The Office of the National Coordinator for Health Information Technology

Health Information Technology Patient Safety Action & Surveillance Plan

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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*[1]

Introduction

Over a decade ago, the Institute of Medicine (IOM) report *To Err is Human* raised an alarm about the failure of health care to recognize and reduce the large number of avoidable medical errors harming patients.[2] The ability of health information technology (health IT) to reduce medical errors is one of the reasons for the creation of the Office of the National Coordinator for Health Information Technology (ONC) under the Department of Health and Human Services (HHS) through the Health Information Technology for Economic and Clinical Health (HITECH) Act[3]—passed as part of the American Recovery and Reinvestment Act (Recovery Act) of 2009.[4] In addition to creating ONC, the HITECH Act also provided economic incentives for eligible health care providers to adopt and meaningfully use certified EHR technology.

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

- Medication errors can be substantially reduced and clinical decisions can more easily be made based on evidence. Electronic health records (EHRs) eliminate prescription and other errors resulting from illegible handwriting, while capabilities such as clinical decisions 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. CDS also supports delivery of care to patients based on clinical guidelines, including for preventative care, such as immunizations and routine screening tests.

- Patient records can be stored centrally and easily accessed from multiple locations, making crucial health information available when and where needed as patients move within and between health care organizations. When a patient arrives at an emergency room, providers can begin treatment with electronic access to historical patient records.

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[1] Institute of Medicine (IOM), *Health IT and Patient Safety: Building Safer Systems for Better Care* (National Academy Press, 2012) (hereinafter "IOM Report"), 21, available at http://www.iom.edu/Reports/2011/Health-IT-and-Patient-Safety-Building-Safer-Systems-for-Better-Care.aspx (last accessed May 17, 2013).

[2] IOM, *To Err Is Human: Building a Safer Health System* (National Academy Press, 2000), available at http://www.iom.edu/Reports/1999/To-Err-is-Human-Building-A-Safer-Health-System.aspx (last accessed May 17, 2013).

[3] Pub. L. 111-5, 123 Stat. 115, Division A, Title XIII & Division B, Title IV. The HITECH Act directs the National Coordinator to coordinate the development of a nationwide health IT infrastructure that, *inter alia*, "reduces medical errors" and "improves health care quality." 42 U.S.C. § 300jj-11(b).

[4] Pub. L. 111-5.

- 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 widespread threats to health, such as flu epidemics.

While health IT presents many new opportunities to improve patient care and safety, it can also create new potential hazards.[5] For example, poor user interface design or unclear information displays can contribute to clinician errors.[6] Health IT can 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 this, ONC commissioned an IOM study to determine how government and the private sector can maximize the safety of health IT-assisted care. "The [IOM] 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."[7] The IOM Report, *Health IT and Patient Safety: Building Safer Systems for Better Care*, was published in November 2011.[8]

This *Health IT Patient Safety Action and Surveillance Plan* (the "Health IT Safety Plan" or "Plan") addresses the role of health IT within HHS's commitment to patient safety. Building on the IOM committee's recommendations, the Plan leverages existing authorities 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. Importantly, the Plan outlines specific and tangible actions through which all stakeholders can fulfill their shared obligation to increase knowledge of the impact of health IT on patient safety, and maximize the safety of health IT and health IT-assisted care.

Successfully implementing this Plan will require a coordinated effort among multiple government agencies, private organizations, and individuals (e.g., clinicians, software engineers, health IT support staff, and usability experts). To coordinate this effort, ONC has established the Health IT Patient Safety Program ("Safety Program") within the Office of the Chief Medical Officer with support from the Office of Policy and Planning. Through the Safety Program, ONC will collaborate with stakeholders to incorporate health IT and patient safety into their organizations, and will work closely with all actors to help them fulfill their responsibilities under this Plan. ONC will oversee the aggregation and analysis of data from the sources identified in this Plan, among others, in order to identify trends in patient safety and health IT, provide feedback to developers and providers, and inform policies and interventions to achieve this Plan's objectives.

ONC will continuously evaluate the outcomes and effectiveness of this Plan and ensure its efficient implementation. Information about this Plan and its implementation will be available at http://www.healthit.gov/policy-researchers-implementers/health-it-and-patient-safety.

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[5] IOM Report, *supra* note 1, at 31 (collecting sources).
[6] *Id.*
[7] IOM Report, *supra* note 1, at 2 (emphasis in original).
[8] *Supra* note 1.

Health IT Patient Safety Goal

Inspire Confidence and Trust in Health IT and Health Information Exchange

HHS's goal is that patients and providers have confidence in the safety of the health care 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.[9] Many efforts in the public and private sectors are already in place to improve patient safety and the overall quality of care.[10]

Despite a growing body of research on patient safety, the IOM found little published evidence quantifying the magnitude of risks associated with health IT.[11] 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 one percent of reported errors.[12] All the reviewed papers also point to "the need for human diligence when using [health information systems]."[13]

It is difficult to interpret this initial research, which suggests that health IT is a modest cause of medical errors. Because health IT is so tightly integrated into care delivery today, the extent to which health IT may have caused or contributed to medical errors is often unclear. For example, determining whether an error was caused by or associated with health IT is problematic where:

- The harm to the patient could have been prevented by more sophisticated or improved implementation of CPOE or CDS; or
- The clinician did not use certain health IT functionality that could have prevented the error.

> *"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 socio-technical system"*
> *IOM Report (P. 64)*

Another limitation of this early data is the low rate of EHR utilization prior to passage of the HITECH Act in 2009. As a result, the dearth of reported incidents of health IT-related harm may be due less to the inherent safety of health IT and more to its lack of use.

As EHR adoption becomes more widespread, the incidence of health IT-related harm may increase. At the same time, the increase in EHR adoption also creates a unique opportunity to improve patient safety. For example, EHRs can:

- Increase clinicians' awareness of potential medication errors and adverse interactions;

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[9] *See, e.g.*, AHRQ, *Advancing Patient Safety: A Decade of Evidence, Design, and Implementation*, AHRQ Pub. No. 09(10)-0084 (November 2009), available at http://www.ahrq.gov/legacy/qual/advptsafety.htm (accessed May 17, 2013) (describing progress in patient safety research over the period 1999–2009).
[10] *See, e.g.*, *supra* note 9.
[11] IOM Report, *supra* note 1, at 3.
[12] IOM Report, *supra* note 1, Appendix C.
[13] *Id.*

- 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.

Objectives of the Health IT Patient Safety Plan

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. The first objective, to use health IT to make care safer, focuses on the use of health IT as a tool to mitigate or prevent adverse events and hazards,[14] regardless of their cause (e.g., CDS systems can warn providers of drug allergies or dangerous drug-drug interactions before the patients receive the drugs). The second objective, continuously improving the safety of health IT, focuses on preventing adverse events and hazards that are caused by or closely associated with health IT itself (e.g., medical errors caused by incomplete or poorly designed graphical user interfaces).

Achieving these objectives is a shared responsibility. No one entity or group can fully realize the potential of health IT to improve patient safety. Therefore, this Plan seeks to coordinate the actions of the relevant stakeholders, including:

- Clinicians;
- Care Delivery Organizations, including,
  - Administrators
  - IT staff
  - Quality improvement staff;
- Patients and their caregivers;
- Federal and state governments;
- Health IT developers;
- Usability experts;
- Patient safety organizations;
- Accrediting bodies; and
- Other organizations and stakeholders, including,
  - 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)*

[14] The term "hazard" as used in this Plan refers to any condition that is unsafe for patients (i.e., a condition that if not corrected could lead to an adverse event). Several other terms are commonly used to refer to hazards, including "unsafe conditions," "close calls," "near misses," and "malfunctions that could lead to death or serious injury." This Plan treats these terms as interchangeable.

1. Use health IT to make care safer

Health IT has enormous potential to improve the quality and safety of health care. When properly integrated into health care organizations, it enables an infrastructure for identifying patient safety risks, deploying interventions, and using technology to advance national health and safety aims. Indeed, the potential for health IT to improve patient safety is one of the reasons for the creation of the Medicare and Medicaid EHR Incentive Programs, which provide incentive payments to eligible providers who adopt and meaningfully use health IT to advance national priorities.[15]

The opportunity to use health IT to make care safer also informs broader federal initiatives to improve patient safety, including the *National Strategy for Quality Improvement in Health Care* ("National Quality Strategy").[16] For example, the National Quality Strategy incorporates the goals of the Partnership for Patients,[17] which aims to reduce preventable hospital-acquired conditions and hospital readmissions. Health IT can be used to track and analyze these adverse events, which can then become the focus for CDS and other health IT interventions, resulting in decreased patient harm. 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 VTE prophylaxis methods can potentially diminish the risk of development of hospital-acquired VTE.[18] In this manner, quality measurement efforts and EHR functionality can be leveraged to improve clinical outcomes and avoid patient harm. Standardized order sets have also been implemented in labor and delivery setting and demonstrated significant reductions in obstetrical adverse events.[19] 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.[20] CDS also

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[15] *See supra* note 3 and accompanying text.

[16] *See* AHRQ, *National Strategy for Quality Improvement in Health Care* (2012) (hereinafter "National Quality Strategy"), available at http://www.ahrq.gov/workingforquality/nqs/nqs2012annlrpt.pdf (accessed May 17, 2013).

[17] *See* CMS, *Partnership for Patients: Better Care, Lower Costs*, http://partnershipforpatients.cms.gov (accessed May 17, 2013). The Partnership for Patients is a national patient safety and quality improvement initiative that has two goals: reducing preventable hospital-acquired conditions by 40 percent, and reducing 30-day hospital readmissions by 20 percent by the end of 2014. Through the Partnership, the CMS Center for Medicare and Medicaid Innovation (CMMI) is investing in public-private hospital engagement networks that will help hospitals adopt proven strategies to reduce hospital-acquired conditions in their own facilities. So far, these hospital engagement networks include more than 3,700 hospitals nationwide, and quality improvement work is well underway. As part of the Partnership, CMS is also investing in the Community-based Care Transitions Program to fund care transition services to keep high-risk Medicare beneficiaries out of the hospital after discharge.

[18] Haut ER, et al., *Improved prophylaxis and decreased rates of preventable harm with the use of a mandatory computerized clinical decision support tool for prophylaxis for venous thromboembolism in trauma*, 147 Arch Surg., no. 10, Oct. 2012, 901–07; Kucher N, et al., *Electronic alerts to prevent venous thromboembolism among hospitalized patients*, 352 N.Engl. J.Med., no. 10, 2005, 969–77. *See also* AHRQ, VTE Safety Toolkit, http://vte.washington.edu/default.asp.

