



# Improving Patient Care Through Safe Health IT

Collaboration can improve the safety of patient health records



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The Pew Charitable Trusts is driven by the power of knowledge to solve today's most challenging problems. Pew applies a rigorous, analytical approach to improve public policy, inform the public, and invigorate civic life.

## Overview

The transition from paper medical charts to electronic health records (EHRs) has streamlined many of the ways that health care is delivered in the United States and contributed to safety improvements in a number of areas. While health information technology includes many types of products, patient records are a critical aspect of care, as they inform clinicians' decisions and are used when medical orders are placed. Clinicians now have their patients' information at their fingertips, along with new data tools to help guide their decisions and reduce medical errors.

But the increased use of electronic health records has also given rise to new, unanticipated safety challenges. For example, patients may receive the incorrect dose of a medication or clinicians may select the wrong person when inputting an order. The nonprofit ECRI Institute, which studies patient safety, listed health IT configuration and workflow—the design and use of EHR systems—as its top concern in 2016.

To address these and other health IT safety concerns, multiple expert panels have proposed the establishment of a safety collaborative composed of EHR developers, hospitals, government, health practitioners, and other key organizations to work together to resolve problems. These efforts emphasize that health IT has the potential to improve safety and that hospitals, clinicians, EHR developers, and others have responsibilities in reducing avoidable patient harm.

In recent years, several high-profile reports have called for broader cooperation to reduce health IT-related harm to patients. A 2012 Institute of Medicine report emphasized that health IT safety is a shared responsibility that requires involvement and action by EHR developers, users, and government. In addition, several federal agencies—following another expert panel recommendation—called in 2014 for establishing a risk-based regulatory framework for health IT, including through the creation of a health IT safety collaborative. The Department of Health and Human Services' Office of the National Coordinator for Health Information Technology (ONC), as part of a health IT safety roadmap, in 2015 also encouraged private-public sector collaboration to address health IT safety.

The Pew Charitable Trusts and ONC held a Health IT Safety Day in December 2016 to discuss this critical issue. The event, which focused on EHRs because of the critical role they play in patient care, featured health IT developers and representatives from hospitals, government agencies, and other organizations. Participants discussed how a product's usability—the records' layout, design, integration within health care facilities' workflow, and customization by institutions—can affect patient safety while recognizing that other issues can also cause patient harm. They also noted that usability can affect the effectiveness of EHRs, how satisfied clinicians are with health IT, and many other aspects of care.

### Usability

The International Organization for Standardization's ISO 9241 standard defines usability as "the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use."

Experts noted that health care facilities and health IT developers can detect safety concerns throughout a product’s development—as it is being designed, when it is submitted for government certification, during implementation in hospitals and other institutions, and through staff training and use. Safety challenges can arise from the base design of a product, customizations during installation and implementation in health care organizations, or unique workflows within a facility.

### Safety Events

The Agency for Healthcare Research and Quality categorizes patient safety events in three ways:

- Incidents. Events that reached the patient, whether or not there is harm.
- Near misses (or close calls). Events that do not reach the patient.
- Unsafe conditions. Circumstances that increase the likelihood of a patient safety event.

Drawn from Health IT Safety Day and subsequent conversations with experts, this report explains how an EHR’s usability can affect patient safety, gaps in EHR safety monitoring, the genesis of efforts to improve health IT safety through multistakeholder activity, and the potential benefits of a national health IT safety collaborative.

## How usability can affect safety

Health IT safety includes how EHRs have improved patient care and how their use may contribute to medical errors. EHRs can improve patient safety in many ways. Instead of reams of paper with handwritten notes, they can contain clear and structured data, enabling better communication among doctors, nurses, pharmacists, and other health care providers.<sup>1</sup> EHRs also make more data available to a clinician, such as a patient's medical history—including information shared by other health care providers.<sup>2</sup> And software tools can help clinicians analyze trends in their patients' health, such as blood pressure or sugar levels.<sup>3</sup>

However, EHRs can also lead to unexpected safety concerns, some of which are tied to inadequate usability. Many of the issues that can frustrate clinicians when they use EHRs can also lead to safety concerns. This challenge is not unique to the health IT industry. The aviation, nuclear power, and medical device sectors have recognized that addressing the usability of technology is central to boosting safety and have worked to make improvements.

Problems can arise from health care professionals entering information incorrectly because the design of a system may not fit their workflow well or the layout may be confusing. In addition, records may not display information clearly—meaning clinicians may base decisions on incomplete data. In 2012, the ECRI Institute analyzed 211 cases of patients injured because of a mistake related to their digitized records and identified the top safety problems:

- 16 percent involved system interface issues, such as systems not being able to communicate properly, leading to missed information.
- 14 percent were the result of an incorrect input into an EHR.
- 14 percent resulted in problems that prohibited data entry and related issues as a result of software configuration.<sup>4</sup>

In addition, when issues arise, doctors, nurses, and other clinical staff may develop workarounds to use the technology in a way it was not intended, which can also introduce practices that can harm patients.<sup>5</sup>



[Medical errors are] one of the major causes of mortality in the United States. But our investments to address this issue, to address this challenge, pale in comparison to the investments that are made in diseases like cardiovascular disease and cancer.”

**Andrew Bindman**, former director of the Agency for Healthcare Research and Quality, at Health IT Safety Day

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In all of these situations, the cause of errors cannot be attributed solely to the EHR or the health care provider, but rather reflect the complex interaction between individuals and technology. How different health IT systems or components work with each other may also contribute to errors that can harm patients.

Table 1  
How Health IT Use Can Harm Patients

Types of health IT failures	Real-world examples
<b>Health IT fails or is not working properly*</b>	An internet connection was lost, preventing data from being transmitted from a chronically ill patient's medical device to the EHR <sup>†</sup>
<b>A product is working properly but does not meet the user's needs or expectations<sup>‡</sup></b>	A weight-based dosing algorithm and the wrong setting caused a clinician to prescribe a medication at 38 times the normal level <sup>§</sup>
<b>Health IT is designed properly and working correctly but was not configured, implemented, or used as designed</b>	A mobile computer cart with a bar-code scanner attached could not fit into a patient's room, forcing the nurse to scan the medication before she entered; a warning on the computer screen indicated that the medication was intended for another patient, but the nurse could not see the alert and gave the medication to the patient in the room <sup>  </sup>
<b>Health IT is working as designed and is being used correctly, but it interacts incorrectly with external systems<sup>#</sup></b>	A system monitoring a patient's thyroid function stopped working when a drug identifier was changed during automated communications between different systems <sup>**</sup>

Source: Dean F. Sittig, David C. Classen, and Hardeep Singh, "Patient Safety Goals for the Proposed Federal Health Information Technology Safety Center," *Journal of the American Medical Informatics Association* 22, no. 2 (2015): 472-8, <http://www.ncbi.nlm.nih.gov/pubmed/25332353>

\* Peter Kilbridge, "Computer Crash: Lessons From a System Failure," *New England Journal of Medicine* 348, no. 10 (2003): 881-2, <http://dx.doi.org/10.1056/NEJMp030010>.

