The Office of the National Coordinator for Health Information Technology

FDASIA Health IT Report

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HealthIT.gov

Background

- Health IT can offer tremendous benefits:*
  - Prevention of medical errors
  - Improved efficiency and health care quality
  - Reduced costs
  - Increased consumer engagement

- Health IT can pose risks to patients if it is not designed, developed, implemented, maintained, or used properly.*

**** Institute of Medicine. 2012. Health IT and Patient Safety: Building Safer Systems for Better Care. Washington, DC: The National Academies Press.***

FDASIA Section 618 - Charge

- Charged FDA, in consultation with ONC and FCC, to develop and post on their respective websites:
  - *"a report that contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health information technology, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication."*
- Permitted the convening of external stakeholders and experts for input.

Broad Stakeholder Input

- ONC Health IT Policy Committee - FDASIA Workgroup
  - 28 members + Agency ex-officio members (FDA, FCC, and ONC)
  - experts representing patients, consumers, health care providers, startup companies, health plans, venture capitalists, IT and health IT vendors, small businesses, purchasers, and employers
- More than 28 Workgroup meetings (open to public)
  - Subgroups:
    - Taxonomy
    - Risk & Innovation
    - Regulations
- Federal Register docket
- Recommendations as input to the framework

FDASIA Committee Membership

- **David W. Bates, Chair,** Brigham and Women's Hospital
- **Patricia F. Brennan,** University of Wisconsin-Madison
- **Geoff Clapp,** Better
- **Todd Cooper,** Breakthrough Solutions Foundry, Inc.
- **Meghan Dierks,** Harvard Medical Faculty, Division of Clinical Informatics
- **Esther Dyson,** EDventure Holdings
- **Richard Eaton,** Medical Imaging & Technology Alliance
- **Anura Fernando,** Underwriters Laboratories
- **Lauren Fifield,** Practice Fusion, Inc.
- **Michael Flis,** Roche Diagnostics
- **Elisabeth George,** Philips Healthcare
- **Julian Goldman,** Massachusetts General Hospital/ Partners Healthcare
- **T. Drew Hickerson,** Happtique, Inc.
- **Jeffrey Jacques,** Aetna
- **Keith Larsen,** Intermountain Health
- **Robert Jarrin,** Qualcomm Incorporated
- **Mo Kaushal,** Aberdare Ventures/National Venture Capital Association
- **Mary Anne Leach,** Children's Hospital Colorado
- **Meg Marshall,** Cerner Corporation
- **Mary Mastenbrook,** Consumer
- **Jackie McCarthy,** CTIA - The Wireless Association
- **Anna McCollister-Slipp,** Galileo Analytics
- **Jonathan Potter,** Application Developers Alliance
- **Jared Quoyeser,** Intel Corporation
- **Martin Sepulveda,** IBM
- **Joseph Smith,** West Health
- **Paul Tang,** Palo Alto Medical Foundation
- **Bradley Thompson,** Epstein Becker Green, P.C
- **Michael Swiernik,** MobileHealthRx, Inc.
- **Jodi Daniel,** ONC
- **Bakul Patel,** FDA
- **Matthew Quinn,** FCC

Key Workgroup Recommendations

- Scope of risk-based oversight should be based on functionality
- Agencies should address current deficiencies, ambiguities, and duplications
- Substantial regulation beyond current FDA regulations is not helpful
- FDA should expedite guidance on mobile medical apps
- Agencies should reevaluate and clarify current regulations

- Implement IOM Health IT safety recommendations to create a "*learning environment*"
  - Listing of Health IT products
  - Better post market surveillance
  - Allow aggregation of safety issues
  - Agencies should discourage vendors from limiting free flow of safety-related information
  - Cross-agency group should establish governance of Health IT safety

Key Public Comments

- Health IT should be categorized into administrative, clinical, and medical device software
- Risk assessment should focus on functionality
- Create a learning environment to promote safety and innovation
- Use existing non-punitive voluntary safety reporting systems
- Leverage recognized standards to ensure patient safety
- Frame should be flexible and agile to accommodate evolving technologies
- Quality management systems should allow manufacturers to satisfy requirements for all agencies
- Agencies' roles should be clarified
- Emphasize interoperability
- Agencies should conduct outreach to stakeholders and provide opportunities for collaboration and public input