[19] Mazza F, et al., *Eliminating birth trauma at Ascension Health*, 33 Jt. Comm. J.Qual. Patient Saf., no. 1, Jan. 2007, 15–24. *See also* Institute for Healthcare Improvement (IHI), *How-to Guide: Prevent Obstetrical Adverse Events. Cambridge* (IHI, 2012), available at http://www.ihi.org/knowledge/Pages/Tools/HowtoGuidePreventObstetricalAdverseEvents.aspx (accessed May 17, 2013); IHI, *Perinatal Community Care Bundle Sequencing, Elective Induction and Augmentation Bundles* (IHI, 2012), available at http://www.ihi.org/knowledge/Pages/Changes/ElectiveInductionandAugmentationBundles.aspx (accessed May 17, 2013).

[20] Spears GV, et al., *Redesign of an electronic clinical reminder to prevent falls in older adults*, 51 Med. Care, no. 3 suppl. 1, Mar.

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.[21] These adverse events can be further reduced using additional CDS functionalities such as drug-medical condition notifications, triggers for lab results indicating risk for adverse drug events, and decision support for medication treatments.[22] Finally, two of the most common medication errors are improper dose or quantity; CDS can be used to identify these errors early in the prescribing process and can mitigate or prevent harm before it reaches the patient.[23]

Using health IT to improve patient safety is the first objective of the Health IT Safety Plan. It will also continue to be a driving force behind HHS programs.

2. Continuously improve the safety of health IT

To achieve the first objective of the Health IT Safety Plan, using health IT to make care safer, physicians and other clinical users of health IT must be able to rely on these systems to perform safely in real clinical environments. This requires continuous improvement in the development, implementation, and use of health IT. For instance, the developers and users of CPOE and CDS must ensure that these complex, interactive functions are designed, tested, implemented, supported, and used correctly and safely. These technologies must be easy to use in efficient clinical workflows, and their content must be accurate, up-to-date, and clinically relevant. Problems and hazards should be identified and promptly mitigated, and providers must be trained to use health IT properly and effectively, and to report problems to entities that have responsibility for evaluating and improving health IT safety.

The second objective of the Health IT Safety Plan addresses these concerns with a focus on continuously improving the safety of health IT so that it enables providers to deliver high quality care.

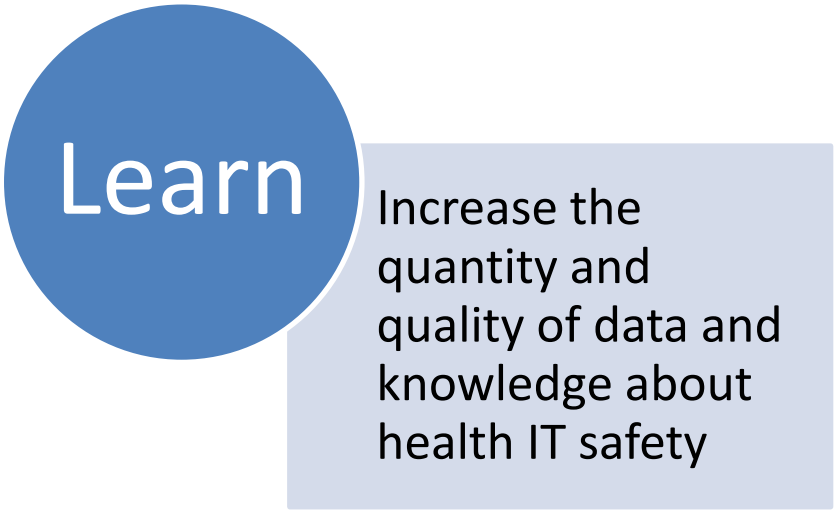
2013, 37–43; Teigland C., et al, *Clinical Informatics and Its Usefulness for Assessing Risk and Preventing Falls and Pressure Ulcers in Nursing Home Environments*, *in* 3 ADVANCES IN PATIENT SAFETY: FROM RESEARCH TO IMPLEMENTATION (Henriksen K, et al., ed., 2005), available at http://www.ncbi.nlm.nih.gov/books/NBK20539/ (accessed May 17, 2013).

[21] Tham E, et al., *Sustaining and spreading the reduction of adverse drug events in a multicenter collaborative*, 128 Pediatrics, no. 2, Aug. 2011, 438–45; Classen, DC, et al., *Critical drug-drug interactions for use in electronic health records systems with computerized physician order entry: review of leading approaches*, 7(2) J. Patient Saf. 61-65 (June 7, 2011).

[22] Levick, DL, et al., *Reducing unnecessary testing in a CPOE system through implementation of a targeted CDS intervention*, 13 BMC Med. Inform. Decis. Mak. , no. 43, Apr. 2013.

[23] *See* IOM, *Preventing Errors*, *in* QUALITY CHASM SERIES (Aspden, P., Wolcott, J., Bootman, JL, Cronenwett, LR, ed., 2007), available at http://www.nap.edu/catalog.php?record_id=11623#description (accessed May 17, 2013).

Health IT Patient Safety Strategies and Actions



To achieve the objectives of this Health IT Safety Plan—(1) using health IT to make care safer while (2) continuously improving the safety of health IT—a better understanding is needed regarding the impact of health IT on patient care, both as a cause of and means of preventing patient harm across a wide array of care settings. The need for more research on the role of health IT in the delivery of safe care was emphasized throughout the IOM Report.[24]

The following strategies and actions are designed to improve knowledge about the types, frequency, and severity of health IT-related adverse events and hazards, as well as ways to mitigate the risks of health IT while using it to make care safer. In particular, the following steps are designed to:

- Establish mechanisms that facilitate reporting among users and developers of health IT;
- Enhance the ability of patient safety organizations and other public and private sector entities to identify and address health IT-related safety issues; and
- Aggregate and analyze data on health IT-related adverse events and hazards.

> *"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)*

[24] IOM Report, *supra* note 1, at 13. The report recommends that research inform "the design, testing, and use of health IT." The report identified as a priority the following areas of research: user-centered design and human factors applied to health IT; safe implementation and use of health IT by all users; socio-technical systems associated with health IT; and the impact of policy decisions on health IT use in clinical practice.

1. **Make it easier for clinicians to report patient safety events and hazards to Patient Safety Organizations (PSOs) using AHRQ's Common Formats and health IT.**

   To understand the impact of health IT on patient safety, better data is needed about how these technologies function in real clinical environments. Inevitably, much of the necessary raw data will originate from clinicians and other persons directly involved in the delivery of care to patients. To improve the overall quantity and quality of data about health IT, these front-line staff must be encouraged to report health IT-related safety events and hazards and empowered with tools that make it easy for them to do so.

   HHS is developing and implementing policies and programs that encourage safety event reporting and make reporting easier for health IT users. The Patient Safety Rule authorizes the creation of Patient Safety Organizations (PSOs), organizations dedicated to improving the quality and safety of health care delivery.[25] Because PSOs and their members have federal privilege and confidentiality protections for patient safety work product,[26] PSOs provide a secure environment where clinicians and provider organizations can collect, aggregate, and analyze data in order to identify and reduce risks associated with patient care, including issues related to health IT.

   To facilitate reporting to PSOs (and other appropriate entities), AHRQ maintains the Common Formats, a set of common definitions and reporting formats that allow health care providers to collect and submit standardized information regarding patient safety events and hazards, including those involving health IT.[27] The Common Formats enable one-time data collection and subsequent routing to whoever needs or requests the data.[28] AHRQ has published Common Formats for the acute hospital setting (Hospital v 1.1 and 1.2) and a beta version for skilled nursing facilities or nursing homes. AHRQ is currently developing a version of the Common Formats for the ambulatory setting.

   Patient safety reporting can also be made easier through the use of health IT. In particular, EHRs can enable providers to easily initiate reports at the time of discovery without interrupting clinical workflow; and can reduce reporting burden by pre-populating and transmitting incident reports to multiple entities,

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[25] The Patient Safety and Quality Improvement Final Rule ("Patient Safety Rule"), 42 C.F.R. Part 3, administered by AHRQ and the Office for Civil Rights (OCR), implements select provisions of the Patient Safety and Quality Improvement Act of 2005, Pub. L. 109-41 ("Patient Safety Act"). The Patient Safety Act authorized the creation of PSOs to improve the quality and safety of U.S. health care delivery by enabling clinicians and health care organizations to voluntarily report and share quality and patient safety information confidentially. AHRQ has responsibility for listing and delisting of PSOs, as described in Subpart B of the Patient Safety Rule. OCR has responsibility for interpreting and implementing the confidentiality protections described in Subpart C and the enforcement provisions described in Subpart D.

[26] 42 U.S.C. § 299b–22.

[27] *See* AHRQ, *Common Formats*, http://www.pso.ahrq.gov/formats/commonfmt.htm. The most recent version of the Common Formats includes a "Device with Health IT" format that allows collection of standardized information about health IT-related adverse events as well as events where health IT may be a contributing factor.

[28] The Common Formats also provide local facility reporting capabilities for rapidly identifying quality and safety problems, facilitating changes to correct identified problems, and aggregating and comparing adverse events across care delivery organizations and federal and state programs.

including PSOs, internal hospital reporting systems, and patient safety oversight bodies. ONC will propose standards and certification criteria to ensure that, where appropriate, certified EHR technology can facilitate reporting of patient safety events and hazards using the Common Formats.

Work on these standards is already underway. With support from AHRQ and the National Library of Medicine (NLM), ONC is pursuing a structured data capture (SDC) initiative through its Standards and Interoperability (S&I) Framework to identify standards that will enable adverse event data to be extracted from EHRs and translated into the Common Formats, thereby allowing clinicians to quickly and easily generate incident reports at the time of discovery or occurrence and without disrupting their workflows.[29] Use cases for these standards have been developed, and work on an initial set of standards has begun. ONC expects to receive recommendations from the Health IT Standards Committee (HITSC) in October 2013 concerning the adoption of these and other standards for Stage 3 of Meaningful Use.

While this work is being completed, ONC has sponsored a Patient Safety Reporting Challenge Award to address the immediate 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.[30] ONC expects these and similar tools to become much more widely used to help organizations build a culture of safety[31] that includes adverse event reporting and follow-up.