† Derek W. Meeks et al., "An Analysis of Electronic Health Record-Related Patient Safety Concerns," *Journal of the American Medical Informatics Association* 21, no. 6 (2014): 1053-9, <http://dx.doi.org/10.1136/amiainl-2013-002578>.

‡ Jan Horsky, Gilad J. Kuperman, and Vimla L. Patel, "Comprehensive Analysis of a Medication Dosing Related to CPOE," *Journal of the American Medical Informatics Association* 12, no. 4 (2005): 377-82, <http://dx.doi.org/10.1197/jamia.M1740>.

§ Bob Wachter, "How Technology Led a Hospital to Give a Patient 38 Times His Dosage," *Wired*, March 30, 2015, <https://backchannel.com/how-technology-led-a-hospital-to-give-a-patient-38-times-his-dosage-ded7b3688558#.by1mwjwpw>.

|| Ross Koppel et al., "Workarounds to Barcode Medication Administration Systems: Their Occurrences, Causes, and Threats to Patient Safety," *Journal of the American Medical Informatics Association* 15, no. 4 (2008): 408-23, <http://dx.doi.org/10.1197/jamia.M2616>.

# Donald C. Spencer et al., "Effect of a Computerized Prescriber-Order-Entry System on Reported Medication Errors," *American Journal of Health-System Pharmacy* 62 (2005), 416-9, <http://www.ajhp.org/content/62/4/416>; Charles Perrow, *Normal Accidents: Living With High-Risk Technologies* (Princeton, New Jersey: Basic Books, Princeton University Press, 1984), <http://press.princeton.edu/titles/6596.html>.

\*\* Adam Wright et al., "Analysis of Clinical Decision Support System Malfunctions: A Case Series and Survey," *Journal of the American Medical Informatics Association* 23, no. 6 (2016): 1068-76, <http://dx.doi.org/10.1093/jamia/ocw005>.

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Clinicians themselves may not recognize errors as technology-related.<sup>6</sup> A patient may have an allergic reaction to a drug or an overdose, for example, but only upon further investigation does it become clear that use of an EHR system may have contributed. A clinician may have overlooked or ignored a drug allergy alert in the patient's EHR or have been confused about how to enter the correct dose of a medication. In 2013 at UCSF Benioff Children's Hospital in San Francisco, a 16-year-old patient was administered 38 times the intended dose of an antibiotic due to a series of errors related to how clinicians used an EHR system.<sup>7</sup> The technology may have contributed to—or could have averted—a safety problem, but the mistake happened because of how the clinician used the system. As outlined in an Institute of Medicine report on health IT, safety issues may also occur when the technology is not used as designed.<sup>8</sup>

## Factors that influence EHR safety and usability

Some factors that influence EHR safety include a system's design and layout, variability across technologies, customization by hospitals and other health care facilities, how they fit into the workflow, and training.

### Design and layout

The design and layout refer to the user interface: what doctors, nurses, and other clinicians see when they view the screen to retrieve information in the system and enter new data or orders, such as a prescription or request for a laboratory analysis.

An interface that is cluttered may cause confusion or an inability to locate key information, whereas an overly bare display may force the clinician to search for information in multiple places. Important design principles include knowing what users need for a simple interface, removing complexity, using simple and clear terminology, emphasizing key elements, and using color effectively to draw users to important areas.<sup>9</sup>

At the same time, EHRs also allow for new data to be documented, including allergies discovered by health care professionals and orders to be entered—from X-ray requests and antibiotic prescriptions to dietary restrictions for hospitalized patients. The user interface can enable accurate entry of these orders or can introduce confusion based on the layout and design.

### Variability across and within technologies

While each product has unique characteristics, some features of EHRs are typical. For these components, such as an alert that a lab result is abnormal, EHRs may not display the information in a consistent, standard, or similar manner. For example, the EHRs that providers use in hospitals and the ones in their offices may have different interface designs, such as fonts, icons, and colors.<sup>10</sup> This variability can create delays for clinicians accessing the system for patient information, confusion as to where things are on the screen, and uncertainty about the meaning of different icons. Variability can also occur within a facility's shared EHR system. For example, nurses in a hospital may have a different landing page for the patient than the doctor has.

### Customization

When an EHR system is put in place, health care facilities may customize certain aspects to fit the specific workflow within a hospital or office, display information that is most critical to clinicians at a particular facility, or address other unique characteristics.

These customizations—which may be requested by a health care facility or staff—may not have undergone rigorous testing by the care team or the product developer to detect potential safety concerns.

## Workflow

Workflow is the sequence of processes, services, and steps used to care for patients and how health care providers interact with an EHR to perform various tasks.<sup>11</sup> It reflects how and when things are done within a health care setting. Workflow can include clinical actions such as ordering a medicine or administrative tasks, including finding the right patient in the EHR. It also encompasses actions that occur at a very granular level—such as the tasks of an individual nurse or physician—or among larger entities, including communications between hospital departments, with laboratories, or across facilities.

The specific workflows used within facilities—especially given that each hospital, clinic, and physician's office has unique characteristics—can also contribute to EHR-related safety concerns. For example, the order-entry process involves several steps: The physician identifies the patient in the ordering system, the physician orders a medication, the pharmacist verifies and fills the order, the drug is delivered to the unit, and the nurse administers it.<sup>12</sup> Any disruption to this workflow may lead to patient harm. For example, critical-care physicians may need an emergency medication that would be documented retroactively in an EHR.

Testing certain EHR features outside of a particular workflow may not reveal safety problems. However, introducing these technologies into a health care facility with its unique workflow may unearth challenges that were previously undetected or that would not represent safety concerns in a different workflow. In addition, clinicians may develop their own workarounds in the system if they believe that the EHR does not support how they work, which could also place patients at risk.