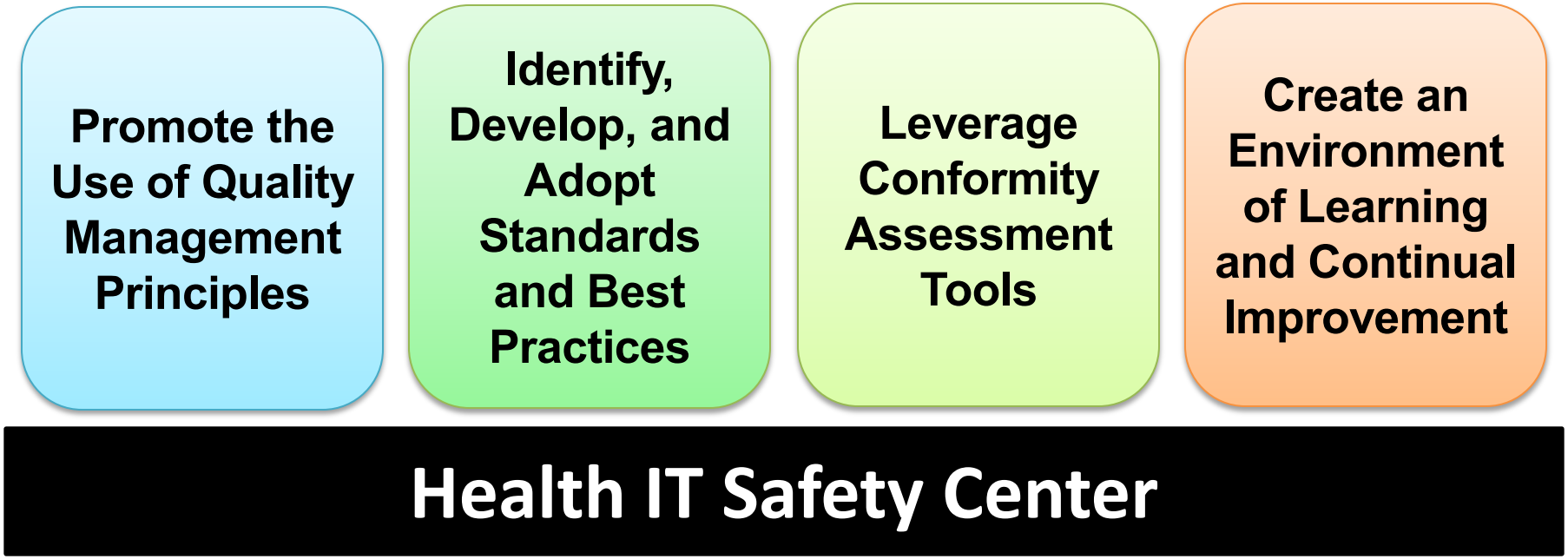
Framework Principles

- Employ a risk-based approach to appropriately mitigate patient safety risks while avoiding unnecessary regulatory oversight;
- Leverage private sector knowledge, experience, and expertise;
- Facilitate, rather than impede, innovation;
- Promote transparency on product performance and safety; and
- Create/support an environment of learning and continual improvement.

Categories of Health IT Functionality

Administrative Functionality*	Health Management Functionality*	Medical Device Functionality*
• Admissions; • Billing and claims processing; • Practice and inventory management; • Scheduling; • General purpose communications; • Analysis of historical claims data; • Determination of health benefit eligibility; • Reporting communicable diseases; • Reporting on quality.	• Health information and data management; • Data capture and encounter documentation; • Electronic access to clinical results; • Some clinical decision support; • Medication management; • Electronic communication (e.g. provider-patient, provider-provider, etc.); • Provider order entry; • Knowledge management; • Patient ID and matching.	• Computer aided detection software; • Remote display or notification of real-time alarms from bedside monitors; • Radiation treatment therapy planning software; • Arrhythmia detection. * Examples provided. Not intended to be an exhaustive list of functionalities.
No Additional Oversight	Primary Focus of Proposed Health IT Framework	Primarily FDA Oversight

Strategy and Recommendations for Health Management Health IT Framework



Promote the Use of Quality Management Principles

- Selective adoption and application of existing quality management principles and processes to health IT have been advocated by the IOM, FDASIA WG, and health IT stakeholders.
- Conclusion: The application of quality management principles, including a quality systems approach by health IT stakeholders, is necessary for the safe design, development, implementation, customization, and use of health IT.
- Proposed Action: The Agencies will work with health IT stakeholders to identify the essential elements of a health IT quality framework, leveraging existing quality management principles and identifying areas where quality management principles can or should be applied.