2. Provide support to PSOs to identify, aggregate, and analyze health IT safety event and hazard reports.

By making it easier for providers to report health IT-related safety events and hazards to PSOs using the Common Formats, this Plan seeks to increase the quantity and quality of available data regarding the impact of health IT on patient safety. An equally important objective, however, is to ensure that, once reported, this data is used to increase knowledge about health IT patient safety and ways through which it can be improved. HHS will assist PSOs to improve the range and consistency of health IT safety data that they collect, as well as the ability of PSOs to use this data to identify, analyze, and mitigate health IT-related events and hazards. HHS will also assist PSOs to de-identify and share this data, in compliance with applicable laws, so that it can be aggregated and used to analyze national health IT patient safety risks and trends.

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[29] Earlier pilots of reporting medication adverse event data from EHRs to the FDA Medwatch System resulted in significant increases in reports received at the FDA. Linder, J., et al., *Secondary use of electronic health record data: spontaneous triggered adverse drug event reporting*, 19 Pharmacoepidem. Drug Safe. 1211–1215 (2010).

[30] Challenge.gov, *Reporting Patient Safety Events*, http://challenge.gov/ONC/349-reporting-patient-safety-events (accessed May 17, 2013).

[31] A "culture of safety" encompasses these 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." AHRQ, *Safety Culture*, http://psnet.ahrq.gov/primer.aspx?primerID=5 (accessed May 17, 2013).

As a first step, HHS will support PSOs to leverage the Common Formats in order to efficiently identify, aggregate, and analyze health IT patient safety data. Specifically, AHRQ will continue to provide technical assistance to PSOs on using the Common Formats, and will continue to encourage PSOs to assist providers in using the Common Formats when reporting adverse events and hazards related to health IT. The Centers for Medicare and Medicaid Services (CMS) will support these efforts by encouraging the use of Common Formats in hospital incident reporting programs. CMS has already issued guidance in this regard and will educate state survey agencies and surveyors to look for the use of the Common Formats in these programs.[32]

Using the Common Formats will allow PSOs to more effectively collect and analyze data about health IT-related adverse events and hazards. Several PSOs have already demonstrated increasing expertise in analyzing these types of issues,[33] and other PSOs will likely increase their capabilities in this domain in the future. HHS does recognize that not all PSOs have expertise in health IT safety. Therefore, AHRQ plans to issue guidance on how to more effectively involve health IT expertise, including from health IT developers, in reporting to PSOs and in analysis and correction of problems. This guidance will address common concerns among health IT developers, who have specialized knowledge about the safety and safe use of their products, but who may be reluctant to share this knowledge for legal reasons.[34] While health IT developers, unlike providers, cannot invoke the Patient Safety Rule's[35] federal confidentiality and privilege protection for data they submit to a PSO, they can nevertheless bring their health IT analytic expertise to working relationships with PSOs by: 1) establishing Business Associate Agreements (BAA) with health care provider clients; 2) contracting in a consultant role to PSOs; and 3) establishing a component PSO. ONC will similarly encourage and help to facilitate these working relationships.

At this time, there are 77 PSOs in 29 states that are listed by AHRQ.[36] As more data on health IT patient safety becomes available in the Common Formats, it will be possible to aggregate this data across PSOs in order to analyze national trends and areas for improvement or further research. For this purpose, AHRQ has established the Network of Patient Safety Databases (NPSD), which provides a mechanism for aggregating and analyzing data from multiple PSOs.[37] Using the Common Formats, PSOs will submit non-identified and aggregated patient safety event information to the NPSD. AHRQ will analyze the data in the NPSD to identify national trends and patterns, and will identify specific safety events or hazards 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. AHRQ will publish its findings, as appropriate, in reports such as the National Healthcare Quality Report, and will share its NPSD analysis and data with ONC. ONC will combine this information with analysis from other data sources discussed in this Plan to identify areas in which the

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[32] *See infra Learn* section 4, *Align CMS patient safety standards and initiatives with the safety of health IT.*
[33] *See, e.g.,* ECRI Institute PSO, *Deep Dive: Health Information Technology* (December 2012).
[34] *See infra Lead* section 1, *Encourage private sector leadership and shared responsibility for health IT safety.*
[35] The Patient Safety Rule, 42 C.F.R. Part 3, administered by AHRQ and the Office for Civil Rights (OCR), implements select provisions of the Patient Safety Act. AHRQ has responsibility for listing and delisting of PSOs, as described in Subpart B of the Rule. OCR has responsibility for interpreting and implementing the confidentiality protections described in Subpart C and the enforcement provisions described in Subpart D.
[36] AHRQ, *Geographic Directory of Listed Patient Safety Organizations*, http://www.pso.ahrq.gov/listing/geolist.htm (accessed May 17, 2013).
[37] *See* AHRQ, *Network of Patient Safety Databases*, http://www.pso.ahrq.gov/npsd/npsd.htm (accessed May 17, 2013).

safety or safe use of health IT can be improved and coordinate corresponding policies, activities, and interventions.

To assist PSOs to submit data to the NPSD, AHRQ has established the PSO Privacy Protection Center (PSO-PPC),[38] which will provide technical assistance to PSOs to assist them in de-identifying their data and submitting it to the NPSD using the Common Formats.

3. Incorporate health IT safety in post-market surveillance of certified EHR technology.

ONC will use its health IT certification program to monitor how certified EHR technology functions in operational settings. This knowledge will provide insight into how specific types of EHR capabilities (e.g., CPOE) perform in actual clinical environments in which they are used, leading to a better understanding of the risks associated with particular capabilities as well as ways to make those capabilities safer.

As ONC described in the permanent certification program final rule,[39] ONC expects that ONC-Authorized Certification Bodies (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 these capabilities were certified. ONC will issue guidance to ONC-ACBs to add a specific focus on safety-related capabilities—such as CPOE and drug-drug/drug-allergy interaction checking—to their surveillance activities. This guidance will also prioritize the surveillance of EHR developers' processes for receiving and responding to user complaints concerning developers' products. ONC will work with the ONC-Approved Accreditor (ONC-AA)—currently the American National Standards Institute (ANSI)—to provide direction to ONC-ACBs on the complaint records that developers of certified EHR technology are required to keep and make available to them under the ONC HIT Certification Program.[40] ONC will work with ANSI to ensure consistency and reliability in the: (1) format and content of complaints; (2) process by which records are made available to the ONC-ACBs; and (3) documentation of actions taken by EHR technology developers to address complaints. Consistent and reliable complaint records will permit ONC-ACBs to sample, review, and validate complaints reporting concerns about safety-related capabilities of certified EHR technology as part of surveillance.[41]

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[38] PSO Privacy Protection Center, https://www.psoppc.org. The PSO-PPC was created by AHRQ to support the implementation of the Patient Safety Act. The PSO-PPC works with all PSOs and can check for duplicate reports prior to the non-identification process.

[39] 76 Fed. Reg. 1283.

[40] ONC-ACBs are accredited to ISO/IEC Guide 65. Section 15 of Guide 65 instructs an ONC-ACB to ensure that the developers of the health IT that it certifies have a process in place for receiving and addressing complaints related to certified products. Section 15 also requires that the developers make complaint records available to the ONC-ACB upon request.

[41] ONC-ACBs are required to report surveillance results to ONC annually. 45 C.F.R. § 170.523(i). In reporting its annual surveillance results to ONC, an ONC-ACB will be expected to indicate whether the certified 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). The ONC surveillance guidance will specify the type and level of information that should be included in surveillance results.

4. Align CMS patient safety standards and initiatives with the safety of health IT.

CMS is engaged in patient safety and quality improvement initiatives that can be leveraged to support efforts to increase reporting of health IT-related adverse events and hazards and improve knowledge of health IT patient safety.

CMS maintains Conditions of Participation (CoPs) that health care organizations must meet in order to begin and continue participating in the Medicare and Medicaid programs.[42] The CoPs include a requirement for covered health care organizations to have a Quality Assurance and Performance Improvement (QAPI) program that includes internal adverse incident reporting and effective follow-up of a wide range of patient safety events.[43] CMS recently published interpretive guidance for hospitals and state survey agencies that clarifies the types of adverse events that hospitals should report and strongly encourages the use of AHRQ's Common Formats in hospital QAPI programs.[44] Deploying the Common Formats in QAPI programs will create an additional source of information about the role of health IT across a broad range of patient safety events, and will make it easier for hospitals to share this information with PSOs and other oversight entities.

CMS will work with ONC to develop training for state survey agencies and surveyors, who conduct thousands of complaint investigation surveys on CMS's behalf each year. When surveys identify deficient practices, providers and suppliers must submit to CMS a plan of correction for achieving compliance. CMS will educate its surveyors on EHRs and electronic incident reporting, as well as safety considerations associated with the use of EHRs by Medicare participating providers.[45] CMS is also working with ONC to develop educational materials that will assist surveyors as they survey EHR-enabled health care organizations.

CMS will continue to use Quality Improvement Organizations (QIOs) to focus on specific patient safety interventions, and will leverage health IT and health safety data collected to identify, analyze, and mitigate health IT-related events and hazards.

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

AHRQ is currently building the Quality & Safety Review System (QSRS). The QSRS is a software system designed to perform retrospective surveillance for adverse events. A replacement for the Medicare Patient Safety Monitoring System (MPSMS), the QSRS incorporates the Common Formats to broaden surveillance to harm from all causes. The QSRS will provide national estimates of adverse events and will make it possible to explore the role of health IT in these events. QSRS software will initially be deployed

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[42] *See* CMS, *Conditions for Coverage (CfCs) & Conditions of Participation (CoPs)*, http://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/index.html (accessed May 17, 2013).

[43] 42 C.F.R. 482.21(a)(2).

[44] CMS, *AHRQ Common Formats-Information for Hospitals and State Survey Agencies (SAs)-Comprehensive Patient Safety Reporting Using AHRQ Common Formats*, Ref: S&C: 13-19-HOSPITALS (March 15, 2013), available at http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions-Items/Survey-and-Cert-Letter-13-19.html (accessed May 17, 2013).

[45] *Id.*

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.

While work on the QSRS is still underway, AHRQ intends to support research in the interim that will provide better estimates of the frequency, type, and level of harm occurring with adverse events related to health IT. Additionally, while the QSRS is under development, AHRQ has added a new query to the MPSMS. For 2012 and 2013 data, MPSMS abstractors will identify which patient records in the sample are from EHRs, paper records, and mixed records. This data will provide insight into the extent to which the adverse events measured by MPSMS are correlated with levels of health IT integration.

