more complex in the future.
- David Bulter said drugs can now be associated with specific genes and side effects. He added that even if nomenclature is developed, the data would still be vague. He said he is concerned there will be no connection between standardization and drug class.
    - Mark said pharmacogenomics is not a panacea for alleviating adverse drug effects; there are many factors to consider. If more people can be tested for genetics and improve standardized reporting of adverse drug effects, it can drive a better understanding of how genetics affect drug response.
- Scott Robertson asked if there is an organization that will take on the responsibility of building something where there are multiple axes to track. He asked Mark if he knew any organization that could be included or consulted regarding that kind of testing standardization.
    - Mark said the Clinical Pharmacogenetics Implementation Consortium (CPIC) would not do that. He added that the public health benefit is not great enough to generate interest in creating an organization for pharmacogenomics. He said that are focusing on using existing frameworks and noted that all the problems Scott described are problems for genomics in general.
    - Scott said it would not be useful for pharmacogenomics to use a standard incompatible with the rest of genomics.
- Hans gave a review of what he understood from the presentation and asked if ONC can help advance a solution or if it is still up to the pharmacies.
    - Mark said ONC should work on HL7 and FHIR-based standards to communicate metadata for lab reports.
    - Hans asked if additional activity from ONC is necessary to ensure its smooth progression, for clarification.
    - Stephanie suggested further Sync for Genes pilots.
- Steven Eichner asked for a suggestion of a recommendation to ONC regarding managing volume to reduce duplicative data storage and transmission.
    - Mark said big data is not an issue; there are few data points.
    - Steven Eichner asked if it would be fair to recommend including the exchange of genomic data critical for clinical decision-making.
    - Mark said yes.

Task 1 Review of Recommendations

- Hans gave an overview of progress on recommendation drafts and asked everyone to put additional thoughts and recommendations in the chat. He asked Stephen Eichner to review R2 for any additional refinements needed. He informed Alexis Snyder that her comments were found and added to R3 and asked her to review them for accuracy and completeness. He asked everyone to look through the drafts and make sure all notes were included. He asked Anna to make sure nothing was lost in merging her recommendations.
    - Anna asked for clarification on what he was asking her to do.
    - Hans asked her to review R10 and R11 to make sure her recommendations were captured accurately and completely.
- Shelly reminded the group of the importance of consolidating recommendations to reduce repetition.
- Hans said they are trying to generalize recommendations without changing the intent behind them.

Recommendation 10 (R10)

- Hans reviewed the recommendation and noted that it is not specific to public health. He asked for any thoughts and suggestions.
    - Anna detailed her personal experience behind her making this recommendation.
    - Pooja said she liked it but noted it needs revision. She said it was confusing and suggested splitting it into two separate recommendations.
    - Anna asked if adding “NCD code” would be a solution.
    - Hans asked Pooja and Anna to meet outside of this meeting and suggest changes.
    - Pooja agreed.
    - Shelly told them to make sure it is not for public health but general.
    - Hans made a note of the time and suggested maybe splitting this recommendation into two parts. He asked if there was anything that could be added.
    - Scott asked them to make sure it is more focused when rewritten.
    - Steven Eichner said the purpose was great, but it needs rewording.
    - Hana asked if that clarifies the recommendation.
    - Pooja said yes.
    - Steven Eichner said the focus needs to be on whether a drug needs prior authorization and what information is required to be communicated from Pharmacy Benefit Manager (PBM) to the provider.
    - Hans asked Steven Eichner to review it again once Pooja and Anna have an update.

Recommendation 11 (R11)

- Hans reviewed the recommendation.
    - Shelly suggested using Anna’s use case.
    - Anna said she has several use cases for this recommendation; they are in the rationale.
    - Hans asked Anna if the use cases are reflected in the recommendation sufficiently.
    - Anna said she will need to review it again.

- Christian said this request is incredibly complex as inventory levels vary from minute to minute. He raised concern about this becoming problematic and misinforming, given the current state of the medication supply chain. He suggested adding, “timeliness of medication is urgent.”
- Hans asked Christian to review the recommendation for wording.
- Afton Wagner agreed with Christian and suggested focusing on acute situations where medications are needed immediately to minimize patient confusion.
- Anna used Amazon and other online retailers, as examples of successful inventory management systems. She said it is about identifying data elements to reduce patient burden.
- Hans asked Christian, Afton, Anna, and Alexis to discuss language to balance all concerns before the next PhIET meeting.
- They agreed.
- Alexis says she agrees with lowering the patient burden and confusion. She added that it is not just the point of inventory in a retail pharmacy but also supply.
- Shelly asked Alexis and Anna if they had a case manager on their health plan side that would help with this.
    - Anna said they are useless.
    - Alexis said that is not something they take a lead on.
- Jim Jirjis said he supports comments on inventory, and it should not be avoided just because it is difficult. He added that it is a mistake to limit this to emergent use only.

Recommendation 12 (R12)

- Hans reviewed the recommendation and said it may be out of scope for ONC. He asked Anna to clarify.
    - Anna agreed it may be out of cope for ONC and detailed personal experience regarding sudden formulary changes done without notice to patients or providers.
    - Hans asked if that can be used as a use case for patient engagement instead of having it as a recommendation.
    - Tricia Lee said this is out of scope for ONC as currently written.
    - Hans said this recommendation will be dropped unless there is another way to phrase it.
    - David said formulary updates should be made visible to patients so they can make informed decisions. He added that health plans and coverage need to be part of the patient record, and medical devices should be a part of the formulary as well.
    - Hans asked David to rewrite this recommendation otherwise, it would be dropped.

