



The Office of the National Coordinator for
Health Information Technology



Health Information Technology Patient Safety Action & Surveillance Plan for Public Comment

December 21, 2012

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“It is widely believed that, when designed and used appropriately, health IT can help create an ecosystem of safer care...”
—Institute of Medicine “*Health IT and Patient Safety: Building Safer Systems for Better Care*” (P. 21)

Introduction

Over a decade ago, the Institute of Medicine’s (IOM’s) report *To Err is Human* raised an alarm about the failure of healthcare to recognize and reduce the large number of avoidable medical errors harming patients. Health information technology (health IT), in particular electronic health records (EHRs) and health information exchange, create the potential to reduce medical errors. This potential is part of the reason for the creation of the Office of the National Coordinator for Health Information Technology (ONC), first by executive order in 2004 and then through the Health Information Technology for Economic and Clinical Health (HITECH) Act — passed as part of the American Recovery and Reinvestment Act of 2009. In addition to creating ONC, the HITECH Act also provided economic incentives for eligible providers to adopt and meaningfully use certified EHR technology.

The premise of these initiatives is that health IT, when fully integrated into health care delivery organizations, facilitates potentially enormous improvements in health care quality and safety as compared to paper records. For instance:

- Medication errors can be reduced. Clinical decision support (CDS) and computerized provider order entry (CPOE) provide clinicians with best practice guidance and information on the allergies and medications of specific patients as part of the clinical decision - making process. With this guidance, patients can also receive more of the care they require (e.g., immunizations or preventive care) at each clinical encounter.
- Patient records can be stored centrally and can be easily accessed from multiple locations. Crucial health information can be available when needed, as patients move within and between health care organizations. When a patient arrives at an emergency room, providers can begin treatment with immediate access to patient records.
- Health IT can be used to more efficiently report, track, and aggregate patient data within and across organizations. This allows providers to more efficiently track and manage hospital acquired illnesses. Disease outbreaks can be monitored, which allows for improved population health and identification of potentially widespread threats to health, such as flu epidemics.

Just as health IT can create new opportunities to improve patient care and safety, it can also create new potentials for harm. For example, poor user interface design or unclear information displays can contribute to clinicians ordering medications not appropriate for their patients’ condition.¹ Health IT will only fulfill its enormous potential to improve patient safety if the risks associated with its use are identified, if there is a coordinated effort to mitigate those risks, and if it is used to make care safer. Recognizing the need to identify

¹ IOM (Institute of Medicine). 2012 *Health IT and Patient Safety: Building Safer Systems for Better Care*. Washington, DC: The National Academies Press. Page 31.

and mitigate the risks, ONC commissioned an IOM study to determine how government and the private sector can maximize the safety of health IT-assisted care. “The committee interpreted its charge as making health-IT assisted care *safer* so the nation is in a better position to realize the potential benefits of health IT.”² The IOM Report, *Health IT and Patient Safety: Building Safer Systems for Better Care*, was published in November 2011.

“As with any new technology, health IT carries benefits and risks of new and greater harms. To fully capitalize on the potential that health IT may have on patient safety, a more comprehensive understanding of how health IT impacts potential harms, workflow, and safety is needed.”
IOM Report (P. 49)

This *Health IT Patient Safety Action and Surveillance Plan* (the “Health IT Safety Plan”), which builds on IOM’s recommendations, addresses the role of health IT within HHS’s commitment to patient safety. This plan builds upon and seeks to strengthen patient safety efforts across government programs and the private sector — including patients, health care providers, technology companies, and health care safety oversight bodies. HHS’ approach builds on existing authorities.

ONC is accepting public comments on the Health IT Safety Plan. Public comments will be accepted through February 4, 2013, and can be emailed to ONC.Policy@hhs.gov. Based on the public comments, ONC will publish the final Health IT Safety Plan.

² IOM. 2012 *Health IT and Patient Safety: Building Safer Systems for Better Care*. Washington, DC: The National Academies Press. Page 2.

Health IT Patient Safety Goal

Inspire Confidence and Trust in Health IT and Health Information Exchange

HHS' goal is that patients and providers have confidence in the safety of the healthcare system, including its health IT infrastructure, based on evidence of safety. Patient safety and the factors by which it is affected have been studied for decades. The IOM, the Agency for Healthcare Research and Quality (AHRQ), and other such organizations have contributed to a body of literature focused on patient safety. Many efforts in the public and private sectors are already in place to improve patient safety and the overall quality of care.

Despite a growing body of research on patient safety, the IOM found “little published evidence”³ quantifying the magnitude of risks associated with health IT. In a research appendix to the IOM Report, a review of seven papers using large databases of reported errors found that health information systems were involved in less than 1 (one) percent of reported errors.⁴ All the reviewed papers also point to “the need for human diligence when using [health information systems].” The Pennsylvania Patient Safety Authority recently published an advisory notice outlining safety issues related to the use of EHRs and found that only 3,900 of 1.7 million reports were found to involve health IT. The vast majority of reported EHR-related events (81%) involved medication errors.⁵

“A traditional perspective on technology draws a sharp distinction between technology and human users of the technology.... [I]n the traditional perspective, health IT-related adverse events are generally not recognized as systemic problems, that is, as problems whose causation or presence is influenced by all parts of the sociotechnical system”
IOM Report (P. 64)

Because health IT is so tightly integrated into care delivery today, it is difficult to interpret this initial research, which would seem to suggest that health IT is a modest cause of medical errors. However, it is difficult to say whether a medical error is health IT-related. For example, it is difficult to determine whether an error is caused by or associated with health IT if:

- A medical error could have been prevented by more sophisticated or improved implementation of CPOE or CDS; or
- A clinician does not use certain health IT functionality that could have prevented an error because the functionality was frustrating or inefficient to use.

Additionally, EHR adoption in the past has been low. This means the lack of patient harm attributed to health IT may not be due to how safe health IT is, but to its lack of use.⁶ However, as EHR adoption

³IOM (Institute of Medicine). 2012 Health IT and Patient Safety: Building Safer Systems for Better Care. Washington, DC: The National Academies Press. Page 3 (Available at <http://www.iom.edu/Reports/2011/Health-IT-and-Patient-Safety-Building-Safer-Systems-for-Better-Care.aspx>).

⁴ *Id.* Appendix C, page 186.

⁵Pennsylvania Patient Safety Authority. *The Role of Electronic Health Record in Patient Safety Events*. [http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2012/Dec:9\(4\)/Pages/113.aspx](http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2012/Dec:9(4)/Pages/113.aspx) (last accessed 12/19/12).

becomes more widespread, the opportunity for harm may also increase. The increase in EHR adoption also creates a unique opportunity to improve patient safety. For example, EHRs can:

- Increase clinicians' awareness of potential errors and adverse interactions;
- Improve the availability and timeliness of information to support treatment decisions, care coordination, and care planning;
- Make it easier for clinicians to report safety issues and hazards; and
- Give patients the opportunity to more efficiently provide input on data accuracy than what paper records would allow.

⁶ For example, the Pennsylvania Patient Safety Authority's Advisory Notice found that only 3,900 of 1.7 million reports involved health IT. However, the database that the 1.7 million reports were collected from began collecting reports in 2004, when the rate of EHR adoption was minimal. Pennsylvania Patient Safety Authority. *The Role of Electronic Health Record in Patient Safety Events*. [http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2012/Dec:9\(4\)/Pages/113.aspx](http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2012/Dec:9(4)/Pages/113.aspx) (last accessed 12/19/12)

Health IT Patient Safety Objectives

1. *Use health IT to make care safer*
2. *Continuously improve the safety of health IT*

This Health IT Safety Plan has two fundamental objectives: first, to promote the health care industry's use of health IT to make care safer, and second, to continuously improve the safety of health IT itself.

Achieving these objectives is a shared responsibility. No one entity or group can fully realize the potential of health IT to improve patient safety. Instead, the Health IT Safety Plan aims to coordinate the actions required of the different actors in the health IT and patient safety community, including but not limited to:

- Clinicians
- Care Delivery Organizations, including
 - Administrators
 - IT staff
 - Quality improvement staff
- Patients and their caregivers
- Federal and state governments
- Health IT developers
- Patient safety organizations
- Accrediting bodies
- Other organizations and stakeholders, including
 - Liability insurers
 - Educational organizations
 - Health insurers
 - Professional associations
 - Publishers

“An environment of safer health IT can be created if both the public and private sectors acknowledge that safety is a shared responsibility.”
IOM Report (P. 125)

Use health IT to make care safer

The Department's *National Quality Strategy*⁷ incorporates the goals of the *Partnership for Patients*,⁸ which aims to reduce hospital acquired conditions and avoidable hospital readmissions. Health IT creates an infrastructure for identifying and monitoring patient safety events in these areas, making it possible to deploy more effective clinical decision support and other health IT to help achieve health and safety objectives. Hospital-acquired conditions and adverse events targeted in the Partnership for Patients program can be the focus for CDS, resulting in decreased harm to patients. Examples of CDS that can be integrated into EHRs include standardized checklists to prevent central venous catheter associated bloodstream infections, criteria for verification of the proper position of catheters, and notifications to discontinue medications or other interventions. For venous thromboembolism (VTE), a risk assessment linked to an order set of preferred

⁷ *National Quality Strategy*. <http://www.ahrq.gov/workingforquality/index.html>. (last accessed on December 6, 2012).