Incorporating end users—nurses, doctors, and other staff—in developing and testing digital products within health care facilities can reveal potential patient safety issues that would otherwise become apparent only after EHRs are put in place.<sup>13</sup>

## Training

The safe use of health information technology also relies on doctors, nurses, and other health care providers knowing how to effectively use the system as designed. As a result, effective implementation and use of EHRs requires that these professionals be trained.<sup>14</sup>

EHR developers offer their customers a wide range of training. This can include classroom and web-based sessions, self-paced courses, customized programs, and simulation training. Some also offer continuing education courses through multiple platforms and end user certification in a specific EHR product.<sup>15</sup>

ONC's National Learning Consortium also offers resources for training and education. Its website allows users to share experiences with EHRs, helps to solve obstacles, and is a hub for EHR implementation materials.<sup>16</sup> The consortium also offers training and other resources on workflow redesign, EHR implementation, and even vendor selection and management.

## Examples of usability-related errors

Safety problems can stem from an EHR product's design, variability, customization, and users' workflows, including when clinicians view information, attempt to order a drug, or check lab results.

- **Missing lab test results.** Results are normally returned to the requesting clinician when they are completed. He or she may request a blood screen consisting of 11 tests; 10 results may be returned as normal, with the 11th not returned—and without an indication that it is still pending. The health care provider may discharge the patient or provide other care without recognizing that an additional lab result is outstanding.<sup>17</sup>
- **Patient identification.** A lack of strong EHR usability can also be a factor in a clinician selecting the wrong patient—and then ordering an inappropriate drug or medical procedure. A clinician may customize a display by sorting a list of patients by criteria such as last name or room number. However, if the EHR periodically refreshes the patient list and re-sorts it according to a default setting, the screen may refresh just as the doctor selects a patient, leading inadvertently to selection of the wrong person.<sup>18</sup>
- **Order overwrite.** In Maryland, a health care provider ordered a pureed diet for a patient who had failed a swallowing evaluation. Subsequently, a nurse indicated that the man also should be on a calorie-controlled diet. By adding the new diet into the system, the EHR overrode the entry that he required pureed food. As a result, he received a normal meal, choked, and died.<sup>19</sup>

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### Safety Examples

At Health IT Safety Day, Raj Ratwani and Rollin J. “Terry” Fairbanks, two usability and EHR safety experts for MedStar Health, showcased several of the examples in this report.

Their presentation focused on examples from EHR systems they have used and cases that garnered media attention related to patient identification, incomplete lab results, and nonstandard landing screens.

## The current approach to monitoring EHR safety

The federal government, EHR developers, hospitals and health care providers that use these systems, and other health care stakeholders use three main approaches to detect safety concerns:

- Testing throughout a product's development and implementation.
- Government oversight, certification, and development of best practices.
- Reporting of problems once they occur.

### Product testing throughout development

Testing EHRs with a focus on patient safety helps detect problems as the products are being developed. Continuing testing after they are put in place in a hospital or health care organization helps to identify flaws in a product's customization within that facility. Testing can occur in three phases of design and use:

- **Formative testing.** Testing as developers design a new product or modify an existing one. Typically, EHR developers conduct the formative testing for their products. A system's end users, such as doctors or nurses, may not be deeply involved in the testing based on each EHR company's protocols.<sup>20</sup>
- **Summative testing.** Testing of a system after it has gone through its design phase and the developer prepares to market it. This is required to obtain certification of the product by ONC in accordance with its criteria.<sup>21</sup>
- **Post-implementation testing.** Testing a product's usability after a facility installs it. The real-world use of EHRs can unearth safety concerns that were not apparent when a product was developed or that emerge because of the workflows in a given facility. As health care facilities implement EHRs, they may also modify them. For example, a cancer center may have integrated a proprietary imaging system into its EHR, turned off certain alarms, or allowed more than the recommended number of patient records to be open at once. Those types of modifications may introduce unanticipated safety problems.

## ONC's Role in Testing

The Office of the National Coordinator for Health Information Technology is authorized under the Health Information Technology for Economic and Clinical Health Act to certify health IT products that hospitals and health care providers must use to participate in federal programs that provide financial incentives to implement and use electronic health records.<sup>22</sup>

ONC requires EHR developers to test their products to ensure they meet its certification criteria. The testing is conducted by specialized testing facilities and the results are posted on ONC's website. For example, under the 2015 certification criteria, ONC requires that developers test computerized physician order entry, the documentation of patients' medications, electronic prescribing, and other functions.<sup>23</sup>

Private sector organizations conduct the tests on ONC's behalf.<sup>24</sup>

- Accredited testing laboratories. ONC-accredited testing laboratories focus on whether a system uses the correct standards and meets the criteria on usability and other issues outlined by ONC. They document their findings in a report for each system.
- Accredited certification body. ONC-accredited certification bodies receive the reports from the testing laboratories and determine whether to award certifications.<sup>25</sup> This means checking once a product is in use to see if it continues to meet the requirements and if its developers are complying with ONC's criteria. Examples include computerized provider order entry, drug allergy checks, and clinical information reconciliation.<sup>26</sup>

The National Institute of Standards and Technology (NIST) developed the initial voluntary testing scenarios and other tools used to evaluate the usability of EHRs. NIST and ONC collaborate on developing the voluntary certification program and its testing mechanism.<sup>27</sup> It also administers the National Voluntary Laboratory Accreditation Program, which accredits the testing laboratories.<sup>28</sup>

The 2015 edition certification criteria also introduced companion guides for each criterion. The guides, designed for use by EHR developers, provide development guidance and technical clarifications.<sup>29</sup>

## Testing scenarios

Testing focuses primarily on whether certain functions work—not whether those features can introduce a safety concern. Developers test various clinical and administrative operations and scenarios, such as looking up a patient, entering vital signs, refilling or changing medications, or printing a discharge summary, and more complicated actions such as printing a quality measure analysis. The testing method, frequency, and depth vary among developers.<sup>30</sup>

The test scenarios cover various EHR development functions, such as evaluating whether the patient has an up-to-date problem list, detecting the risk of a drug-drug interaction, facilitating the ordering of new medicines, and enabling the review of laboratory results.<sup>31</sup>

Usability tests can include scenarios about patients in specific settings, such as an outpatient clinic or hospital. Patients' conditions can range from mild to severe, simple to complex. The testers—nurses and doctors, for example—use the EHR to complete a series of tasks. In some instances, testers complete a usability rating form when finished testing. Once the testing is complete, the testers analyze the data and report their findings.<sup>32</sup>

## Government oversight and development of best practices

ONC and NIST have several other initiatives aimed at improving EHR safety.

