Patient safety goals for the proposed Federal Health Information Technology Safety Center

Dean F Sittig1, David C Classen2, Hardeep Singh3,4

ABSTRACT

The Office of the National Coordinator for Health Information Technology is expected to oversee creation of a Health Information Technology (HIT) Safety Center. While its functions are still being defined, the center is envisioned as a public–private entity focusing on promotion of HIT related patient safety. We propose that the HIT Safety Center leverages its unique position to work with key administrative and policy stakeholders, healthcare organizations (HCOs), and HIT vendors to achieve four goals: (1) facilitate creation of a nationwide ‘post-marketing’ surveillance system to monitor HIT related safety events; (2) develop methods and governance structures to support investigation of major HIT related safety events; (3) create the infrastructure and methods needed to carry out random assessments of HIT related safety in complex HCOs; and (4) advocate for HIT safety with government and private entities. The convening ability of a federally supported HIT Safety Center could be critically important to our transformation to a safe and effective HIT enabled healthcare system.

Key words: Health Information Technology; Electronic Health Records; Patient Safety; Health Policy

The Institute of Medicine’s 2012 report on health information technology (HIT) and patient safety called for the establishment of an independent federal entity for monitoring and analyzing patient safety data and investigating serious incidents related to HIT. In an attempt to address this recommendation, President Obama requested US$5 million in his 2015 federal budget for the Office of the National Coordinator (ONC) for HIT to create a roadmap for a HIT Safety Center. This was followed a week later by an influential and much awaited report that responded to the US Food and Drug Administration Safety and Innovation Act (FDASIA). Briefly, this act required ONC, Food and Drug Administration (FDA), and Federal Communication Commission (FCC) to describe “strategy and recommendations on an appropriate, risk based regulatory framework pertaining to HIT, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication.” This report, a culmination of deliberations of the FDASIA workgroup chartered by the FDA, ONC, and FCC, reinforced the call for an ONC based HIT Safety Center. The HIT Safety Center is envisioned as a public–private entity that will serve as “a trusted convener of HIT stakeholders in order to focus on activities that promote HIT as an integral part of patient safety with the ultimate goal of assisting in the creation of a sustainable, integrated HIT learning system that avoids regulatory duplication and leverages and complements existing and ongoing efforts.”

The initial funding to establish this new center represents only a fraction of what will be required to put its infrastructure in place and to maintain its functionality. Assuming that the US Congress provides the necessary funding and oversight authority, the HIT Safety Center has the potential to play a key operational role for major national initiatives related to HIT and patient safety. This also assumes that recent questions regarding the authority of ONC to even create it are answered satisfactorily. More recently, ONC issued a 2 year, task order entitled, ‘HIT Safety Center Road Map’ that asks contractors to develop a diversified plan, including federal funding options, public–private collaboration, and potential private sector funding of activities.

In this paper, we assume the best case scenario and propose several specific patient safety goals that the HIT Safety Center could adopt to deliver on the promise of creating safe and effective HIT enabled healthcare systems.

As noted in a recent endorsement by the HIT policy committee, the time is ripe for the HIT Safety Center. The FDASIA report’s high level vision created momentum for its development, given the increasing recognition by both frontline clinicians and health care organizations (HCOs) of both the benefits.
and unintended consequences of the rapidly increasing use of HIT, including electronic health records (EHRs). For example, safety concerns have arisen from the design and functioning of HIT and from the disruptions in clinicians’ workflow in settings where EHRs have been implemented. Emerging evidence from the scientific literature as well as anecdotal reports suggest that ‘HIT related safety events’ (ie, events arising from unsafe technology or unsafe use of technology) are occurring. Given that neither the FDA nor any other agency will be regulating most forms of HIT, the HIT Safety Center could be instrumental in unifying key ‘frontline’ stakeholders (ie, clinicians, HCOs, quality and safety personnel, and HIT vendors) with key administrative and policy stakeholders to develop the necessary methods and infrastructure to ensure a cohesive national approach to HIT safety.

To facilitate rapid cycle improvements related to patient safety and to benefit the maximum number of patients, we posit that the HIT Safety Center must lead the coordination of activities to achieve four goals:

- facilitate the creation of a nationwide ‘post-marketing’ surveillance system to monitor HIT related patient safety events, including events that lead to patient harm and ‘near misses’;
- develop the methods and governance structure to support the investigation of major HIT related safety events;
- create the infrastructure and methods needed to carry out random assessments of large, complex, HIT enabled health care organizations; and
- advocate for HIT safety with various government (eg, US Congress, Centers for Medicare and Medicaid Services (CMS), Office of Civil Rights, Department of Defense (or state departments of health), and private entities (eg, EHR vendors, healthcare provider organizations).

