



Health IT Policy Committee

A Public Advisory Body on Health Information Technology to the National Coordinator for Health IT

April 22, 2010

David Blumenthal, MD, MPP
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Dr. Blumenthal:

The HIT Policy Committee (Committee) gave the following broad charge to the Adoption-Certification Workgroup:

Broad Charge to the Workgroup: To make recommendations to the HIT Policy Committee on issues related to the adoption of certified electronic health records, that support meaningful use, including issues related to certification, health information extension centers, patient safety, and workforce, training.

This letter provides recommendations to the Department of Health and Human Services (HHS) on the topic of patient safety.

BACKGROUND AND DISCUSSION

On February 25, 2010, the Adoption-Certification Workgroup (Workgroup) held a hearing on the topic of patient safety related to the use of electronic health records. A summary of the hearing is attached. After the hearing was held, the Workgroup conducted several public phone conference calls during which possible approaches to this vitally important topic were discussed. Preliminary findings were discussed with the HIT Policy Committee during its meeting on March 19, 2010. On April 21, 2010, the HIT Policy Committee approved the following recommendations and the following goal:

Establish a patient-centered approach to HIT safety that supports national patient safety goals by monitoring, evaluating, and guiding deployment of HIT systems to maximize their safety benefits and minimize their risks. To achieve this goal, each healthcare entity needs a culture of continuous learning and improvement.

HIT POLICY COMMITTEE RECOMMENDATIONS AND COMMENTS:

NATIONAL OVERSIGHT PROCESS AND INFORMATION SYSTEMS

In order to create the conditions that enhance the ability to prevent unsafe conditions that could lead to injuries, information is needed on hazards and "near-misses."

Recommendation 1.0 - A national, transparent oversight process and information system is proposed, similar to a Patient Safety Organization (PSO), with the following components:

- *Capacity to monitor actual and near-miss patient harms and classify those associated with HIT systems.*
- *Confidential reporting with liability protection (e.g., whistle-blower protection, confidential disclosure of adverse events)*
- *Ability to investigate serious incidents potentially associated with HIT.*
- *Provision of standardized data reporting formats that facilitate analysis and evaluation*
- *Receive reports from patients, clinicians, vendors, and healthcare organizations*
- *A reporting process to cover multiple factors including usability, processes, and training*
- *Receive reports about all health information technology (HIT) systems*
- *Receive reports from all Software Sources (e.g., vendors, self-developed, and open source)*
- *Ability to disseminate information about reported hazards*

While this recommendation appears to be necessary, it might not represent a complete response to all HIT patient safety concerns. Additional research is needed.

Recommendation 1.1 - We recommend that the Office of the National Coordinator (ONC) commission a formal study to thoroughly evaluate HIT patient safety concerns, and to recommend additional actions and strategies to address those concerns.

FACILITATE AND ENCOURAGE REPORTING

We learned that most unsafe conditions are not the result of a single software error. Instead, multiple factors are involved, including challenges with usability, processes, and interoperability. Healthcare organizations and clinicians represent a primary source of information about unsafe conditions. In order to encourage healthcare organizations and clinicians to report unsafe conditions, we make the following recommendations.

Recommendation 2.0 - Stage 2 of Meaningful Use should include a requirement that EPs and hospitals report HIT-related patient safety issues to an organization authorized by

ONC to receive HIT-related safety reports (“HIT safety organization”). Copies of those reports should be sent to any vendors that might be involved.

Recommendation 2.1 - Certification criteria for EHRs should include functionality that makes it easier for clinician-users to immediately report any problems/concerns with information that appears on screens (a “feedback button”) to appropriate staff who can either make modifications themselves or escalate the problem to those who can. This feedback button could also be used by clinician-users to request corrections to data.

Recommendation 2.2 - The Regional Extension Centers should provide HIT-related patient safety reporting training.

VENDOR PATIENT SAFETY ALERTS

The certification process can be used to ensure that vendors provide safety alerts to their customers, and it can also be used to improve patient safety.

Recommendation 3.0 - We recommend that the Stage 2 EHR certification criteria should include requirements that vendors maintain records on all patient safety concerns reported by their customers, and that vendors have established processes to promptly provide all impacted customers with safety alerts.

PATIENT ENGAGEMENT

Patient Engagement plays a major role in identifying errors and preventing problems. For example, in ambulatory settings, in nearly every encounter when it is possible for patients to observe and discuss information as it is entered during the health care encounter, potential errors can be avoided. Through a personal health record (PHR) or patient portal, patients obtain the ability to review some of the data in their EHR, and, as a result, PHRs and/or patient portals should continue to be encouraged. Access by family members to inpatient medication lists should also be encouraged (assuming appropriate authorization from the patient). Mechanisms that make it easier for patients to report inaccurate or questionable data need to be encouraged as “best practices.” Examples include (a) the use of a “feedback button” that makes it easy for a patient to communicate with and receive feedback about system problems, and (b) a secure communication link, perhaps through a PHR, that permits patients to link back to the provider to report data corrections and omissions.