### Enhanced oversight authority

Since 2016, ONC has had the authority to review EHRs suspected of posing serious risks to patients. The direct review could involve ONC entering health care facilities where products are in use and testing functions to evaluate the potential risk to patients. ONC can require EHR developers to correct identified flaws and, if necessary, suspend the certification of products with unresolved issues.<sup>33</sup>

### SAFER guides

ONC publishes Safety Assurance Factors for EHR Resilience (SAFER) guides, which provide best practices for hospitals and other health care facilities on how to evaluate the safety of the systems they use.<sup>34</sup> The nine published SAFER guides cover various EHR features, such as computerized order entries, the sharing of information among clinicians, and methods to select the correct patient record. The guides include safety recommendations, a checklist for health care facilities to rate the products they use on different features, and a practice worksheet on how to implement the recommended best practices.<sup>35</sup>

Use of the SAFER guides is voluntary. They have been available on ONC's website for over two years and have received little attention from developers and organizations.<sup>36</sup> During Health IT Safety Day, participants suggested ways to expand the use of the guides, including incentives or awards programs.<sup>37</sup> One developer noted that their company installed the SAFER guides as a tool within its EHR system to ensure ready access to best practices. Some of its customers have put patient pictures in the EHR.

Even after multiple updates since their initial release in 2014—ONC released updates to the SAFER guides March 21, 2017, that include many new recommendations and references—the guides still are not widely used.<sup>38</sup>

## NIST best practices

NIST also develops best practices for designing and using EHRs. In January 2017, the agency released an analysis of EHR functions that allows health care providers to copy and paste information—such as a medication or allergy list—from an EHR to save time. However, this function may create safety concerns if the information is outdated, irrelevant, or inaccurate.<sup>39</sup> For example, NIST recommended that key data—such as allergies, medications, and discharge information—contain clear information on who entered the data. NIST issued this recommendation after studying copy-and-paste practices developed by ECRI's Partnership for Health IT Patient Safety, which were also supported by more than 25 health care organizations.<sup>40</sup> By issuing the recommendation, NIST endorsed findings developed through a collaborative model.<sup>41</sup>

## 21st Century Cures Act

New policies included in the 21st Century Cures Act, passed by Congress in 2016, seek to improve EHR usability. Among other provisions, the law requires ONC to develop measures to evaluate various aspects of the records, including usability. By December 2017, with health care industry input, ONC will need to develop a way for EHR developers to report to a third party information on the usability of their products. Developers will need to create such reports to maintain their certifications.

Another provision grants EHR developers the same legal protections available to health care providers when reporting problems to patient safety organizations (PSOs), which aggregate safety challenges across facilities. These safeguards are designed to encourage EHR developers to share information about incidents involving patient injuries to help improve safety and can serve as a building block for establishing a health IT safety collaborative.

## Reporting problems once they occur

Once doctors, nurses, and other health care professionals begin using EHRs, safety concerns with these systems will inevitably arise. Health care providers often report them to internal quality and safety leaders, who then determine whether to alert a PSO for further investigations.

### Front-line staff

Doctors, nurses, and other health care professionals are the front-line users of EHRs. Their daily use of these systems enables them to detect errors or potential problems that harmed patients or could have. For example, nurses often have deep knowledge of a patient's health and regularly administer medications after physicians submit an order, enabling them to identify inaccurate prescriptions that could have stemmed from the use of an EHR.<sup>42</sup>

Once health care providers identify a problem that caused harm or a near miss, nurses, physicians, and other health care providers should report the event to the facility's quality improvement department or safety staff, or use other mechanisms to document and address the issue.

While most health care professionals are inclined to report safety concerns, these incidents are not always documented for several reasons. Health care providers may have to rush from one patient to the next and forget to file an incident report. Or if no patient was harmed, the provider may not have deemed the incident worth reporting. Finally, some EHR-related incidents may be perceived as broader IT problems that are not clinical in nature.

## Hospital leadership and a culture of safety

Hospital and health care facility leadership has two key roles related to EHR safety: fostering a culture throughout its workforce that promotes the submission of reports and processing them once received.

Hospital chief information officers (CIOs) oversee health care technology used at their facilities, including EHRs. They lead the researching, purchasing, customization, and implementation of EHRs to ensure patient privacy and data security; foster the safe use of these systems through training; and optimize the technology's integration with other systems, including medical devices and clinical suite software.

CIOs and other health care facility leaders, therefore, have the opportunity to build a culture of safety around the use of EHRs by creating incentives for staff to report safety concerns and reducing barriers to the submission of reports. For example, health care facility leaders could convene staff huddles to discuss safety problems, recognize staff with awards for identifying and preventing serious EHR-related harm, or facilitate the reporting of safety concerns by enabling audio or screen recording software for more efficient safety event documentation by health care providers.<sup>43</sup> Safety huddles effectively promote discussion among administrative, clinical, and health IT staff. In one instance, a review of 249 days' worth of such discussions found 245 EHR-related safety concerns such as hardware and software problems, clinical content issues, and user issues.<sup>44</sup> Some concerns found in this review included device failures, design issues, loss or delay of data, workflow issues, and human-computer interface issues.<sup>45</sup>

Once a health care facility's leadership receives a report, it should, when appropriate, instruct in-house technical staff to make product changes, notify the developers of the safety concerns, submit data to PSOs regarding the incident, or take other actions.

## PSOs

The Patient Safety and Quality Improvement Act of 2005 created PSOs to collect voluntary reports of safety concerns from hospitals, doctors, and other health care providers. PSOs collect data, analyze it and detect commonalities and anomalies, develop solutions and best practices, and then share the findings with their members. In assessing health care delivery, PSOs permit the evaluation of how the people, processes, and equipment work together in a complex system to continuously improve patient safety, the quality of patient care, patient outcomes, systems efficiency, and value in a confidential environment.

To encourage the submission of reports, the law protects the information that PSOs receive from hospitals and clinicians from discovery in lawsuits. The 21st Century Cures Act of 2016 extends those protections to EHR developers, which can facilitate their participation in PSO activities.

