Patient Safety and Information Technology

Improving Information Technology's Role in Providing Safer Care

May 2017

BIPARTISAN POLICY CENTER

Leadership

Senator William H. Frist, M.D.
Former U.S. Senate Majority Leader
Senior Fellow and Chair, Advancing Medical Innovation
Bipartisan Policy Center

Representative Bart Gordon
Former Member, U.S. House of Representatives
Chair, Advancing Medical Innovation
Bipartisan Policy Center

Karen DeSalvo, M.D.
Former Acting Assistant Secretary for Health, HHS;
Former National Coordinator for Health IT

Andrew von Eschenbach, M.D.
President, Samaritan Health Initiatives
Senior Advisor, Advancing Medical Innovation
Bipartisan Policy Center

Janet Corrigan, Ph.D.*
Chief Program Officer for Patient Care
The Gordon and Betty Moore Foundation

*ex-officio

Staff

G. William Hoagland
Senior Vice President
Bipartisan Policy Center

Janet M. Marchibroda
Director, Health Innovation Initiative and
Executive Director, CEO Council on Health and Innovation
Bipartisan Policy Center

Tim Swope
Senior Policy Analyst
Bipartisan Policy Center

HEALTH INNOVATION INITIATIVE

The Bipartisan Policy Center's Health Innovation Initiative is focused on conducting research and engaging stakeholders to accelerate the discovery, development, and delivery of safe and effective cures and treatments for patients and advance innovative strategies—including those related to digital technology—to improve health and health care in the United States.

Efforts associated with this report benefited from the general guidance of former Senate Majority Leader William H. Frist, MD, former Representative Bart Gordon, Andrew von Eschenbach, M.D., Karen DeSalvo, M.D., and Janet Corrigan, Ph.D. Janet Marchibroda, BPC's Health Innovation director, served as staff director for this effort.

AUTHORS

The paper was authored by Janet Marchibroda and Tim Swope, and was developed based on a review of the literature, interviews with experts and stakeholders, and the results of roundtable discussions. BPC would like to acknowledge others who contributed to the research, including Robert Kopp and Alex Hernandez. Finally, BPC would like to acknowledge those who reviewed the report, including Joann Donnellan, G. William Hoagland, and Ashley Ridlon.

ACKNOWLEDGMENTS

BPC would like to thank the Gordon and Betty Moore Foundation for their generous support.

BPC would also like to thank its Advancing Medical Innovation co-chairs and leaders for their general guidance and leadership on this effort. BPC would also like to thank Susan Baade Song for her general guidance on the project.

Finally, BPC would like to thank the 40 individuals who participated in interviews and roundtable discussions to offer their insights and expertise. A full list of individuals who contributed their insights is provided in Exhibit I.

DISCLAIMER

The findings and recommendations expressed herein do not necessarily represent the views or opinions of the Bipartisan Policy Center's founders or its board of directors.

Table of Contents

Executive Summary

More than 15 years ago, the Institute of Medicine released two landmark reports that catalyzed efforts to improve patient safety and quality in the U.S. health care system. Both reports, *To Err is Human: Building a Safer Health System* and *Crossing the Quality Chasm: A New Health System for the 21st Century*, highlighted the critical role that health information technology (IT) plays in improving the safety and quality of health care.[1,2]

Since that time, more than $36 billion in federal investments have been made in electronic health records with the goal of improving health and health care.[3] As a result of these investments, the vast majority of hospitals and physicians practicing in the United States are now using health IT.[4,5]

Numerous studies have shown that health IT reduces medication errors, improves quality outcomes, and reduces the cost of care. However, there are instances in which health IT has the potential to create harm if not effectively developed, implemented, or used.

Several steps have been taken by Congress, the executive branch, and the private sector to advance an oversight framework for health IT, but additional actions are needed.

This report explores the intersection of patient safety and IT, assesses progress made, and makes policy recommendations for implementing a health IT framework that both protects patient safety and promotes innovation.

A recap of BPC's recommendations, outlined in more detail in the report, is provided below.

1. Launch a coordinated effort—supported by public and private sector funding—to set health IT safety priorities, drawing upon existing reporting and analysis efforts.

2. Accelerate the widespread dissemination of existing best practices that address priority health IT safety issues and coordinate efforts to address gaps.