⁸ *Partnership for Patients: Better Care, Lower Costs*. <http://www.healthcare.gov/compare/partnership-for-patients/>. (last accessed on December 6, 2012).

VTE prophylaxis methods can potentially diminish the risk of development of hospital acquired VTE. Standardized order sets have also been implemented in labor and delivery setting and demonstrated significant reductions in obstetrical adverse events. CDS enables electronic integration of protocols to prevent injury from falls or pressure ulcers, such as risk assessments or prompts to reevaluate the patient's risk with a change in status or upon transfer.

CDS also enhances the safety of e-Prescribing by providing drug - drug interaction notifications and drug – allergy warnings, which have been shown to decrease adverse drug events. These adverse events can be further reduced using additional CDS which support drug – medical condition notifications, triggers for lab results indicating risk for adverse drug events, and medication treatments. One of the most common medication errors involves improper dose or quantity. CDS can often be used to identify these errors early in the prescribing process and can mitigate or prevent harm before it reaches the patient.

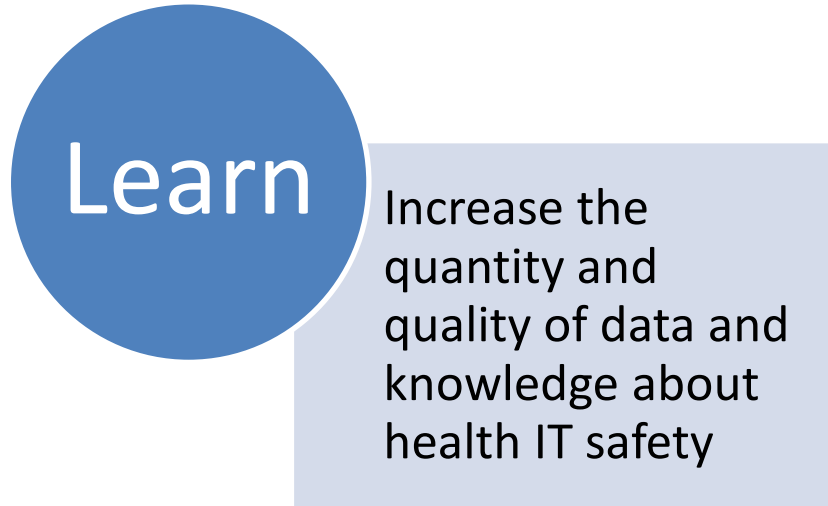
HHS has already taken steps toward improving patient safety through health IT. For example, EHR payment incentive requirements — such as maintaining lists of patient medications, allergies, and problems, and the use of computerized provider order entry (CPOE) — are tangible steps towards growing a safety infrastructure.

Continuously improve the safety of health IT

The purpose of this objective is to ensure that when physicians, nurses, therapists, and other clinical users of health IT care for patients, they are using a safely designed and implemented system, are properly informed and trained to use the health IT system, are using that system safely, and have processes in place to identify and correct unsafe conditions or unsafe uses of health IT.

CPOE and CDS, which have the enormous potential to help avoid medical errors, must be safely designed, tested, implemented, supported, and used correctly. The content must be accurate, up-to-date clinically relevant, and the functionality must be easy to use in efficient clinical workflows. Providers must be trained to use the systems properly and effectively. This objective ensures a focus on continuously improving the safety of health IT so that it enables providers to deliver high quality care safely.

Health IT Patient Safety Strategies and Actions



The proper steps to improve the safety of health IT can only be taken if there is better information regarding health IT's risks, harms, and impact on patient safety. The Health IT Safety Plan will improve knowledge on the types, frequency, and severity of health IT-related patient safety events. It also aims to use health IT as a tool to facilitate the reporting of patient safety events in general. The following steps are designed to:

- Establish mechanisms that facilitate reporting among users and developers
- Assist Patients Safety Organizations (PSOs), ONC-Authorized Certification Bodies (ONC-ACBs) and Centers for Medicare & Medicaid Services (CMS) surveyors in identifying and addressing health IT-related safety issues
- Aggregate and analyze data on health IT-related safety events.

“To fully capitalize on the potential that health IT may have on patient safety, a more comprehensive understanding of how health IT impacts potential harms, workflow, and safety is needed.”
IOM Report (p. 49)

1. **Make it easier for clinicians to report patient safety events and risks using EHR technology.**

To understand the impact of health IT on patient safety, clinicians must collect data on how health IT functions in real clinical environments. Clinicians reporting adverse events and risks that are perceived to be related to health IT provides the raw data necessary for developers, providers, researchers and policymakers to understand the root causes of such events and subsequently improve health IT. While caring for patients, health care providers should be able to use EHRs to easily initiate patient safety reports at the time of discovery or occurrence. ONC intends to propose using certification criteria to ensure that, where appropriate, EHR technology can facilitate reporting of safety events in AHRQ's Common Formats.

AHRQ's Common Formats are a reporting tool that standardizes and promotes increased reporting of adverse events, near misses and unsafe conditions.⁹ The most recent version of the Common Formats includes a "Device with Health IT" format that allows collection of standardized information about IT-related adverse events as well as events where health IT may be a contributing factor. The Common Formats have the goal of improving the efficiency of patient safety reporting by enabling one - time data collection and subsequent routing to whomever needs or requests the data. The Common Formats also provide local facility reporting capabilities for rapid identification of quality and safety problems and for the facilitation of changes to address the problems. The Common Formats also make it possible to aggregate and compare adverse events across care delivery organizations and federal and state programs.

To help inform ONC's work with standards and certification criteria related to patient safety, AHRQ plans to support research that will explore extraction of data elements identical and related to AHRQ's Common Formats from multiple established EHR implementations and exportation of this data to hospital incident reporting systems.

ONC recently funded a Patient Safety Reporting Challenge Award to address the need for development of software tools and interfaces that decrease adverse event reporting burden, incorporate the Common Formats to enable aggregation and consistency in reporting, and improve workflow efficiency regarding adverse event reporting to healthcare organizations. Three winners of this award were announced in November 2012.¹⁰ ONC expects these and similar tools to become much more widely used to help organizations build a culture of safety¹¹ that includes adverse event reporting and follow-up.

In response to recent HHS Office of the Inspector General reports on adverse events in hospitals, AHRQ has already taken steps to promote increased reporting of all adverse events, near misses and unsafe conditions using the AHRQ Common Formats.¹² This includes patient safety events related to health IT and using Patient Safety Organizations (PSOs)¹³ to report, analyze, and mitigate these events.

⁹ AHRQ. *Common Formats*. <http://www.pso.ahrq.gov/formats/commonfmt.htm>. (last accessed 12/15/12).

¹⁰ Challenge.gov. *Reporting Patient Safety Events*. <http://challenge.gov/ONC/349-reporting-patient-safety-events> (last Accessed 12/16/12).

¹¹ AHRQ. *Safety Culture*. <http://psnet.ahrq.gov/primer.aspx?primerID=5> (last accessed October 30, 2012). ("A culture of safety" encompasses the following key features: acknowledgment of the high-risk nature of an organization's activities and the determination to achieve consistently safe operations; a blame-free environment where individuals are able to report errors or near misses without fear of reprimand or punishment; encouragement of collaboration across ranks and disciplines to seek solutions to patient safety problems; organizational commitment of resources to address safety concerns.)

¹² OIG (Office of the Inspector General). *Report (OEI-06-09-00091): Hospital Incident Reporting Systems Do Not Capture Most Patient Harm*. <https://oig.hhs.gov/oig/reports/oei-06-09-00091.asp> (last accessed 11/2/12). See also *infra*: *Learn Step 3* for ONC's plan to promote use of PSOs by providers.

¹³ The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) authorized the creation of Patient Safety Organizations (PSOs) to improve the quality and safety of U.S. health care delivery. The Patient Safety Act encourages clinicians and health care organizations to voluntarily report and share quality and patient safety information without fear of legal discovery.

2. Engage health IT developers to embrace their shared responsibility for patient safety and promote reporting of patient safety events and risks.