6. Learn from health IT adverse event reports submitted to the Manufacturer and User Facility Device Experience (MAUDE) database.

ONC will coordinate with the FDA to identify and evaluate health IT adverse event reports made to the FDA MAUDE database. MAUDE is a searchable database of adverse event reports on devices that contains data from several sources, including voluntary reports, user facility reports, and device manufacturers' reports.[46] This database will provide ONC with an additional source of data from which to analyze potential safety trends and risks associated with health IT.

7. Identify opportunities to make care safer through the use of health IT.

Health IT has enormous potential to improve the quality and safety of health care. Realizing this potential is both the first objective of this Plan as well as an important component of HHS's patient safety and quality improvement initiatives.

ONC will work within the apparatus of the National Quality Strategy[47] and related public and private sector initiatives to identify opportunities to make care safer through the use of health IT. For example, through the Partnership for Patients,[48] over 3,700 hospitals collaborated at the regional, state, national, and hospital levels to identify and share knowledge of clinical practices, interventions, and quality measures for improving patient safety in several critical domains. In consultation with its federal advisory committees, ONC will exploit lessons learned through the Partnership for Patients and other patient safety and quality improvement initiatives in order to determine specific areas in which health IT has the greatest potential to make care safer. This work will also provide a focus for public and private sector research into specific health IT interventions, such as CDS, that have the greatest potential to improve patient safety.

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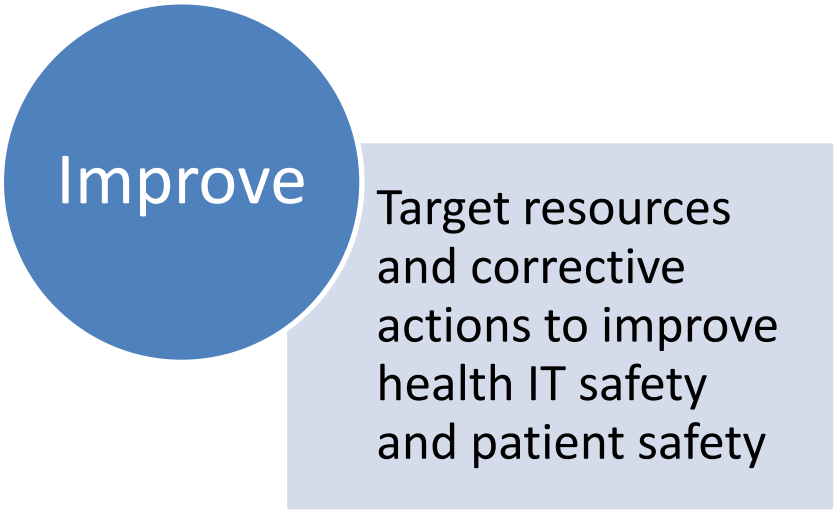
[46] MAUDE-Manufacturer and User Facility Device Experience, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm

[47] National Quality Strategy, *supra* note 16; *see also Lead* section 1, *infra*.

[48] Partnership for Patients, *supra* note 17.

Health IT Patient Safety Strategies and Actions



This Health IT Safety Plan seeks not only to increase knowledge about the impact of health IT on patient safety, but also to use that knowledge to improve the safety of health IT and make care safer.

As early as 1999, the IOM recognized the enormous potential of health IT to improve patient safety.[49] Compared with paper based systems, health IT provides an efficient mechanism with which to identify problem areas, monitor trends, measure success, and implement improvements. As knowledge of health IT safety continues to improve, HHS will take the following steps to ensure that such knowledge is used to make health IT safer and to realize its potential to deliver safer care.

1. **Use Meaningful Use and the National Quality Strategy to establish and advance health IT patient safety priorities.**

   HHS will use knowledge of health IT safety risks and trends to establish priorities for improving patient safety through health IT. These priorities will align with national health care quality improvement efforts outlined in the National Quality Strategy, and will focus on areas in which improving the safety of health IT will have the greatest potential to advance patient safety. In particular, the National Quality Strategy seeks to make care safer by reducing patient harm caused in the delivery of care, specifically by reducing hospital readmissions and preventable hospital-acquired conditions.[50] To further these goals, CMS launched the Partnership for Patients,[51] through which it identified ten patient safety domains in which evidence confirms the greatest need for intervention as well as the greatest opportunities for

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[49] *See* IOM, *To Err Is Human: Building a Safer Health System*, *supra* note 2; *see also* IOM, *Crossing the Quality Chasm* (National Academy Press, 2001) (available at http://www.iom.edu/reports/2001/crossing-the-quality-chasm-a-new-health-system-for-the-21st-century.aspx (last accessed 5/1/2013) (calling for "the elimination of most handwritten clinical data by the end of the decade.").

[50] National Quality Strategy, *supra* note 16.

[51] Partnership for Patients, *supra* note 17.

improvement (see Table 1). Building on this work, ONC is developing electronic clinical quality measures (eCQMs) for specific adverse drug events, and will soon expand this work to other patient safety domains. In addition, ONC will establish a public-private mechanism for developing health IT-related patient safety measures and targets in order to align improvement efforts across government programs and the private sector, and target and measure success.

Table 1: Partnership for Patients Priority Domains

Adverse Drug Events	Pressure Ulcers
Catheter Associated Urinary Tract Infection	Surgical Site Infections
Central Line Associated Blood Stream Infection	Obstetrical Adverse Events
Readmissions	Venous Thromboembolism
Ventilator Associated Pneumonia	Injuries from Falls and Immobility

HHS will provide leadership and incentives to advance health IT patient safety in priority areas. ONC will release a health IT focused quality improvement strategy that aims to coordinate evidence-based guidelines, CDS tools, and eCQMs, and that defines specific actions for payers, providers, and developers in order to improve patient safety and health care quality using health IT. In addition, HHS expects to incorporate improvement priorities into the Medicare and Medicaid EHR Incentive Programs ("Meaningful Use Programs"), which offer incentive payments to eligible providers who adopt and meaningfully use certified EHR technology that aims to improve health care quality, improve health outcomes, and lower costs. These incentives have already given considerable momentum to efforts to improve health care quality and safety through the meaningful use of health IT. As of April 2013, more than half of eligible providers have qualified for and received incentive payments for adoption of certified EHR technology, exceeding HHS's target for the end of 2013.[52] Moreover, nearly 80 percent of eligible hospitals have reached this milestone. The increase has been rapid; adoption of electronic health records doubled among office based physicians from 2008 to 2012 and quadrupled in hospitals.[53]

HHS expects to continue to use the Meaningful Use Programs to advance health IT patient safety priorities. Already, to receive an incentive payment, eligible providers must demonstrate several core objectives that advance patient safety, such as using CPOE and maintaining lists of patient medications, allergies, and problems. Stage 2 of Meaningful Use, which will begin in 2014, will similarly advance patient safety through core safety-related objectives that include: using CDS to improve clinical performance with respect to high-priority health conditions; performing electronic medication reconciliation when receiving patients from another setting of care or provider; and providing summary of care records when referring patients to another provider or care setting. For future regulation, ONC plans to work with its federal advisory committees to determine ways to improve clinical documentation,

[52] *See* CMS, *Data and Program Reports*, http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html (accessed May 17, 2013); *see also* The White House Blog, *More than Half of Doctors Now Use Electronic Health Records Thanks to Administration Policies*, http://www.whitehouse.gov/blog/2013/05/24/more-half-doctors-now-use-electronic-health-records-thanks-administration-policies (accessed June 27, 2013).

[53] *Id.*

thereby reducing the risk that records will be inaccessible or their accuracy or completeness compromised. ONC will also explore ways to make existing health IT capabilities safer and maximize their potential for enhancing patient safety.

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

As knowledge of health IT safety grows, ONC expects to update its standards and certification criteria to ensure that the capabilities of certified EHR technology support improvement priorities, including efforts to improve patient safety through the meaningful use of health IT. As necessary, ONC would update its standards and certification criteria to improve safety-related capabilities (e.g., CDS and CPOE) or add capabilities that enhance patient safety.

ONC expects to further incorporate safety into its standards and certification criteria by requiring developers of certified EHR technology to integrate safety principles into their software design and development processes. The 2014 Edition EHR Standards and Certification Criteria final rule[54] adopted two such requirements, which were drawn from the IOM committee's recommendations identifying usability and quality management principles as key elements of health IT product safety.[55] First, EHR technology developers are required to publicly identify the method used to incorporate user-centered design processes into the development of their EHR technology for the capabilities included in eight medication-related certification criteria.[56] Second, EHR technology developers are required to provide transparency regarding their approach to "quality management systems" in the development of their products.[57] ONC intends to build on these certification criteria in future rulemaking as means for enhancing health IT patient safety through continued focus on human factors, safety culture, and user-centered design in EHR technology development.

As part of the ONC HIT Certification Program, ONC established the Certified HIT Product List (CHPL).[58] The CHPL is a publicly available database of health IT products that have been certified in accordance with ONC's standards and certification criteria. Each individual EHR product listed in the database notes the presence or absence of safety features, such as drug-drug interaction or drug-allergy checking. If there is a need for further registration and listing to promote transparency related to the

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[54] 77 Fed. Reg. 54163 (September 4, 2012).

[55] IOM Report, *supra* note 1, at 81. The IOM committee concluded that "poor usability . . . is one of the single greatest threats to patient safety. *Id.* On the other hand, once improved, it can be an effective promoter of patient safety." *Id.* The committee explained that usability is a necessary component of effective design, the goal of which should be to make "the right thing to do the easy thing to do." *Id.* The committee also recommended the use of quality management principles and processes, which it described as focusing on "driving performance characteristics at each level to make sure that the product and specifications are in line with the users' needs and expectations," and which it concluded "can help health IT vendors take into account characteristics such as interoperability, usability, and human factors principles as they design and develop safer products." *Id.* at 143.

[56] 45 C.F.R. § 170.314(g)(3) requires that user-centered design processes be applied to each capability an EHR technology includes that is specified in the following certification criteria: § 170.314(a)(1) (CPOE), (a)(2) (drug-drug, drug-allergy interaction checks), (a)(6) (medication list), (a)(7) (medication allergy list), (a)(8) (CDS), (a)(16) (eMAR), (b)(3) (e-prescribing), and (b)(4) (clinical information reconciliation).

[57] 45 C.F.R. § 170.314(g)(4).