The following sections provide a brief description of the rationale for these goals and specific actions that could be undertaken.

**FACILITATE CREATION OF A NATIONWIDE HIT RELATED PATIENT SAFETY SURVEILLANCE SYSTEM**

Currently, we are unable to quantify the rate of HIT related patient safety events with any precision using the existing patient safety reporting and analysis infrastructure, which consists of a small number of reports within very large public databases that are not specific to HIT (eg, FDA MAUDE, Pennsylvania Patient Safety Authority, MEDMARX). Moreover, there is still no clear consensus on taxonomy and measurement methods for HIT related safety events. Thus the HIT Safety Center could create a robust foundation for improving future measurement and surveillance of patient safety at a national level. For example, ONC could partner with not for profit entities (eg, ECRI’s recently formed ‘Partnership for promoting HIT patient safety’) to create a federally funded research and development center for event reporting, analysis, and information sharing, similar in concept to the Veterans Affairs’ Informatics Patient Safety office’s case tracking database. These centers, in conjunction with local and national patient safety organizations (PSOs), could play pivotal roles in establishing key safety benchmarks that EHR developers and HCOs could use to assess safety performance. This surveillance system should gather data to help HIT developers and clinicians better understand and mitigate risks associated with HIT implementation and use.

A major limitation of existing HIT related safety event reporting systems is that most clinicians either do not understand what should be reported or cannot recognize that near misses or events have occurred. To facilitate measurement and monitoring of HIT safety, we propose the term ‘HIT related safety concern’ to broadly describe patient safety events that reached the patient (regardless of whether harm occurred), near misses, and unsafe conditions. Although this terminology of ‘safety concern’ is consistent with Agency for Healthcare Research and Quality (AHRQ) common format reporting standards, these standards do not adequately capture the breadth of HIT related safety concerns defined below and thus need to be broadened. We propose that the AHRQ common format should address five major types of HIT related safety concerns (table 1), including instances in which:

- HIT fails during use or is otherwise not working as designed. The safety concern is directly attributable to the HIT.
- HIT is working as designed, but the design does not meet the user’s needs or expectations (ie, bad design). HIT is a contributing factor to the safety concern.
- HIT is well designed and working correctly, but was not configured, implemented, or used in a way anticipated or planned for by system designers and developers. These events are related to use of HIT (ie, rather than HIT itself) and may be referred to as configuration errors, ‘work arounds’ or incorrect usage.
- HIT is working as designed, and was configured and used correctly, but interacts with external systems (eg, via hardware or software interfaces) so that data are lost or incorrectly transmitted or displayed. These events are inevitable due to the interactive complexity of tightly coupled systems. They are often referred to as HIT system interface safety concerns.
- Specific HIT safety features or functions were not implemented or not available.

At a minimum, event types 1–4 should be subjected to reporting and surveillance. To standardize this process, we propose development of a small set of safety concerns that HCOs and EHR vendors should be required to report at regular intervals to the HIT Safety Center via a PSO. Voluntary event reporting by clinicians should be incentivized by providing Continuing Medical Education or Maintenance of Certification credits. In addition, automated reporting mechanisms could
Table 1: Definitions and examples of different types of HIT related safety concerns

<table>
<thead>
<tr>
<th>Type of HIT related safety concern</th>
<th>Examples</th>
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<tbody>
<tr>
<td>1. Instances in which HIT fails during use or is otherwise not working as designed</td>
<td>Broken hardware or software ‘bugs’</td>
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<tr>
<td>2. Instances in which HIT is working as designed, but the design does not meet the user’s needs or expectations</td>
<td>Usability issues</td>
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<tr>
<td>3. Instances in which HIT is well designed and working correctly, but was not configured, implemented, or used in a way anticipated or planned for by system designers and developers</td>
<td>Duplicate order alerts that fire on alternative ‘as needed’ pain medications</td>
</tr>
<tr>
<td>4. Instances in which HIT is working as designed, and was configured and used correctly, but interacts with external systems (e.g., via hardware or software interfaces) so that data are lost or incorrectly transmitted or displayed</td>
<td>Medication order for extended release morphine inadvertently changed to immediate release morphine by error in interface translation table</td>
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<tr>
<td>5. Instances in which specific safety features or functions were not implemented or not available (i.e., HIT could have prevented a safety concern)</td>
<td>Hospitalized patient inadvertently receives 5 g of acetaminophen in 24 h because maximum daily dose alerting was not available</td>
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HIT, health information technology.

greatly advance these surveillance efforts. For instance, the capability to generate and report HIT safety eMeasures (i.e., standardized performance measures in an electronic format) directly from EHRs could be added to future EHR certification requirements. These eMeasures could be modeled after the ‘near misses’ within the airline safety reporting system, the types of events and threats reported to the USA Department of Homeland Security’s Computer Emergency Readiness Team (US-CERT), or events tracked in mandatory public health reporting systems maintained by the FDA and CDC. Some examples of potential HIT safety eMeasures, which would be a good place to start, are listed in Table 2.

