The May 28, 2019, meeting of the Interoperability Standards Advisory Task Force of the Health IT Advisory Committee (HITAC) was called to order at 10:00 a.m. ET by Lauren Richie, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC).

Roll Call

Kensaku Kawamoto, co-chair, University of Utah Health
Steven Lane, co-chair, Sutter Health
Ricky Bloomfield, Member, Apple
Tina Esposito, Member, Advocate Aurora Health
Tamer Fakhouri, Member, Livongo Health
Cynthia Fisher, Member, WaterRev, LLC
Ming Jack Po, Member, Google
Anil K. Jain, Member, IBM Watson Health
Edward Juhn, Member, Blue Shield of California
Victor Lee, Member, Clinical Architecture
David McCallie, Jr., Member, Individual
Terrence O’Malley, Member, Massachusetts General Hospital
Mark Roche, Federal Representative, Centers for Medicare and Medicaid Services (CMS)
Ram Sriram, Member, National Institute of Standards and Technology
Sasha TerMaat, Member, Epic
Sheryl Turney, Member, Anthem Blue Cross Blue Shield

MEMBERS NOT IN ATTENDANCE
Valerie Grey, Member, New York eHealth Collaborative
Leslie Lenert, Member, Medical University of South Carolina
Arien Malec, Member, Change Healthcare
Clement McDonald, Member, National Library of Medicine
Raj Ratwani, Member, MedStar Health
Andrew Truscott, Member, Accenture
Scott Weingarten, Member, Cedars-Sinai Health System

ONC STAFF
Denise Joseph, Public Health Analyst, ONC ISP Task Force Lead
Lauren Richie, Branch Chief, Coordination, Designated Federal Officer
Call to Order

Lauren Richie called the meeting to order, conducted roll call, and turned the meeting over to the co-chairs.

Review of Charge

Steven Lane reviewed the agenda and charge and reminded those in attendance that the ISP TF will be publishing a report with the findings and recommendations that will be shared with the HITAC and transmitted to ONC. He noted that the ISP TF initially focused on orders and results and then moved into referrals/closed loop referrals and care coordination. He also referenced the need for standards to support referrals in terms of clinical content and what data needed to be exchanged between referring providers and referred to providers (the ISP TF is working with the American Medical Association (AMA) on this effort).

Recap Medication & Pharmacy Domain Preview presented to HITAC March 19, 2019

Ken Kawamoto reviewed the sub domains and medication and pharmacy domain preview and turned it over to Steven Lane.

Steven Lane reviewed the medication recommendations within the shared Google document. He also noted the cost related to accessing prescription drug monitoring programs (PDMP) data and stated that in California, they are struggling with integrating the PDMP into electronic health record (EHR) workflows.

Discussion

- David McCallie noted the issues being discussed often represent policy and business problems but not necessarily standards problems. He suggested the ISPT TF segregate out problems that await policy work and those that fall on the business side.
  - Steven Lane stated that the ISP TF is charged with the prioritization and identification of the relevant standards as well as how they are being implemented. He noted that it is within the charge of the task force to make suggestions back to ONC as to how these categories of changes could be encouraged and incentivized.
  - David McCallie answered that at a minimum, the ISP TF should understand the business process barriers that need to be addressed and identify them.
- Terry O’Malley referred to medication reconciliation (med rec) and noted that part of the problem is with payment and formulary access. He also noted that it is often not as simple as just creating a med rec from one place and sending it on to the next. It needs to be an iterative process that goes back and forth.
  - After extensive discussion, Steven Lane asked the ISP TF members if there are suggestions that can be made to ONC or HITAC regarding med rec.
  - David McCallie noted that the process of performing reconciliation is time-consuming for the provider and highly valuable to the patient; at a minimum, one would hope to get paid for it. There was broad agreement that this would incentivize medication reconciliation.
Terry O’Malley agreed with prior statements that 360X has issues, but it’s a first step in automating communication. He expressed his hope that Fast Healthcare Interoperability Resources (FHIR) will be implemented to support 360X.

Ricky Bloomfield noted that accurate medication dispense information is difficult to come by and to improve this would contribute to med rec. He suggested requiring the availability of dispense information by an API similar to how the clinical information is currently required from health systems. He went on to state that further profiling the medication dispense resource within FHIR would help. He noted that this is both a policy problem and an ecosystem problem.

Steven Lane suggested that Ricky propose language for the med rec recommendation which Ricky agreed to do.

