Background
In February, 2010, Jeffery Shuren, Director of the Center for Devices and Radiological Health at FDA, testified before the HIT Policy Committee. Dr. Shuren stated that electronic health records were medical devices and therefore subject to regulatory oversight by the FDA. At the April, 2010 HIT Policy Committee meeting, the HITPC Certification/Adoption Workgroup issued a series of recommendations designed to establish a patient-centered approach to HIT safety that would be consistent with the ONC’s vision of a learning healthcare system. In September, 2010, the Institute of Medicine was awarded a $989,000 contract from the U.S. Department of Health and Human Services to:

- Summarize existing knowledge of the effects of HIT on patient safety
- Identify approaches to promote the safety-enhancing features of HIT while protecting patients from any safety problems associated with HIT
- Identify approaches for surveillance and reporting activities to bring about rapid detection and correction of patient safety problems
- Address the potential roles of private sector entities such as accrediting and certification bodies as well as patient safety organizations and professional and trade associations
- Discuss existing authorities and potential roles for key federal agencies, including FDA, AHRQ, and CMS.

IOM launched the The Committee on Patient Safety and Health IT with a public meeting in December, 2010. During the course of two public meetings, where the Committee heard testimony from FDA, ONC, AHRQ, and numerous private sector stakeholders, the Committee developed a letter of recommendations to HHS.

IOM Evaluation of the Current State of Patient Safety and Health IT

- While some studies exist indicating that patient safety is improved through the meaningful use of health IT, and some instances of health IT associated harm have been reported, there is currently little published evidence that attempts to quantify the risk of health IT implementation.
- The current environment in which health IT is designed and used does not adequately protect patient safety. The private sector currently consists of a broad variety of stakeholders lacking a uniform approach, and potentially misaligned goals.
- There is an absence of measures and repositories to collect, analyze, and measure the impact of health IT on patient safety.
- Contractual restrictions, such as non-disclosure and confidentiality clauses required by some vendors, limit transparency, which contributes to the gaps in knowledge of HIT-related patient safety risks. Such restrictions pose “unacceptable risks” to patient safety.
- Safer implementation and use of health IT is a complex, dynamic process that requires a shared responsibility between vendors, hospitals, and providers.
- Health IT associated threats to patient safety include a lack of system interoperability, poor user-interface design, poor workflow and complex data interfaces.
- Application of quality management practices and usability should be a high priority for vendor design, development and certification.
- The private sector must play a major role in making health IT safer, but it will need support from and collaboration with the public sector.
• Lack of vendor action to build safer products, or regulatory requirements to do so, threatens patient safety.
• Successful adoption of change requires education and training of workforce.
• In other countries and industries, reporting systems all differ with respect to their design, but the majority employ reporting that is voluntary, confidential, and non-punitive.

IOM Recommendations for EHRs and Patient Safety

The IOM Committee on Patient Safety concluded that an environment of safer health IT can be created only if private (hospitals, providers, payor, patients, and vendors) and public sectors recognize that patient safety is a shared responsibility. The private sector can create safer health IT by promoting shared learning environments, while the public sector should provide strategic guidance and oversight in order to correct misaligned market-forces.

The Committee recommends that any federal government oversight focus on shared learning, maximize transparency, be non-punitive, identify appropriate levels of accountability, and minimize burden.

Recommendation 1: 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 implementation and use. The plan should specify:

a. AHRQ and the National Library of Medicine should expand 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.

b. ONC should expand funding of processes that promote safety which should be followed in the development of health IT products, including standardized testing procedures to be used by manufacturers and healthcare organizations to assess the safety of health IT.

c. ONC and AHRQ should work with vendors and healthcare organizations to promote post deployment safety testing of EHRs for high-prevalence, high-impact EHR related patient safety risks.

d. ONC certification bodies should adopt criteria relating to EHR safety.

e. AHRQ should fund the development of new methods for measuring the impact of health IT on safety utilizing data collected by EHRs.

