

Meeting Notes

Health Information Technology Advisory Committee (HITAC)
Interoperability Standards Priorities Task Force
June 25, 2019, 10:00 a.m. – 11:30 a.m. ET
Virtual

Executive Summary

Patient safety and adverse drug events were discussed by representatives of the Agency for Healthcare Research and Quality (AHRQ) and Medstar Health. Techniques to identify adverse medication reactions were presented and discussed, and the importance of prevention was emphasized. CMS provided an overview of a recent proposed rule impacting E-prior authorization transaction standards. The task force discussed and posed questions regarding the presentations. There were no public comments. There were comments and questions from the online public chat window.

Event Summary

10:00 a.m. Call to Order/Roll Call

10:05 a.m. Adverse Drug Events (ADE)

10:10 a.m. AHRQ CQuIPS, MPSMS and QSRS, and Measuring Adverse Drug Events

10:20 a.m. Techniques to Identify Medication Adverse Events

10:35 a.m. E-Prior Authorization Standards

10:40 a.m. Discussion

11:20 a.m. Public Comment

11:30 a.m. Adjourn

Roll Call

Steven Lane, Sutter Health, Co-Chair
Ricky Bloomfield, Apple
Tamer Fakhouri, Livongo
Anil Jain, IBM Watson Health
Edward Juhn, Blue Shield of California
Arien Malec, Change Healthcare
David McCallie, Jr., Individual
Clement McDonald, National Library of Medicine
Ram Sriram, National Institute of Standards and Technology
Sasha TerMaat, Epic

MEMBERS NOT IN ATTENDANCE

Kensaku Kawamoto, University of Utah Health, Co-Chair Tina Esposito, Advocate Aurora Health Cynthia A. Fisher, WaterRev, LLC Valerie Grey, New York eHealth Collaborative Victor Lee, Clinical Architecture Leslie Lenert, Medical University of South Carolina

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Terrence O'Malley, Massachusetts General Hospital
Ming Jack Po, Google
Raj Ratwani, MedStar Health
Mark Roche, Centers for Medicare and Medicaid Services (CMS)
Andrew Truscott, Accenture
Sheryl Turney, Anthem Blue Cross Blue Shield
Scott Weingarten, Cedars-Sinai Health System

ONC STAFF

Cassandra Hadley, HITAC Back up/ Support
Denise Joseph, Public Health Analyst, ONC ISP Task Force Lead

Welcome

Steven Lane welcomed all attendees and reviewed the overarching and specific charge of the Interoperability Standards Priorities Task Force (ISP TF).

AHRQ CQuIPS, MPSMS, and QSRS, and Measuring Adverse Drug Events NOEL ELDRIDGE AND ERIN GRACE, AGENCY FOR HEALTHCARE RESEARCH & QUALITY

The Agency for Healthcare Research and Quality (AHRQ) is one of 11 operating divisions in the U.S. Department of Health and Human Services (HHS). AHRQ is the lead federal agency charged with improving the safety and quality of America's health care system. Three of the five divisions within the AHRQ Center for Quality Improvement and Patient Safety (CQuIPS) focus on patient safety. AHRQ partners with CMS to estimate rates of hospital acquired conditions, including adverse drug events. Historically this has been done through manual chart review as part of the Medicare Patient Safety Monitoring System (MPSMS).

AHRQ currently reviews ~0.1% of hospital charts from 4-800 hospitals. There are also companies with proprietary software for hospitals to self-monitor. Peer-reviewed publications suggest that the rates of hospital acquired conditions have been decreasing steadily over the past decade.

Reference: National Trends in Patient Safety for Four Common Conditions, 2005–2011. N Engl J Med 2014; 370:341-351. https://www.nejm.org/doi/full/10.1056/NEJMsa1300991

- To increase their ability to monitor for adverse events CQuIPS is working to replace the MPSMS with a new more automated Quality and Safety Review System (QSRS).
 - Medication adverse events represent one of 11 modules within the QSRS software program.
 The module includes 64 questions that require responses which may be numeric, structured data (coded or un-coded) or free text. QSRS algorithms have been made available to hospitals for use in self-monitoring programs.

 Reference: Predictors of warfarin-associated adverse events in hospitalized patients:
 - Opportunities to prevent patient harm. J. Hosp. Med. 2016 April;11(4):276-282. https://www.journalofhospitalmedicine.com/jhospmed/article/127055/warfarin-associated-adverse-events
 - QSRS is currently focusing on medication adverse events related to anticoagulant, hypoglycemic, and opioid use. An automation feasibility study of the QSRS in 2016, focusing on the abstraction of data from 6 Electronic Health Records (EHRs) related to hospitalacquired C. Difficile infections, revealed variation in how relevant clinical information is

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- stored in the EHRs. This variation limits the extent to which the system can be completely automated.
- QSRS is able to extract patient information from EHRs, but needs to be equipped to accept the information pulled from the EHR to achieve partial automation capabilities.
- Automation of the QSRS is hindered by its ability to identify temporal relationships between events during patient care.