The Electronic Health Record Association's (EHRA) Statement of Commitment to Patient Safety and Learning Healthcare System is a first step in ensuring that developers embrace a shared responsibility and support a culture of safety.¹⁴ ONC will work with EHRA, health IT developers, and other professional groups to develop a code of conduct – within 12 months of the release of this Health IT Patient Safety Plan – that is aligned with a credible mechanism for holding health IT developers accountable. At a minimum, this code of conduct should:

- Ensure business practices are in place to promote the usability and safety (safe design) of health IT products and adverse event reporting.
- Ensure health IT developers work with a PSO,¹⁵ or a similar entity, to report, aggregate, and analyze health IT-related safety events. Developers should collaborate and provide safety information related to their product for the purposes of improving patient safety. Currently, the patient safety work product (PSWP) protections¹⁶ do not extend to developers reporting events to PSOs. However, HHS believes there may be ways developers can mitigate risks of reporting. HHS will monitor this and would consider suggestions on how to expand PSWP protections.
- Support provider reporting of safety events. The IOM identified legal (contractual nondisclosure clauses and intellectual property protections) and other factors that may inhibit the free exchange of information to be a potential barrier to patient safety and transparency. Although ONC recognizes the importance of contractual and intellectual property protections, it also recognizes that many EHR users may be deterred from exchanging information or from reporting if those contract provisions are not qualified or clarified to encourage such activities. Most patient safety event reporting does not violate such protections, and developers should not use such protections to prevent users from reporting patient safety - related events.
- Ensure developers cooperate with efforts to compare user experiences across different EHR systems. Publicly available information on comparative user experience can help health IT purchasers make more informed choices related to the safety of products.

ONC will monitor developers progress towards these goal and ensure that they are complying with their commitments to a culture of safety.

¹⁴ Electronic Health Record Association. *Statement of Commitment to Patient Safety and Learning Healthcare System*. http://www.himsssehra.org/docs/20120221_EHRAPatientSafetyStatementofCommitment.pdf (last accessed 11/1/12).

¹⁵ AHRQ. *Patient Safety Organizations*. <http://www.pso.ahrq.gov>. (last accessed 12/17/2012.)

¹⁶ Office of Civil Rights (OCR). *Understanding Patient Safety Confidentiality*. <http://www.hhs.gov/ocr/privacy/psa/understanding/index.html> (last accessed 12/20/2012)

In addition to the code of conduct, ONC will work with private organizations, developers, and providers to make more health IT – related safety information available. Workgroups or common interest groups that focus on health IT and safety could be established at professional forums, such as the Healthcare Information and Management Systems Society (HIMSS)¹⁷ or the American Medical Informatics Association (AMIA),¹⁸ to help educate developers and users on how to identify and report adverse events, the benefits of using Common Formats, and working with PSOs.

3. Provide support to Patient Safety Organizations (PSOs) to identify, aggregate, and analyze health IT safety event and hazard reports.

AHRQ will provide technical assistance on using Common Formats, rendering patient safety event data non-identifiable (as needed) and making health IT – related patient safety reports available in the Network of Patient Safety Databases (NPSD).¹⁹ AHRQ will encourage PSOs to help providers use AHRQ Common Formats when submitting health IT - related patient safety events to PSOs. This will allow PSOs to more efficiently identify, aggregate, and analyze health IT – related patient safety reports. AHRQ also funds a technical assistance center for PSOs -the PSO Privacy Protection Center (PSO – PPC), an entity that makes information that is collected by the PSOs nonidentifiable and submits the nonidentified data to the NPSD.²⁰ The NPSD will analyze reported events that are related in some way to the use of health IT or that can be avoided or mitigated by more effective use of health IT. HHS will publish a report of its findings. To complement aggregate analysis done at the NPSD, PSOs and individual hospitals can conduct both aggregate analysis and in-depth analysis on individual events using the Common Formats.

To improve the ability to analyze data and collaboratively address health IT – related safety issues, AHRQ will issue guidance on how all stakeholders can incorporate health IT expertise and collaborate for the purposes of analyzing and correcting health IT – related adverse events, trends, and risks. ONC will encourage PSOs, providers, and developers to work with private

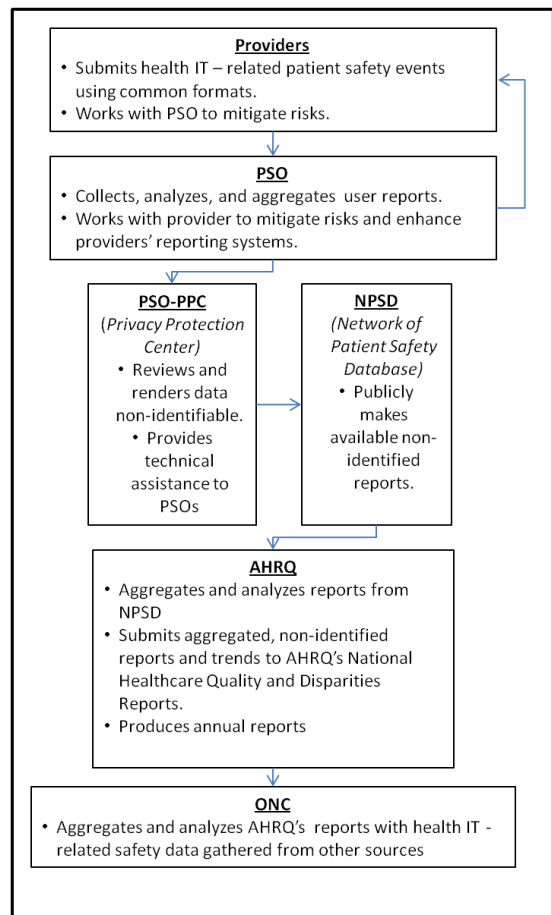


Figure 1: AHRQ/PSO

¹⁷ HIMSS. <http://www.himss.org/> (last Accessed 12/19/2012)

¹⁸ AMIA <http://www.amia.org/> (last Accessed 12/19/2012)

¹⁹ Network of Patient Safety Databases <http://www.pso.ahrq.gov/npsd/npsd.htm> (last accessed 11/29/2012)

²⁰ The PSO Privacy Protection Center. <https://www.psoppcc.org> (last accessed 12/20/2012)

organizations that already have experience collaborating with and analyzing safety issues in other industries, such as aviation.

4. Incorporate health IT safety in post-market surveillance of certified EHR technology through ONC-Authorized Certification Bodies (ONC-ACBs).

ONC will work with ONC-ACBs and the ONC-Approved Accreditor (currently the American National Standards Institute (ANSI)) to add a focus on health IT safety surveillance through ONC’s certification program.

ONC will provide guidance regarding: 1) developers keeping a record of complaints; 2) making complaint records available to the certification body upon request; 3) taking appropriate action with respect to complaints; and 4) documenting actions taken. ONC will also provide guidance to ONC-ACBs on reviewing complaints, safety issues related to capabilities for which certification is required, and the type and level of information included in the annual surveillance report submitted to ONC.

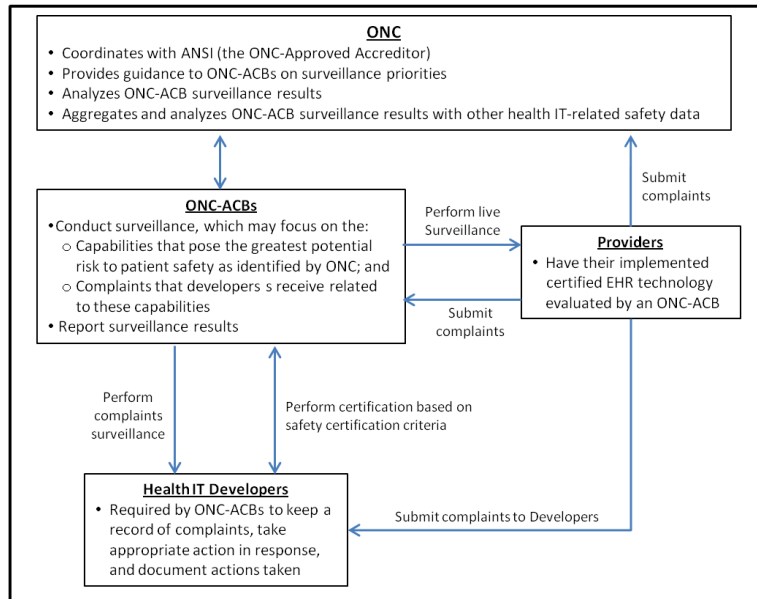


Figure 2: ONC-ACB

ONC expects that ONC-ACBs will conduct surveillance to ensure that the capabilities of certified EHR technology work in operational settings (in the field or in a live environment) to the same extent as when they were certified, and ONC-ACBs could review and validate a sample of the complaints EHR technology developers receive.

In reporting its surveillance results to ONC, an ONC-ACB will be expected to indicate whether the EHR technology was functioning in a manner consistent with its certification and, if not, the reasons why it was not functioning in this manner (e.g., implementation error, a misapplication by a user, or other factors). ONC will provide more specific guidance to the ONC-ACBs in coordination with ANSI for conducting surveillance under the ONC HIT Certification Program.

5. Align CMS health and safety standards with the safety of health IT, and train surveyors.

CMS plans to align its health and safety standards for providers and suppliers and its interpretive guidance, as needed, related to the safety of health IT with this Health IT Safety Plan. Working with ONC, CMS plans to also develop training for surveyors that enhances their ability to identify safe and unsafe practices associated with health IT.

State survey agencies conduct thousands of complaint investigation surveys on CMS' behalf each year. When surveys identify deficient practices, providers and suppliers must submit to CMS a plan of correction for achieving compliance.

