

Adoption/Certification Workgroup -

DRAFT Recommendations -

Goal

Establish a patient-centered approach to HIT safety that is consistent with the National Coordinator's vision of a learning health and healthcare system. To achieve this goal, a culture of improvement needs to be created by each healthcare entity.

Recommendation

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". A national, transparent, information system is proposed, similar to a Patient Safety Organization (PSO), with the following components:

- Confidential reporting with liability protection (e.g. whistle-blower protection)
- Capability to investigate serious incidents
- Standardized Data Reporting formats that facilitate analysis and evaluation
- Reporting by patients, clinicians, vendors, and healthcare organizations
- Reporting process to cover multiple factors including usability, processes, and training
- All HIT systems included
- All Software Sources (e.g. vendors, self-developed, and open source)
- Ability to disseminate information

While this proposal appears to be necessary, it might not represent a complete response to all HIT patient safety concerns. Additional research is needed. As a result, we recommend that ONC commission a formal study to thoroughly evaluate HIT Patient Safety concerns, and to recommend additional actions and strategies to address those concerns.

We make the following recommendations and observations.

Recommendations and Observations:

1. 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:

- a. Stage 2 of Meaningful Use should include a requirement that EPs and Hospitals report HIT-related patient safety issues (“HIT safety organization”) to an organization authorized by ONC to receive HIT-related safety reports. Copies of those reports should be sent to any vendors that might be involved.
 - b. 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”). This feedback button could also be used by clinician-users to request corrections to data.
 - c. The Regional Extension Centers should provide HIT-related patient safety reporting training.
2. Vendor Alerts: The certification process can be used to insure that vendors provide safety alerts to their customers and it can also be used to improve patient safety. We recommend that:
- a. 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. Similar processes can be developed for self-developed and open-source users.
 - b. Reflecting many of the concepts of the FDA's QSR program, the certification process should require vendors to utilize development processes that insure patient safety.
3. 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 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.
4. 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.
5. Interoperability problems are a significant source of patient safety concerns. As a result, ONC’s interoperability efforts continue to be extremely important. The 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 Standards Committee is asked to consider techniques like requiring the use of audit trails or “logs” of interface transactions.

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. Tools, such as Jim Walker’s Hazard Evaluation tool and Dave Classen’s flight simulator should be explored as possible resources for providers

7. Accreditation organizations, like the Joint Commission, can play an important role in assuring HIT patient safety. 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.

8. The time period between the publication of Stage 2 and Stage 3 certification criteria is a safety concern, especially for large healthcare organizations. Any software changes or updates must be carefully tested by each organization that receives those updates. As a result, we recommend that Stage 2 certification criteria be released as soon as possible. A late release of stage 2 criteria could, eventually, make it difficult for stage 3 of Meaningful Use to require significant new functionality.

9. The FDA: *** To be discussed ***