[58] Certified Health IT Product List, http://oncchpl.force.com/ehrcert?q=chpl.

safety of health IT beyond ONC's existing CHPL, ONC will consider using its current authorities to broaden the list.

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

Policies and incentives alone cannot ensure that health IT will be safe, nor that it will be used to make care safer. Achieving these objectives requires a concerted effort by all stakeholders to understand and address the potential risks of harm associated with health IT in every stage of its design, development, implementation, and use. Government can facilitate this process through strategies and actions to improve knowledge of health IT safety, such as those described earlier in this Plan. Just as important, government can play a central role in synthesizing this knowledge and making it available to those who need it in a way that is easy to understand, practically relevant, and actionable.

To this end, HHS and its federal partners are currently supporting research and development of evidence-based tools and interventions designed for various stakeholder audiences, including health IT developers, implementers, clinical staff, and PSOs. Several of these resources are already available, and several others are currently under development (see Appendix B).

In 2013, ONC will begin packaging and disseminating a new class of health IT safety tools and interventions designed to improve the ability of health IT implementers and users to assess patient safety within their organizations and benefit from the latest applied knowledge of health IT safety. As part of an ONC contract on Anticipating Unintended Consequences,[59] health IT safety researchers are developing health IT safety guides, Safety Assurance Factors for EHR Resilience (SAFER) Guides, comprising self-assessment tools and checklists, best practices, and more. The SAFER Guides—which are being developed based on existing research, expert opinion, stakeholder engagement, and field work—will enable everyone who is responsible for safety in health systems and ambulatory settings to implement health IT safety programs in critical areas, including:

- High Priorities for Health IT Safety
- Organizational Activities and Responsibilities
- System Interfaces
- System Configuration
- Contingency Planning
- Patient Identification
- Order Entry with Decision Support
- Test Reporting and Follow-up
- Clinician Communications.

The safety self-assessment recommended in the SAFER Guides, while led by EHR users and clinicians, often requires input from a team of people dedicated to health IT patient safety, including EHR developers, laboratory and pharmacy IT personnel, and others. Under an existing ONC contract, the

[59] Unintended Consequences of Health IT and HIE, Task Order HHSP23337003T/HHSP23320095655WC.

SAFER Guides will be used and evaluated in hospitals and ambulatory practices, and in this way provide a foundation from which to develop additional evidence-based tools and interventions as knowledge of health IT safety continues to improve.[60] ONC will refine and make these resources available to health IT implementers and users so that they can improve the safety of care delivery and develop a culture of safety within their organizations.

Health IT developers, like their customers, must also apply new knowledge of health IT safety to improve the overall safety and efficacy of health IT-assisted care. Therefore, ONC will coordinate with the National Institute for Standards and Technology (NIST) to develop design and testing tools that developers can use to integrate safety concepts and principles—such as usability and quality management—into their software design and development processes. With support from ONC, NIST has already developed several tools for usability testing of certified EHR technology. Building from this work, ONC's Strategic Health IT Advanced Research Projects-C (SHARP-C) Program is researching and conducting usability testing and vendor surveys to provide feedback to ONC on best practices in usability, cognitive assistance, and decision support. ONC and NIST will use this feedback to develop additional tools and resources to enable health IT developers to meet ONC's standards and certification criteria and to develop better and safer products.

4. Incorporate health IT safety into education and training for health care professionals.

ONC will strengthen health IT-related patient safety improvement efforts by working to integrate knowledge of health IT safety into the education and training of health IT professionals.

Through the Workforce Development Program, funded by the Recovery Act, ONC awarded grants to universities and community colleges to develop health IT-based curricula and expand health IT education and training programs. As of May 2013, over 18,000 health IT professionals have completed training through these programs.[61] Most of these programs are self-sustaining and will continue after the Workforce Development Program ends in FY 2013. Similarly, curriculum development functions will continue under the leadership of the American Health Information Management Association (AHIMA). ONC will work with these and other organizations to add a focus on health IT patient safety in existing education and training programs.

To support these efforts, ONC will repurpose cutting-edge knowledge and tools related to health IT safety (e.g., SAFER Guides) and make these available for use as educational or instructional materials. ONC will also encourage the dissemination of these materials by accrediting bodies, PSOs, liability insurers, educational organizations, and professional associations, and will work with these organizations to integrate health IT patient safety into their programs and practices, and foster a culture of safety.

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[60] ONC has awarded a contract, Promoting Patient Safety Through Effective Health Information Technology Risk Management, contract no. HHSP23337003T, to identify and evaluate both risk management implementation processes and specific interventions (such as SAFER Guides) and to make recommendations on risk management implementation processes and interventions related to health IT-related risks that contribute to a healthcare system that continually improves the safety and safe use of health IT. ONC expects that this contract will be completed in March 2014.

[61] Health IT Dashboard, http://dashboard.healthit.gov.

5. Investigate and take corrective action to address serious adverse events or hazards involving health IT.

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.[62] HHS's approach builds on existing federal authorities, as well as private sector safety programs.

HHS will work with private sector organizations that have the ability to investigate, take corrective actions, and publicly report on their analysis of health IT-related events and hazards. ONC has awarded a contract to The Joint Commission[63] that will enable it to build upon its existing sentinel events program to better identify and address health IT-related events.[64] The Joint Commission will expand its capacity, when appropriate, to investigate the role of health IT as a cause of adverse events, and will develop educational materials and training opportunities, which will be widely available publicly, to enable health care providers to better identify, investigate, and analyze health IT-related adverse events and develop follow-up and corrective action. The Joint Commission will also make the results of its investigations available to ONC in summary format (excluding identifiable information and subject to privilege, confidentiality, and privacy protections). The Joint Commission will also create a de-identified database of sentinel events that will allow it to analyze and report on the role of health IT in such events.

CMS will support efforts to investigate and take corrective action to address serious adverse events or hazards involving health IT. As previously noted, CMS has issued guidance clarifying the requirements for internal adverse event reporting and follow-up of patient safety events in health care organizations subject to the Medicare and Medicaid Conditions of Participation.[65] CMS is also working with ONC to develop training materials for state survey agencies and surveyors, who conduct complaint investigation surveys on CMS's behalf, to enhance their ability to identify unsafe conditions associated with health IT. When surveys identify deficient practices, providers and suppliers must submit to CMS a plan of correction achieving compliance.

HHS will continue to evaluate other mechanisms for investigating and taking corrective action to address serious adverse events or hazards involving health IT.

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[62] The National Transportation Safety Board is an independent federal agency charged by Congress with investigating every civil aviation accident the United States.

[63] The Joint Commission evaluates and accredits more than 20,000 health care organizations and programs in the United States. An independent, not-for-profit organization, The Joint Commission is the nation's oldest and largest standards-setting and accrediting body in health care. To earn and maintain accreditation by The Joint Commission, an organization must undergo an on-site survey by a Joint Commission survey team at least every three years.

[64] Investigation of Health IT-related Deaths, Serious Injuries, or Unsafe Conditions, Contract No. HHSP233201300019C.

[65] *See supra Learn* section 4, *Align CMS patient safety standards and initiatives with the safety of health IT*.

Health IT Patient Safety Strategies and Actions

Leadership is essential to building high reliability organizations with strong safety cultures. This section describes how HHS will collaborate with the private sector to promote patient safety in a health IT-enabled care delivery system. It also lists additional steps that HHS will take to improve federal coordination and integrate health IT patient safety into existing federal programs.

1. Encourage private sector leadership and shared responsibility for health IT patient safety.

Responsibility for health IT patient safety is shared by all stakeholders, including developers and users of health IT and the private organizations that support them.[66] As the IOM committee explained, these actors are part of a complex, adaptive socio-technical framework in which health IT software, hardware, and services are integrated with people, processes, and ongoing programs.[67] For health IT to achieve its full potential to make care safer, the private sector must work together to develop a culture of safety, shared responsibility, learning, and continuous improvement.

ONC will encourage health IT industry groups and trade associations, such as the Electronic Health Record Association (EHRA), to educate their members on shared responsibility for patient safety and a culture of safety in a health IT-enabled learning health care system, which includes a commitment to:

- Engage clients in health IT-related safety efforts;

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[66] IOM Report, *supra* note 1, at 111 ("Building health IT for safer use by health professionals is indeed a shared responsibility. Vendors, care providers, provider organizations and their health IT departments, and public and private agencies focused on quality of care are all partners in building a safer system in which health IT is used.")

[67] IOM Report, *supra* note 1, at 2 ("Health IT is not a single product; it encompasses a technical system of computers and software that operates in the context of a larger sociotechnical system—a collection of hardware and software working in concert within an organization that includes people, processes, and technology.")

- Promote learning and improvement, including by supporting the exchange of information about the safety of health IT products, consistent with reasonable intellectual property protections;[68]
- Cooperate on investigations and follow-up to identify and mitigate health IT-related problems;
- Facilitate adverse event reporting using the Common Formats;
- Accept shared responsibility for system interface and configuration;
- Support continuous availability of electronic records, including through terminations and wind downs; and
- Embrace responsibility in areas where developers can control or minimize risks.

On June 11, 2013, the Electronic Health Records Association (EHRA) announced adoption of a voluntary industry code of conduct, which, among other important issues, includes prominent attention to EHR developer responsibility for patient safety and for interoperability and data portability.[69] ONC supports this step and other private sector leadership that will promote a culture of safety, shared learning, and continuous improvement.

Like developers, users of health IT also have a responsibility for ensuring patient safety. Health care providers, in the years since 1999 when the IOM report *To Err is Human*[70] galvanized efforts to improve patient safety, have built patient safety programs and organizations, including in professional associations and the PSOs and accreditation programs previously mentioned. Now is the time to fully integrate health IT safety into those programs, as both an infrastructure for improving the safety of care and to continuously improve the safety of health IT. Providers should pay particular attention to implementation strategies and activities to support patient safety, including actions to:

- Establish a strong executive and clinical leadership commitment to patient safety as a major priority;
- Engage EHR developers in shared responsibility for the safety and safe use of health IT;
- Address, with EHR developers, shared responsibility for the safety of system interfaces and configuration;
- Select systems that will connect data from clinical and other related health IT and that also support clinical and administrative workflows;
- Create and sustain an approach for managing clinical content and change requests;
- Design mechanisms and metrics to promptly identify, escalate, and remediate health IT-related patient safety issues; and
- Provide user training and periodically assess user competence.