The Medicare health and safety standards for many types of health care facilities already address areas of patient safety in which health IT is critical. For example, the Hospital Conditions of Participation (CoPs) include a requirement for each hospital to have a Quality Assessment and Performance Improvement program that includes internal adverse incident reporting and effective follow - up. By using health IT to promote effective reporting and follow - up, health IT can make patient care safer overall, as well as identify and improve patient safety issues related to health IT itself. For instance, hospitals are required under the CoPs to track adverse drug events. Inasmuch as health IT may be one cause of a medication error, the hospital's incident reporting system should be able to identify the error and its potential causes. This is true of many of the other areas addressed in the Medicare health and safety standards.

Additionally, CMS is currently educating its surveyors to look for use of the AHRQ Common Formats in hospitals' internal adverse incident reporting systems.

6. Collect data on health IT safety events through the Quality & Safety Review System (QSRS).

AHRQ is currently building the Quality & Safety Review System (QSRS), a replacement for the Medicare Patient Safety Monitoring System (MPSMS), which incorporates the AHRQ Common Formats to broaden the surveillance to harm from all causes.

The QSRS, a software system designed to perform retrospective surveillance for adverse events and scheduled for completion in 2014, will provide national estimates of adverse events using the Common Formats and can explore the role of health IT in these events. QSRS software will initially be deployed at the CMS Clinical Data Abstraction Center and is being designed for use on a voluntary basis by local entities such as states, hospital networks, or individual hospitals.

Since the QSRS will not be completed until 2014, in the interim, AHRQ intends to support research that will provide better estimates of the frequency, type, and harm level occurring with adverse

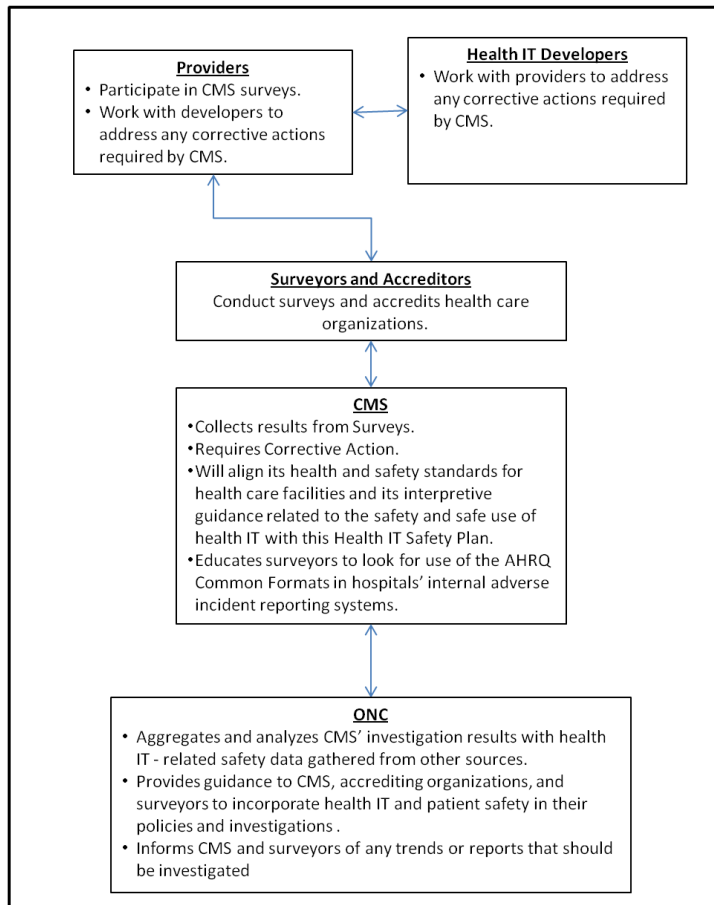


Figure 3: CMS

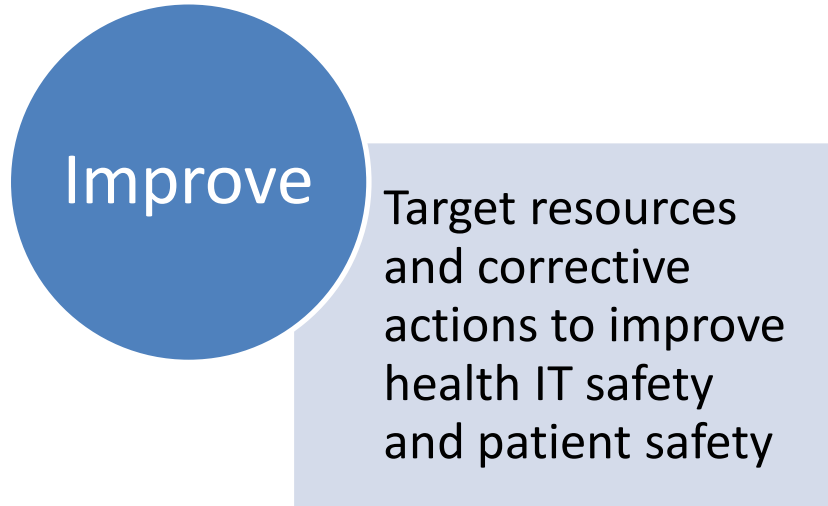
events related to health IT. Additionally, while the QSRS is under development, AHRQ has added a new query to the MPSMS. For 2012 data, MPSMS abstractors will identify which patient records in the sample are from EHRs, paper records, and mixed records. This may provide insight into whether the incidence of the combined rate of adverse events measured by MPSMS is different varies with levels of health IT integration.

7. Monitor health IT adverse event reports to the Manufacturer and User Facility Device Experience (MAUDE) database.

ONC will monitor health IT adverse event reports to the FDA MAUDE database²¹ to identify potential trends of health IT patient safety risks. MAUDE is a searchable database of adverse event reports on devices, containing data that includes voluntary reports, user facility reports and device manufacturers' reports.

²¹ MAUDE - Manufacturer and User Facility Device Experience.
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm>

Health IT Patient Safety Strategies and Actions



IOM's 1999 report, *To Err is Human*, states that the use of information technology can improve patient safety through automated order entry, clinical reminders, and drug - drug interaction and drug - allergy checking.²² When clinicians, managers, and health care executives and board members act to reduce hospital acquired conditions and avoidable readmissions, health IT can be an essential tool to support those efforts. Compared with paper based systems, health IT provides an efficient mechanism to identify problem areas, monitor changes in those areas, measure success, and implement improvements.

While the magnitude of establishing such a national infrastructure was hard to imagine in 1999, the Medicare and Medicaid EHR Incentive Program is a realization of that goal. As of September 2012, more than 150,000 providers met the criteria to receive CMS Medicare or Medicaid EHR Incentive Program payments; 80 percent of eligible hospitals (4,057 hospitals) successfully registered for the incentive program; 55 percent of Medicare eligible professionals (208,331 eligible professionals) have successfully registered; and 94,741 Medicaid eligible providers have also successfully registered in 44 states.

1. Use Meaningful Use of EHR technology to improve patient safety.

HHS has already taken steps toward this end through the Medicare and Medicaid EHR Incentive Program and the ONC regulations for certified EHR technology. This program directly addresses “the absence of real progress toward restructuring health care systems to address both quality and cost concerns, or toward applying advances in information technology to improve administrative and

²² IOM. *To Err Is Human: Building a Safer Health System*. Washington, DC: The National Academies Press, 2000 (available at <http://www.iom.edu/Reports/1999/To-Err-is-Human-Building-A-Safer-Health-System.aspx>).

clinical processes.”²³ For example, EHR payment incentive requirements such as maintaining lists of patient medications, allergies, and problems, as well as the use of computerized provider order entry (CPOE) are very tangible elements of a growing safety infrastructure. As part of a request for public comment on Meaningful Use Stage 3, the HIT Policy Committee is seeking comments on whether there should be a Meaningful Use requirement for providers to conduct a health IT safety risk assessment.

Health IT products provide inherent safety advantages over paper records in that patient record is rarely physically lost, is legible, is rapidly available in multiple locations, and often provides clinical decision support. But just as paper records can be incomplete, inaccurate, and inaccessible, so can electronic records, compromising their safe use. ONC plans to work with its federal advisory committees determine ways to improve clinical documentation, thereby, reducing the risk that records will be inaccessible or their accuracy or completeness compromised.

2. Incorporate safety into certification criteria for health IT products.

Features — such as CPOE functions and maintaining lists of patient medications, allergies, and medical conditions— are already requirements for EHR certification. The safety of EHR developer products and services can be improved by encouraging the development and adoption of recognized industry standards for usability and quality management processes can further ensure.

As part of the 2014 Edition Standards and Certification Criteria final rule, ONC adopted two enhanced certification criteria drawn from IOM recommendations. Certified EHR technology developers will be required to publicly identify a method of incorporating user - centered design of eight certification criteria that have a high likelihood of helping to prevent medical errors.²⁴ IOM characterized this type of user - centered design as a way of making “the right thing to do the easy thing to do.”²⁵ Certified EHR technology developers will also be required to provide transparency regarding their approach to “quality management systems,”²⁶ which IOM characterized as “driving performance characteristics at each level to make sure that the product and specifications are in line with the users’ needs and expectations.”²⁷ ONC intends to continue using its standards and certification criteria and certification program rulemaking in ways that enhance health IT patient safety, focusing on human factors, safety culture, and user - centered design.

