ONC Fact Sheet:
Health Information Technology
Patient Safety Action and Surveillance Plan

Background

Health information technology (health IT) enables substantial improvements in health care quality and safety, compared to paper records. Yet health IT can only fulfill its enormous potential if 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.

The *Health IT Patient Safety Action and Surveillance Plan* ("Health IT Safety Plan" or "Plan") addresses the role of health IT within HHS's commitment to patient safety. Building on recommendations in the 2011 Institute of Medicine (IOM) Report *Health IT and Patient Safety: Building Safer Systems for Better Care*,[1] the Plan provides a roadmap for increasing knowledge of health IT safety and ensuring that health IT is used to make care safer.

On behalf of HHS, ONC has released the final Health IT Safety Plan based on a draft issued for public comment on Dec. 21, 2012. ONC is coordinating the implementation of the Plan through the ONC Health IT Safety Program. More information about the Plan and its implementation is available at http://www.healthit.gov/policy-researchers-implementers/health-it-and-patient-safety.

Summary of the Health IT Safety Plan
The Health IT Safety Plan has two fundamental objectives:

1. To promote the health care industry's use of health IT to make care safer; and
2. To continuously improve the safety of health IT.

Proceeding from the premise that all stakeholders have a shared responsibility to ensure that health IT is used to make care safer, the Plan leverages existing authorities to strengthen patient safety efforts across government programs and the private sector—including health care providers, health IT developers, patient safety organizations, and accrediting and oversight bodies. The Plan also identifies specific strategies and actions for increasing knowledge about the impact of health IT on patient safety and using that knowledge to improve the safety of health IT and patient care.

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[1] IOM, *Health IT and Patient Safety: Building Safer Systems for Better Care* (2011).

Plan Strategies

The Health IT Safety Plan lays out immediate actions that HHS and private sector stakeholders can take to improve health IT safety. These actions are organized under three strategies:

A. **Learn**: Increase the quantity and quality of data and knowledge about health IT safety
B. **Improve**: Target resources and corrective actions to improve health IT safety and patient safety
C. **Lead:** Promote a culture of safety related to health IT

Plan Highlights

1. **Improve knowledge of health IT safety:**

- Make it easier for clinicians to report health IT-related events and hazards:
  o The Agency for Healthcare Research and Quality (AHRQ) will update its Common Formats so that clinicians can more easily record and report information about health IT-related events and hazards to Patient Safety Organizations.
  o The Centers for Medicare & Medicaid Services (CMS) will encourage the use of Common Formats in hospital incident reporting programs and will develop training resources to educate CMS surveyors on health IT safety and event reporting.
  o ONC will propose standards and certification criteria that make it easier for providers to quickly generate incident reports from data stored in electronic health records (EHRs).
  o AHRQ and ONC will provide tools and resources to help providers identify, describe, and report health IT-related events and hazards.

- Collect, aggregate, and analyze patient safety reports:
  o AHRQ and ONC will work with PSOs, providers, and developers to add a focus of health IT to their collection, aggregation, analysis, and mitigation of providers' adverse event reports. AHRQ will also provide guidance to PSOs on how they can work with EHR developers to identify and mitigate health IT risks.
  o AHRQ will develop the Quality & Safety Review System (QSRS). The QSRS will provide national estimates of adverse events using the Common Formats and will make it possible to explore the role of health IT in these events.
  o ONC will monitor health IT adverse event reports to the Food and Drug Administration's (FDA's) Manufacturer and User Facility Device Experience database.

- Incorporate health IT safety in post-market surveillance of certified EHR technology (CEHRT):
  o ONC has issued guidance to ONC-Authorized Certification Bodies (ONC-ACBs) regarding the surveillance and live testing of CEHRT. ONC-ACBs will be expected to verify whether the capabilities of CEHRT continue to function properly when deployed in a live clinical setting. This knowledge will provide insight into how specific types of EHR capabilities (e.g., computerized physician order entry 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.

- o ONC-ACBs will also review health IT developers' processes for receiving and responding to complaints about their certified products. When reviewing developers' complaint processes, ONC-ACBs will be expected to focus on safety-related capabilities.

2. **Establish and advance health IT patient safety priorities**:

- In consultation with its federal advisory committees, ONC will leverage 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 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.
- ONC will lead a public-private process to establish priorities for improving health IT safety and using health IT to make care safer. These priorities will enable HHS to align improvement efforts across the government and private sector, and target and measure success.
- CMS and ONC will continue to use the Medicare and Medicaid EHR Incentive Programs and related standards and certification criteria to advance improvement priorities through the adoption of safety-related objectives, measures, and CEHRT requirements.[2]
- ONC will also explore ways to make existing health IT capabilities safer and maximize their potential for enhancing patient safety.

3. **Support research and development of tools and best practices:**

- AHRQ and ONC will support the research and development of tools and guidance for using health IT to improve safety and mitigate health IT safety risks.
- ONC will package and disseminate a new class of health IT safety tools and interventions that will 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.
- ONC will coordinate with the National Institute for Standards and Technology 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.

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[2] For example, in 2014 eligible providers will be required to demonstrate several new safety-related objectives such as using CDS to improve clinical performance with respect to high-priority conditions and performing electronic medication reconciliation when receiving patients from another setting of care. Health IT developers will be required to incorporate user-centered design in the development of their products, and to publicly identify their approach to quality management. ONC will continue to work with its federal advisory committees to propose additional objectives, measures, and CEHRT requirements that support priorities for improving patient safety through the meaningful use of health IT.

4. **Investigate and take corrective action:**
   - ONC awarded a contract to The Joint Commission that will assist ONC in detecting and proactively addressing potential health IT-related safety issues across a variety of health care settings. 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. The Joint Commission will make the results of its investigations available to ONC in summary format (excluding identifiable information and subject to privilege, confidentiality, and privacy protections) and 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. The Joint Commission will identify high priority areas for expected types of health IT-related sentinel events and develop a corresponding classification scheme based on literature, expert opinion, and insights gleaned through its investigations and analyses.
   - CMS will support efforts to investigate and take corrective action to address serious adverse events or hazards involving health IT.

5. **Encourage private sector leadership and shared responsibility:**
   - ONC will encourage industry groups and trade associations to educate their members on their shared responsibility for patient safety and a culture of safety in a health IT-enabled learning health care system.
     - On June 12, 2013, the Electronic Health Record Association adopted a voluntary industry code of conduct which includes principles that support patient safety.
   - ONC will assist providers to implement strategies and activities to support patient safety, and will encourage providers to engage developers in these improvement efforts.

6. **Administer the ONC Safety Program:**
   - ONC has established the Health IT Patient Safety Program, led by ONC's Chief Medical Officer in coordination with the Office of Policy and Planning, to coordinate and implement this Plan. The functions of the Safety Program include:
     - Coordinating implementation of the Health IT Safety Plan;
     - Comprehensively analyzing data from multiple sources;
     - Eliminating or significantly reducing inefficiencies across the programs; and
     - Establishing an ad hoc HHS multi-agency committee to address major health IT safety policy issues.
   - ONC will continually evaluate the effectiveness of the Health IT Safety Plan and ensure its efficient implementation. 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)[3]—to accomplish its objectives.

- ONC will collaborate with FDA and the Federal Communications Commission as FDA continues to develop a report that proposes a strategy and recommendations for an appropriate risk-based regulatory framework for health IT that protects patient safety, promotes innovation and avoids regulatory duplication.

More information about the Health IT Safety Plan and its implementation can be found at http://www.healthit.gov/policy-researchers-implementers/health-it-and-patient-safety.

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[3] 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).