

DRAFT
Adoption/Certification Workgroup

Working Document Created for Discussions Purposes
March 12, 2010

Learnings and Observations from Hearing:

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.
2. We reviewed information about several areas where potential hazards exist. Unfortunately, there is very little data about these hazards. 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.
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 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 "flight simulator" that is similarly positive, non-punitive, and voluntary.

Possible Recommendations and Comments:

Goal: We want to establish a patient-centered approach to safety that is consistent with David Blumenthal's vision of a learning health and healthcare system. A "patient-centered" approach focuses more on the patient and less on accountability for an error. We also want to focus attention on hazards and "near-misses". We want to prevent unsafe conditions that might lead to serious injuries or deaths. The following components are needed:

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. In support of this improvement culture, we have the following recommendations:

1. Patient engagement plays a major role in identifying errors and preventing problems. For example, in ambulatory settings, when patients observe data as it is entered, 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.

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 information.

3. A national database and reporting system needs to be established 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 the Patient Safety Organization (PSO).
- b. The PSO must be able evaluate data received from these reports and provide findings that will assist other providers.
- 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.

While data from a PSO is necessary, by itself, it is not a complete response to all HIT Patient Safety concerns. There may be areas that PSO data does not cover. Continued attention to Patient Safety, along with additional research, will be needed.

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.

Questions and Topics for Discussion

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?
2. . Do we want to add a recommendation that says, The Stage 2 certification process should cover vendor development and communications processes. Reflecting some of the concepts of the FDA's QSR program, certification should include requiring vendors to have a process that records patient safety problems and communicates alerts to their customers.
3. Do we want to add a recommendation that says, Because interoperability is a potential source of patient safety problems, Stage 2 should include an expanded group of interfaces. While information exchange in Stage 1 focused on data exchanged between organizations, information exchange within organizations (between applications) needs to be included in Stage 2.
4. Do we want to add a recommendation that says PHR Certification Criteria should be developed that would make it easier for patients to report to their clinicians questionable data.
5. Do we want to add a recommendation that says, Develop a set of best safety practices for selecting, installing, using, and maintaining HIT, and disseminate those best practices to providers.
6. Should we be making any recommendations concerning expansion/utilization of Jim Walker's Hazard Evaluations tool, or Dave Classen's flight simulator?

7. 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?
8. Is there a role for accreditation organizations (e.g. Joint Commission) in assuring IT Patient Safety?
9. Are special considerations needed for organizations with small administrative staffs, like small physician groups or rural hospitals or safety-net institutions?
10. The relationship between incident reporting and liability is a requested topic for discussion.
11. Do we want to make a recommendation about the speed of EHR implementations?
12. The impact of FDA regulation is an important area for discussion. Do we have any recommendations for the ONC concerning the FDA?