²³ IOM. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Page 3. Washington, DC: The National Academies Press, 2001 (Available at <http://www.iom.edu/Reports/2001/Crossing-the-Quality-Chasm-A-New-Health-System-for-the-21st-Century.aspx>).

²⁴ 77 Fed Reg 54186-54189 (September 4, 2012).

²⁵ IOM (Institute of Medicine). 2012 *Health IT and Patient Safety: Building Safer Systems for Better Care*. Washington, DC: The National Academies Press. Page 81. See Chapter 4, Opportunities to Build a Safer System for Health IT.

²⁶ 77 Fed Reg 54189-54191 (September 4, 2012). The final rule gives CEHRT developers the option during Stage 2 to satisfy this certification criteria by publicly declining to identify a quality management system program used in software development.

²⁷ IOM Report at 143.

3. Support research and development of testing, user tools, and best practices related to health IT safety and its safe use.

The National Institute for Standards and Technology (NIST), with support from ONC, has developed tools for usability testing of certified EHR technology. Building from NIST's work the Strategic Health IT Advanced Research Projects - C (SHARP - C) Program is developing usability testing tools. ONC and NIST will continue to build on this work, and ONC may use it to strengthen safety-enhanced certification criteria.

ONC, AHRQ, and NLM are each supporting development and piloting of different interventions and tools aimed at improving health IT safety, and evaluating the effectiveness of those tools in hospitals and provider practices (e.g., Hazard Manager, Promoting Patient Safety through Effective Health IT Risk Management, SAFER Guides, Workflow Assessment for Health IT Toolkit, Guide to Reducing Unintended Consequences of Electronic Health Records, Implementation Toolsets for E-Prescribing – see also Appendix A). AHRQ already has a portfolio of useful tools and reports for addressing the potential safety issues that arise when implementing and using EHRs.

The accurate and efficient matching of patients to their health information is critical to ensuring patient safety. Incorrect matching can result in misinformation and medical error. In 2013, ONC is moving ahead on recommendations to improve patient matching, including approaches that address workflow issues, data quality, functional and technical requirements, data standards and policy.

ONC is also conducting analysis using CMS and AHRQ datasets to determine the association between health IT and adverse drug events and the association between meaningful use and hospital acquired conditions.

4. Incorporate health IT safety into medical education and training for all health care providers.

Accrediting bodies, patient safety organizations, liability insurers, educational organizations, and professional associations should support an open culture of safety and integrate health IT patient safety into their programs and practices.

To that end, ONC will work with the organizations to foster a culture of safety and the dissemination of best – in - class tools and strategies to effectively reduce health IT related adverse events and to use health IT to make care safer.

As part of an ONC contract on Anticipating Unintended Consequences,²⁸ health IT safety researchers²⁹ are developing health IT safety guides, Safety Assurance Factors for EHR Resilience (SAFER) Guides. The SAFER Guides — which are being developed based on existing research, expert opinion, stakeholder engagement, and field work — should enable everyone who is

²⁸ Westat Task Order HHSP23337003T/HHSP23320095655WC. Unintended Consequences of Health IT and HIE.

²⁹ Dean Sittig, University of Texas at Houston; Hardeep Singh, MD, Baylor University and VA; Joan Ash, Oregon Health and Science University.

responsible for safety in health systems and ambulatory settings to implement safety programs for health IT in critical areas.³⁰

5. Investigate and take corrective action, when necessary, to address serious adverse events or unsafe conditions involving EHR technology.

Reports of specific adverse events or patterns of serious events must trigger investigations and, when appropriate, corrective actions.

The IOM recommended establishing a new federal entity, similar to the National Transportation Safety Board (an independent federal agency charged by Congress with investigating every civil aviation accident the United States). HHS' approach builds on existing Federal authorities (e.g. CMS, AHRQ, and ONC).

HHS is also interested in working with private sector organizations that have the ability to investigate, take corrective actions, and publicly report on their analysis of events.

CMS plans to provide guidance to state surveyors and accreditation organizations with CMS-approved programs, so that these entities can recognize and investigate health IT – related adverse events. Accreditation organizations and surveyors should conduct investigations, when necessary, to determine the causes of adverse events or unsafe conditions involving EHR technology.

ONC will work with developers to request voluntary corrective action when HHS becomes aware of a potential serious safety risks through the programs described in this Health IT Safety Plan. HHS will consider issuing public notices related to serious adverse events or unsafe conditions involving EHR technology.

³⁰ SAFER Guides are being developed in the following areas: inpatient ordering process and computerized provider order entry (including for medications, laboratory tests, radiology, nutrition, etc.); ambulatory physician practice medication ordering process, e-Prescribing; inpatient and outpatient system customization/configuration and upgrades; system–system interfaces, both inpatient and ambulatory; patient identification processes, both inpatient and ambulatory; clinical decision support, inpatient and ambulatory; communication between providers – ambulatory physician practice and hospital discharge; laboratory results review processes – ambulatory physician practice and hospital discharge; downtime events, both inpatient and ambulatory; roles and skills of people needed for EHR safety, both inpatient and ambulatory.

Health IT Patient Safety Strategies and Actions



Leadership is essential to building high reliability organizations with strong safety cultures. HHS has already taken a leadership role by promoting adoption and meaningful use of health IT to improve health care safety and outcomes.

This Health IT Safety Plan lays out concrete steps to improve federal coordination and integrate health IT patient safety into existing federal programs. It also outlines how HHS plans to collaborate with the private sector to promote patient safety in a health IT enabled care delivery system.

1. Develop health IT safety priority areas, measures, and targets.

ONC plans to lead a public - private process to identify health IT safety priority areas within that larger context general patient safety, and create related measures and targets for reduction of health IT – related adverse events.

ONC has already initiated research that will inform this process by contracting to develop health IT safety guides (i.e., SAFER Guides) and to pilot test and evaluate health IT risk management interventions in hospitals and ambulatory settings (i.e., Promoting Patient Safety Through Effective Health IT Risk Management)³¹ (see Appendix B for more research and development of guides, tools, and interventions). The SAFER Guides will be a checklist tool available to all providers to use in assessing and mitigating risks related to health IT.

³¹ Rand Corporation, Task Order HHSP23337026T

2. Publish a report on a strategy and recommendations for an appropriate, risk-based regulatory framework for health IT.

Congress passed the FDA Safety and Innovation Safety Act of 2012. This Act tasked the FDA – in collaboration with ONC and the Federal Communications Commission (FCC) – with creating a report, within 18 months, which proposes a strategy and recommendations for an appropriate, risk-based regulatory framework for health IT which promotes safety and innovation. This report will be developed with significant public input and will incorporate what HHS learns about risk, safety, and opportunity for innovative technologies to support improved health outcomes.

It is clear that there are opportunities to consider how to make it easier for innovators to understand the regulatory landscape, ways to minimize regulatory burden – such as the complexity of navigating numerous agencies, and to design an oversight approach that supports innovations and patient safety.

3. Establish an ONC Safety Program to coordinate the implementation the Health IT Safety Plan.

ONC plans to establish an ONC Safety Program to coordinate and implement this Health IT Safety Plan (See figure in Appendix D). The function of this program is to:

- Coordinate the implementation of the Health IT Safety Plan by
 - Ensuring all actors are fulfilling their responsibilities under the Plan
 - Collaborating with actors to incorporate health IT and patient safety in their organizations
- Comprehensively analyze data from the data streams, which includes
 - Collecting and aggregating data among the different data streams
 - Identifying trends in patient safety and health IT
 - Providing feedback to developers and providers
 - Submitting policy recommendations to government agencies and Congress
- Eliminate or significantly reduce inefficiencies across the programs by
 - Identifying any unnecessary overlap that occurs when implementing the Health IT Safety Plan
 - Evaluating the outcomes and effectiveness of the Health IT Safety Plan as it is implemented
 - Determining from the outcomes what actions are beneficial, unnecessary, or insufficient (and whether additional actions are required)

Although led and run by ONC, this program will work with and gather input from federal partners — including AHRQ, CMS, FDA, and OCR³² — to accomplish the above goals. Also, HHS will

³² OCR administers the HIPAA Security Rule, which sets national standards for the confidentiality, integrity and availability of electronic protected health information. These are key components to addressing health IT patient safety. OCR has also been delegated responsibility for enforcing the confidentiality provisions of the Patient Safety and Quality Improvement Act (PSQIA).

develop policies and procedures to establish an ad hoc HHS multi-Agency steering committee to address major health IT safety issues.

4. Encourage state governments to incorporate health IT into their patient safety oversight programs.

State governments play a vital role in patient safety oversight. In some cases federal and state patient safety programs are aligned, such as the coordination of Medicare and Medicaid on health and safety standards required for participation in those programs. States also license health care professionals and facilities. In addition, 26 states have mandatory adverse event reporting laws requiring, in certain circumstances, reporting of adverse events to the state.