Recommendation 13 (R13)

- Hans reviewed the recommendation.
    - Anna shared personal experiences behind this recommendation.
    - Hans suggested combining this recommendation with the ONC certifications recommendation.
    - Anna asked for clarification.

- Hans explained there is a general recommendation for advancing a certification approach for pharmacy management systems. He asked if this recommendation should be included in the patient engagement aspect of that recommendation as opposed to standing alone.
- Anna said she is not opposed to combining them, though she does not see it as an issue of patient engagement.
- Scott noted pharmacies are limited to passing along information. They cannot provide more information than they receive.
- Shelly added that oftentimes, the pharmacy is put in the middle. They try to coordinate as best as possible, but the lack of interoperable exchange between providers and payers makes it difficult.

Recommendation 14 (R14)

- Hans reviewed the recommendation and asked Anna if it was ok to combine it with the recommendation for certification.
  - Anna agreed.
  - Steven Lane said he liked this recommendation.
  - Hans said it will address the opportunity to share information once it is available.

QUESTIONS AND COMMENTS RECEIVED DURING PUBLIC COMMENT

None received.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

David Butler: David Butler is present

Mike Berry (ONC): Welcome to the Pharmacy Interoperability and Emerging Therapeutics Task Force.

Mike Berry (ONC): When using Zoom chat, please tag "Everyone" so that all can see your message.

Jim Jirjis: Jim Jirjis Just joined

Pooja Babbrah: https://ncpdp.org/NCPDP/media/pdf/Resources/Precision-Medicine-Executive-Summary-August-2023.pdf?ext=.pdf

Jim Jirjis: Wouldn't CPIC do that?

Stephanie Garcia: The recommendation refers to the description of genomic variations and the annotated knowledge associated with those variations. Areas of focus for standards-based content include variant representation, vocabularies, and terminologies, all used by genomic knowledge bases to annotate alleles, genotypes, haplotypes, and phenotypes. In many cases, the description of genomic knowledge is domain or use-case-specific.

Stephanie Garcia: This recommendation would support the development of computable knowledge supporting higher quality CDS.

Shelly Spiro: @Stephanie thank you.

David Butler: Recommendation 1: All patient assessment forms (both paper and electronic) need to be corrected in EHRs to replace the question "Do you have any allergies?" with "Have you ever had an adverse event from a drug?" and, for electronic systems, that allow a more refined specification of both the specific drug-product dosage and the adverse event that occurred.

Pooja Babbrah: Just FYI - the CodeX work is today is primarily focused on sharing genomic data with multiple providers in a grand rounds scenario which is more inpatient focused

Steven Eichner: I reviewed R2 and made some minor changes.

Hans Buitendijk: How much does RTPB already cover of R10? Is anything missing we need to highlight?

Pooja Babbrah: RTPB would only flag that a prior auth is required. The prior auth transaction within script would bring back the prior auth requirements and questions

Katie Russell: RTPB is at point of prescribing not pharmacy

Katie Russell: This has to do with the Info Blocking Actors in the Cures Act Final Rule, and PBMs/Payers are not covered actors, and are not required to share. I would think that we could recommend that Payers are added as covered actors so that info is not blocked and price transparency increased

Alexis Snyder: I provided a use case somewhere in the doc as well a while back regarding this

Shelly Spiro: @Alexis thank you.

Katie Russell: Drug shortages and supply chain are and not something within ONC jurisdiction but rather FDA or legislative bodies (ie Congress) not regulation (CMS etc)

Pooja Babbrah: +1 Katie

Alexis Snyder: I would think this is about transparency to update info before rx is sent out… and therefore could be added to R10?

Kim Boyd: The formulary does change even after plan selection

Kim Boyd: The patient doesn't always have insight into that until a prescription is written

Pooja Babbrah: Some of what David is referring to is already covered under the CMS rules I think. I thought CMS covered plans have to provide their medication coverage so consumers can search before they choose a plan

Kim Boyd: +1 Pooja

Alexis Snyder: As an aside, I have had drugs covered that were denied bc of formulary change but bc of lack of transparency about change to patient/provider it needed to be covered one more time with time to find new next time around

Katie Russell: Yes it is already covered under MMA for Medicare, cant regulate for Commercial plans (out of scope would need to be legislated)

Pooja Babbrah: thanks for the clarification, Katie

Alexis Snyder: Could we combine some of these recommendations into one about transparency?

Pooja Babbrah: +1 Alexis

Kim Boyd: The SCRIPT standard (eRX and ePA) has codes that define reason for rejection by the PBM/plan

Kim Boyd: That is why the pharmacy has specifics on the reason for a delay in fulfilling a prescription

Pooja Babbrah: Christian - is this notification being sent electronically? Or through paper?

Alexis Snyder: Transparency is a huge piece of patient engagement

Pooja Babbrah: I wonder if this could be delivered electronically

Kim Boyd: The health plan/pbm would be the ones to provide the information to the patient

Kim Boyd: +1 Shelly

Kim Boyd: +Pooja - expand Patient Access API

Alexis Snyder: Don't need to bypass, all parties need transparency

Shelly Spiro: @Alexis agree

Pooja Babbrah: Thanks all! Great discussion!

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

No comments were received via email.

Task Force Work Planning

- Hans said next week's discussion will resume with R15. He asked the group to make suggestions in red and asked the subgroups created today to meet and identify opportunities to advance the recommendations discussed.

Resources

Pharmacy Interoperability and Emerging Therapeutics 2023 Webpage
Pharmacy Interoperability and Emerging Therapeutics 2023 – September 20, 2023 Meeting Webpage
HITAC Calendar Webpage

Adjournment

The meeting adjourned at 12:01 PM.