DEVELOP A FRAMEWORK TO SUPPORT INVESTIGATION OF MAJOR HIT RELATED SAFETY EVENTS

The HIT Safety Center can also address the problem of slow progress in learning from HIT related safety events by creating criteria and methods needed to conduct investigations of major HIT related safety events, defined as those causing severe patient harm or placing more than 100 patients at risk for harm or an HIT related ‘sentinel event’ reported to the Joint Commission. As more organizations rush to implement comprehensive EHRs, we expect more serious EHR related safety events. These events would need to be investigated under the auspices of PSOs to identify causes and prevention strategies; most likely similar events will occur at other institutions. Alternatively, Congress could create a new independent agency within the ONC, similar to the National Transportation Safety Board within the Department of Transportation that is authorized to conduct investigations and make recommendations. While the creation of such a new agency may currently appear doubtful given the current socio-political climate, the increasing reliance on the use of HIT within all aspects of healthcare may justify the cause.

For example, over the past several years, several reports have documented long term (>4 h) or widespread (i.e., affecting multiple organizations or sites of care) periods of EHR unavailability. As the consolidation of HCOs continues, coupled with increasing numbers of large scale remotely hosted EHR implementations, similar events are certain to occur. An example of a major HIT related safety event, that might warrant further investigation to identify generalizable lessons, is a widespread HIT downtime that lasts for more than 24 h, is unrelated to a natural disaster, and affects at least two of the following EHR functions simultaneously: admission/discharge/transfer; clinical results review; provider order entry, communication, verification; barcode medication verification; picture archiving and communication; clinical documentation; alert notification; or participation in local health information exchange.

The types of safety events that need investigation could be further refined by the HIT Safety Center. The investigation format and approach will also depend on the type and severity of the event but in general, analysis should be conducted by independent investigators with deep technical knowledge of the underlying hardware and software systems and extensive clinical knowledge of various healthcare work processes, in conjunction with patient safety experts from PSOs. Investigations should produce comprehensive publically available reports that outline how similar events can be prevented at other institutions. This HIT Safety Center created investigative framework would be essential for transformation to a ‘learning’ HIT enabled healthcare system as the Institute of Medicine suggests.
FACILITATE SAFETY ASSESSMENTS OF LARGE, COMPLEX, HIT ENABLED HEALTHCARE ORGANIZATIONS

We recently developed self-assessment tools, referred to as Safety Assurance Factors for EHR Resilience (SAFER) guides to help clinicians and HCOs proactively assess the safety and effectiveness of their EHRs. These freely available guides help identify areas of vulnerability and enable creation of solutions and culture change to reduce EHR related concerns. During their development, we learned that even the most highly regarded HIT enabled healthcare organizations often had significant gaps in their EHR features, functions, or usage. For example, one organization noted for its longstanding highly successful computer based provider order entry system did not have an interface between the EHR system used by physicians to enter orders and the laboratory system used to generate and report results. Similarly, another organization noted for its effective use of advanced clinical decision support never implemented computer based provider order entry.

Over the past 15 years, education and outreach alone have been insufficient to improve the safety of the healthcare system. Therefore, we believe that more rigorous assessments are needed to improve the safety of HIT-enabled healthcare. We propose that the HIT Safety Center should work with an independent entity to refine the SAFER methodology and become a coordinating hub (ie, establish the assessment criteria and aggregate the results) for random, preferably unannounced, on site assessments of large complex organizations that have received meaningful use incentives. These assessments could be carried out as part of current CMS site visits or by independent entities such as existing CMS deeming authorities (eg, Joint Commission) as part of their accreditation process site visits. Assessment activities could include interviews with stakeholders, live EHR demonstrations, observations of clinicians as they interact with the EHR, tours of key clinical and technical sites, and reviews of EHR related policies and procedures. Reports of these visits could be submitted to regulatory organizations such as the FDA, US Inspector General, Office of Civil Rights, or CMS for their review and follow-up, and made available on public websites. While this might require additional resources, we believe some form of an EHR assessment strategy is key for organizations to reduce HIT safety issues.