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[68] ONC would also support private sector efforts that aim to make available information comparing user experience with different EHR systems, such as efforts by private organizations that report on products and services in health care to develop ways of reporting and publicizing this information, especially as it relates to patient safety.

[69] EHRA, *EHR Developer Code of Conduct*, available at http://www.himssehra.org/ASP/codeofconduct.asp (accessed June 12, 2013). Previously in 2012 EHRA issued a Statement of Commitment to Patient Safety and a Learning Healthcare System. *See* EHRA, *Statement of Commitment to Patient Safety and a Learning Healthcare System* (2012), http://www.himssehra.org/docs/20120221_EHRAPatientSafetyStatementofCommitment.pdf (accessed May 13, 2013).

[70] *To Err is Human*, *supra* note 2.

A well-informed marketplace for health IT software and services can drive innovations that continuously improve the safety of health IT. Yet many EHR developer contracts contain nondisclosure clauses and other provisions that, if not clarified, could discourage or even prevent users from sharing certain kinds of information (e.g., screenshots) that may be relevant or even critical to understanding how their products impact patient safety.[71] To assist EHR users to better understand contractual terms that could impact patient safety, ONC has contracted for development of a guide to key contractual terms in EHR developer contracts.[72] This guide will assist purchasers and users of EHRs to understand and evaluate contract terms they should consider when purchasing EHR systems and services in order to protect their organizations from patient safety risks that may arise when these organizations rely on EHRs for critical aspects of their operations.

ONC will continue to evaluate whether private sector efforts to address health IT patient safety are sufficient for achieving the objectives of this Plan. ONC will use all of the avenues of communication with stakeholders that are available to it to invite feedback on whether industry self-regulation, including an industry code of conduct, is effective for building confidence in the safety of health IT.

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

Congress enacted the Food and Drug Administration Safety and Innovation Act (FDASIA)[73] on July 9, 2012. Section 618 of FDASIA instructs the Secretary of HHS, acting through the FDA Commissioner—in collaboration with ONC and the Federal Communications Commission (FCC)—to issue a report by January 2014 on a proposed strategy and recommendations on an appropriate risk-based regulatory framework for health IT that promotes innovation, protects patient safety, and avoids regulatory duplication.[74]

This report will be developed with significant public input. FDA, ONC, and FCC have issued a request for comment seeking broad input from stakeholders on elements they should consider in developing the report.[75] The report will also be informed by input from the Health IT Policy Committee (which has formed a FDASIA Workgroup) and will incorporate what the agencies learn about risk, safety, and opportunity for innovative technologies to support improved health outcomes. The agencies will 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 how to design an oversight approach that supports innovations and patient safety.

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[71] IOM Report at 126–127.

[72] This guide is being developed under the contract Unintended Consequences of Health IT and Health Information Exchange, Task Order HHSP23337003T/HHSP23320095655WC. It should not be viewed as legal advice and does not attempt to address all of the many legal and other issues that may arise in contract negotiations. Each healthcare organization presents its own unique circumstances.

[73] Pub. L. 112-144, 126 Stat. 993.

[74] *Id.*

[75] 78 Fed. Reg. 32390.

The Health IT Safety Plan is different from the forthcoming FDASIA report in that it lays out immediate and short-term actions HHS and industry stakeholders can take to improve health IT safety. In contrast, the FDASIA report will focus on responding to the statutory requirement for strategy and recommendations for a regulatory framework. ONC expects this work will be complementary to, but not a substitute or replacement for the actions included in this Plan.

3. 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.

Many states that have enacted patient safety provisions requiring reporting of healthcare associated infections (HAIs) are struggling to implement these initiatives because of the burden associated with this type of reporting using paper-based systems. ONC will work with state administrations to focus on using electronic health information exchange (HIE) to facilitate statutorily mandated reporting of HAIs. By targeting state-based HAI reporting, ONC will:

- Support public health policy at the local and federal level with clinically relevant and measureable targets;
- Help individual states meet these relatively new patient safety statutes; and
- Further demonstrate the utility of health IT and HIE to providers.

Progress in this domain has already been made through the alignment of standards for many HAIs. These standards, developed across HHS departments, have already resulted in the reporting of, among others, central line-associated blood stream infections (CLABSIs) and catheter-associated urinary tract infections (CAUTIs). Both of these conditions are the focus of national patient safety priority domains incorporated in the Partnership for Patients and the *HHS National Action Plan to Prevent Healthcare-Associated Infections*.[76] Currently, providers can report patient safety measures for these infections conditions to both the CDC, through the National Healthcare Safety Network (NHSN), and to CMS, through the inpatient quality reporting program. Expansion of these safety measures to include reporting to state-based programs is a practical next goal.

[76] HHS, *National Action Plan to Prevent Healthcare-Associated Infections: Roadmap to Elimination*, http://www.hhs.gov/ash/initiatives/hai/actionplan (accessed May 17, 2013).

4. Integrate consumer eHealth and patient and family caregiver engagement as an integral part of health IT patient safety.

Both federal and private sector quality initiatives call for patient-centered care that engages patients and their families. Patient feedback can serve as a valuable "second pair of eyes" to improve the accuracy and completeness of information in the EHR, such as medication history. However, consumer eHealth is not automatically safer. For instance, as the IOM observed, these new technologies may introduce opportunities for miscommunication, and raise the need for "rules of engagement" around the use of "patient engagement tools."

HHS will foster methods with which providers can more effectively engage patients and family caregivers in using health IT, especially consumer eHealth, to make care safer. ONC has already sponsored a report on the unintended consequences of consumer eHealth to better understand challenges to effective and safe use of consumer eHealth and ways to build better and safer consumer eHealth products and programs.[77] ONC will encourage private sector health care providers and health IT developers to adopt innovative consumer eHealth technologies and programs. These technologies can lead to safer care by enabling patients and their family caregivers to participate in their care, become more knowledgeable about conditions and treatments, improve communication among health care providers and caregivers, and facilitate shared decision making.

ONC will also lead efforts to identify ways to continuously improve the safety of consumer eHealth. ONC will encourage health IT developers to apply user-centered design and quality management system practices to enhance the safety of consumer eHealth technologies. ONC will encourage health care providers who integrate consumer eHealth technologies into their systems to take steps to ensure their safety and safe use. Consumer eHealth technology, like other health IT, must be designed, implemented, and used correctly.[78]

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

ONC has established the Health IT Patient Safety Program ("Safety Program"), led by ONC's Chief Medical Officer in coordination with the Office of Policy and Planning, to coordinate and implement this Plan (see figure in Appendix D). The functions of the ONC Safety Program are to:

- Coordinate the implementation of the Health IT Safety Plan by
    - Assisting all actors in fulfilling their responsibilities under the Plan, and
    - Collaborating with actors to incorporate health IT and patient safety in their organizations;
- Comprehensively analyze data on the safety of health IT from multiple sources to
    - Identify trends in patient safety and health IT,
    - Provide feedback to developers and providers,
    - Inform policies and other efforts to improve health IT patient safety, and

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[77] Building Better Consumer eHealth, Summary Report of Consumer eHealth Unintended Consequences Work Group Activities, http://www.healthit.gov/policy-researchers-implementers/reports (accessed May 17, 2013).
[78] IOM Report, *supra* note 1, at 122.

    - Develop policy recommendations; and
- Eliminate or significantly reduce inefficiencies across the programs by
    - Identifying any unnecessary overlap that occurs when implementing the Plan,
    - Evaluating the outcomes and effectiveness of the Plan as it is implemented, and
    - Determining from the outcomes what actions are beneficial, unnecessary, or insufficient (and whether additional actions are required).

Although led and run by ONC, the Safety Program will work with and gather input from federal partners—including AHRQ, CMS, FDA, and the Office for Civil Rights (OCR)[79]—to accomplish its objectives.

To further support the implementation of this Plan, ONC will establish an ad hoc HHS multi-agency committee by the end of 2013. The purpose of the ad hoc committee will be to prepare for and, when necessary, coordinate HHS's response to serious or unforeseen health IT safety concerns or issues. The ad hoc committee will comprise all HHS agencies with authority to respond to health IT patient safety issues, including CMS, FDA, OCR, and ONC. The ad hoc committee will also include other federal partners that have an important stake in health IT patient safety, such as AHRQ and the National Institutes of Health (NIH), as well as agencies that administer their own health IT systems, such as the Department of Defense (DoD) and the Department of Veterans Affairs (VA).

Information on the ONC Safety Program and the implementation of this Plan will be available at http://www.healthit.gov/policy-researchers-implementers/health-it-and-patient-safety.

[79] 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).

Summary

Health IT has enormous potential to improve patient safety. In order for physicians and other clinicians to use health IT to make care safer, they must be able to rely on these systems to perform safely in real clinical environments. The foregoing strategies and action steps constitute HHS's approach to achieving these aims, which it has framed in terms of the two objectives: (1) using health IT to make care safer, and (2) continuously improving the safety of health IT.

Learn: Increase the quantity and quality of data and knowledge about health IT safety

HHS will continue to devote resources towards building an infrastructure that encourages and facilitates reporting, collection, and analysis of health IT-related events and hazards. HHS will promote the use of the Common Formats to standardize and streamline reporting. HHS will also support PSOs to use the Common Formats to identify, aggregate, and analyze health IT safety event and hazard reports to increase knowledge about health IT patient safety and ways through which it can be improved. ONC will propose standards and certification criteria to ensure that, where appropriate, certified EHR technology can facilitate reporting of patient safety events and unsafe conditions using the Common Formats. ONC will also incorporate health IT safety in post-market surveillance of certified EHR technology.

Improve: Target resources and corrective actions to improve health IT safety and patient safety.

HHS will leverage the Meaningful Use and Health IT Certification Programs to align private sector efforts with national patient safety priorities. HHS will also disseminate tools and interventions that will improve the ability of health IT implementers and users to assess patient safety within their organizations, and enable health IT developers to incorporate the latest applied knowledge of health IT safety in their products. The Joint Commission will expand its capacity to identify and investigate the role of health IT as a cause of adverse events, and will develop educational materials and training opportunities, which will be widely publicly available, to enable health care providers to investigate and analyze health IT-related adverse events and develop follow-up and corrective action.

Lead: Promote a culture of safety related to health IT

For health IT to achieve its full potential to make care safer, the private sector must work together to develop a culture of safety, shared responsibility, learning, and continuous improvement. HHS will coordinate with health IT developers, users, PSOs, and other stakeholders to work together to advance patient safety through health IT. HHS will promote business practices that support a well-informed health IT marketplace that can drive innovations that continuously improve the safety of health IT.