The Agency for Healthcare Research and Quality (AHRQ) maintains a list of more than 80 PSOs. These private sector entities often focus on a specific geographic region and serve the needs of their members. Hospitals and health care providers participate in PSOs to obtain information on how to improve safety, including fixing their own reported problems. For example, a hospital may report a problem to a PSO, which then reviews it and provides information on how to fix it. Beginning in 2015, the Affordable Care Act required that all hospitals with more than 50 beds implement an evidence-based patient safety system to improve readmission rates and hospital performance.<sup>46</sup> Still, there is no centralized repository of all EHR-related reports, a function that a national health IT safety collaborative could provide.

Given that potential function, a health IT safety collaborative could seek data from different organizations, such as PSOs. To make reporting simpler, AHRQ maintains the Common Formats, a standardized method for



health care providers to document safety events to facilitate comparisons and aggregate information from various facilities.<sup>47</sup>

Version 1.2 of the Common Formats included health IT reporting questions in the “Device and Medical Surgical Supply” format. Version 2.0 removed the health IT portion from that format but indicated that it may be added later.<sup>48</sup> Versions 1.2 and 2.0 remain in use while the industry transitions to a newer version. The two active versions are supported for data submission to the PSO Privacy Protection Center, which is discussed below.

Although PSOs are not required to collect data according to the AHRQ Common Formats, each must adopt a reporting standard for all of its members. Alternative formats for reporting may exist or emerge to provide more robust data on health IT safety concerns. Some PSOs elect to use an alternative to the AHRQ Common Formats to accommodate legacy electronic systems that can submit safety events in a different standard.<sup>49</sup>

PSOs that use the AHRQ Common Formats may forward reports to the PSO Privacy Protection Center, a government program that de-identifies the information for future aggregation for research purposes.<sup>50</sup> AHRQ administers the Network of Patient Safety Databases, a national network that provides resources for health care providers and others to improve the health care system, including aggregated reports on patient safety events.<sup>51</sup> PSOs are not required to send data to the safety database, however, and data submitted may not contain health IT-specific information.<sup>52</sup>

Despite the current activities to reduce harm, an abundance of EHR-related patient safety activity continues across the health care environment. Additional gaps remain in the ability to detect safety problems and develop best practices to resolve them. The creation of a national health IT safety collaborative could help generate better data to prevent errors and improve care.<sup>53</sup>

### Measures of patient safety

In 2016, the National Quality Forum (NQF)—a nonprofit organization that leads collaborative activities to improve health care through measurement—developed a set of metrics meant to identify the nature, scope, and prevalence of health IT-related safety problems.<sup>54</sup> One addresses user-centered design and the use of testing and simulation to improve safety.<sup>55</sup> This includes using existing standards for user-centered design; involving end users in health IT design, development, and use; promoting patient safety with usability; and other conceptual areas.<sup>56</sup>

NQF has also adopted a “retract and reorder” measure that evaluates how often a clinician cancels a prescription for one patient and reorders it for another. This process suggests that the initial drug might have been ordered for the wrong patient, potentially because of a usability problem that could have harmed the patient if the error had not been detected.<sup>57</sup>

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“ It’s not just how the system is built. It’s the human factor. It’s the processes that we use. And it’s the ability as leaders, nursing leaders, physician leaders, to understand that and bring your expertise to the table to build better systems that will provide the outcomes that we all, as practitioners in this room and researchers in this room, strive for.”

**Patricia Mook**, *chief nursing information officer, Inova Health System*

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## The genesis of efforts to foster collaboration

Despite these institutionalized efforts to reduce mistakes associated with electronic records that could harm patients, gaps remain in the health care industry's ability to detect safety problems and develop best practices to resolve them. While enhanced testing could improve health IT, representatives from the health care industry, academia, patient safety organizations, and the federal government at Health IT Safety Day focused on the potential benefits of creating a national health IT safety collaborative.<sup>58</sup>

Several expert panels have recommended that a collaborative be established, mirroring similar efforts in other industries. Such a collaborative, involving all of these stakeholders, could help generate better data to prevent errors and improve care.<sup>59</sup> It would collect, identify, and analyze health IT patient safety problems, and develop and disseminate solutions.

### Roots of a health IT safety collaborative

#### Institute of Medicine

In 2011, an expert panel from the Institute of Medicine (IOM), now the National Academy of Medicine, authored a landmark report on EHR safety, "Health IT and Patient Safety: Building Safer Systems for Better Care."<sup>60</sup> The panel recommended the creation of a health IT safety center, wherein:

- EHR developers support the free exchange of detailed patient safety information, including screenshots of their products.
- Health IT users exchange information on their experiences with products.
- Developers and EHR users report safety events.

#### Health IT safety center roadmap

Since the release of the IOM report, the concept of a collaborative evolved further in "Health IT Safety Center Roadmap," a 2015 report by the consultant firm RTI International for ONC.<sup>61</sup> RTI had convened a task force of clinicians, EHR developers, and experts from universities and government, including from the American Medical Association, American Hospital Association, MedStar Health, ECRI Institute, the AHRQ, the Centers for Medicare & Medicaid Services, the University of Utah, and the University of Texas Health Sciences Center.

The roadmap lays out steps to create a system that allows health IT stakeholders to share information and resources, identify safety concerns, and develop solutions.<sup>62</sup>

During Health IT Safety Day, Doug Johnston of RTI explained these focus areas:<sup>63</sup>

- The convening role would include the assembly of EHR developers, providers, policymakers, and others who would identify health IT safety issues and the necessary solutions.
- The research function would include collecting and assessing health IT safety event data and identifying existing solutions.
- The dissemination role would involve the promotion of best practices and other findings from collaborative participants.

The collaborative would have an open membership, meaning anyone interested in health IT patient safety could join. The expert panel convened by RTI did not define a governance structure but called for balanced efforts between the private sector and federal government representatives, including ONC, AHRQ, and the Food and Drug Administration.<sup>64</sup>

The panel estimated that funding the collaborative for the first five years, based on functions outlined in the RTI report, would cost \$17.8 million-\$20.6 million, though it said significantly lower funding could still lead to an effective collaborative.<sup>65</sup> It would have an executive director and staff, along with an advisory board and groups that would be responsible for developing work products. At the outset, an open federal contracting competition would determine the organization to host the collaborative under a five-year cooperative agreement with ONC, AHRQ, or others, with the aim of it eventually become self-sustaining.<sup>66</sup>

The various proposed funding levels, outlined in Table 2, are:<sup>67</sup>

- **100 percent funding:** \$17.8 million-\$20.6 million for an optimal center, as outlined by RTI, where all activities would be high priority.
- **75 percent funding:** \$12.9 million-\$14.9 million for a functional center where all activities remained but with a reduced volume and scope.
- **50 percent funding:** \$9.1 million-\$10.5 million for a lower-impact center where major functional areas remained but the volume of activities would be further reduced.