3. Continue to advance development and adoption of safety standards.

Introduction

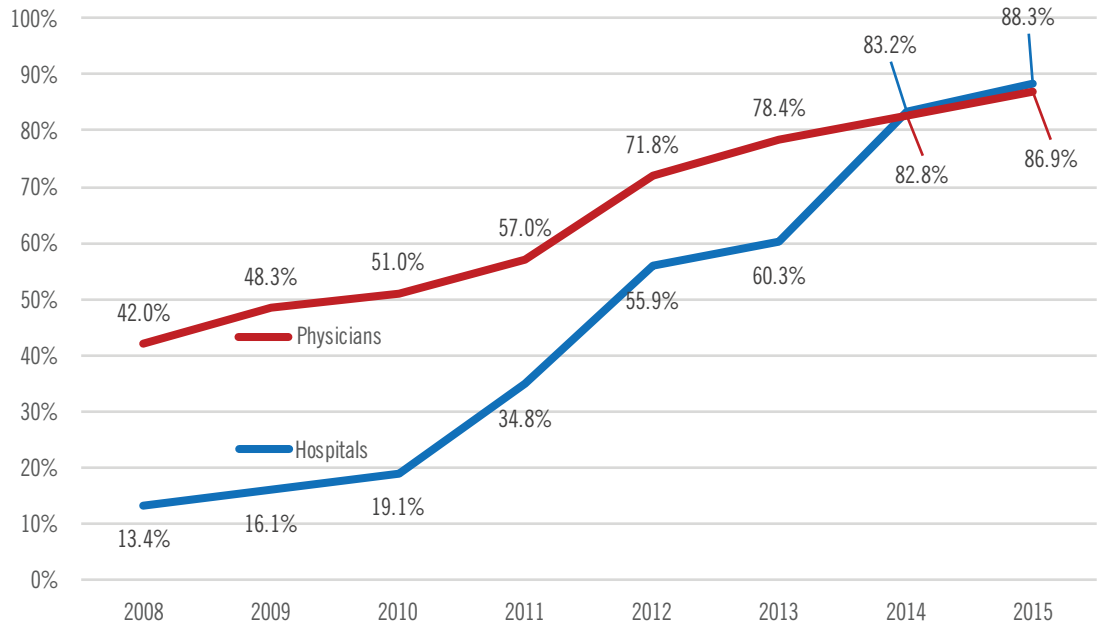
Preventable harm to patients is one of the leading causes of death in the United States. Multiple studies indicate that more than 200,000 Americans die each year from preventable medical errors, ranking third behind heart disease and cancer.[6,7,8,9,10,11]

Examples of harm include medication errors, missed or delayed diagnoses, and avoidable delays in treatment and response to abnormal tests.[12]

The release of the Institute of Medicine's report, *To Err is Human: Building a Safer Health System* in 1999, raised considerable awareness of the magnitude of patient safety issues in the United States and catalyzed a significant amount of leadership and action in the field.[13]

Numerous studies show that IT plays a key role in improving the quality and safety of health care.[14] Recognizing this role, the federal government has invested more than $36 billion in health IT and the meaningful use of electronic health records (EHRs).[15] As a result, the use of health IT is now widespread, with 88 percent of hospitals and 87 percent of physicians now using an EHR.[16,17]

Figure 1: EHR Adoption Levels Among Hospitals and Physicians



Sources: Office of the National Coordinator for Health Information Technology. *ONC Data Brief, no.35.* 2016. Office of the National Coordinator for Health Information Technology. *Health IT Quick-Stat, no.50.* 2016.

While health IT has been shown to improve safety and quality, technological advances can also introduce different types of risk. Several studies show that health IT can create harm if not effectively developed, implemented, or used.[18]

In 2012, through the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), Congress directed the Food and Drug Administration (FDA), in consultation with the Office of the National Coordinator for Health IT (ONC) and the Federal Communications

Commission (FCC), to develop a proposed strategy and recommendations for an appropriate, risk-based regulatory framework pertaining to health IT—including mobile applications—that promotes innovation, protects patient safety, and avoids regulatory duplication.[19]

To support and inform federal government efforts, the Bipartisan Policy Center conducted research and engaged more than 100 experts and stakeholders to develop principles and recommendations for a health IT oversight framework, the results of which were released in 2013 in the report, *An Oversight Framework for Assuring Patient Safety in Health Information Technology*.[20] Many of the principles and recommendations contained in the BPC report were reflected in the *FDASIA Health IT Report: Proposed Strategy and Recommendations for a Risk-Based Framework*, developed by the FDA, ONC, and the FCC and released in 2014 in response to Congress' request.[21]

The 21st Century Cures Act—passed and signed into law in December 2016 with nearly unanimous, bipartisan support—took an important step foward on advancing a regulatory framework for health IT, by clarifying regulatory authority. Section 3060 of the Act provided clarification that software functions used for administrative, healthy lifestyle, clinical, and simple information transfer purposes, should not be regulated as a device by the FDA.[22]

Much has occurred in the five years since passage of FDASIA. The purpose of this report is to explore the intersection between patient safety and IT, assess progress made since the passage of FDASIA, and make policy recommendations for fully implementing a framework that both protects patient safety and promotes innovation.