Implementation of the Health IT Patient Safety Plan

Through the ONC Health IT Safety Program, HHS will monitor progress across all actors towards this Plan's objectives. HHS will continue to assess policies and other efforts to advance patient safety through health IT, and to ensure that patients and providers have confidence in the safety of the health care system, including its health IT infrastructure.

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
Recommendation 1. 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:	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.
Recommendation 1.a. 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.	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: • 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., continued
 	
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.
	• 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:
	  ○ 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.
	• 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).
	• 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.
	
	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,[1] health IT safety researchers are developing health IT safety guides, Safety Assurance Factors for EHR Resilience (SAFER) Guides.

[1] Unintended Consequences of Health IT and Health Information Exchange, Task Order HHSP23337003T/HHSP23320095655WC.

IOM Recommendation	Actions
Recommendation 1.b. 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.	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. The Strategic Health IT Advanced Research Projects–C (SHARP-C) Program is developing usability testing tools using NIST protocols.
Recommendation 1.c. 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.	ONC will collaborate with the ONC-Approved Accreditor on surveillance and provide guidance to ONC-ACBs for the surveillance of EHR technology capabilities that pose the greatest potential for patient harm and greatest opportunity to improve patient safety in future regulatory cycles.
Recommendation 1.d. Health care accrediting organizations should adopt criteria relating to EHR safety.	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. 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.

IOM Recommendation	Actions
Recommendation 1.e. AHRQ should fund the development of new methods for measuring the impact of health IT on safety using data from EHRs	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. 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. 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.

IOM Recommendation	Actions
Recommendation 2. 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.	On June 11, 2013, the Electronic Health Records Association (EHRA) announced adoption of voluntary industry code of conduct, which, among other important issues, includes prominent attention to EHR developer responsibility for patient safety and for interoperability and data portability. ONC supports this step and other private sector leadership that will promote a culture of safety, shared learning, and continuous improvement. As part of the ONC HIT Certification Program, ONC established the Certified HIT Product List (CHPL). The CHPL provides a comprehensive list of Complete EHRs and EHR Modules that have been certified by ONC-ACBs. This list is a publicly available database of health IT products that are certified in accordance with the certification criteria adopted by the Secretary and the ONC HIT Certification Program. Currently, each EHR product listed in the database notes the presence/absence of safety features such as drug-drug interaction or drug- allergy checking. The 2014 Edition EHR certification criteria also require developers to incorporate user-centered design and indicate their approach to quality management, 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. ONC-ACBs are required to submit a hyperlink of the test results used to issue a certification to an EHR technology. Test results hyperlinks are publicly accessible via the CHPL.

IOM Recommendation	Actions
Recommendation 3. The ONC should work with the private and public sectors to make comparative user experiences across vendors publicly available.	ONC will support and collaborate with the private sector to publish information on comparative user experiences. The Plan encourages 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). 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.

IOM Recommendation	Actions

Recommendation 4.
 	
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.
	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:
	• Coordinate the implementation of the Health IT Safety Plan by
	  ○ Assisting all actors in fulfilling their responsibilities under the Plan, and
	  ○ Collaborating with actors to incorporate health IT and patient safety in their organizations;
	• Comprehensively analyze data on the safety of health IT from multiple sources to
	  ○ Identify trends in patient safety and health IT,
	  ○ Provide feedback to developers and providers,
	  ○ Inform policies and other efforts to improve health IT patient safety, and
	  ○ Develop policy recommendations; and
	• Eliminate or significantly reduce inefficiencies across the programs by
	  ○ Identifying any unnecessary overlap that occurs when implementing the Plan,
	  ○ Evaluating the outcomes and effectiveness of the Plan as it is implemented, and
	  ○ Determining from the outcomes what actions are beneficial, unnecessary, or insufficient (and whether additional actions are required).
	
	The ONC Safety Program will develop policies and procedures to establish an ad hoc HHS multi-agency committee that would address major or systemic health IT patient safety issues through the coordination of policies and programs based on existing authorities.

Recommendation 5. 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.	Registering and listing EHR developer products certified for Meaningful Use is already being performed by ONC via the CHPL. The Health IT Safety Plan also highlights additional health IT-related safety criteria for adoption by the Secretary and inclusion in the ONC HIT Certification Program.

IOM Recommendation	Actions
Recommendation 6. 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.	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. ONC will support health IT safety interventions in hospitals and physician practices to evaluate risk management implementation processes and interventions related to the safety of health IT. ONC will support research of approaches that would inform the processes necessary to mitigate risks and improve the quality and accuracy of patient matching.
Recommendation 7. The Secretary of HHS should establish a mechanism for both developers and users to report health IT-related deaths, serious injuries, or unsafe conditions.	HHS will work to expand reporting in general by promoting the adoption of technology that makes it easier to do reporting, by building on the Common Formats, and by promoting use of PSOs. HHS will develop education and training materials on how to identify and report health IT-related events for use by EHR users and EHR developers. CMS will support efforts to report adverse events or hazards involving health IT using the Common Formats. CMS has issued guidance clarifying the requirements for internal adverse event reporting and follow-up of patient safety events in health care organizations subject to the Medicare and Medicaid Conditions of Participation.

IOM Recommendation	Actions
Recommendation 7.a. Reporting of health IT-related adverse events should be mandatory for developers.	ONC supports the EHRA Code of Conduct, which promotes reporting by EHR developers to PSOs and close collaboration with their customers. ONC-ACBs will conduct surveillance to ensure that the capabilities of certified EHR technology work in operational settings to the same extent as when these capabilities were certified. ONC will issue guidance to ONC-ACBs to add a specific focus on safety-related capabilities to their surveillance activities. This guidance will also prioritize the surveillance of EHR developers' processes for receiving and responding to user complaints concerning developers' products. ONC will also work with the ONC-Approved Accreditor (ANSI) to provide direction to ONC-ACBs on the complaint records that developers of certified EHR technology are required to keep and make available to them under the ONC HIT Certification Program. ONC will monitor health IT adverse event reports using the FDA's Manufacturer and User Facility Device Experience (MAUDE) database.
Recommendation 7.b. Reporting of health IT-related adverse events by users should be voluntary, confidential, and nonpunitive.	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). AHRQ is already developing the Quality & Safety Review System (QSRS) to facilitate retrospective surveillance of harm from all causes, including 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. 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.

IOM Recommendation	Actions
Recommendation 7.c. Efforts to encourage reporting should be developed, such as removing the perceptual, cultural, contractual, legal, and logistical barriers to reporting.	The Plan 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. 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. ONC recently funded a challenge 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. 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 used to report safety events in AHRQ's Common Formats. ONC has established a Structured Data Capture Standards and Interoperability Framework initiative that will pilot this technology and standards. (http://wiki.siframework.org/Structured+Data+Capture+Initiative). ONC believes EHR contracts should promote reporting and should not include terms that would discourage reporting. ONC has contracted for a guide to key EHR contract terms that will help EHR purchasers understand and evaluate such terms in EHR developer contracts.

IOM Recommendation	Actions
Recommendation 8. 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.	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. HHS will work with private sector organizations that have the ability to investigate, take corrective actions, and publicly report on their analysis of health IT-related events and hazards. Under a contract with ONC, The Joint Commission will expand its capacity to identify and investigate the role of health IT as a cause of adverse events, and will develop educational materials and training opportunities, which will be widely publicly available, to enable health care providers to investigate and analyze health IT-related adverse events and develop follow-up and corrective action. CMS will support efforts to investigate and take corrective action to address serious adverse events or hazards involving health IT. CMS has issued guidance clarifying the requirements for internal adverse event reporting and follow-up of patient safety events in health care organizations subject to the Medicare and Medicaid Conditions of Participation. CMS is also working with ONC to develop training materials for state survey agencies and surveyors, who conduct complaint investigation surveys on CMS's behalf, to enhance their ability to identify unsafe conditions associated with health IT. When surveys identify deficient practices, providers and suppliers must submit to CMS a plan of correction achieving compliance. HHS will continue to evaluate other mechanisms for investigating and taking corrective action to address serious adverse events or hazards involving health IT.

IOM Recommendation	Actions
Recommendation 9.a. 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.	This Health IT Patient Safety Plan serves as the HHS report on the progress of health IT safety for 2012.
Recommendation 9.b. 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 9.a. above.	In fulfilling FDASIA requirements, the Secretary, acting through the FDA Commissioner, and in collaboration with ONC and the FCC, will issue a report proposing a strategy and recommendations for an appropriate, risk-based regulatory framework for health IT that promotes innovation, protects patient safety, and avoids regulatory duplication. This report will be developed with significant public input. FDA, ONC, and FCC have issued a request for comment seeking broad input from stakeholders on elements they should consider in developing the report. The report will also be informed by input from the Health IT Policy Committee (which has formed a FDASIA Workgroup) and will incorporate what the agencies learn about risk, safety, and opportunity for innovative technologies to support improved health outcomes. The agencies will 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 how to design an oversight approach that supports innovations and patient safety.

IOM Recommendation	Actions
Recommendation 10. 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 a. User-centered design and human factors applied to health IT, b. Safe implementation and use of health IT by all users, c. Socio-technical systems associated with health IT, and d. Impact of policy decisions on health IT use in clinical practice.	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 B). AHRQ already has a portfolio of useful tools and reports for addressing the potential safety issues that arise when implementing and using EHRs.

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

Date	Research/Development Projects
2011	**IOM study (9/2010-11/2011)** • IOM was commissioned by ONC and published the report, "Health IT and Patient Safety: Building Safer Systems for Better Care."
2012	**Patient Safety Reporting Challenge Award** • 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. **Usability Development** • NIST developed tools for usability testing of certified EHR technology. • Usability Workshop. **Hazard Manager** • AHRQ has developed the Hazard Manager,[1] a software tool for proactive identification and remediation of health IT-related hazards. Hazard Manager can alert users to potential health IT-related hazards and can be used by health care organizations, health IT developers, PSOs, researchers, and policy-makers to characterize and communicate information about hazards and their potential causes and adverse effects. **Workflow Assessment for Health IT Toolkit** • AHRQ has developed the Workflow Assessment for Health IT Toolkit,[2] which helps small and medium-sized outpatient practices better assess their workflows and determine when and how health IT may be used. **Guide to Reducing Unintended Consequences of Electronic Health Records** • AHRQ has developed the Guide to Reducing Unintended Consequences of Electronic Health Records,[3] which helps health care organizations anticipate, avoid, and troubleshoot problems that can occur when implementing and using EHRs. **Implementation Toolsets for E-Prescribing** • AHRQ has developed the Implementation Toolsets for E-Prescribing,[4] a guide for preparing for and launching an e-prescribing system.