IMPLEMENTATION, EDUCATION, AND TRAINING

The implementation, education, and training processes can impact patient safety conditions. Training programs should include information about the value of reporting patient safety incidents and unsafe conditions in the context of broader educational efforts to create and continuously enhance cultures of patient safety.

INTEROPERABILITY

Interoperability problems are a significant source of patient safety concerns. As a result, ONC's interoperability efforts continue to be extremely important.

***Recommendation 4.0** - The HIT Standards Committee should consider the concept of "traceability" of interface transactions. "Traceability" refers to the ability to trace and analyze the source of problems. The HIT Standards Committee is asked to consider techniques like requiring the use of audit trails or "logs" of interface transactions.*

BEST SAFETY PRACTICES

***Recommendation 5.0** - We recommend that ONC work with the Regional Extension Centers (RECs) and with organizations such as the American Medical Informatics Association (AMIA) to create a set of best safety practices for selecting, installing, using, and maintaining HIT, and disseminate those best practices to providers. Tools, such as Geisinger/Jim Walker's Hazard Evaluation tool and Dave Classen's flight simulator should be explored as possible resources for providers.*

ACCREDITATION

Accreditation organizations such as The Joint Commission can play an important role in assuring HIT patient safety.

***Recommendation 6.0** - ONC should discuss HIT patient safety concepts with these organizations to determine, for example, if they are examining whether large institutions have a patient safety review committee, and whether processes are in place that encourage reporting of problems.*

TIMING OF STAGE 2 AND STAGE 3

The time period between the publication of certification criteria and the beginning of the eligibility period is a safety concern for both of the next two stages. Any software changes or updates must be carefully tested by each healthcare organization that receives those updates.

***Recommendation 7.0** - We recommend that, for each stage, certification criteria should be available at least 18 months prior to the beginning of the eligibility period.*

With this proposed schedule, a vendor could have 12 months to develop, test, certify, and distribute their software, and then customers could have 6 months to test, train and implement changes prior to the beginning of the eligibility period. For example, this schedule would require that Stage 2 certification criteria be finalized by April 1, 2011, which would allow vendors to complete their programming, testing, certification, and

distribution work by April 1, 2012, and existing customers to train, test and implement by October 1, 2012. For vendors with a large number of customers, the six month window is probably difficult, and an even longer period might be requested. In this example, in order to finalize the certification criteria for Stage 2 by April 1, 2011, the initial publication needs to occur by December 31, 2010.

FOOD AND DRUG ADMINISTRATION

A number of concerns were expressed about the potential for increased Food and Drug Administration (FDA) regulation of EHR systems. These concerns include:

- a. The FDA focuses on problems caused by individual “devices.” As a result, it does not seem to cover situations where problems occur even though the software is operating correctly. This is only one example of a situation that arises because HIT is embedded in a sociotechnical system that includes a complex mix of people, technology, work processes, and factors outside the organization that influence it.
- b. The FDA reporting system focuses on serious injuries and death caused by individual devices. That reporting process might not cover many unsafe conditions and hazards, such as incompatible work-processes in which no actual injuries occur, that might be another result of sociotechnical factors beyond the technology.
- c. The FDA’s Quality Systems Regulation (QSR) process is inconsistent with the incremental nature of HIT development, and, as a result, could harm innovation and increase vendor and product costs. By hampering and slowing the ability of vendors to continuously improve systems, thus making them safer, such a process could actually work against the safety efforts we are proposing.
- d. The increased costs of FDA class II regulation could become a barrier to entry for small vendors.

While we have concerns, we have also seen that the FDA has valuable experience that could help the ONC accomplish its goals. Two possible ways that the ONC and the FDA could collaborate are:

1. Collaborate on certification criteria that improve patient safety.
2. Focus on selected HIT areas that are creating safety risks for EHR implementations. For example, retail pharmacies create safety problems because they do not process electronic order cancellations, which can result in over-medication of patients. Additionally, most retail pharmacies are not providing

compliance data. The FDA could be a valuable ally to address this type of patient safety issue with non-certified software systems that connect to the EMR.

***Recommendation 8.0** - We recommend that the ONC work with the FDA and representatives of patient, clinician, vendor, and healthcare organizations to determine the role that the FDA should play to improve the safe use of Certified EHR Technology.*

FINAL OBSERVATION

The workgroup did not hear any testimony that indicated that EHR systems and CPOE systems should not be implemented. We detected, however, frustration that these systems are not reaching their full potential. We also clearly heard concerns that these systems need to be properly and safely implemented. In the public comments, we were also reminded of the 1999 Institute of Medicine report, which indicated that over 90,000 lives could be saved each year through computerized ordering. As a result, we believe that the biggest risk to patient safety would be to either avoid or delay the proper implementation of EHR and CPOE systems.