The findings and recommendations in this report were developed by BPC based on a review of the literature, as well as interviews and roundtable discussions with 40 experts and stakeholders, a list of which is provided in Exhibit I.

Patient Safety and Information Technology: An Overview

Information Technology's Role in Improving Safety

Several systematic reviews of health IT indicate that health IT improves the safety and quality of care. The use of health IT and EHRs has been shown to reduce medication errors, improve adherence to clinical guidelines and protocols, and improve the efficiency of care.[23,24,25,26,27] Combined with information sharing, EHRs also help to improve the cost of care, by helping clinicians avoid duplicative tests and identify and address gaps in care.[28]

Health IT can also be used to improve internal monitoring of patient safety events to facilitate more rapid intervention and improvement.[29] The Institute for Healthcare Improvement's Global Trigger Tool for Measuring Adverse Events has been used to improve the measurement of all-cause harm, but its implementation can be labor-intensive and costly.[30,31] Recently, health care systems have been using technology to automate their all-cause harm trigger identification systems. Through the use of automated trigger tools, provider organizations are able to identify patterns of harm as they evolve, allowing the opportunity to intervene more rapidly and respond proactively by providing awareness, education, and training as needed.[32]

Risks Introduced by Information Technology

Medical errors are ordinarily caused by faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them.[33] While health IT is a tool that can support reductions in medical errors and improvements in patient safety, it can introduce different types of risk. Research has shown that the development, implementation, or use of health IT has been associated with medication errors, diagnostic errors, complications or delays in treatment, wrong-site surgery, and problems related to laboratory tests.[34,35,36] Such errors have been attributed to a range of factors, including user-computer interfaces, system-to-system interfaces,

unmet display needs, lack of availability of data or systems, software changes or upgrades, and software configuration problems.[37,38] A review of numerous studies indicates that health IT has been a factor in anywhere from 2 percent to nearly 7 percent of total safety events reported.[39,40,41,42,43]

Clinicians and other health professionals work in complex, high-risk, and frequently chaotic environments fraught with interruptions, time pressures, and incomplete, disorganized, and overwhelming amounts of information.[44] One of the primary intentions of introducing technology into the health care system was to streamline workflow and improve the ability for clinicians to both access and share information needed to provide safe, high-quality, cost-effective, coordinated care. While physicians approve of EHRs in concept and note their potential to improve care, one study indicates that factors such as poor usability, time-consuming data entry, interference with face-to-face patient care, inefficient and less fulfilling work content, inability to exchange information between EHR products, and degradation of clinical documentation, have had a negative impact on professional satisfaction.[45] A survey of physicians conducted by American EHR Partners and the American Medical Association has also shown some physician dissatisfaction with EHRs.[46] While not all usability issues translate into medication errors, research indicates that some do. The Institute of Medicine report, *Health IT and Patient Safety: Building Safer Systems for Patient Care*, indicates that poor usability is one of the single greatest threats to patient safety.[47]

Interoperability of EHRs and other clinical systems helps bring information about the patient—such as laboratory and other test results, medication lists, allergies, and diagnoses—to the clinician and the care team to enable safe, well-informed, coordinated, patient-centered care.[48] The lack of interoperability can lead to medication errors, delays in treatment or response to abnormal tests, and other medical errors. Failure to accurately and effectively match patient data can also introduce medical errors.[49] While some progress on interoperability has been made, more work is needed to assure that systems are interoperable and can support safer, higher-quality, more cost-effective care.

EHR unavailability, which occurs in every EHR-enabled health care environment, represents a significant potential patient safety hazard that directly affects patient care. Documented potential hazards include an increased risk of medication errors, unavailability of images, and canceled procedures.[50] Extended downtime can occur unexpectedly due to natural disasters or cybersecurity threats. There are a number of strategies and best practices that can be used to enable health care organizations to effectively carry out ongoing clinical and administrative processes in the event of unexpected downtime.

Key Principles for a Health IT Framework

Several common principles for a health IT safety framework have emerged from numerous initiatives conducted by both public and private sector organizations, including BPC. BPC's recent research, including interviews and roundtable discussions with numerous experts and stakeholders, have further validated these principles, all of which should be adhered to when advancing a health IT safety framework.