[1] Available at http://healthit.ahrq.gov/HealthITHazardManagerFinalReport (accessed May 17, 2013).
[2] Available at http://healthit.ahrq.gov/workflow/ (accessed May 17, 2013).
[3] Available at http://www.healthit.gov/unintended-consequences/ (accessed May 17, 2013).
[4] Available at http://healthit.ahrq.gov/portal/server.pt/community/health_it_tools_and_resources/919/implementation_toolsets_for_e-prescribing/30593 (accessed May 17, 2013).

Date	Research/Development Projects
2012, continued	**Designing Consumer Health IT: A Guide for Developers and Systems Designers** • AHRQ's Health IT Portfolio has published Designing Consumer Health IT: A Guide for Developers and Systems Designers,[5] which presents suggested recommendations for designers and developers of consumer health IT products to incorporate safe design.
2013[6]	**Professional Forums** • Workgroups or common interest groups have been or are being established at professional forums, such as HIMSS, AMIA, AMA, and other medical professional associations. **SAFER Guides** • ONC has contracted to develop health IT safety guides, such as SAFER Guides. **Usability Development** • 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. **Promoting Patient Safety Through Effective Health IT Risk Management Contract** • ONC has contracted [7] to identify and evaluate both risk management implementation processes and specific interventions (such as SAFER Guides) and to make recommendations on risk management implementation processes and interventions related to health IT-related risks that contribute to a healthcare system that continually improves the safety and safe use of health IT. ONC expects that this contract will be completed in March 2014. **Provider's Guide to Key Terms in EHR Developer Contracts** • To assist EHR users to better understand key contractual terms that could impact patient safety, ONC has contracted for development of a guide to key terms in EHR developer contracts.[8] This guide will assist purchasers and users of EHRs to understand and evaluate contract terms they should consider when purchasing EHR systems and services in order to protect their organizations from patient safety risks that may arise when these organizations rely on EHRs for critical aspects of their operations. **Investigation of Health IT-related Deaths, Serious Injuries, or Unsafe Conditions (The Joint Commission)** • Under a contract with ONC, the Joint Commission will build upon existing programs to better identify, understand, and investigate health IT-related deaths, serious injuries, and potentially unsafe conditions (sentinel events) in the private sector. It will develop and make widely publicly available educational materials and training opportunities to enable health care providers to investigate and analyze health IT-related adverse events and develop follow-up and corrective action.

[5] Available at http://healthit.ahrq.gov/health-it-tools-and-resources/designing-consumer-health-it-guide-developers-and-systems-designers (accessed May 17, 2013).
[6] 2013 action items reflect planned activities.
[7] Promoting Patient Safety Through Effective Health IT Risk Management, Task Order HHSP23337026T.
[8] This guide is being developed under the contract Unintended Consequences of Health IT and Health Information

Date	Research/Development Projects
2014[9]	**Report on appropriate, risk-based regulatory framework for health IT** The Secretary, acting through the FDA Commissioner, and in collaboration with ONC and the FCC, will issue a report on strategy and recommendations for an appropriate, risk-based regulatory framework for health IT that promotes innovation, protects patient safety, and avoids regulatory duplication.

Exchange, Task Order HHSP23337003T/HHSP23320095655WC. It should not be viewed as legal advice and does not attempt to address all of the many legal and other issues that may arise in contract negotiations. Each healthcare organization presents its own unique circumstances.

[9] 2014 action items reflect planned activities.

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

Date	Actions/Programs
2010	

	Meaningful Use (Stage 1) and 2011 Edition Standards & Certification Criteria
	• Stage 1 of the CMS Medicare and Medicaid EHR Incentive Programs (Meaningful Use Programs) requires use of features that can improve patient safety, such as:
	  ○ CPOE;
	  ○ CDS; and
	  ○ Maintaining lists of patient medications, allergies, and problems.

2011	
	Certified Health IT Product List (CHPL) • Established by ONC, the CHPL[1] provides a comprehensive list of Complete EHRs and EHR Modules that have been certified by ONC-ACBs.
2012	

	Meaningful Use (Stage 2) and 2014 Edition Standards & Certification Criteria
	• Stage 2 of Meaningful Use specifies two safety-enhanced certification criteria requiring developers to:
	  ○ Publicly identify a method of ensuring user-centered design; and
	  ○ Publicly identify an approach to quality management.
	• ONC and CMS will continue to use rulemakings to enhance patient safety.
	• ONC intends to use certification criteria to ensure that EHR technology can be used to easily initiate health IT-related adverse event reports using AHRQ's Common Formats.
	• HIT Policy Committee will continue to review patient safety-related comments to inform their recommendations for future MU recommendations.

2013[2]	
2013 Q1	**Manufacturer and User Facility Device Experience (MAUDE) Database** • ONC will monitor the MAUDE database for health IT-related adverse event reports.

[1] Certified Health IT Product List, http://oncchpl.force.com/ehrcert?q=chpl.
[2] 2013 action items reflect planned activities.

Date	Actions/Programs
2013 Q1 con't	**Align CMS standards and initiatives with the safety of health IT** • CMS will consider options for realignment of its health and safety standards with efforts to increase reporting of health IT-related adverse events and hazards using the Common Formats. • CMS and ONC will develop training for surveyors that enhances their ability to identify safe and unsafe practices associated with health IT. • 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. **Medicare Patient Safety Monitoring System (MPSMS)** • 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.
2013 Q2	**Encourage private sector leadership and shared responsibility for health IT patient safety** • EHRA has adopted a voluntary industry code of conduct to encourage an increased level of industry self-regulation. ONC will continue to support private sector leadership that will promote a culture of safety, shared learning, and continuous improvement. • ONC is developing a guide to several important terms commonly included in EHR developer contracts. [3] This guide will assist providers to understand common EHR developer contract terms and their implications for providers' patient safety programs. It will explain what information users and purchasers should consider when purchasing EHR systems and services in order to protect their organizations from patient safety risks that may arise when these organizations rely on EHRs for critical aspects of their operations. **Encourage medical education and training in health IT and patient safety** • ONC will work with the following types of organizations to foster a culture of safety and the dissemination of tools (e.g., SAFER Guides) and strategies: o Accrediting bodies; o Patient safety organizations; o Liability insurers; o Educational organizations; and o Professional associations.

[3] This guide is being developed under the contract Unintended Consequences of Health IT and Health Information Exchange, Task Order HHSP23337003T/HHSP23320095655WC. It should not be viewed as legal advice and does not attempt to address all of the many legal and other issues that may arise in contract negotiations. Each healthcare organization presents its own unique circumstances.

Date	Actions/Programs

2013 Q2 con't	**<u>Establish the ONC Safety Program</u>**
	• Through the Safety Program, ONC will:
	  o Coordinate the implementation of the Health IT Safety Plan;
	  o Comprehensively analyze data from the data streams; and
	  o Ensure that there are no redundancies or inefficiencies across the programs.
	
	<u>Enable The Joint Commission to investigate health-IT related deaths, serious injuries, and potentially unsafe conditions</u>
	• The Joint Commission will investigate health IT-related deaths, serious injuries, and potentially unsafe conditions in the private sector, and provide public safety information based on such investigations. The Joint Commission will expand its capacity to investigate the role of health IT as a cause of adverse events, and will develop educational materials and training opportunities to enable health care providers to investigate and analyze health IT-related adverse events and develop follow-up and corrective action.

2013 Q3	**<u>Issue ONC-ACB surveillance guidance</u>**
	• ONC will incorporate health IT and patient safety into ONC-ACB surveillance and certification of EHRs.
	• ONC will provide guidance to ONC-ACBs, regarding specific elements of surveillance, including:
	  o Focusing on certain safety capabilities included in the 2014 Edition EHR certification criteria; and
	  o Reviewing complaints received by EHR technology developers on their certified Complete EHRs or EHR Modules related to certain safety capabilities.

2013 Q4	**<u>Establish an ad hoc HHS multi-agency committee</u>**
	• ONC will establish an ad hoc HHS multi-agency committee to prepare for and, when necessary, coordinate HHS's response to serious or unforeseen health IT safety concerns or issues.
	
	<u>Support PSOs to collect, aggregate, and analyze safety event and hazard reports</u>
	• 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 supported by AHRQ will incorporate health IT and patient safety when:
	  o Facilitating reporting of patient safety events;
	  o Investigating patient safety events;
	  o Working with providers to mitigate patient safety hazards; and
	  o Aggregating and analyzing reports to identify trends in health IT-related patient safety events.

Date	Actions/Programs
2014[4]	
2014 Q1	**Meaningful Use (Stage 2) and 2014 Edition Standards & Certification Criteria** • Stage 2 of Meaningful Use will take effect beginning in 2014 (federal fiscal year 2014 for eligible hospitals and CAHs; calendar year 2014 for eligible professionals). • Stage 2 specifies two safety-enhanced certification criteria requiring developers to: o Publicly identify a method of ensuring user-centered design; and o Publicly identify an approach to quality management. • The HIT Policy Committee will continue to review patient safety-related comments to inform their recommendations for future stages of MU. • ONC and CMS will continue to use rulemaking to enhance patient safety. • ONC intends to use certification criteria to ensure that EHR technology can be used to easily initiate health IT-related adverse event reports using AHRQ's Common Formats. **Incorporation of health IT and patient safety reporting by state governments** • 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. **Report on appropriate, risk-based regulatory framework for health IT** • HHS will submit to Congress a proposed strategy and recommendations on an appropriate risk-based regulatory framework for health IT that promotes innovation, protects patient safety, and avoids regulatory duplication.
2014 Q2	**Develop safety priority areas, measures, and targets** • ONC will lead a public-private process to identify health IT safety priority areas within the larger context of general patient safety, and create related measures and targets for reduction of health IT-related adverse events.
2014 Q3	**AHRQ's QSRS** • To increase surveillance, AHRQ will develop the Quality & Safety Review System (QSRS) that incorporates AHRQ's Common Formats (in development during 2013).

[4] 2014 action items reflect planned activities.

Appendix D: ONC Patient Safety Program