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Safe Electronic Health Record use requires a comprehensive monitoring and evaluation framework

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Recent passage of the American Reinvestment and Recovery Act (ARRA) increases pressure on healthcare practitioners and organizations to implement currently available electronic health records (EHRs). Research and experience gained to date shows that such implementation efforts are difficult, costly, time-consuming, and fraught with many unintended consequences[1]. Evaluation of these systems after implementation suggests that they do not routinely meet safety standards of other safety-critical industries[2]. The aggressive timeline proposed in the ARRA bill means that a large number of practitioners and organizations will soon be attempting a monumental feat without the time or ability to customize these systems to their local workflows[3]. In a previous article, we proposed 8 dimensions or "rights" of EHR safety that addressed the complex social, technical, and personal issues associated with EHR use[4]. The goal of this article is to describe an approach for a comprehensive EHR monitoring and evaluation framework (i.e., the 8th dimension of EHR safety). Without such a comprehensive framework, safe and effective EHR use cannot be assured. This proposed framework has five essential components: 1) ability for practitioners and organizations to report patient safety events or potential hazards related to EHR use [5,6]; 2) enhanced EHR certification that includes specific assurances that good software development procedures[7] have been followed along with evidence that previously reported adverse events and hazards have been addressed; 3) self-assessment, attestation, testing, and reporting by both clinicians and healthcare organizations that all eight dimensions of safe EHR use have been addressed; 4) Local, state, and national oversight in the form of an on-site, in-person accreditation of EHRs as implemented and used by clinicians in the healthcare setting; 5) A national EHR-related adverse event investigation board that reviews incident reports and has the authority to investigate.

Reporting EHR safety issues

Currently there is no clear organization or other entity for healthcare practitioners to report adverse events or potential safety hazards that result from inadequate design, development, implementation or use of EHRs. As Koppel and Kreda state, that many EHR vendors legally limit the ability of their clients to publically report these types of problems[6]. Such a national EHR hazard reporting system, as described in detail by Walker et al. could increase awareness of safety concerns among users as well as help vendors identify items that need their attention[5]. This reporting system might be operationalized through the new Patient Safety

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Conflicts of Interest

Dean F. Sittig: None

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Organization Statute and associated Agency for Healthcare Research and Quality (AHRQ) common reporting formats[8].

Enhanced EHR certification

The organizations responsible for certifying EHRs should add the following types of checks to their current certification criteria. All EHR vendors should have to demonstrate that they follow good software engineering practices including: performing hazard analyses of their products; designing for safety; documenting these designs; and verifying that their systems work as designed[7]. All systems should have their user interfaces tested for usability. All vendors should be prepared to demonstrate that they have successfully addressed all critical software issues identified within the national hazard reporting and investigation system within the previous year at any time. In addition, each EHR should be "load tested" to simulate its response time when multiple users are accessing the system simultaneously. Moreover, each vendor should be required to present data collected from multiple implementations describing their system's reliability and response time as implemented. In conclusion, EHR vendors must demonstrate that their applications have been designed for safety, developed correctly, work as designed, and had all their defects fixed.

Self-Assessment of EHR use

A national, vendor-independent, federally-funded and managed EHR oversight organization should develop a self-assessment guide for all individual EHR users as well as the organizations responsible for implementing them. This guide for users should include at a minimum approximately 25 common actions that a user should be capable of performing (e.g., look up a patient by name or medical record number or review the 3 most recent laboratory test results); the organization's EHR downtime and reactivation procedures, and any EHR-related adverse events or potential hazards the user has been directly involved in. This self-assessment tool could be developed and implemented similarly to the way the AHRQ/LeapFrog EHR/clinical decision support assessment tool has been[9].

In addition, each organization should perform and document a more extensive review of their clinical information systems on a yearly basis. This review should address each of the eight dimensions of safe EHR Use framework that includes: hardware and software; clinical content; user interfaces; user training and authorization procedures; clinical workflow and communication; organizational policies and procedures; compliance with state and federal rules and regulations; and periodic measurements of system activity.

The results of these self- and organizational assessments should be submitted to a central clearinghouse that would facilitate the creation and dissemination of national EHR safety benchmarks.

Onsite accreditation of EHRs as Implemented and Used

Although the first 3 proposals will most likely help to significantly improve the safety and effectiveness of EHR usage nationwide, there is still no substitute for periodic, unannounced, random, onsite inspections of EHR systems. These inspections could be conducted as part of ongoing organization-wide, quality and patient safety accreditation activities by organizations such as The Joint Commission or local state departments of health. Once again, these inspections should address all eight dimensions of Safe EHR use[4]. Organizations could be given six months to address all of the reviewers' concerns or face significant financial penalties.

National EHR Adverse Event Investigation Board

As EHRs begin to play an increasingly important role in patient care on a large scale, community-wide basis, the Office of the National Coordinator for Health Information Technology (ONC) could create a National EHR Adverse Event Investigation Board similar to the National Transportation Safety Board or the Commercial Aviation Safety Team[10], to investigate serious EHR-related adverse events or hazards that involve complex, sociotechnical interactions between clinicians or patients and software systems. The findings of these investigations could be reported to the ONC and made public so that patients, other vendors, healthcare organizations, and practitioners can learn from them. This board would be provided with unlimited access to all aspects of the EHR including for example: key system backups, change logs, and minutes from the local EHR safety oversight committees. This board would have the authority to investigate all serious EHR-related adverse events or near misses. In conclusion, President Obama has taken an important step toward improving the clinical computing infrastructure of the US healthcare delivery system by stating the goal of all citizens having access to an EHR. However, the extremely aggressive timeline in the ARRA stimulus package places enormous pressure on healthcare practitioners and their organizations to rapidly implement EHRs. Such rapid implementations could lead to significant patient safety events. To help ensure that these implementations are as safe and effective as possible, this 5-stage proposal to create a comprehensive EHR monitoring and evaluation framework should be considered. Using such a framework, the ONC, or another designated national body, could begin to provide the oversight needed to ensure that all EHR implementations are safe and effective and to provide the mechanisms to help healthcare organizations using these systems to deliver the highest quality, lowest cost, and safest healthcare possible.

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