Recommendation 2: HHS should ensure that vendors support the free exchange of information about health IT experiences and issues and not prohibit sharing of such information, including details related to patient safety.

The Committee suggests solutions such as ONC certification requiring contracts that allow EHR safety and user experience information to be shared and that ONC develop model contract language that would establish the ability of users to provide content and contextual information when reporting an adverse event or unsafe condition. The Committee also recommends that

HHS develop guidance for users regarding patient safety to review prior to signing a contract, shared through CMS QIOs or ONC Regional Extension Centers.

The Committee also calls HHS to conduct a review of existing EHR contracts to determine how pervasive non-disclosure and confidentiality clauses are in the health IT marketplace.

**Recommendation 3:** ONC should work with the private and public sectors to make comparative user experiences across vendors publicly available.

a. To support this recommendation, the Committee suggests that ONC develop a Common Reporting format for health IT-related adverse events

**Recommendation 4:** 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. The council should operate within an existing voluntary consensus standards organization (such as National Quality Forum.)

a. Measurements created by organizations (see Recommendation 1) for determining patient safety should be NQF-endorsed.

**Recommendation 5:** All health IT vendors should be required to publicly register and list their products with ONC, initially beginning with EHRs certified for the CMS EHR Incentive program.

**Recommendation 6:** HHS should specify the quality and risk management process requirements that health IT vendors must adopt, with a particular focus on human factors, safety culture, and usability.

**Recommendation 7:** HHS should establish a mechanism for both vendors and users to report health IT–related deaths, serious injuries, or unsafe conditions.

a. Reporting of health IT-related adverse events should be mandatory for vendors. The report suggests that the new oversight agency would be empowered to penalize vendors who do not comply.

b. Reporting of health IT-related adverse events by users should be voluntary, confidential, and non-punitive.

c. Efforts to encourage reporting should be developed, such as removing the perceptual, cultural, contractual, legal, and logistical barriers to reporting.

**Recommendation 8:** 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.

**Agency Responsibilities**

- Aggregate reports of health IT-related adverse events from at least vendors and users
- Analyze the aggregated reports to identify patterns
- Investigate reports of health IT-related patient deaths or serious injury
- Investigate trends of reports of unsafe conditions
- Recommend corrective actions to HHS
- Provide feedback to vendors and users following investigations
- Disclose results of the investigations to the public, including researchers and consumers

Why is a new federal entity is required?

- The current FDA medical device regulatory framework is oriented toward conventional, out-of-the-box, turnkey devices. Health IT’s characteristics suggesting that a more flexible regulatory framework will be needed to achieve the goals of product quality and safety without constraining market innovation.
- In order to regulate HIT, FDA would need to commit sufficient resources and add capacity and expertise that FDA does not currently have available.
- AHRQ supports research and technical assistance activities regarding quality and safety. It is not an oversight or investigative agency.
- CMS is an administrative agency that uses punitive elements for enforcement and are inappropriate for completing the aggregative, analytic, and investigative functions.
- ONC does not have the clinical and operations expertise to conduct investigations of health IT-related adverse events. ONC also is not an operating division of HHS and doesn’t have regulatory authority.
- Private-sector organizations such as The Joint Commission, NCQA, and NQF are mostly dependent on short-term funding and content may be shaped in part by funders. They also do not have the influence of a federal entity.

Recommendation 9a: 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 HHS, HHS should direct the FDA to exercise all available authority to regulate EHRs, health information exchanges, and PHRs.

Recommendation 9b: HHS should direct the FDA to begin developing the necessary framework for regulation. Such a framework should be in place if and when the HHS decides the state of health IT safety requires FDA regulation (see Recommendation 9a.)

Recommendation 10: HHS should collaborate with other research groups to support cross-disciplinary research toward the use of health IT as part of a learning health care system. Products developed should:
  a. Include user-centered design and human factors applied to health IT
  b. Ensure safe implementation and use of health IT by all users
  c. Ensure application of socio-technical systems associated with health IT
  d. Reflect the impact of policy decisions on health IT use in clinical practice