The Office of the National Coordinator for Health Information Technology

RTI INTERNATIONAL

Health IT Safety Center Road Map Task Force

Introduction and Background

The mission of the Office of the National Coordinator for Health IT (ONC) includes developing a health IT infrastructure to promote safety, reduce medical errors, and increase quality and value in health care.

ONC supported that patient safety mission by commissioning the Institute of Medicine (IOM) to produce a report in 2011: *Health IT and Patient Safety: Building Safer Systems for Better Care*.[i] The report recommended a number of actions which, when implemented, would result in a learning health system that leverages health IT to provide safer, better care. The IOM stated that "shared responsibility" among public and private sector stakeholders for the safety and safe use of health IT is essential.

Building on the IOM Report, ONC released the Department of Health and Human Services' *Health IT Patient Safety Action and Surveillance Plan*[ii] (Health IT Safety Plan) in July 2013, which identified strategies to achieve two core objectives: 1) use health IT to make care safer, and 2) continuously improve the safety of health IT.

In April 2014, ONC, the U.S. Food and Drug Administration (FDA), and the Federal Communications Commission (FCC) published the congressionally mandated *FDASIA Health IT Report, Proposed Strategy and Recommendations for a Risk-Based Framework*.[iii] The draft report identified the potential creation of a Health IT Safety Center as a key non-regulatory component of an effective risk-based framework for health IT safety. For health IT not currently regulated by the FDA, the FDASIA draft report suggested four priorities: promote the use of quality management principles; identify, develop, and adopt standards and best practices; leverage conformity assessment tools; and create an environment of learning and continual improvement. The FDASIA draft report envisioned a Health IT Safety Center as a public-private entity that helps create a sustainable, integrated learning system for health IT safety that would promote innovation and leverage and complement existing and ongoing safety initiatives.

Health IT Safety Center Road Map Project

Based on this work, in September 2014, the ONC contracted with RTI International to develop a Road Map for a potential Health IT Safety Center. As a central component of this work, RTI has convened a Task Force of private-sector stakeholders to provide input into the development of the Road Map. Representatives from ONC, the Agency for Healthcare Research and Quality (AHRQ), the FDA, the FCC and, as appropriate, other Federal agencies will also participate in the Task Force.

Defining Core Health IT Safety Center Objectives and Functions in the Road Map

In developing the Road Map, the Task Force will be asked to prioritize the value of potential core activities, as well as to consider options for governance and for funding mechanisms/levels for a Health IT Safety Center. Initially, the focus will be on health IT-related clinical processes that rely upon interoperable certified electronic health record technology, although that focus may broaden over time. **Table 1** provides a broad summary of operational considerations for a potential Health IT Safety Center. The Task Force may consider other factors that might strengthen the Health IT Safety Center's value proposition and engage private-sector stakeholders in ways that support (and do not supplant) private-sector health IT safety initiatives and responsibilities.

Table 1. Operational Considerations for the Health IT Safety Center Road Map

Potential Core Activities

• Provide educational programs about research and activities, including programs by key stakeholders.
• Promote opportunities for engagement in health IT-related safety activities and programs in the public and private sectors.
• Analyze evidence on health IT safety and safety tools/interventions, including producing periodic written reports on:
  ○ research on types, severity, and frequency of health IT-related events, and related methodology and classification/taxonomy issues;
  ○ research on specific priority areas related to health IT safety;
  ○ identification and evaluation of tools and interventions intended to mitigate risks of the use of health IT or that use health IT to make care safer; and
  ○ identification of gaps in the research or the need for development or refinement of tools/interventions that could improve health IT safety or use health IT to make care safer.
• Foster health IT safety research and practical, actionable tool/intervention development in the private sector and by government.
• Identify health IT safety goals, priorities, and related measures to help align and harmonize public- and private-sector initiatives related to patient safety in health IT-enabled environments.
• Encourage stakeholders to: (1) measure and evaluate progress toward identified goals, and (2) share learning about making health IT safer and using health IT to improve patient safety.
• Provide a forum for private-sector stakeholders and Federal Government representatives to dialogue and work together.