AHRQ has encouraged states to use the Common Formats to make it possible to aggregate and compare adverse events across federal and state programs. Today, state adverse event reporting programs do not identify the role health IT may play in patient safety, including in monitoring, reporting and improving care processes. HHS will encourage state involvement in the public-private process to refine health IT patient safety priorities, measures, and targets. Also, HHS will coordinate with state governments to effectively integrate health IT into existing patient safety efforts.

5. Encourage private sector leadership and shared responsibility for health IT patient safety. (IOM Report, Chapter 6, "Shared Responsibility for Improving Health IT Safety")

All stakeholders have an interest in ensuring that health IT is safe and that health IT enhances patient safety. The Health IT Safety Plan aims to engage and align private sector efforts. Clinical users of health IT and health IT developers are primarily responsible for ensuring patient safety, with full support and engagement of professional and trade associations, medical educators, liability insurers and private organizations supporting patient safety.

Throughout the Health IT Safety Plan, HHS identifies ways that private sector stakeholders can lead critical efforts to improve health IT safety.

Appendices

Appendix A: Crosswalk of Health IT Patient Safety Plan & IOM's 2011 Recommendations from *Health IT and Patient Safety: Building Safer Systems for Better Care*

IOM Recommendation	Actions
<p>Recommendation 1.</p> <p>The Secretary of Health and Human Services (HHS) should publish an action and surveillance plan within 12 months that includes a schedule for working with the private sector to assess the impact of health IT on patient safety and minimizing the risk of its implementation and use. The plan should specify:</p>	<p>This Health IT Patient Safety Plan is the action and surveillance plan prescribed in Recommendation 1. ONC will coordinate the various actors among the public and private sectors to improve the safety of health IT and use health IT to improve patient safety.</p>
<p>Recommendation 1.a.</p> <p>The Agency for Healthcare Research and Quality (AHRQ) and the National Library of Medicine (NLM) should expand their funding of research, training, and education of safe practices as appropriate, including measures specifically related to the design, implementation, usability, and safe use of health IT by all users, including patients.</p>	<p>ONC, AHRQ and NLM are disseminating and piloting interventions and tools aimed at improving health IT safety, and evaluating the effectiveness of those tools in hospitals and provider practices (e.g., Hazard Manager, Promoting Patient Safety through Effective Health IT Risk Management, SAFER Guides). AHRQ already has a significant portfolio of useful tools and reports for addressing the potential safety issues that arise when implementing and using EHRs, including the following:</p> <ul style="list-style-type: none"> ● Hazard Manager is a software tool that will alert users to potential health IT-related patient safety events. It evaluates near misses and unsafe conditions, which allows users to avoid patient harm before it occurs. Although not yet available, the Hazard Manager will support a wide variety of health industry professionals by helping them discover, identify, and communicate hazards. ● Promoting Patient Safety through Effective Health IT Risk Management ● SAFER Guides

IOM Recommendation	Actions
Recommendation 1. a. <i>continued</i>	<ul style="list-style-type: none"> • Workflow Assessment for Health IT toolkit available at www.healthit.ahrq.gov/workflow is designed to help small and medium-sized outpatient practices better assess their workflows and determine when and how health IT may be used. This comprehensive compendium of information describing workflow in the context of health IT includes: <ul style="list-style-type: none"> ○ information on how to analyze workflow, ○ tools to analyze workflow, ○ examples of workflow analysis and redesign, ○ others’ experiences with health IT and workflow, and ○ research on health IT and workflow.
Recommendation 1. a. <i>continued</i>	<ul style="list-style-type: none"> • Guide to Reducing Unintended Consequences of Electronic Health Records – an online resource posted on healthIT.gov that helps organizations and their consultants anticipate, avoid, and troubleshoot problems and challenges that can emerge when implementing and using an electronic health record (EHR).
Recommendation 1. a. <i>continued</i>	<ul style="list-style-type: none"> • Implementation Toolsets for E-Prescribing – These two toolsets, one for physicians in small practices and one for independent pharmacies, for supporting e-prescribing implementation are designed to offer a step-by-step guide preparing for and launching an e-prescribing system. They include advice on topics ranging from planning the implementation process, launching the system, troubleshooting common problems, and navigating into more advanced practice and pharmacy services. Both toolsets and supporting tools are available at http://healthit.ahrq.gov/eprescribingtoolsets

IOM Recommendation	Actions
Recommendation 1. a. <i>continued</i>	ONC will coordinate with liability insurers, educational organizations, and professional associations to foster a culture of safety and the dissemination of best-in-class tools and strategies to effectively reduce health IT related adverse events and to use health IT to make care safer. As part of an ONC contract on Anticipating Unintended Consequences, ³³ health IT safety researchers ³⁴ are developing health IT safety guides, Safety Assurance Factors for EHR Resilience (SAFER) Guides.
<p>Recommendation 1.b.</p> <p>The Office of the National Coordinator for Health Information Technology should expand its funding of processes that promote safety that should be followed in the development of health IT products, including standardized testing procedures to be used by manufacturers and health care organizations to assess the safety of health IT products.</p>	<p>The National Institute for Standards and Technology (NIST), with support from ONC, has developed tools for usability testing of certified EHR technology. NIST and ONC will continue to build upon this work, and ONC will use it to strengthen safety-enhanced certification criteria.</p> <p>The Strategic Health IT Advanced Research Projects – C (SHARP -C) Program is developing usability testing tools using NIST protocols.</p>
<p>Recommendation 1.c.</p> <p>The ONC and AHRQ should work with health IT vendors and health care organizations to promote post deployment safety testing of EHRs for high-prevalence, high-impact EHR-related patient safety risks.</p>	<p>The Plan calls for ONC to inform ONC-ACBs of our surveillance priorities in order identify those EHR technology capabilities that ONC believes pose the greatest potential for patient harm and greatest opportunity to improve in future regulatory cycles. ONC will encourage ONC-ACBs to conduct surveillance to ensure that these capabilities work in operational settings and validate a sample of the complaints EHR technology developers.</p>

³³ Westat Task Order HHSP23337003T/HHSP23320095655WC. Unintended Consequences of Health IT and HIE.

³⁴ Dean Sittig, University of Texas at Houston; Hardeep Singh, MD, Baylor University and VA; Joan Ash, Oregon Health and Science University.

IOM Recommendation	Actions
<p>Recommendation 1.d.</p> <p>Health care accrediting organizations should adopt criteria relating to EHR safety.</p>	<p>ONC will work with CMS to align the health and safety standards with the Health IT Safety Plan and train surveyors to improve their ability to identify safe and unsafe practices related to health IT.</p> <p>States, in enforcing the existing health and safety regulatory standards, investigate complaints on CMS’ behalf. CMS can require corrective action (as needed) for these standards related to the safety of health IT.</p> <p>ONC’s regulations establish standards and certification criteria for certified EHR technology, and ONC intends to use certification criteria to ensure that, where appropriate, EHR technology is used to report safety events.</p>
<p>Recommendation 1.e.</p> <p>AHRQ should fund the development of new methods for measuring the impact of health IT on safety using data from EHRs</p>	<p>AHRQ has developed “Common Formats,” which would standardize the reporting of adverse events. These Formats make it possible to aggregate and compare adverse events across healthcare providers and federal and state programs.</p> <p>The most recent version of the Formats includes a “Device with Health IT” format that allows collection of standardized information about IT-related adverse events as well as all events where health IT may be a contributing factor.</p> <p>AHRQ is currently building the Quality & Safety Review System (QSRS) that incorporates the AHRQ Common Formats to broaden the surveillance of harm from all causes. This system will provide national estimates of adverse events and can explore the role of health IT in these events.</p>

IOM Recommendation	Actions
<p>Recommendation 2.</p> <p>The Secretary of HHS should ensure insofar as possible that health IT developers support the free exchange of information about health IT experiences and issues and not prohibit sharing of such information, including details (e.g., screenshots) relating to patient safety.</p>	<p>ONC will engage developers and facilitate the development of a voluntary code of conduct that ensures business practices are in place that promote adverse event reporting.</p> <p>As part of the ONC HIT Certification Program, ONC established the Certified HIT Product List (CHPL). The CHPL provides the comprehensive listing of Complete EHRs and EHR Modules that have been certified by ONC-Authorized Certification Bodies (ONC-ACBs). This listing is a publicly available database of health IT products that are certified in accordance with ONC’s standards and certification criteria regulations. Currently, each individual EHR product listed in the database notes the presence/absence of safety features such as drug - drug interaction or drug- allergy checking. ONC’s newest certification criteria also require developers to incorporate user centered design and these details will be included in EHR technology test reports. If there is a need for further registration and listing to promote transparency related to the safety of health IT beyond ONC’s existing CHPL, ONC will consider using its current authorities to broaden the list.</p> <p>ONC-ACBs are required to submit a hyperlink of the test results used to issue a certification to EHR technology that are publicly accessible</p>

