



Institute of Medicine Committee on Health IT and Patient Safety

Meeting Notes December 14th, 2010

Meeting Agenda

Background

In September, 2010, the Institute of Medicine was awarded a \$989,000 contract from ONC to:

- Summary of existing knowledge of the effects of HIT on patient safety;
- Identifying approaches to promote the safety-enhancing features of HIT while protecting patients from any safety problems associated with HIT;
- Identifying approaches for preventing HIT-related patient safety problems before they occur;
- Identifying approaches for surveillance and reporting activities to bring about rapid detection and correction of patient safety problems;
- Addressing the potential roles of private sector entities such as accrediting and certification bodies as well as patient safety organizations and professional and trade associations; and
- Discussion of existing authorities and potential roles for key federal agencies, including the Food and Drug Administration (FDA), the Agency for Healthcare Research and Quality (AHRQ), and the Centers for Medicare & Medicaid Services (CMS).

The Committee will be chaired by Mr. Gail Warden of the Henry Ford Health System in Detroit and is staffed by Samantha Chao of the Institute of Medicine.

Introduction, Committee Charge, and ONC Resources

Dr. David Blumenthal, National Coordinator for Health Information Technology, kicked off the session by reviewing the Institute of Medicine's role in getting HITECH passed by Congress, over-viewing the tasking of the Committee, and highlighting ONC resources that can help the Committee develop recommendations. Click here to [read his statement](#) that was submitted to the Committee. Please note, Dr. Blumenthal expanded greatly on the prepared statement during his comments.

- stated that IOM was critical in "creating the political will to pass" HITECH
- "Whenever one undertakes a major social change and does so rapidly, there are transitional issues, risks, and unintended consequences. It behooves the federal government to understand those issues."
- The Committee on Patient Safety and Health IT is tasked with helping HHS understand if day to day, healthcare encounters with a provider or hospital are safer with electronic systems rather than with paper based systems
- The Committee is tasked with identifying vulnerabilities with the MU implementation and how can "we" fix them (problems like ergonomics, training, usability) and summarizing currently available data on HIT impact on patient safety
- Noted that "anecdotal reports, that have not been thoroughly analyzed, are trickling in highlighting potential problems. We need you to analyze these reports"
- The Committee is tasked to recommend what should federal agencies do to fully maximize impact on patient safety, including who has regulatory authority and what appropriate levers should be used to achieve maximum safety.
- Dr. Blumenthal stated that the 62 Regional Extension Centers (REC), funded by ONC through the HITECH Act, may be a tool to mitigate implementation problems that cause EHR related adverse events. RECs provide technical assistance such as training healthcare workers workflow improvement best practices.
- Dr. Blumenthal noted that it "is no accident" that 1/3 of RECs are quality improvement organizations



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- ONC sees University-Based Health IT training and Community College Consortium Health IT training programs as another tool that can mitigate adverse event risk through more effective workforce training.
- ONC has contracted Westat and AMIA to study unintended consequences
- Dr. Blumenthal also stated that FDA and AHRQ both have reporting systems (using a common reporting format) for tracking EHR-related adverse events. He suggested that IOM utilize them as data sources.
- Dr. Blumenthal also lauded private sector efforts. He cited the I-Health Alliance effort to create a patient safety org (PSO) to receive and analyze reports on EHRs related adverse events www.ehrevent.org
- Dr. Blumenthal announced that there are currently five ONC Authorized Temporary Certification Bodies and those organizations have certified 130 EHRs to date
- Dr. Blumenthal commented that ONC "shortly" will be issuing a FINAL RULE on permanent certification bodies.
- Dr. Blumenthal noted that the SHARP program has funded cutting edge private sector usability lab work in Texas. He stated that for Stage 2 or Stage 3 of Meaningful Use, EHR Certification could include usability requirements. He commented offhand that "private sector usability testing for patient safety" "may be a good recommendation" and within the scope of the committee.
- Tasks them to make recommendations on FDA levers to maximize patient safety through the use of HIT and commented "the federal government is balancing need to rapidly push forward HIT adoption and preserve/advance new innovation in healthcare against the need to be vigilant with safety concerns.
- Dr. Blumenthal asks the Committee to "be deliberate and weigh the uniqueness of EHRs"
- Dr. Blumenthal stated that he is hoping to receive the Committee's recommendation as soon as possible, so the recommendations can be weighed before the release of the Stage 2 Meaningful Use NPRM, which is scheduled to be published by December, 2011.
- During Q and A he noted that Personal Health Technologies are within the scope of IOM Committee recommendations.

Reporting and surveillance of patient safety events

During briefing panels, Committee members asked vendors (CISCO) for a report of every "bug-fix" they have completed over the past year. They also asked both CISCO and Geisinger Health System for a report of "every event cause EHR that has killed or harmed a human being" over the past calendar year. When neither organization could produce a report, the Committee member commented that the inability to get such information would be reflected in their report.

Oversight of Health IT: Roles of Federal Agencies and the Private Sector

Dr. Jeffery Shuren, Director, Center for Device and Radiological Health, Food and Drug Administration

- FDA has received reports that from January 2008-December 2010 there have been 370 adverse events/near misses associated with HIT. The causes: usability, interoperability, design, etc
- Dr. Shuren noted that disincentives to self report mean these findings are likely a small sample of actual number of incidents.
- FDA currently regulates some health IT as medical devices. FDA uses regulatory discretion not to regulate EHRs, even though they are medical devices. Patient management systems are not regarded as
- FDA is eager for IOM to make recommendations on if FDA should use their regulatory authority to ensure safe EHRs
- FDA has 4 recommendations for any federal electronic health record safety oversight
 - It should use a risk based approach
 - Expect operational quality



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- Develop clear interoperability standards
 - Establish a robust learning infrastructure/ surveillance system
- FDA and AHRQ partner on The Common Format for adverse event reporting on health IT
- FDA has experience in delivering the above 4 goals while balancing public health interests with the benefits of technical innovation
- FDA has power to:
 - list manufacturers
 - can force manufacturers to provide data on adverse events
 - can require vendor to have a quality manufacturing management system
 - can require submission of data before higher risk products go to market (510K or premarket)
 - FDA develops interoperability standards
- FDA has two major health IT focus areas for 2011
 - FDA will release mobile medical device guidance in 2011
 - FDA will also release guidance on stand-alone applications requiring quality management systems