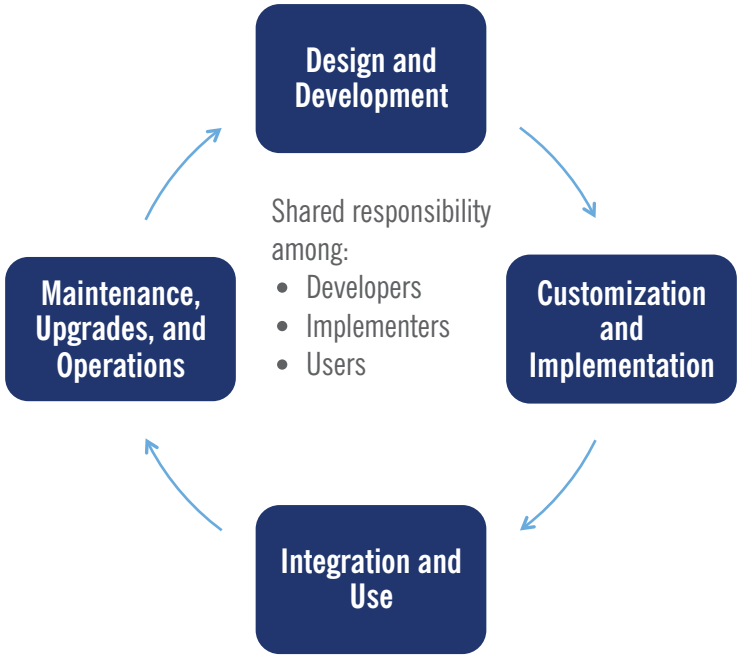
1. Health IT Safety Should be Integrated into Broader Patient Safety Efforts

Health IT requires a systems approach and is an essential component of a comprehensive strategy for improving patient safety and the quality, cost, and patient experience of care. Health IT, once implemented, is part of a larger sociotechnical system within health care that also includes people—such as clinicians and patients—organizations, processes, and the external environment.[51] Therefore, efforts associated with health IT safety should not be siloed, but instead aligned with and integrated into broader patient safety efforts and programs.

2. Patient Safety Efforts Should Address the Entire Health IT Life Cycle

Health IT safety and the safe use of health IT depend on how the technology is designed, customized, implemented, used, and integrated into workflows. Actions taken around maintenance, upgrades, and operations associated with health IT can also have an impact on safety. Patient safety efforts should focus on the entire life cycle of health IT.

Figure 2: Health IT Lifecycle



3. Patient Safety is a Shared Responsibility

As noted previously, health IT is part of a larger sociotechnical system that includes not only technology, but also people, organizations, processes, and the external environment.[52] Safety also depends on how the technology is designed, customized, implemented, integrated, and used. The quality of the data, the interoperability of systems and level of information sharing, and the appropriateness of clinical interventions also have an impact on safety. Education, training, and proficiency of users can also play a critical role. Therefore, improving the safety of health IT and its use is a shared responsibility among developers and implementers of health IT and users—such as clinicians, other health care professionals, hospitals, and other provider organizations. Other stakeholders also play an important role, including laboratories, pharmacies, payers, researchers and educators, government, and patients.

4. A Non-Punitive, Learning System Approach Will Drive Improvement

According to the Institute of Medicine report, *To Err is Human: Building a Safer Health System*, a majority of medical errors do not result from individual recklessness or the actions of a particular group, but instead are caused by faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them.[53]

Concerns about liability can deter users and developers from sharing information about near-misses and hazards, representing a missed opportunity for learning and improvement. A non-punitive, learning system approach toward health IT safety is necessary to encourage participation of all stakeholders, enable a more accurate and comprehensive assessment of actions that may cause harm, and advance the development and adoption of best practices, methods, and standards to mitigate risk and support effective interventions.

The Patient Safety and Quality Improvement Act of 2005 was enacted to improve patient safety by encouraging voluntary reporting of information on patient safety events to patient safety organizations (PSOs) without fear of liability.[54] Such voluntary reporting, combined with root-cause analysis, enables a greater understanding of the cause of errors and near-misses, and the ability to develop and widely disseminate solutions to prevent or address such errors, and facilitate widespread improvement.

5. Health IT Safety Approaches Should be Evidence-Based and Data-Driven

Identification of health IT safety issues that warrant intervention should be data-driven. The aggregation and analysis of information from across many organizations is necessary to identify, characterize, and prioritize issues that will benefit from further action. De-identified, aggregated information, collected in a way that protects privacy and confidentiality, can be drawn from voluntary and mandatory reporting systems, root cause analyses performed by PSOs and other organizations, and other data sources. Standards, best practices, methods, and other tools should also be evidence-based.

