Overview

Although the United States has invested tens of billions of dollars to encourage providers to adopt electronic health records (EHRs), many clinicians have found that these systems have poor “usability.” EHRs can put patients at risk of medical error, do little to enhance clinical care, and increase the time clinicians spend documenting patient care. Indeed, one study found that 15 percent of physicians reported that their EHR had caused a potential medication error within the past month. For example, in a well-publicized case, a child received a near-fatal dose of a routine antibiotic due to the poor design of the EHR’s medication ordering system and the repetitive alerts that were ignored by clinicians.

To identify the root causes of—and potential solutions to—usability problems, The Pew Charitable Trusts, in collaboration with the Johns Hopkins Armstrong Institute for Patient Safety and Quality, convened 70 experts representing makers of EHR systems, hospitals, clinicians, patient safety advocates, and the federal government at a July 28, 2015 workshop. Following a day of robust discussion, a set of core problems that inhibit EHR usability emerged along with a number of promising solutions. Since then, several reports have also looked at ways to address EHR usability and patient safety.
This fact sheet incorporates findings from the meeting and recent publications, and outlines a comprehensive approach to address EHR usability that:

- Requires appropriate safety testing of the products before they are used.
- Gives providers the ability to assess how well the products protect patient safety.
- Ensures that any lessons learned are disseminated across the health care system.

**Problem 1: Inadequate testing requirements**

Not all makers of EHR systems (vendors) perform a comprehensive assessment of usability before the products are deployed in hospitals and doctors’ offices. Throughout the development and installation of these systems, even the smallest changes can introduce the opportunity to cause patient harm. To help detect design problems, vendors should conduct three types of usability testing with their products and with the clinicians who will be using them:

- **Formative testing.** As a new EHR system is being developed, vendors observe how clinicians and other health care staff (providers) use it and receive feedback on the system’s design and interface. This information is fed back into the layout and subsequent versions of the product. Conducting formative testing throughout the design process ensures that usability is a central element of the product design and that problems are identified early, when they can best be addressed.

- **Summative testing.** This type of testing occurs once an EHR has gone through the design process. Vendors assess usability by measuring how easily and successfully providers can perform various functions (such as ordering a medication) and by obtaining formal feedback on the product from the users. Vendors can perform a final check of a system’s usability to ensure that any problems are detected and fixed—essentially a test of the “off the shelf” usability of the EHR.

- **Post-implementation testing.** Staff at a hospital or doctor’s office often request significant changes to the EHR before it is installed and clinicians use it. These changes, however, can affect the usability of the product and introduce new patient safety hazards. Testing of the product after it is implemented at a hospital or office can find and fix these new problems.

The Office of the National Coordinator for Health Information Technology (ONC), the federal agency that sets requirements for EHRs, mandates only summative testing. Requirements are limited to evaluation of EHR functionality—for example, simply assessing whether a clinician can successfully order a medication, rather than examining how likely it is for a clinician to order a wrong medication or dosage. As a result, EHRs can meet ONC’s summative testing requirements but still have the potential to cause patient harm through poor design.

**Solution**

A major theme emerged at the meeting: All EHR vendors should meet minimum standards for formative, summative, and post-implementation testing. As a first step, providers, usability experts, ONC, and vendors should agree on what these standards should include. Hospitals and clinicians should then insist that the products they purchase meet these requirements. Ultimately, ONC should incorporate the standards for formative, summative, and post-implementation testing as requirements in EHR certification criteria.
This comprehensive testing will ensure that all products meet basic usability needs and thus protect patient safety. The results could also help hospitals and clinicians compare products as they decide which EHR to buy. For this dissemination to occur, ONC should require vendors to use uniform templates to describe their testing and findings in plain language and make them available to the public.

**Problem 2: Insufficient measures of EHR safety and usability**

There are currently no widely accepted metrics for EHR performance that would allow providers and vendors to track patient safety problems or set targets for improvement after systems have been implemented in a hospital or office. Providers could use information, for example, on the percentage of orders made on incorrect patients, the frequency of EHR-related medication errors, and the percentage of alerts for situations that do not warrant alerting.

In other patient safety areas, quality measures have been used to drive improvements. For example, hospital-acquired infections had long been recognized as a patient safety problem, but only the development and implementation of ways to assess the frequency of these infections resulted in major reductions.

**Solution**

The National Quality Forum recently called for the development of measures to improve EHR usability and safety. Using its recommendations as a guide, vendors, hospitals, clinicians, and patient safety advocates should prioritize developing these measures, funded by the federal government, foundations with an interest in patient safety, or private sector stakeholders. Providers can then assess the performance of their systems and work with vendors to improve areas of weakness. Health insurers can determine whether providers in their network are effectively preventing avoidable EHR-related safety issues. To facilitate the development of this data, ONC could update certification criteria to ensure EHRs can provide the information necessary to calculate the quality measure.

**Problem 3: Inability to learn from EHR usability and safety issues**

Attendees at the meeting highlighted the difficulties they face in sharing valuable lessons to inform EHR development and implementation at other facilities. For example, after identifying that clinicians were ignoring alarms about potential medication dosing errors because these were similar to other alerts, one facility worked with its vendor to differentiate among alarms within the EHR. Another health system reported that it had found ways to improve the efficiency and accuracy with which the EHR system matched patients with their records, improving patient safety and saving clinicians significant amounts of time. However, neither health facility was able to share either the identification of the problem or the solution with other systems.

Meeting attendees felt that one key impediment to information sharing is that providers fear violating restrictive nondisclosure and intellectual property clauses in their contracts with vendors (often referred to as gag clauses). Furthermore, participants highlighted that no organization has responsibility for identifying systemic problems with EHRs and educating vendors and providers about ways to address these issues.
In other areas, patient safety organizations (PSOs) allow hospitals and clinicians to share information on a range of safety problems, study the root causes, and recommend solutions. These PSOs have broad mandates, addressing problems that include the poor management of behavioral health, inadequate disinfection of reusable supplies, and improper use of antibiotics. Providers feel free to share information with PSOs because the reports cannot be used in lawsuits.

This approach to PSOs, though, inadequately addresses EHR usability for two reasons. First, given their expansive mission, PSOs lack the resources to focus on health information technology in a comprehensive and sustainable manner. Second, issues reported by nonproviders—in particular, vendors—are not protected from lawsuits, which decreases the likelihood that they would participate.

Solution

To address these gaps, many meeting participants recommended creating an organization that can facilitate the sharing of providers’ experiences—without fear of violating a gag clause—and can systematically examine EHR-related issues reported by providers and vendors at the national level. Both the Institute of Medicine and ONC have called for the establishment of such a group.

Given the importance of addressing this problem, meeting participants suggested that Congress pass legislation that would:

- Designate an entity to assess EHR-related patient safety problems and disseminate findings.
- Provide initial financial support for the organization while it develops a long-term business plan.
- Specify protections for vendors equal to those of providers when sharing information within the safety group.
- Have the organization convene providers and vendors to agree on ways to share best practices and lessons learned from their use of EHRs, including eliminating contract provisions that prevent information sharing.

Conclusion

While federal legislation and financial incentives have achieved widespread adoption of EHRs, Congress, ONC, providers, and vendors should now address the unexpected risks and hazards to patient safety associated with these new systems. By raising the bar on testing for usability, measuring performance, and opening up ways to share learning on problems and solutions, stakeholders can make progress on EHR usability and safety and help clinicians deliver safe, patient-centered, high-quality care.
Endnotes


For further information, please visit:
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