Adoption/Certification Workgroup -

DRAFT Summary and Recommendations -

March 25, 2010 -

Learnings and Observations from Hearing

This document 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. (After the hearing, several WG members expressed additional concerns about FDA regulation, which are not summarized in this message.)

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.

Recommendations and Comments

Goal

Establish a patient-centered approach to safety that is consistent with David Blumenthal's vision of a learning health and healthcare system. In order to create the conditions that prevent unsafe conditions that might lead to injuries, we want to focus attention on hazards and "near-misses". In support of this goal, a national, transparent, information system is needed with the following components:

Reporting and Monitoring
Evaluation and analysis
Dissemination of information----learning

To achieve this goal, a culture of improvement needs to be created by each healthcare entity.

Preliminary Recommendations:

1. Patient engagement plays a major role in identifying errors and preventing problems. For example, in ambulatory settings, 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 PHR, patients obtain the ability to review some of the data in their EHR, and, as a result, PHRs 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.

2. The implementation and training process has a significant impact on patient safety. Training programs should include information about reporting Patient Safety incidents and unsafe conditions. We recommend that the Regional Extension Centers provide patient safety reporting training.

3. A national database and reporting system needs to be established by ONC to create the information needed for the learning process. The national HIT reporting system needs to have the following components:

a. To be patient-centered, all "incidents" or "potential hazards" need to be confidentially reported by the provider directly to a national patient safety organization (PSO). Patients and vendors should also be able to make reports.
b. The PSO must be able evaluate data received from these reports and provide findings that will assist other providers. As a result, standardized formats for data collection and reporting, such as those used by AHRQ, are needed.
c. Data from the PSO should be used to influence future certification criteria.

We recommend that Stage 2 of Meaningful Use include a requirement that each Hospital and EP report potential hazards and incidents to the national PSO. Copies of those reports should be sent to any vendors that might be involved.

4. We recommend Certification criteria be created that will make it easier for clinician-users to immediately report any problems/concerns with information that appears on screens (a "feedback button"). This feedback button could also be used by clinician-users to request corrections to data.

5. The Stage 2 certification criteria should include vendor development and communications processes. Reflecting some of the concepts of the FDA's QSR program, certification should require vendors to have a process that records patient safety problems and communicates alerts to their customers.

6. We recommend that ONC work with the Regional Extension Centers and with organizations like AMIA to create a set of best safety practices for selecting, installing, using, and maintaining HIT, and disseminate those best practices to providers. As part of this process, utilization of Jim Walker's Hazard Evaluation tool and Dave Classen's flight simulator should be examined as best-practice candidates.

While these recommendations are necessary, by themselves, they do not represent a complete response to all HIT Patient Safety concerns. For example, there may be areas that PSO data does not cover. Additional research is needed. A formal, independent evaluation of current Patient Safety issues is recommended.

<u>Open Topics for Discussion</u>

1. Do we want to have a recommendation for a special HIT Patient Safety Oversight function or an NTSB like entity that investigates serious patient safety concerns?

**There is not a consensus on this issue. Guidance is requested.

2. How should we respond to the interoperability patient safety issues?

**There is not a consensus on this issue. Additional discussion needed.

3. Should whistleblower protection be expanded/changed as part of this process? Should we respond to the community physician with admitting privileges (who is not employed by the hospital), who is concerned about being branded a "disruptive force" for reporting incidents?

**We were informed that PSOs already provides protection, and PSOs also permits confidential reporting. Bill Munier provided this detail:

….the Patient Safety Act includes "reporter protections" that give an employee a "right of action" if the employer takes an adverse personnel action for filing a report with a PSO. ONC staff can find the provision at 42 U.S.C. 2699b-22e (Section 922(e) of the Public Health Service Act).

While the identifiable information held by the PSO is confidential and privileged, ONC can benefit from the knowledge developed by the PSO. The PSO can aggregate, analyze, and publicly release information and "lessons learned" as long as the information is made contextually non-identifiable. Information that is confidential and privileged can only be disclosed if there is a specific permission in the Patient safety Rule and, in some cases, there are requirements for how they can take place (e.g., to make disclosures of protected information to vendors as your statement suggests requires specific procedures to be followed).

4. Is there a role for accreditation organizations (e.g. Joint Commission) in assuring IT Patient Safety?

5. Are special considerations needed for small physician groups or rural hospitals or safety-net institutions?

**Michael Stearns provided this comment: "We did at one point consider during our meeting taking different approaches to acute vs. ambulatory HIT safety. At least when compared to hospital based CPOE, we are hearing less about issues in the ambulatory space. However, this does not mean they are not occurring. Of concern, they may be more difficult to recognize as adverse events and near misses may be more challenging to identify and isolate. This may require a more longitudinal approach and the PSO may need to analyze a greater number of variables such as care multiple care settings and HIT platforms. "

6. The relationship between incident reporting and liability is a requested topic for discussion.

**Does the PSO protection described above respond to this question?

7. Do we want to make a recommendation about the speed of introducing Stage 2 and Stage 3?

8. The impact of FDA regulation is an important area for discussion. Do we have any recommendations for the ONC concerning the FDA?

**We were reminded that the FDA is an independent agency that already has regulatory authority over HIT. As a result, our workgroup won't be making recommendations about FDA regulation. We can, however, make recommendations about how ONC should work with the FDA. Possible recommendations might include:

a. Collaborate with the FDA on certification criteria that increases patient safety.
b. Perform a formal evaluation, including a public discussion, on the possible impact of HIT regulation.