Identify, Develop, and Adopt Standards and Best Practices

- Consensus standards provide requirements, specifications, guidelines, or characteristics that can be used consistently to ensure that products, processes, and services are fit for their purpose. Best practices can be used to promote and maintain consistency.
- Conclusion: The identification, development, and adoption of applicable health IT standards and best practices can help to deliver consistently high-quality health IT products and services to consumers.
- Proposed Action: The Agencies have identified specific focus areas for standards and best practices implementation:
  - health IT design and development, including usability;
  - local implementation, customization and maintenance;
  - interoperability;
  - quality management, including quality systems;
  - and risk management.

Identify, Develop, and Adopt Standards and Best Practices: Interoperability

- Interoperability:
  - "the ability of two or more systems or components to exchange information and to use the information that has been exchanged." - IEEE
- Interoperability supports improvements in safety, encourages innovation and facilitates new models of health care delivery by making the right data available to the right people at the right time across products and organizations in a way that can be relied upon and used by recipients.
- Proposed Action: The Agencies recommend that entities be identified to develop tests to validate interoperability, test product conformance with standards, and transparently share results of product performance to promote broader adoption of interoperable solutions.

Identify, Develop, and Adopt Standards and Best Practices: Best Practices

- Local Implementation, Customization and Maintenance of Health IT
  - Successful implementation of health IT is critical to optimizing its benefits and mitigating patient safety risks.
  - The development and widespread adoption of best practices could address an important need and should be complemented by a framework that provides independent assessments of organizational conformity to established best practices, with transparency and accountability

Leverage Conformity Assessment Tools

- Conformity assessment tools (e.g. product testing, certification, accreditation) can provide assurance that health IT products, services, systems, or organizations meet specified standards or fulfill certain requirements.
- Conclusions: These tools should be used and applied in a risk-based manner to distinguish high-quality products, developers, vendors, and organizations from those that fail to meet a specified level of quality, safety, or performance.
- Proposed Action: Seek public input on the areas where non-governmental, independent conformity assessment programs could be developed to fill current gaps.

Create an Environment of Learning and Continual Improvement

- The creation of an environment of learning and continual improvement, including transparent reporting, aggregation, and analysis of safety issues is central to a health IT framework that promotes innovation and protects patient safety.
- Conclusion: The public and private sector must work together to develop a culture of safety, transparency, learning, continual improvement, and shared responsibility with better-defined accountability.
- Proposed Action: Creation of a public-private entity – the Health IT Safety Center – that would serve as a trusted convener of health IT stakeholders and identify the governance structures and functions needed for the creation of a sustainable, integrated health IT learning system.

Create an Environment of Learning: Health IT Safety Center

- **Public-private entity** would be created by ONC, in collaboration with relevant agencies and other stakeholders
- Serve as a **trusted convener** of health IT stakeholders and a forum for the exchange of ideas and information to promote health IT as an integral part of patient safety
- **Focus**
  - Education
  - Engagement
  - Evidence

Create an Environment of Learning: Questions for Input

- *What should be the Health IT Safety Center governance structure and functions?*
- *How can comparative user experiences with health IT be captured and made available to the health IT community and other members of the public to promote learning?*
- *How can the private sector help facilitate the development of a non-governmental process for listing selected health IT products?*
- *In terms of risk management, what type of safety-related surveillance is appropriate for health IT products categorized as health management functionality?*
- *What continued or expanded role(s), if any, should the ONC Health IT Certification Program play in the safety-related surveillance of health IT products?*
- *What role should government play in creating an environment of learning and continual improvement for health IT?*

Clinical Decision Support

- CDS: Encompasses tools intended to enhance, inform, and influence health care decisions.
- Most CDS functionalities would be health management health IT.

Health Management Functionality	Medical Device Functionality[2]
• Clinician order sets; • Drug-drug interactions and drug-allergy contraindication alerts; • Drug dosing calculations; • Drug formulary guidelines; • Reminders for preventative care; • Access to treatment guidelines; • Calculation of prediction rules.	• Computer aided detection/diagnostic software; • Remote display or notification of real-time alarms from bedside monitors; • Radiation treatment planning; • Robotic surgical planning and control; • Electrocardiography analytical software.

- FDA:
  - does not intend to focus its oversight on Health Management Functionality
  - will continue to focus on Medical Device Functionality
  - will work with federal and private stakeholders to clarify the types of medical device clinical decision support that should be the focus of FDA's oversight.

Next Steps

- **90-day Comment Period**
- **Public Workshop**
  - May 13-15, 2014
  - At National Institute of Standards and Technology (NIST)
  - The workshop will be webcast
- For the **report** and more information: http://www.healthit.gov/FDASIA