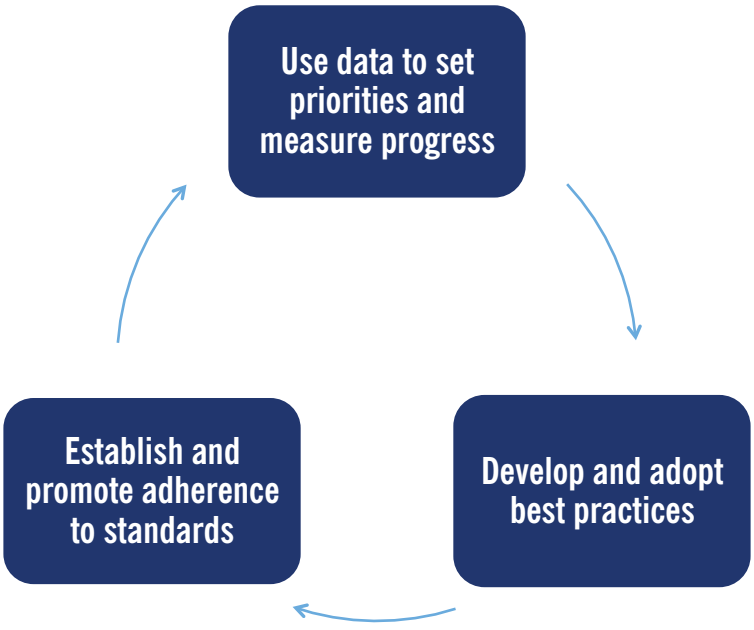
Patient Safety and Information Technology: A Framework for Improvement

Key Elements of the Framework

Improving the role of IT in providing safe care requires focus on three key elements—which together with the key principles, comprise a framework for improving patient safety and information technology.

1. Use data to set priorities and measure progress.
2. Develop and support adoption of best practices.
3. Establish and promote adherence to standards.

Figure 3: Framework for Patient Safety and Information Technology



1. Use Data to Set Priorities and Measure Progress

A number of peer-reviewed and other studies have been conducted to identify and characterize safety events attributed to health IT. There are also other sources of data that can support the identification of health IT issues that would benefit from intervention, which are described below.

- The results of voluntary reporting and root cause analyses performed by more than 80 PSOs operating across the United States;
- Analyses of sentinel events reported to Joint Commission's Sentinel Event Database;[55]
- Mandatory reporting to states on events that cause death or serious harm;[56]
- Information reported to the FDA, including MedWatch, MedSun, and MAUDE;[57,58,59]
- User complaints submitted to ONC-Authorized Certification Bodies, which are required to be submitted to ONC under the *ONC Health IT Certification Program: Enhanced Oversight and Accountability* final rule;[60]
- Aggregated de-identified reports received through the EHR reporting program authorized by Section 3009A of the 21st Century Cures Act;[61]
- Expected reporting on all-cause harms through the the Centers for Medicare and Medicaid Services (CMS) Hospital Improvement and Innovation Network;[62]
- Information derived from medical malpractice claims databases; and
- Other reports developed through internal risk management and quality improvement processes within independent organizations.

Patients also have an important role to play. Given ONC Health IT Certification requirements enable patients to view, download, and transmit their health information from EHRs, patients and caregivers have the opportunity to play a role in identifying medical errors and near-misses attributed to health IT, when they occur.

Learnings from this vast array of data sources have never been systematically aggregated and analyzed in a comprehensive fashion, to both characterize and assess the prevalence of various safety issues and set priorities and goals for intervention and action. Such analyses can lay the groundwork for the development and widespread dissemination of best practices, tools, standards, or other methods that will help prevent safety events in the future and also help measure progress over time. They can also help measure progress against goals over time.

There have been multiple recommendations —in various forms—for advancing such an effort, including those recommended by organizations both within the private and public sectors.[63,64,65,66] However, to date, no action has been taken. Concerns about additional regulatory burden, lack of designated resources, fear of liability, concerns about confidentiality, lack of clarity about regulatory authority, and lack of common agreement regarding "who should lead" has prevented the coordination and sharing of health IT safety information at the national level.

To address concerns about confidentiality and liability, a coordinated effort need not capture individual events. Simply aggregating and reviewing the de-identified results of the various reporting and analyses described above for purposes of priority-setting and the development of tools, can provide leadership and coordination, and accelerate efforts to improve safety.