These estimates reflect the costs of collaborative functions outlined in the RTI report; the full costs associated with the collaborative could differ based on the specific functions that it would conduct.

## FDASIA

Under the Food and Drug Administration Safety and Innovation Act of 2012, Congress required FDA, ONC, and the Federal Communications Commission to examine regulating the health IT industry with the aim of reducing risks to patients. The legislation said the agencies should focus on health IT functionality and a framework that is flexible enough to allow for product improvements.<sup>68</sup> In a report that responded to that directive, the agencies urged that a health IT safety collaborative be formed to aggregate and analyze health IT safety events, such as incidents, injuries, and near misses.

## Sample pilot projects

Several private sector organizations have piloted approaches that could serve as examples or a foundation for a health IT safety collaborative.

### ECRI Institute

ECRI, based in suburban Philadelphia, is one of the largest patient safety organizations (PSOs) in the United States, with more than 5,000 members.<sup>69</sup> In 2012, it founded the Partnership for Health IT Patient Safety to convene health care providers, EHR developers, experts in human interactions with technology, and other stakeholders to improve the safety of health information technology.<sup>70</sup>

The partnership examines data that ECRI collects to identify safety concerns with EHRs and address them through a collaborative discussion. As of mid-2017, the partnership had formed four working groups to develop best practices on:

- The use of copy-and-paste functions with EHRs.
- Accurate patient identification.
- Establishing and maintaining a health IT safety program within health care facilities.
- Preventing missed and incorrect diagnoses.

The discussions had led to recommendations for improving electronic records' patient identification and cut-and-paste functions.<sup>71</sup> The partnership demonstrates the potential for a collaborative to identify common problems, develop solutions to those challenges, and disseminate best practices.

## CRICO

Controlled Risk Insurance Co. is both the PSO and provider of medical malpractice insurance for the Harvard medical community. Given these two functions, CRICO can identify common safety concerns, develop best practices to address them, and encourage its members to follow those protocols. As safety improves—resulting in fewer lawsuits—CRICO can adjust the cost of premiums for its members.<sup>72</sup>

Using a proprietary coding system, it identified 147 EHR-related patient safety cases over a five-year period.<sup>73</sup> CRICO maintains a system that allows participating organizations to use data from open and closed malpractice cases to evaluate their safety performance.<sup>74</sup>

## Mitre Corp.

Mitre, a federally funded research center, also piloted a health IT safety program that could function similarly to the collaborative.<sup>75</sup> Already operating an aviation safety lab, Mitre applied that model to health care and started the National Patient Safety Partnership in 2015. It collected, analyzed, and shared data to understand the causes of patient injuries linked to EHRs in order to reduce errors, improve care, and cut costs.<sup>76</sup> As with the airline safety work, Mitre used advanced analytics on diverse metrics—such as self-reported safety event information, physiological data from monitors, and administrative data—to predict what problems could arise. Mitre partnered with Boston Children's Hospital, Children's National Medical Center, and Cincinnati Children's Hospital Medical Center to focus on the root causes of incidents, alarm fatigue, patient deterioration, and medication safety.<sup>77</sup> It fused data from disparate EHR systems, identified some potential errors associated with the medication ordering process, and created strategies to reduce unnecessary alarms.<sup>78</sup>

## HIMSS Electronic Health Record Association<sup>79</sup>

EHRA, a trade association of EHR developers, also convenes its member companies and involves their clients, such as hospitals, in discovering ways to improve the use of health IT. It established an EHRA code of conduct in 2013, which contained principles for improving patient safety, usability, and other aspects of health IT.<sup>80</sup> EHRA developed the code with input from government representatives, health care provider associations, and consumers, and released a second version July 1, 2017.<sup>81</sup>

## Aviation Safety

The health IT safety collaborative approach has parallels to efforts in other industries, particularly aviation, as explained during Health IT Safety Day by executives from the Federal Aviation Administration (FAA), United Airlines, and American Airlines.

In 1996, two fatal events shook the aviation industry: the crash in the Florida Everglades of a ValuJet plane in May and, three months later, the explosion of TWA Flight 800 over Long Island.<sup>82</sup> Following these incidents, two commissions were established to review airline safety.<sup>83</sup> The White House Commission on Aviation Safety and Security called for an 80 percent reduction in fatalities over the next decade, and the National Civil Aviation Review Commission, created by Congress, urged the airline industry to convene and determine how to reduce airline risk.<sup>84</sup> In 1997, industry and government responded by creating the Commercial Aviation Safety Team,<sup>85</sup> which:

- Analyzes safety data.
- Identifies hazards and other underlying factors.
- Develops and implements cost-effective safety improvements.
- Tracks and monitors the effectiveness of these measures.
- Conducts other safety-related initiatives.<sup>86</sup>

The aviation industry collects information through the Aviation Safety Information Analysis and Sharing (ASIAS) System, which collects data from every flight, person, and function involved with a flight to increase safety. The plethora of information includes flight and air traffic control data, weather information, input from the ground and flight crews, and information from others who may be involved with the operations of the flight.<sup>87</sup> The data enable airlines' safety personnel to conduct predictive analytics to identify potential areas of risk. It can reveal, for example, that a single event for one airline is actually problematic across the industry.

Another benefit of this system is that airlines can compare their data with that of the industry as a whole. An airline's own data may indicate that it has a strong safety record, but an industry comparison might show that certain safety issues may need to be improved. Or it may discover that it is performing better than the industry average and can give other airlines information on its approach.

ASIAS, decades in the making, has succeeded because of trust built among companies, the FAA, and other key industry players. The airlines, unions (for pilots, ground crews, air traffic controllers, flight attendants, and others), and the FAA enabled the establishment of a process that allows anyone to report anything related to safety without fear of being targeted by the FAA for punitive action. As a result of this and other activities, the commercial aviation industry reduced fatalities by 83 percent from 1998-2008. Its next goal is to reduce them by another 50 percent from 2010-25.<sup>88</sup>

## The benefits of a health IT collaborative

Today, health care organizations and developers evaluate health IT safety in different ways, and some work with regional PSOs on the problems they encounter. There is no single, national organization that aggregates health IT safety data from across the country. Through this distributed model, health IT safety is evaluated along with other aspects of care.