Techniques to Identify Medication Adverse Events

TECHNIQUES: MEDICATION ADVERSE EVENTS PRESENTATION - ZACH HETTINGER, MEDSTAR HEALTH, National Center for Human Factors in Healthcare

The challenges of detecting Adverse Drug Events were discussed, and a holistic approach to addressing these events was proposed.

- To impact adverse drug events, it is necessary to understand the circumstances that create the
 hazard (primary prevention) and identify ways to prevent the hazard from harming the patient
 (secondary prevention), as well as dealing with adverse events that occur (tertiary prevention). This,
 in conjunction with detection algorithms to determine what events occur, will help to ensure
 patient safety. It is important to understand the circumstances that create hazards to patients.
- In most healthcare systems adverse events are documented in applications separate from the EHR
 so that this information is not discoverable as a part of malpractice proceedings. This can make it
 difficult to access and analyze. Some are beginning to use natural language processing in order to
 evaluate free text reports.
- There is a general trend toward increased reporting of patient safety events as well as greater willingness to discuss adverse events with patients and families.
- Practitioners can voluntarily submit safety event data to Patient Safety Organizations (PSOs). The 2005 Patient Safety Act provides protection for reporting providers. The PSO Privacy Protection Center aggregates the reported event data that can be used for national learning. ~2M patient safety events have been reported. The first cut of this data is now available for analysis.
- Signals of adverse drug events (ADEs) are difficult to identify in EHR data. Algorithms are being
 developed based on temporal event analysis. These may identify potential events that then must be
 evaluated through manual chart review.
- Data from state Prescription drug monitoring programs (PDMPs) could help identify opiate-related ADEs, though this data is not being used for surveillance and reporting.
- Patient-reported outcomes, e.g., 911 calls for hypoglycemic events, were noted as valuable in identifying possible adverse events.
- New medical technology, such as internet-enabled glucometers, could also support this effort.
- It was suggested that alerts marking a potential adverse event action be presented to a patient safety officer or pharmacist who can intervene without affecting the administering provider.
- To locate contacts within the Food and Drug Administration (FDA) who can contribute to the ISP TF
 Zach Hettinger agreed to connect the ISP TF with contacts at IBM who may be able to assist with
 locating these individuals.

E-Prescribing Standards-Updates

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On June 17, 2019 CMS issued a proposed rule that would improve patients' access to needed medications by updating the prior authorization process for Medicare Part D, the program that provides coverage for prescription drugs that beneficiaries pick up at a pharmacy counter.

 $\underline{https://www.federalregister.gov/documents/2019/06/19/2019-13028/medicare-program-secure-electronic-prior-authorization-for-medicare-part-\underline{d}$

The rule proposes that providers adopt the National Council for Prescription Drug Program (NCPDP) Scrip Standard version 217-071 for electronic prior authorization (PA) transaction. The proposed standard will go into effect January 1, 2021 if finalized. Public Comments on the proposed rule can be submitted through August 16, 2019 at 5 p.m.

The proposed standard would be required for transactions in which prescribers query plans regarding whether a PA is required for a medication. The standard also returns PA requirements to the prescribing provider in real time. This is similar to eligibility checks currently used in e-prescribing and adjudication transactions. This new standard would replace the X12 278 transaction standard currently required by HIPAA.

Task Force Discussion

A task force member pointed out that NCPDP standards are available to members but not to the general public. This can be problematic when a standard needs to be reviewed. This may be an area where the task force wants to provide input to ONC.

Where should focus be directed to improve medication safety – patient differences leading to idiosyncratic responses, clinician error, or EHR user interface issues? When focusing on the detection of errors it is difficult to know what preceded an adverse drug event. It is important to understand the sequence of events.

It is valuable to focus on detection algorithms.

The absence of ambulatory discrete sig data can present challenges to ADE investigation.

Studies have shown that daily INR testing in hospitals for patients receiving anticoagulants increases the detection of ADEs.

ADE identification could be incorporated into clinical decision support algorithms. This could, however, lead to additional alert fatigue.

Public Comment

There were no public comments.

QUESTIONS AND COMMENTS FROM THE CHAT WINDOW

Patrice Kuppe: Real time ePA is supported by the standard transactions. It pulls information from the prescription order

Patrice Kuppe: There are four transactions PAInitiationRequest and PAInitiationResponsePARequest and PAResponsePAAppealRequest and PAAppealResponsePACancelRequest and PACancelResponse

Patrice Kuppe: It supports question sets

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Patrice Kuppe: Surescripts staff would be happy to explain it to Clem.

Closing Remarks and Adjourn

The next meeting for the ISP TF is scheduled for July 9, 2019 at 10:00 a.m. It was suggested that the ISP TF use the next meeting to discuss progress and draft recommendations based on presentations at the past few meetings. The meeting was adjourned at 11:30 a.m.