To clear other barriers and accelerate the establishment of this coordinated research effort, a non-profit independent effort should be launched, supported by federal research grants that are matched by private sector funding. This approach is practical, politically feasible, and can be implemented in the near-term to lay the foundation for improving safety. Data efforts have been funded in the past by agencies such as the Agency for Healthcare Research and Quality, the Health Resources and Services Administration, and the National Institutes of Health. The National Institute of Standards and Technology has a history of engaging the private sector in standards and technology-related activities. The 21st Century Cures Act also authorizes funding for an independent body to engage in convening, data collection, and reporting. The budget for advancing such an effort is nominal, ranging from $3 million to $4 million per year.[67]

A coordinated effort that leverages existing reporting and analysis activities to identify, characterize, and prioritize health IT issues for which intervention is needed, is crucial to developing and implementing solutions that will reduce patient harm in the United States.

2. Develop and Support Adoption of Best Practices

Software developers and implementers, clinicians, hospitals and other health care provider organizations, ancillary service providers—such as laboratories and pharmacies, PSOs, experts and academic researchers, and others, should work together to identify best practices and tools that will help prevent or address health IT safety issues that arise during software development, implementation, and use. Such best practices and tools should focus on high-priority issues identified through the coordinated data gathering and prioritization effort.

A number of organizations and individuals—many with federal funding support—have already developed best practices that should be leveraged and disseminated more widely to promote greater uptake and adoption. Examples include toolkits for patient identification and copy and paste issues developed by the ECRI Institute's Partnership for Health IT Patient Safety and the Safety Assurance Factors for EHR Resilience (SAFER) Guides developed by health IT safety researchers and informatics experts with the support of ONC.[68,69,70]

Several principles and tools have also been developed by numerous organizations to support usability of EHRs, including those developed by NIST, the American Medical Association, the American Medical Informatics Association, and the National Center for Human Factors in Healthcare at MedStar.[71,72,73,74,75] While a number of best practices and tools have been developed, they are not widely used among software developers, implementers, and users. Additional actions should be considered to support more widespread dissemination and use.

3. Establish and Promote Adherence to Safety Standards

Standards are widely used across multiple industries and can set the minimum expectations necessary for an acceptable level of performance. The use of standards is common in assuring safety in products, processes, and services. Well-established international standards for product safety already exist and are developed under the auspices of the International Organization for Standardization (ISO). Examples of such existing process standards include those that address quality management (ISO 9001) and information security management (ISO/IEC 27001).[76] The Association for the Advancement of Medical Instrumentation (AAMI)—an ANSI-accredited, standards organization—is in the process of developing standards that address both risk management practices and quality system principles for health IT.[77]

Standards are generally developed and/or adopted by independent, voluntary consensus bodies that—as defined by OMB Circular A-119—exhibit the attributes of openness, balance of interest, due process, an appeals process, and consensus.[78] Under the National Technology Transfer and Advancement Act of 1995 and OMB Circular A-119, the federal government is required to use standards developed by voluntary consensus bodies in its regulatory and procurement activities, unless the use of such standards would be inconsistent with applicable law or otherwise impractical.[79,80]

Standards adherence within EHRs is largely overseen by the ONC Health IT Certification Program. The program—established by the Health Information Technology Economic and Clinical Health Act of 2009 (HITECH)—certifies EHR technology used by providers that receive financial incentives under the CMS Medicare and Medicaid EHR Incentive Programs.[81] While ONC's Health IT Certification Program primarily focuses on assuring that EHR products include various capabilities that will support provider requirements under the CMS EHR Incentive Programs, both the 2014 Edition and the 2015 Edition of ONC Health IT Certification Criteria do contain certain requirements that promote patient safety.[82,83]

A limited number of baseline standards that promote safety currently exist within the ONC Health IT Certification Program. The Program requires health IT developers to identify the quality management systems used to develop, test, implement, and maintain capabilities of a certified EHR. Health IT developers must also demonstrate safety-enhanced design by identifying and submitting specific information about user-centered design processes used and applied and assuring that a minimum number of participants participate in summative testing.[84]

Section 4002 of the 21st Century Cures Act included provisions requiring health IT developers to both provide assurance and attest that they have not taken actions to prohibit or restrict communications regarding usability and users' experiences when using health IT, which will help to address some user concerns about being able to share information about their systems.[85]

The *ONC Health IT Certification Program: Enhanced Oversight and Accountability* final rule also enables ONC to directly review certified health IT if there is a reasonable belief that the technology may present a serious risk to public health or safety.[86]

A recent analysis of 41 of the 50 EHR products with the highest number of providers attesting to meeting CMS Medicare and Medicaid EHR incentive requirements showed that about one-third had not met the 2014 Edition ONC Certification requirement of stating their user-centered design processes, and about two-thirds included less than the 15 representative end-user participants required.[87,88]

The evaluation described above indicates that greater enforcement of existing standards within the ONC Health IT Certification program may be necessary. It also shows that the sharing of best practices and tools for user-centered design among developers may be of benefit and improve performance.