This model, however, has not adequately addressed health IT safety challenges. Several limitations are clear: Each organization analyzing safety may lack the expertise to address complex health IT issues, the ability to disseminate its findings on a national scale, or sufficient data to generalize its research.

A centralized model—a national health IT safety collaborative—also has some drawbacks. It could risk siloing health IT from other aspects of care. And the failure of a single organization to adequately address safety could hinder similar efforts. However, while it may not solve every concern, a national collaborative has the potential to provide data and best practices to all who develop health IT and use it to provide care in the United States.

Establishing a national collaborative would:

- **Encourage more efficient participation from all stakeholders.** Many PSOs are regional. As a result, EHR developers that sell products across the country would need to participate in many PSOs that represent different geographic areas. By consolidating activities in a single organization, EHR developers could have a better understanding of potential safety risks not only with their products, but also with similar issues confronting other stakeholders. The collaborative could also have a relationship with local PSOs to obtain a nationwide perspective. This would give it the responsibility for health IT safety and ensure that it interacts with PSOs and databases as part of AHRQ's Network of Patient Safety Databases so that its findings are not isolated from other facets of health care.
- **Facilitate government participation.** Similarly, government participation in EHR safety activities would benefit from having a single organization responsible for efforts to improve it. Given scarce resources, federal agencies might not have the funding and personnel needed to participate in multiple efforts—even if only a small number of initiatives desired federal involvement. Consolidating activities in a single organization could improve the government's ability to work collaboratively with the health IT industry to boost safety. Through their participation, government agencies could provide perspective on issues identified across the industry. At the same time, agencies participating in the collaborative could learn from its members to have a more nuanced and accurate perspective on the industry. This type of education could ensure that any policies developed would better reflect the actual use of health IT.
- **Provide needed expertise.** When EHR-related safety events occur, many factors underlie them. This may differ from other safety-related issues, such as alerts for problems detected with certain medical procedures or devices. Some organizations lack personnel with the background to adequately evaluate EHR safety, so a single organization could more readily consolidate the needed expertise. Further, a single organization could develop and leverage its health IT analytics tools to more efficiently evaluate safety. Under the current system, organizations have to develop their own tools and expertise, which is both inefficient and potentially less effective.

- **Have actionable data.** Organizations that are aware of safety events—such as PSOs, hospitals, or vendors—may not receive many reports about a specific problem. As a result, analyses regarding specific safety events (for example, how frequently they occur) may lack enough data—or power—to reach actionable conclusions. Consolidating safety events in a single collaborative, even if reports were initially sent to other organizations, could provide analyses with sufficient data.
- **Ensure nationwide reach.** A single collaborative could collect information, analyze it, develop solutions, and disseminate best practices on a national scale more easily than regional efforts.
- **Prioritize health IT.** In many respects, health IT influences the care of every patient in a facility—unlike many other aspects, such as medications or medical devices, that affect only a subset of patients. Organizations with multiple mandates, such as to evaluate safety events that occur during surgery or associated with medical devices, may not be able or choose to prioritize examinations of health IT safety, which is a cross-cutting issue for all patients and clinicians in facilities that use EHRs. As a result, EHR-related issues may not be examined in depth. A single collaborative dedicated to health IT safety could maintain focus on this subject. As with aviation, a collaborative would enable thorough, sectorwide analyses of root causes. A single collaborative would enable the collection and use of enough data to better determine which perceived problems are legitimate—and whether they are widespread. This prioritization risks siloing health IT from the many other aspects of care. To prevent this, an organization focused on health IT safety should collaborate closely with PSOs or other institutions that can provide expertise on other aspects of care.

A health IT safety collaborative would need to address these and other challenges in order to be successful.

## Establishing a collaborative: Value, trust, governance, funding

For EHR developers, hospitals, and clinicians to benefit from a single nationwide health IT safety collaborative, the organization should demonstrate value, build trust among participants, establish a governance model, and secure the necessary funding.

### Demonstrating value

During Health IT Safety Day, participants identified many ways that a collaborative could help EHR developers, hospitals, and others improve patient safety. As stakeholders begin to develop the collaborative, they should prioritize its activities and determine which can be launched in the short term.

These activities include:

- **Developing a database.** The collaborative could serve as a nationwide repository for reports on health IT safety incidents. Creating a database for this information would enable health care providers and developers to have greater access to aggregate health IT safety data to conduct research and root-cause analyses on safety risks associated with certain customizations, workflows, and other factors that can introduce patient harm. Aggregating the data could support research that cannot be done when data are dispersed across many organizations (the dozens of PSOs that may not share information). Sharing safety data held by PSOs and other organizations could also provide a plethora of information for analysis.

- **Convening a forum.** The collaborative could host a forum for developers, health care providers, ONC, and other health IT experts to share common safety challenges and develop solutions. The members would participate in conversations about EHR usability and its impacts on patient safety in a nonpunitive forum outside public view. Convening stakeholders would provide an open channel for discussing critical EHR safety issues without fear of reprisal.
- **Supporting other benefits.** Participating in the collaborative would open the door to additional benefits that could lead to improved quality of care and patient safety, and reduced costs. These include:
  - Developers facing fewer enforcement actions from ONC as participation in the collaborative demonstrated a reduction in safety events.
  - Developers receiving formal recognition for following best practices developed or identified by the collaborative.
  - Hospitals and clinicians receiving lower malpractice insurance rates by following health IT safety best practices developed through the collaborative.



It starts by building trust. You have a relationship with the regulator that's very open, very honest, very collaborative in what you're sharing back and forth, what you're seeing."

**Mike Quiello**, vice president for corporate safety, United Airlines

## Building trust

The full benefits of a single nationwide health IT safety collaborative could only be realized through an open, nonpunitive, noncompetitive environment for discussion between all parties. This is one key lesson from the aviation experience, which fostered collaboration among companies and with the federal government.

However, conversations at Health IT Safety Day demonstrated that vendors, providers, developers, and the federal government lack the necessary trust to share information and experiences. EHR developers indicated that they fear that ONC could use information gleaned through the collaborative to take regulatory action against a specific company. They said ONC's enhanced oversight rule, which enables the agency to inspect products, has widened the trust gap between developers and the agency. To ensure that the collaborative is effective, clearly defined roles and rules must be established for all participants.

