



Health IT Policy Committee

A Public Advisory Body on Health Information Technology to the National Coordinator for Health IT

August 6, 2014

Karen DeSalvo, MD
National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Dr. DeSalvo:

The HIT Safety Task Force, chaired by Dr. David Bates, was given the charge of responding to the recommendations in the FDASIA, April 2014, draft Health IT Report. Specifically, the HIT Policy Committee requested the HIT Safety Task Force propose recommendations that address the concept of an HIT Safety Center.

Background

Section 618 of the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012 directed the Secretary of Health and Human Services, acting through the Commissioner of the U.S. Food and Drug Administration (FDA), ONC, and the Chairman of the Federal Communications Commission, to develop a report that contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework for health IT. Additional goals for the framework were to address mobile medical applications, promote innovation, protect patient safety, and avoid regulatory duplication.

Framework for Considering the HIT Safety Center

The HIT Safety Task force was asked to consider how an HIT Safety Center might 1) facilitate reporting of HIT safety issues through such avenues as Patient Safety Organizations (PSOs); 2) promote transparent sharing of information on adverse events/near misses and lessons learned; and 3) disseminate best practices for implementing and operating EHRs. In addition, the Task Force was asked to consider the role and governance of an HIT Safety Center in a learning health system and how it might complement and not duplicate or usurp existing groups' activities.

In formulating its recommendations the HIT Safety Task Force heard from a number of organizations including the:

- National Transportation Safety Board (NTSB)
- Veterans Affairs Safety Center
- Agency for Healthcare Research and Quality (AHRQ)
- ECRI (a PSO focused on patient safety)

- Electronic Health Record Association (EHRA)
- Federal Aviation Administration representatives from the Aviation Safety Information Analysis and Sharing (ASIAS) system

The HIT Safety Task Force recommendations in the key areas of value, focus, functions and governance are listed below. The HIT Policy Committee adopted these recommendations at their July 9, 2014 meeting.

Value Proposition

The HIT Safety Center can provide value to stakeholders through the following activities:

1. Aggregating and analyzing HIT safety data from different sources
2. Convening public and private stakeholders in a common forum
3. Disseminating best practices, tools and defined products
4. Educating and engaging stakeholders in HIT safety

Focus:

The safety center should:

1. Establish a non-regulatory role and focus on recommendations for policy and standards
2. Address all types of HIT, not just electronic health records
3. Emphasize learning, not enforcement
4. Consider sociotechnical issues as well as technical
5. Review longitudinal evidence from a variety of stakeholders and data streams, including adverse event and near miss reports from sources such as vendors, providers, hospitals, patients, advocacy groups, PSOs and other IT stakeholders
6. Maintain transparency, noting the safety center might not have legal protection of PSOs
7. Partner with other organizations (e.g., PSOs) that conduct investigations; the Safety Center would not perform independent investigations of specific events and should avoid duplication of existing activities in the public /private sectors

Functions:

Key functions could include:

1. Engagement of key stakeholders
2. Aggregation and review of evidence from multiple data streams
3. Convening of disparate groups and identification of top priorities
4. Education and providing best practices, definitions, examples, and tools to standardize reporting (e.g., AHRQ Common Formats)
5. Inform usability and ONC's certification criteria for user-centered design; provide two-way learning between safety center and ONC's certification program with a possible (to be defined) role in post-implementation testing
6. Clearinghouse for HIT safety-related theories and ideas for best practices
7. Promote evidence-based guidelines and best practices (e.g. SAFER guides)
8. Disseminate regular reports covering trends in events and improvements

Governance

Governance elements to consider:

1. Public/private partnership operating outside of government but resourced by ONC; additional private funding desirable
2. Look to other industries for examples of successful governance models (e.g., the FAA ASIAs program)
3. Start small in scope and gradually grow; begin with a 10-12 member governance board, then redesign/re-evaluate governance structure at 18-24 months
4. Representation from key healthcare leaders such as CIOs/CMIOs/CNIOs, but driven by front-line provider concerns (multidisciplinary); include patient representation, likely from a consumer organization

As noted previously, the HIT Policy Committee adopted these recommendations at its July 9, 2014 meeting. We appreciate the opportunity to provide these recommendations and look forward to discussing next steps.

Sincerely yours,

/s/

Paul Tang
Vice Chair, HIT Policy Committee