Testing of EHRs and other clinical software within provider organizations upon initial implementation or when upgrades are made, is also very important. Health IT products are rarely installed off the shelf and are almost always customized to meet user needs. Therefore, even if testing is performed before software is introduced to the market, it must be tested again upon implementation. Rigorous implementation testing is routine for larger provider organizations but can be more difficult for smaller provider organizations, including small physician practices.

Research conducted by the Leapfrog Group—an employer-backed health advocacy organization—highlights the risks that may be associated with health IT upon implementation. As part of its annual hospital survey, the Leapfrog Group employs a web-based simulation tool to test the ability of computerized provider order entry systems to catch common medication errors within hospitals. In 2014, 36 percent of the potential harmful medication orders entered into the systems of more than 1,200 hospitals did not receive an appropriate warning in the simulation. The number of potentially fatal medication orders that were not flagged totaled about 14 percent.[89] This—and other studies—demonstrate the importance of rigorous testing upon implementation of clinical software and the need for the development and dissemination of best practices and tools to support implementation testing. Development of such tools, along with their implementation, should be a shared responsibility among developers and users.

There are a vast array of other organizations that develop and support the adoption of standards among providers within the health care system through accreditation, certification, or other conformance processes. For example, the Joint Commission accredits and certifies nearly 21,000 health care organizations and programs in the United States.[90]

As health IT safety issues are identified and prioritized, and their root causes are better understood, both the ONC Health IT Certification Program and other accreditation and certification bodies can be leveraged to support the adoption of baseline standards that will improve the development, implementation, and use of health IT to reduce patient harm.

Recommendations

BPC offers the following recommendations—that can be implemented in the near term—to advance patient safety in the development, implementation, and use of IT.

1. Launch a Coordinated Leadership Effort—Supported by Public and Private Sector Funding—to Set Health IT Safety Priorities, Drawing Upon Existing Reporting and Analysis Efforts

The federal government should direct research grant funding, which should be matched by private sector funding, to an independent, non-profit entity to launch and operate a coordinated effort to support improvements in health IT safety and the safe use of health IT. Key responsibilities of the coordinated effort should include the following:

- Collect and analyze de-identified, aggregated information and related analyses of health IT safety events provided by PSOs, health care organizations, software developers and vendors, researchers, insurance companies, federal and state agencies, and other organizations.
- Based on analysis of the information received, as well as input from clinicians, hospitals and other health care providers, software developers and implementers, patient groups, payers, PSOs, researchers and experts, government, and others, identify and prioritize health IT safety issues that require the development and widespread dissemination of best practices, tools, standards, or other methods that will help prevent and/or address such safety issues;
- To facilitate the availability of best practices, tools, standards, or other methods to address priority health IT safety issues, issue a call to action for their development and both publish and widely communicate their availability once completed; and
- Track progress made and develop and implement strategies to address gaps.

2. Accelerate the Widespread Dissemination of Existing Best Practices and Tools that Address Priority Safety Issues and Coordinate Efforts to Address Gaps

Several best practices and tools that help address safety issues exist but are not widely adopted. Organizations that have sponsored or developed such best practices and tools should develop and execute robust communications strategies to raise awareness of the availability and benefits of such tools and encourage their adoption. Organizations whose members represent developers, implementers, and users of health IT should offer their assistance in accelerating widespread dissemination and use.

Organizations devoted to developing best practices, tools, and other methods—along with the agencies and organizations that support them—should coordinate efforts and prioritize those issues identified by the coordinated effort.

Federal agencies that play a role in health IT safety specifically and patient safety generally, should identify and implement ways to incentivize best practice adoption.

In the near-term, priority areas of focus should include, but not be limited to, usability and user-centered design that promotes safety, developing and implementing effective methods for user testing upon initial software implementation or upgrades, preparing for unexpected downtime which can be caused by cybersecurity threats, and interoperability.

3. Continue to Advance Development and Adoption of Standards

Existing standards and other organizations operating as independent, voluntary consensus bodies should stay informed of priority safety issues that arise from the coordinated effort, and—as needed—facilitate agreement on baseline, evidence-based standards related to safe health IT products and safe use of health IT.