ADVOCACY FOR HIT SAFETY, EVIDENCE GENERATION, AND KNOWLEDGE DISSEMINATION

The HIT Safety Center must work with leading organizations that represent the broad range of ‘users’ of HIT systems and the resulting data, including patients, clinicians, ancillary service providers, policy makers, and payers, for example, to

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<tr>
<th>Proposed HIT safety eMeasures or events</th>
<th>Rationale</th>
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<tr>
<td>Unexpected EHR related downtimes lasting more than 8 h</td>
<td>After 8 h it is likely that the downtime event will increase the risk of ‘change of shift’</td>
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<tr>
<td>Mean EHR response time as measured from the end users viewpoint</td>
<td>As response time increases (eg, past 10 s) the likelihood of ‘functional downtime’ increases</td>
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<td>Interruptive alerts that have fired more than 100 times with 100% override rate</td>
<td>Frequent synchronous alerts that are repeatedly overridden increase the risk of alert fatigue and clinicians missing potentially life threatening events</td>
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<td>Erroneous displays of laboratory test results or medications</td>
<td>Incorrect result or medication displays increase the risk of erroneous diagnosis or treatment</td>
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<td>Per cent of EHR users trained and passing a competency test before getting a login</td>
<td>Allowing untrained users to login to the EHR can lead to missing key data, erroneous data entry, or failed communication and affect patient care</td>
</tr>
<tr>
<td>Rate of computer based provider order entry use</td>
<td>Incomplete CPOE usage, results in duplicative order entry systems which greatly increases risk of errors</td>
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<tr>
<td>Percentage of ‘order–retract–reorder’ events recorded</td>
<td>Order–retract–reorder events are correlated with orders entered on the wrong patient</td>
</tr>
<tr>
<td>Percentage of potential duplicate patients in the live clinical database (ie, same first name, last name, and date of birth)</td>
<td>Duplicate patients increase the risk of clinicians missing key information</td>
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<tr>
<td>Software bugs reported to the EHR vendor</td>
<td>A large quantity of serious software errors increases the risk that data are incorrectly entered, transmitted, stored, or lost</td>
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CPOE, computer based provider order entry; EHR, electronic health records; HIT, health information technology.
inform policy decisions and regulation related to HIT related safety issues. This will ensure that future mandates take into account complex socio-technical and clinical implications of these decisions.\(^4\) In addition, it must work with private entities involved in design, development, and use of these systems to help them understand why certain safety critical mandates were enacted and perhaps suggest potential technical solutions to address them. For example, EHR vendors may be reluctant to implement the eMeasures previously described.\(^4\) The HIT Safety Center should coordinate, along with AHRQ, research required to generate and disseminate best evidence regarding the intricacies of designing, developing, implementing, and overseeing HIT within complex adaptive healthcare organizations.\(^4\) Initially, the focus could be key research topics that need to be quickly resolved, such as development and validation of methods to measure, monitor, and improve EHR usability.\(^4\) and methods to achieve widespread interoperability.\(^4\)

Immediate deliverables could include acceleration of the long-standing work by the National Library of Medicine and the ONC on the standardization of clinical vocabularies and technical data interchange standards.\(^5\) For instance, to resolve the persistent and widespread problem of patient identification across healthcare organizations,\(^5\) the HIT Safety Center could encourage research, development, and implementation of innovative approaches to patient identification and matching.\(^5\) Such solutions may not only reduce the burden of incorrect diagnosis and treatment but also improve the efficiency of healthcare processes by reducing duplicate testing and manpower required to merge and validate duplicate patient records.

**CONCLUSIONS**

We applaud FDASIA’s recommendation to create a federally supported HIT Safety Center. Although the initial funding request is insufficient to establish and maintain such a Center, we are optimistic about its development and future funding decisions. The convening ability of such a center could be critically important to our transformation to safe and effective HIT enabled healthcare systems. To ensure progress and to avoid failure of this transformation, we need to move this recently created vision to reality, in keeping with the rapid pace of HIT implementation. A HIT Safety Center focused on the exemplary goals and activities we outline will more likely realize the transformative benefits of state of the art HIT and enable patients to receive HIT facilitated, safe, and high value healthcare that they deserve.

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**CONTRIBUTORS**

DFS wrote the first draft of the article. HS and DCC revised and re-revised the article significantly, and approved the final version.

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AUTHOR AFFILIATIONS

1University of Texas—Memorial Hermann Center for Healthcare Quality and Safety, School of Biomedical Informatics, University of Texas Health Sciences Center, Houston, Texas, USA

2University of Utah and Pascal Metrics Inc, Salt Lake City, Utah, USA

3Houston VA Center for Innovations in Quality, Effectiveness and Safety, Michael E DeBakey Veterans Affairs Medical Center, Houston, Texas, USA

4Section of Health Services Research, Department of Medicine, Baylor College of Medicine, Houston, Texas, USA