Cynthia Fisher noted that the ISP TF should look at the ability to provide visibility in generic options as well as pricing options. She suggested that there will be many applications (apps) if this can be open for innovation. Finally, she reiterated that it is very important that the ISP TF supports an open architecture for this type of development.

Discussion of Medication Data Sub-Domains

Steven Lane discussed potential new sub-domains that the ISP TF could consider and noted one of the areas to consider is in modernizing the way adverse drug events (ADEs) are reported to the Food and Drug Administration (FDA). He then offered an opportunity for members and the public to weigh-in on ADE data, other FDA needs, and Pharma/research needs.

Discussion

- Terry O’Malley noted that the strategy of asking the FDA what they need and then focusing on supporting those needs was a good approach.

- David McCallie stated that it would make sense to have a one-click adverse event reporting function wherein a clinician could click a button and it would snapshot the patient's current medication profile and pop-up a question on what the adverse event was and communicate that to the FDA for subsequent analysis. However, he noted that the FDA is doing similar work, and the ISPT TF should make sure that it stays consistent. He also noted that patient direct-reporting would be valuable and noted there had been significant contributions from patient-focused adverse event capture.

- Steven Lane asked the members if anyone had contacts at the FDA or any other individuals who might contribute to the discussion.

  - Anil Jain noted he had experience and contacts from working to solve the problem of adverse drug events and offered to connect his contacts with the ISP TF. He also noted that regarding reporting adverse drug events, the ISP TF should be very sensitive to increasing clinician’s workload. He stated that properly capturing the event details was non-trivial, and they should closely consider indemnification and protecting physicians who engage in this type of reporting. He went on to note that a good place to start is to provide pharma with deidentified data so pharma has the minimum data necessary so they can look for signals within the data.

Work Plan
Steven Lane discussed the task force’s timeline and work plan and reviewed some of the areas the task force will focus on in the near-term, including:

- Price transparency related to medications which includes generic options or options within the same pharmaceutical or therapeutic class
- Alternative treatment recommendations
- Vendors such as Surescripts and/or GoodRx with the goal of knowledge-sharing regarding the development that they have done and are planning and whether they find that the lack or inconsistent application of standards present barriers to their progress
- Inviting an FDA representative or some other expert to discuss adverse drug event data capture and reporting
- Data and interoperability needs of the pharmaceutical industry
- Evidence-based clinical guidelines specific to medications

Ken Kawamoto noted that ONC is focusing on prior authorization. He went on to state that focusing on the aspects of medication data and workflows that overlap, including prior authorization and price transparency, makes a lot of sense.

Discussion

- Cynthia Fisher suggested that the ISP TF consider engaging with innovators. She agreed with earlier statements regarding the need to consider generics or other treatment options based on affordability for patients. She also mentioned the need to focus on payment information, especially with regard to the use of mobile devices.
- Steven Lane noted that the ISP TF co-chairs will work with ONC to organize the next couple of meetings where the focus will be on educating the task force regarding price transparency, adverse drug events and probably some of the pharma data exchange.
- Steven Lane referenced EHR vendor members and asked if anyone had done work to address adverse drug events.
  - Sasha TerMaat noted that in her experience when people report a safety incident, they want to do it out of a risk management system and not an electronic health record so that it enters the patient safety protection workspace and is not part of the medical record. She then noted that a safety officer might offer the best insight and best understanding of the related considerations.
  - David McCallie stated that the separation that Sasha TerMaat referenced is driven predominantly by liability concerns and the channels that were created to protect disclosure of that information both from a patient privacy point-of-view as well as a provider liability point-of-view.

Lauren Richie opened the lines for public comment.

Public Comment
There were no public comments.

COMMENTS IN THE PUBLIC CHAT FEATURE OF ADOBE

Cynthia Fisher: Is there a link to the document of the Medications Recommendations that we may have a copy of it. In this screen it is very difficult to read. Our own copy will be helpful. Thank you.
Steven Lane: We will have Accel send the link to the TF members via email.

Ken Kawamoto: Ricky: your recommendations were included in the HITAC Information Blocking Task Force recommendations

Ken Kawamoto: Cynthia: your comments on Rx options are now incorporated in the spreadsheet

Holly Miller, MD: Or patient/family member/caregiver also being able to initiate reporting ADEs

Terry O’Malley: Agree, Dr. Miller

Next Steps and Adjourn
The meeting was adjourned at 11:00 a.m. ET