***Recommendation 9.0** - We recommend that ONC continue its efforts to encourage implementation of EHR systems.*

Sincerely yours,

/s/

Paul Egerman
Co-Chair

Adoption Certification Workgroup

Sincerely yours,

/s/

Marc Probst
Co-Chair

Adoption Certification Workgroup

Attachment: Adoption/Certification Workgroup

February 25, 2010 hearing

This attachment summarizes information received by the Adoption Certification Workgroup during its hearing, on February 25, 2010, on patient safety hazards and adverse events. While formal studies and data exist on the benefits of HIT, there have been very few efforts to similarly collect data on the subject of hazards and unexpected events. For the most part, this summary and these recommendations are based upon anecdotes, impressions, and the experiences shared by the hearing's participants.

1. Overall, patient safety is better in healthcare organizations with IT than in healthcare organizations without IT, provided that the IT systems have been implemented correctly, and provided that an appropriate improvement culture exists. While concerns were expressed about certain patient safety conditions, none of the participants made any recommendations to stop implementing HIT systems. All participants were supportive of HIT systems and wanted to improve their usefulness.

2. We reviewed information about several areas where potential hazards exist. More data are needed on these hazards, unsafe conditions, and adverse incidents. The following four areas appeared to be the largest areas to address:

A. Technology Issues (e.g. Hardware failures and software "bugs").

B. Complex interactions of professionals, workflows, and user interfaces.

The complexity of the health care activity coupled with the number of individuals involved with an activity influences the probability of an incident.

C. Interoperability problems between applications (e.g. the lab results never made it into the EHR)

D. Implementation and training deficiencies.

3. CPOE was discussed, because of its great potential to positively influence quality and to decrease cost. It also represents an area where interactions among professionals, user interfaces, and workflows (processes) need careful attention. For example, the intended benefits might not be fully achieved as a result of:

* Alert fatigue--too many alerts (some of which may lack relevance to the clinician).

* Interoperability--the data sensitive nature of decision support requires a high level of consistent interoperability that might not exist.

* Lack of applicability to a given patient due to absence of a comprehensive rule or incomplete data.

4. Transparent sharing among healthcare organizations about unsafe conditions and patient safety incidents is vitally important, but is frequently not occurring. Many clinicians express frustration that their concerns are not being addressed.

5. The patient can play a major role in patient safety efforts. Dave deBronkart ("ePatientDave") described how patients can find errors in electronic records. He also expressed frustration with any finger-pointing that might exist between vendors and providers. Eloquently, Dave said that he expected everybody to work together and be focused on the patient.

6. The FDA has the authority to regulate HIT and submitted written comments with three possible regulatory classes. In the verbal presentation, the third class, pre-market review, was described as being unlikely to be implemented. Their first two classes focus on vendors ("manufacturers"), and do not address Open Source Software, or Self Developed ("in-house") systems. A capability exists for providers to voluntarily submit information to the FDA.

7. Dr. William Munier described the AHRQ Patient Safety Organization (PSO), which provides a mechanism to report incidents, "near-misses" and unsafe conditions. The program includes common formats for reporting problems, in order to facilitate analysis and, ultimately, dissemination of information. Participation in the PSO is voluntary.

8. Jim Walker (Geisinger) presented an innovative approach to evaluating hazards. The emphasis was on evaluating potential risks before a serious injury or problem occurred. Dave Classen presented information about a CPOE "flight simulator" that is similarly positive, non-punitive, and voluntary.

List of Presenters at Hearing

- Panel 1: Identifying the Issues
 - Ross Koppel, University of Pennsylvania
 - David Classen, University of Utah
 - Alan Morris, Intermountain Healthcare
- Panel 2: Stakeholders
 - Dave deBronkart, ePatientDave
 - Justin Starren, Marshfield Clinic
 - Jean Scott, Veterans Health Administration
 - Michael Stearns, e-MDs
 - Shelley Looby, Cerner
 - Carl Dvorak, Epic
- Panel 3: Possible Approaches
 - Jeff Shuren, Food and Drug Administration/HHS
 - William Munier, Agency for Healthcare Research & Quality
 - James Walker, Geisinger
 - Edward Shortliffe, American Medical Informatics Association

Adoption Certification Workgroup Members

Chairs:

- Paul Egerman
- Marc Probst - Intermountain Healthcare

Members:

- Rick Chapman - Kindred Healthcare
- Adam Clark - Lance Armstrong Foundation
- Charles Kennedy - Wellpoint
- Scott White - SEIU Training & Employment Fund
- Latanya Sweeney - Carnegie Mellon University
- Steve Downs - Robert Wood Johnson Foundation
- Joseph Heyman - American Medical Association
- Teri Takai – State Chief Information Officer, CA
- Micki Tripathi - Massachusetts eHealth Collaborative
- George Hripcsak - Columbia University
- Paul Tang - Palo Alto Medical Foundation
- Carl Dvorak- Epic
- Joan Ash- Oregon Health and Science University
- William Munier, Agency for Healthcare Research and Quality