Governance
• Consider options for a governance structure that promotes effective engagement by private-sector stakeholders and by ONC, AHRQ, FDA, and other Federal entities, and that ensures balance in prioritization and decision-making that supports the public interest. • Discuss options for membership or other forms of participation that promote a broad base of stakeholder engagement, support, and input as well as options for how to build that broad base.
Funding Mechanism and Levels
• Consider the implications of different funding mechanisms, including contracts and grants (including a cooperative agreement). • Consider the potential for private-sector funding of prioritized activities. • Given prioritized activities, identify those activities that may be best funded through the Health IT Safety Center and activities that could be funded outside of a Center by ONC, AHRQ, or others. • Provide an estimate of the total annual cost to operate an optimal Health IT Safety Center and related activities for each of its first 5 years of operation, based on prioritized activities (identified through the Road Map process) at funding levels equivalent to 75 percent, 50 percent, and 25 percent of the optimum level.

Boundaries on Scope of Activities

For the purposes of this Road Map, the activities for a Health IT Safety Center are focused on activities that are consistent with ONC and AHRQ's missions and authorities. As such, we anticipate that the Health IT Safety Center:

- Will not engage in direct investigation or surveillance.
  - The Health IT Safety Center could promote ways to better identify and investigate health IT-related events and unsafe conditions within healthcare organizations, often with support and expertise provided by outside organizations, such as Patient Safety Organizations (PSOs), accrediting organizations, and technology developers.
- Will not include operating or funding the operations of a PSO.
  - The Health IT Safety Center could be based in a larger entity that operates a component PSO.
  - ONC and AHRQ can fund studies and the development of best practices and tools by PSOs.
- Will not include direct data collection.[1]
  - The Health IT Safety Center could draw on analysis and evidence from private sector databases, subject to the willingness and ability of the private sector to share within applicable laws and legal obligations.
  - The Health IT Safety Center could use data from public data sources, such as FDA's Manufacturer and User Facility Device Experience (MAUDE) database, AHRQ's Network of Patient Safety Databases (NPSD), and ONC's Certified Health IT Product List (CHPL), among others.
- Will not include performing functions of Federal Advisory Committees.
  - ONC's Health IT Policy and Health IT Standards Committees and the National Committee on Vital Health Statistics are Federal Advisory Committees that advise the Secretary on these and similar matters.
- Will not include activities that are exclusively the responsibility of federal entities, and, therefore, cannot be delegated to outside parties, such as the exercise of regulatory authority, establishing government programs, and decision-making related to federal budget expenditures and priorities.

Task Force Management

RTI is responsible for assembling the Task Force, ensuring that the membership provides a representative voice from major stakeholder groups and that all perspectives are considered.

A set of standard operating procedures (SOPs) will ensure that Task Force members' roles and responsibilities are clear, and that the processes for engaging members, facilitating discussions, and capturing member input are well documented. All stakeholders on the Task Force will have the opportunity to fully participate and comment on Road Map development. RTI's facilitation practices focus on obtaining robust input from a variety of perspectives, such that no single perspective or small subset of perspectives dominates the discussion or decision-making process.

Leadership Structure of the Task Force

RTI will ask a small subset of Task Force members to serve on a Steering Committee, which will help plan meetings and give input to Task Force processes between meetings. Each Task Force member will be asked to serve on at least one of four smaller workgroups to discuss Road Map input in the general areas of functions and activities, research/evidence, and governance.

At any time RTI may adjust the membership of the Task Force, Steering Committee, or workgroups to ensure the development of a useful and grounded Road Map. RTI encourages Task Force members to attend all meetings, but may allow Task Force members to identify designees if they are unable to attend a particular meeting.

[1] ONC and AHRQ have the ability to collect data related to specific programs and activities separate from any potential Health IT Safety Center. ONC can collect data, for example, related to certification. AHRQ has specific authorities with regard to data collection, including through the Network of Patient Safety Databases.