IOM Recommendation	Actions
<p>Recommendation 3.</p> <p>The ONC should work with the private and public sectors to make comparative user experiences across vendors publicly available.</p>	<p>ONC will support and collaborate with the private sector to publish information on comparative user experiences.</p> <p>The Plan will encourage AHRQ and Patient Safety Organizations (PSOs) to increase data collection and analysis of health IT safety events and hazards. PSOs will work with providers to report adverse events involving health IT using the AHRQ Common Formats, and to report those events to the Network of Patient Safety Databases (NPSD).</p> <p>The Plan also calls for EHR developers to facilitate and encourage adverse event reporting using the AHRQ Common Formats, and allow for the reporting of comparative user experiences related to the safety and reliability of health IT.</p>

IOM Recommendation	Actions
<p>Recommendation 4.</p> <p>The Secretary of HHS should fund a new Health IT Safety Council to evaluate criteria for assessing and monitoring the safe use of health IT and the use of health IT to enhance safety. This council should operate within an existing voluntary consensus standards organization.</p>	<p>The Plan does not call for the creation of a Council, but ONC plans to establish an ONC Safety Program to coordinate and implement this Plan. The function of this program is to:</p> <ul style="list-style-type: none"> • Coordinate the implementation of the Health IT Safety Plan by <ul style="list-style-type: none"> ○ Ensuring all actors are fulfilling their responsibilities under the Plan ○ Collaborating with actors to incorporate health IT and patient safety in their organization ○ Providing funding, if available and when necessary • Comprehensively analyze data from the different data entities, which includes <ul style="list-style-type: none"> ○ Collecting and aggregating data among the different data entities ○ Identifying trends in patient safety and health IT ○ Providing feedback to developers and providers ○ Submitting policy recommendations to government agencies and Congress • Eliminate or significantly reduce inefficiencies across the programs by <ul style="list-style-type: none"> ○ Identifying any unnecessary overlap that occurs when implementing the Plan (e.g., whether multiple agencies are investigating the same events) ○ Evaluating the outcomes and effectiveness of the Plan as it is implemented ○ Determining from the outcomes what actions are beneficial, unnecessary, or insufficient (and whether additional actions are required) <p>The ONC Safety Program will develop policies and procedures to establish an ad hoc steering committee that addresses major health IT safety issues.</p>
<p>Recommendation 5.</p> <p>All health IT developers should be required to publicly register and list their products with the ONC, initially beginning with EHRs certified for the meaningful use program.</p>	<p>Registering and listing EHR developer products certified for Meaningful Use is already being performed by ONC. The Plan will also incorporate additional health IT-related safety criteria for certification.</p>

IOM Recommendation	Actions
<p>Recommendation 6.</p> <p>The Secretary of HHS should specify the quality and risk management process requirements that health IT developers must adopt, with a particular focus on human factors, safety culture, and usability.</p>	<p>As part of the 2014 Edition Standards and Certification Criteria final rule, ONC adopted two safety-enhanced certification criteria. This regulation included requirements for the application of user-centered design and quality management systems.</p> <p>ONC will fund health IT safety interventions in hospitals and physician practices to evaluate risk management implementation processes and interventions related to the safety of health IT.</p> <p>ONC will support research of approaches that would inform the processes necessary to mitigate risks and improve the quality and accuracy of patient matching.</p>
<p>Recommendation 7.</p> <p>The Secretary of HHS should establish a mechanism for both developers and users to report health IT–related deaths, serious injuries, or unsafe conditions.</p>	<p>ONC will work with AHRQ, PSOs, and the FDA to collect and analyze reports of health IT–related deaths, serious injuries, or unsafe conditions.</p>
<p>Recommendation 7.a.</p> <p>Reporting of health IT–related adverse events should be mandatory for developers.</p>	<p>ONC will engage developers and facilitate the development of a voluntary code of conduct that ensures vendors work with safety organizations to aggregate and analyze events and promote adverse event reporting among providers.</p> <p>ONC-ACBs will be encouraged to review documentation of complaints and provide de-identified reports to ONC.</p> <p>ONC will monitor health IT adverse event reports using the FDA’s Manufacturer and User Facility Device Experience (MAUDE) database.</p>

IOM Recommendation	Actions
<p>Recommendation 7.b.</p> <p>Reporting of health IT–related adverse events by users should be voluntary, confidential, and nonpunitive.</p>	<p>AHRQ will encourage PSOs to help providers incorporate AHRQ Common Formats when reporting health IT - related patient safety events to the Network of Patient Safety Databases (NPSD).</p> <p>AHRQ is already developing the Quality & Safety Review System (QSRS) to facilitate retrospective, surveillance of harm from all causes, health IT safety events. AHRQ will also investigate development of a health IT profile for hospitals with QSRS that can detect differences in adverse event rates at hospitals correlated with their level of health IT implementation.</p> <p>AHRQ will also issue guidance on how to more effectively involve health IT expertise, including from EHR developers, in reporting to PSOs and in analysis and correction of problems.</p> <p>ONC will coordinate with state governments to encourage the reporting of health IT-related adverse events and to encourage providers to use AHRQ Common Formats when reporting.</p>

IOM Recommendation	Actions
<p>Recommendation 7.c.</p> <p>Efforts to encourage reporting should be developed, such as removing the perceptual, cultural, contractual, legal, and logistical barriers to reporting.</p>	<p>The Plan also calls for AHRQ to encourage PSOs to help providers use AHRQ Common Formats when reporting patient safety events. The most recent version of the Formats includes a “Device with Health IT” format that allows collection of standardized information about IT-related adverse events as well as all events where health IT may be a contributing factor.</p> <p>To help inform ONC’s work with standards and certification criteria related to patient safety, AHRQ plans to test extraction of data elements identical and related to AHRQ’s Common Formats from multiple established EHR implementations and exportation of this data to hospital incident reporting systems.</p> <p>ONC recently funded a Purple Challenge Award to address the need for development of tools and interfaces that decrease reporting burden and improve workflow efficiency that surround adverse event reporting to hospital incident reporting systems and PSOs.</p> <p>ONC’s regulations establish standards and certification criteria for certified EHR technology, and ONC intends to propose using certification criteria to ensure that, where appropriate, EHR technology is can be used to report safety events in AHRQ’s Common Formats.</p>
<p>Recommendation 8.</p> <p>The Secretary of HHS should recommend that Congress establish an independent federal entity for investigating patient safety deaths, serious injuries, or potentially unsafe conditions associated with health IT. This entity should also monitor and analyze data and publicly report results of these activities.</p>	<p>Currently, the Health IT Safety Plan does not include the establishment of an independent federal entity. However, the plan incorporates many of the functions described in IOM’s recommendation 8 into existing patient safety efforts across government programs and the private sector — including health care providers, technology companies, and health care safety oversight bodies.</p>

IOM Recommendation	Actions
<p>Recommendation 9.a.</p> <p>The Secretary of HHS should monitor and publicly report on the progress of health IT safety annually beginning in 2012. If progress toward safety and reliability is not sufficient as determined by the Secretary, the Secretary should direct FDA to exercise all available authorities to regulate EHRs, health information exchanges, and PHRs.</p>	<p>This Health IT Patient Safety Plan serves as the HHS report on the progress of health IT safety for 2012</p>
<p>Recommendation 9.b.</p> <p>The Secretary should immediately direct FDA to begin developing the necessary framework for regulation. Such a framework should be in place if and when the Secretary decides the state of health IT safety requires FDA regulation as stipulated in Recommendation 9a above.</p>	<p>Under the FDA Safety and Innovation Safety Act of 2012, the FDA, with the collaboration of ONC and the Federal Communications Commission (FCC), will release a report proposing a strategy and recommendations for an appropriate, risk-based regulatory framework for health IT which promotes safety and innovation.</p>
<p>Recommendation 10.</p> <p>HHS, in collaboration with other research groups, should support cross-disciplinary research toward the use of health IT as part of a learning health care system. Products of this research should be used to inform the design, testing, and use of health IT. Specific areas of research include</p> <ol style="list-style-type: none"> a. User-centered design and human factors applied to health IT, b. Safe implementation and use of health IT by all users, c. Sociotechnical systems associated with health IT, and d. Impact of policy decisions on health IT use in clinical practice. 	<p>ONC, AHRQ, and NLM are each supporting development and piloting of different interventions and tools aimed at improving health IT safety, and evaluating the effectiveness of those tools in hospitals and provider practices (e.g., Hazard Manager, Promoting Patient Safety through Effective Health IT Risk Management, SAFER Guides, Workflow Assessment for Health IT Toolkit, Guide to Reducing Unintended Consequences of Electronic Health Records, Implementation Toolsets for E-Prescribing – see also Appendix A). AHRQ already has a portfolio of useful tools and reports for addressing the potential safety issues that arise when implementing and using EHRs.</p>