As part of establishing the collaborative, agreement should be reached on:

- Parameters for when data should be de-identified and by whom.
- Protocols to ensure that members have enough data—including screenshots and computer logs, where applicable—to properly evaluate selected safety events.
- Creation of an open environment for dialogue from health care providers to ensure their experiences are accurately shared with EHR developers.
- Protection of discussions in the nonpunitive environment, including that some may not always include every member (e.g., ONC) of the collaborative at every stage.





Measuring any safety problem is the first step to improvement.”

**Hardeep Singh**, chief of health policy, quality, and informatics, Center for Innovations in Quality, Effectiveness and Safety, Michael E. DeBakey Veterans Affairs Medical Center; and Baylor College of Medicine

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### Establishing a governance model

One session during Health IT Safety Day focused on a collaborative’s potential governance structure.<sup>89</sup>

Two approaches were discussed:

- **A single, specialized PSO with a focus on health IT safety.** Under this model, a single PSO with dedicated operations for health IT safety would convene the collaborative. Private sector and government experts would participate as members of the PSO. The benefits of this approach would include the ability to leverage PSO practices and infrastructure to analyze safety events, disseminate findings, and more efficiently establish an effort to focus on safety.
- **Public-private partnership model.** Through this approach, a new organization dedicated to health IT safety would be created. It would initially reside within an existing organization, such as a PSO, and eventually become independent. The organization would be headed by an advisory board of public and private sector representatives. Under this model, the private sector and government would have more control over the collaborative’s functions, but it could require a longer startup time.

### Securing necessary funding

Finally, the collaborative should have dedicated funding to sustain its operations over a yet-to-be-specified period. That funding could come from both the private sector—such as EHR developers, health care providers, and other participants—and the federal government. The funding would demonstrate a broad commitment to the collaborative’s success. As previously mentioned, the five-year cost estimate for an optimal center outlined by RTI is about \$20 million.<sup>90</sup>

Table 2

## Health IT Safety Collaborative Funding

Level would affect the organization's scope and breadth

	Optimal	Functional	Low-impact
<b>Funding</b>	\$17.8 million-\$20.6 million	\$12.9 million-\$14.9 million	\$9.1 million-\$10.5 million
<b>Executive director</b>	Yes	Yes	Yes
<b>Staff: executive director, researchers, administrators, and others to convene parties and disseminate information</b>	Full-time 12 Part-time 7	Full-time 7 Part-time 9	Full-time 3 Part-time 10
<b>Potential operations</b>			
<b>Advisory board</b>	Yes	Yes	Yes
<b>Working groups</b>	4	3	2
<b>Solution development</b>	4	3	2
<b>Evidence scan and report</b>	Annually	Annually	Annually
<b>Targeted research</b>	4 topics	3 topics	2 topics
<b>Lead solutions implementation</b>	4 solutions	3 solutions	2 solutions
<b>Outcomes evaluation</b>	Yes	Yes	Yes
<b>Market and disseminate solutions</b>	4	3	2
<b>Web-based resource directory</b>	Yes	Yes	Yes
<b>Strategic communications plan</b>	Yes	Yes	Yes
<b>Engagement and educational events</b>	Yes	Yes	Yes
<b>Other costs</b>			
<b>Computer and IT/web conferencing</b>	Yes	Yes	Yes
<b>Travel and in-person meetings</b>	Yes (with in-person meetings)	Yes (with 1 in-person meeting)	No
<b>Subject matter expert funding</b>	\$1 million a year	\$600,000 a year	\$300,000 a year

Source: RTI International, "Health IT Safety Center Roadmap," prepared for the Office of the National Coordinator for Health Information Technology (2015), <http://www.healthitsafety.org/uploads/4/3/6/4/43647387/roadmap.pdf>

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## Recommendations

During Health IT Safety Day, experts from government, clinician organizations, EHR developers, hospitals, and others discussed the value that a single, voluntary, nationwide health IT safety collaborative could provide by facilitating the collection of safety data, convening stakeholders, identifying common problems, and sharing solutions.

Through this approach, the existing safety infrastructure can be leveraged to identify emerging health IT safety issues, collaborate to solve problems, and disseminate solutions. To achieve these goals, Pew has identified the following steps:

- **Determine the functions.** Those taking part in the Health IT Safety Day identified two major ways that a collaborative could serve its participants: as a database for patient safety incidents and as a forum to discuss those problems and develop solutions. EHR developers, health care providers, PSOs, and the government should now reach consensus on its core functions and prioritize short-term activities, such as convening relevant organizations.
- **Establish the governance model and funding methodology.** As part of establishing the collaborative, participants should reach consensus on governance and funding. The governance should include how the collaborative will interact with PSOs throughout the country and policies to address concerns, such as how to maintain data and conversations in a nonpunitive environment that is protected from regulatory enforcement. Key questions include:
  - What roles will government agencies, developers, health care providers, and others have—and will the governance model be sustainable?
  - How will the collaborative work with all PSOs, including if it is housed within a single PSO?
  - How will PSOs be compensated—including through nonfinancial means—for the information they provide?
  - How will the collaborative and the Network of Patient Safety Databases interact?
  - What level of federal seed funding is necessary and for how long?
  - What will be required of private sector participants?
- **Use the 21st Century Cures PSO provisions to encourage developers to report safety incidents.** As previously mentioned, the 21st Century Cures Act extends protections for reporting to PSOs by EHR developers. Once implemented by AHRQ, this provision has the potential to encourage developers to report problems associated with health IT safety, fostering greater information sharing and richer data to enhance safety.
- **Secure public and private sector commitment to action.** During Health IT Safety Day, many government and private sector representatives expressed their support for a health IT safety collaborative. To build on this support, stakeholders should now reach agreement on any outstanding questions or concerns and work together to establish the organization, including by securing any necessary congressional authorization and funding.

By taking these steps, EHR developers, health care providers, and the government can help ensure that health IT fulfills its potential to improve the safety and quality of care.

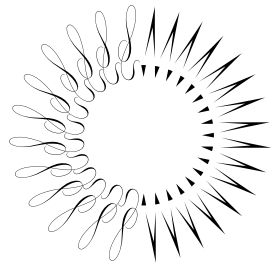
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