Health IT Safety Task Force Members

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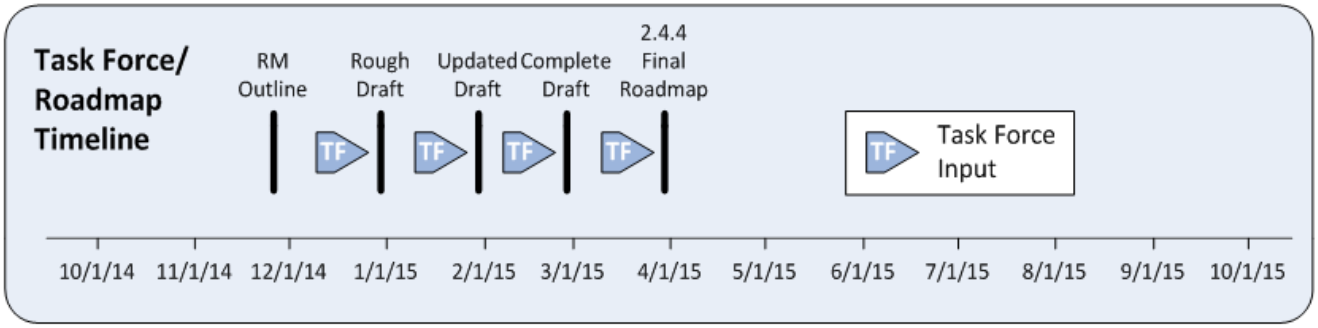
Timeline

The Task Force is expected to meet as a full group four times between December 2014 and March 2015. Each meeting is intended to drill deeper into the specific areas of the Road Map and to produce an increasingly detailed version of the Road Map. A high-level timeline for developing, vetting, finalizing, and submitting the Road Map to ONC is provided in **Figure 1**.

Figure 1. Health IT Safety Center Road Map Development Timeline



Meetings will be conducted via conference calls and supported with online decision-making and collaboration tools. Written meeting notes of all Task Force meetings will identify the main topics of discussion, points of consensus, points of disagreement, and areas for further consideration. The schedule of meetings will be updated as needed throughout the process.

Wider Public Input

Unlike an official Federal advisory committee, which is a public process, the Task Force meetings are part of a contract with RTI to develop a Road Map for a potential Health IT Safety Center and will not be open to the public. However, because wider input could improve development of the Road Map, RTI will post summaries of each full Task Force meeting online at www.healthitsafety.org. A mechanism will be provided for individuals and organizations which are not direct participants in the Task Force to comment on meeting summaries and Road Map development through a unique email address: healthitsafety@rti.org. While RTI will not respond directly to each comment, feedback submitted via email will be summarized and shared, as appropriate, with the Steering Committee, Task Force, and workgroups, and will help inform and improve the development of the Road Map and options for a potential Health IT Safety Center. The schedule of Task Force meetings will be posted on the project Web site to give interested parties a reference for progression of the process and a general idea of when summary materials will be posted.

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[i] IOM (Institute of Medicine). Health IT and Patient Safety: Building Safer Systems for Better Care. Washington, DC: The National Academies Press; 2012. Available at http://www.iom.edu/Reports/2011/Health-IT-and-Patient-Safety-Building-Safer-Systems-for-Better-Care.aspx.

[ii] Office of the National Coordinator for Health Information Technology (ONC). Health Information Technology Patient Safety Action & Surveillance Plan. Washington, DC: U.S. Department of Health and Human Services; 2013. Available at http://www.healthit.gov/policy-researchers-implementers/health-it-and-safety.

[iii] FDA, ONC, FCC. FDASIA Health IT Report on Proposed Risk-Based Regulatory Framework and Strategy for Health Information Technology. Washington, DC: U.S. Department of Health and Human Services; 2014. Accessed at http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhreports/ucm390588.htm.

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