Appendix B: Research and Development of Tools, Measures, and Policies

Date	Research/Development Projects
2011	<p><u>IOM study (9/2010-11/2011)</u></p> <ul style="list-style-type: none"> ○ IOM was commissioned by ONC and published the report, <i>“Health IT and Patient Safety: Building Safer Systems for Better Care”</i>
2012	<p><u>Patient Safety Reporting Challenge Award</u></p> <ul style="list-style-type: none"> ○ ONC funded a Purple Challenge Award to encourage development of tools and interfaces that decrease reporting burden ○ The first winner of this challenge was KBCoreSM of Houston
2012	<p><u>Usability Development</u></p> <ul style="list-style-type: none"> • NIST developed tools for usability testing of certified EHR technology. • SHARP- C is developing usability testing tools using NIST protocols. • ONC and NIST will continue to build upon this work, and ONC will use it to strengthen safety-enhanced certification criteria. • Usability Workshop
2012	<p><u>Hazard Manager</u></p> <ul style="list-style-type: none"> • AHRQ has developed the Hazard Manager, a software tool that will alert users to potential health IT-related patient safety events
2012	<p><u>Workflow Assessment for Health IT Toolkit</u></p> <ul style="list-style-type: none"> • AHRQ has developed the Workflow Assessment for Health IT Toolkit, which helps small and medium-sized outpatient practices better assess their workflows and determine when and how health IT may be used.
2012	<p><u>Guide to Reducing Unintended Consequences of Electronic Health Records</u></p> <ul style="list-style-type: none"> • AHRQ has developed the Guide to Reducing Unintended Consequences of Electronic Health Records, which helps anticipate, avoid, and troubleshoot problems associated with EHR.
2012	<p><u>Implementation Toolsets for E-Prescribing</u></p> <ul style="list-style-type: none"> • AHRQ has developed the Implementation Toolsets for E-Prescribing, a guide for preparing for and launching an e-prescribing system.
2012	<p><u>Designing Consumer Health IT: A Guide for Developers and Systems Designers</u></p> <ul style="list-style-type: none"> • AHRQ’s Health IT Portfolio has published “Designing Consumer Health IT: A Guide for Developers and Systems Designers” which presents suggested recommendations for designers and developers of consumer health IT products to incorporate safe design. The guide is available at: http://healthit.ahrq.gov/developmentmethodguide/

Date	Research/Development Projects
2013 ³⁵	<p><u>Professional Forums</u></p> <ul style="list-style-type: none"> • Workgroups or common interest groups should be established at professional forums, such as HIMSS, AMIA, AMA, and other medical professional associations.
2013 ³⁵	<p><u>SAFER Guides (9/2013*)</u></p> <ul style="list-style-type: none"> • ONC has contracted to develop health IT safety guides, such as SAFER Guides.
2013 ³⁵	<p><u>Promoting Patient Safety Through Effective Health IT Risk Management Contract</u></p> <ul style="list-style-type: none"> • ONC has contracted with RAND to engage hospital and ambulatory providers to implement health IT risk management tools
2014 ³⁶	<p><u>Report on appropriate, risk-based regulatory framework for health IT.</u></p> <ul style="list-style-type: none"> • FDA, in collaboration with ONC and FCC, will publish a report on strategy and recommendations for an appropriate, risk-based regulatory framework for health IT which promotes safety and innovation.

³⁵ 2013 action items reflect planned activities.

³⁶ 2014 action items reflect planned activities.

Appendix C: Timeline of the Health IT Patient Safety Action and Surveillance Plan

Date	Actions/Programs
2010	<p><u>CMS Meaningful Use (Stage 1) and ONC standards & Certification (7/2010)</u></p> <ul style="list-style-type: none"> • CMS' Incentive Program requires use of features that can improve patient safety, such as <ul style="list-style-type: none"> ○ CPOEs, ○ CDSs, and ○ Maintaining lists of patient medications, allergies and problems.
2011	<p><u>Certified HIT Product List (CHPL)</u></p> <ul style="list-style-type: none"> • Established by ONC, CHPL provides the authoritative, comprehensive listing of Complete EHRs and EHR Modules that have been certified by ONC-Authorized ONC-ACBs.
2012	<p><u>Medicare Patient Safety Monitoring System (MPSMS)</u></p> <ul style="list-style-type: none"> • To compare the differences in quality and safety, MPSMS abstractors will identify which patient records in the sample are from EHRs, paper records, and mixed records.
2012	<p><u>CMS Meaningful Use (Stage 2) and ONC standards & Certification (8/2012)</u></p> <ul style="list-style-type: none"> • Increased the required use of EHRs (as compared to Meaningful Use (Stage 1)). • ONC adopted two safety-enhanced certification criteria: <ul style="list-style-type: none"> ○ Publicly identify a method of ensuring user-centered design and ○ Publicly identify an approach to quality management system.
2013 ³⁷	<p><u>ONC-ACB Surveillance</u></p> <ul style="list-style-type: none"> • ONC will incorporate health IT and patient safety into ONC-ACB surveillance and certification of EHRs. • ONC will provide guidance to ONC-ACBs, regarding: <ul style="list-style-type: none"> ○ Developers keeping a record of complaints; ○ Making complaint records available to the certification body upon request; ○ Taking appropriate action with respect to complaints and deficiencies found; and ○ Documenting actions taken.
2013 ³⁷	<p><u>Manufacturer and User Facility Device Experience (MAUDE)</u></p> <ul style="list-style-type: none"> • ONC will monitor the MAUDE database for health IT – related adverse event reports.
2013 ³⁷	<p><u>CMS Surveys and Corrective actions</u></p> <ul style="list-style-type: none"> • Align CMS health and safety standards with the safety of health IT, and train surveyors • ONC will work with CMS, state surveyors, and accreditation organizations with CMS-approved programs, so that these entities can recognize and investigate health IT – related adverse events. • CMS can require corrective actions of health IT – related patient safety issues.

³⁷ 2013 action items reflect planned activities.

Date	Actions/Programs
2013 ³⁸	<p><u>Collecting, aggregating, and analyzing reports from AHRQ</u></p> <ul style="list-style-type: none"> • AHRQ will issue guidance on how to more effectively involve health IT expertise, including from EHR developers, in reporting to PSOs and in analysis and correction of problems. • PSOs and AHRQ should incorporate health IT and patient safety when <ul style="list-style-type: none"> ○ Facilitating reporting of patient safety events ○ Investigating patient safety events ○ Working with providers to mitigate patient safety hazards ○ Aggregating and analyzing reports to identify trends in health IT – related patient safety events. • HHS will publish a report based on the findings from the aggregation and analysis of these reports.
2013 ³⁸	<p><u>Increase Transparency and the Free Flow of Information (ONC and Developers)</u></p> <ul style="list-style-type: none"> • ONC will engage health IT developers to facilitate the development of a voluntary code of conduct that: <ul style="list-style-type: none"> ○ Embraces shared responsibility. ○ Supports and makes it clear that users can engage in the full range of adverse event reporting.
2013 ³⁸	<p><u>Encourage Medical Education and Training of Health IT and Patient Safety</u></p> <ul style="list-style-type: none"> • ONC will work with the following types of organizations to foster a culture of safety and the dissemination of best-in-class tools (e.g., SAFER Guides) and strategies: <ul style="list-style-type: none"> ○ Accrediting bodies, ○ Patient safety organizations, ○ Liability insurers, ○ Educational organizations, and ○ Professional associations
2013 ³⁸	<p><u>Establish the ONC Safety Program</u></p> <ul style="list-style-type: none"> • ONC will <ul style="list-style-type: none"> ○ Coordinate the implementation of the Health IT Safety Plan. ○ Comprehensively analyze data from the data streams. ○ Ensure that there are no redundancies or inefficiencies across the programs.

³⁸ 2013 action items reflect planned activities.

Date	Actions/Programs
2013 ³⁹	<p><u>Incorporation of health IT and patient safety reporting by State Governments</u></p> <ul style="list-style-type: none"> • CMS will work with states to look for health IT –related safety issues when conducting Surveys on CMS’s behalf. • ONC will encourage states to consider health IT when collecting, aggregating and analyzing, patient safety data produced by states’ existing reporting requirements
2013 ³⁹	<p><u>Develop Safety measures and targets</u></p> <ul style="list-style-type: none"> • ONC will lead a public-private process to identify health IT safety priority areas within that larger context general patient safety, and create related measures and targets for reduction of health IT – related adverse events.
2013 ³⁹	<p><u>AHRQ’s QSRS</u></p> <ul style="list-style-type: none"> • To increase surveillance, AHRQ will develop the Quality & Safety Review System (QSRS) that incorporates the AHRQ Common Formats.
2013 ³⁹	<p><u>CMS Meaningful Use (Stage 3) and ONC standards & Certification</u></p> <ul style="list-style-type: none"> • Will propose increasing the required use of EHRs (as compared to Meaningful Use [stage 2]). • ONC and CMS will continue to use rulemakings to enhance patient safety. • ONC intends to use certification criteria to ensure that EHR technology is used to report safety events. • HIT Policy Committee is seeking comments on whether there should be a new Meaningful Use requirement for providers to conduct a health IT safety risk assessment.

³⁹ 2013 action items reflect planned activities.

Appendix D: ONC Program