The federal government, including ONC's Health IT Certification Program, should recognize and rely upon such standards in any health IT-related safety efforts.

Accreditation and certification bodies should incorporate such standards into their programs to support adherence. The ONC Health IT Certification Program should also assure that current certification requirements are enforced, particularly those focused on safety.

Exhibit I: List of Interviewees and Roundtable Participants

David Bates, M.D.
Senior Vice President and Chief Innovation Officer
Brigham and Women's Hospital

Leah Binder
President and Chief Executive Officer
The Leapfrog Group

Peggy Binzer
Executive Director
Alliance for Quality Improvement and Patient Safety

Alice Borrelli
Director of Global Healthcare Policy
Intel Corporation

Gerard Castro, Ph.D.
Project Director for Patient Safety Initiatives
Joint Commission

David Classen, M.D.
Associate Professor of Medicine, University of Utah
Chief Medical Information Officer, Pascal Metrics

Jodi Daniel
Partner
Crowell & Moring

Kay Eron
General Manager, Health and Life Sciences
Intel Corporation

Rollin Fairbanks, M.D.
Associate Director of the MedStar Institute for Innovation
MedStar Health Research Institute

Tejal Gandhi, M.D.
President and Chief Executive Officer
National Patient Safety Foundation

Patricia Hale, M.D.
Chair, Medical Informatics Committee
American College of Physicians

Blair Hedgepeth
Senior Associate, Health IT Policy
American College of Physicians

Gerald Hickson, M.D.
Senior Vice President for Quality, Safety and Risk Prevention;
Joseph C. Ross Chair for Medical Education and Administration;
Professor of Pediatrics
Vanderbilt University Medical Center

Michael Hodgkins, M.D.
Vice President, Chief Medical Information Officer
American Medical Association

Diane Jones
Senior Associate Director of Policy
American Hospital Association

Eva Karp
Chief Clinical Officer and Senior Vice President
Cerner Corporation

Drew Ladner
Chief Executive Officer
Pascal Metrics

Meg Marshall
Senior Director, Public Policy
Cerner Corporation

Nancy McNally
for athenahealth

Bakul Patel
Associate Director for Quality Management
Food and Drug Administration

Lorraine Possanza, DPM
Program Director, Partnership for Health IT Patient Safety
ECRI Institute

Mario Ramao
Global Director, Healthcare and Data Policy
Intel Corporation

Raj Ratwani, Ph.D.
Acting Director, National Center for Human Factors in Healthcare
MedStar Health Research Institute

Jim Russell, R.Ph.
Chief Patient Safety Officer
Epic

Luke Sato, M.D.
Senior Vice President and Chief Medical Officer;
Assistant Clinical Professor of Medicine
CRICO; Harvard Medical School

Mark Savage
Director of Health IT Policy and Programs
National Partnership for Women and Families

Joseph Schneider, M.D.
Assistant Professor
UT Southwestern Medical Center

Jeanie Scott
Director of Informatics Patient Safety VHA Office of Informatics
U.S. Department of Veterans Affairs

Mark Segal, Ph.D.
Vice President, Government and Industry Affairs
GE Healthcare Digital

Patricia Sengstack
Chief Nursing Informatics Officer
Bon Secours Health System Inc.

Hardeep Singh, M.D.
Chief, Health Policy, Quality & Informatics Program, Center for Innovations in Quality, Effectiveness and Safety, Michael E. DeBakey VA Medical Center
Department of Veterans Affairs

Dean Sittig, Ph.D.
The Christopher Sarofim Family Professorship in Biomedical Informatics and Bioengineering
University of Texas

Ronni Solomon
Executive Vice President and General Counsel
ECRI Institute

John Sotos, M.D.
Chief Medical Officer, Intel Health & Life Sciences
Intel Corporation

Bradley Thompson
Member of the Firm
Epstein Becker & Green, P.C.

Robert Wachter, M.D.
Professor and Chair of the Department of Medicine, University of California, San Francisco
Chief of Hospital Medicine, Chief of Medical Service, UCSF Medical Center
Editor, Patient Safety Network, Agency for Healthcare Research and Quality
University of California San Francisco

Steven Waldren, M.D.
Director, Alliance for eHealth Innovation
American Academy of Family Physicians

Chantal Worzala
Director of Policy
American Hospital Association

Stephanie Zaremba
Director of Government and Regulatory Affairs
athenahealth

It is important to note that while the interviewees provided important input to the development of the report, the findings and recommendations in this report were not specifically reviewed or endorsed by those interviewed.

Endnotes

[1] Institute of Medicine Committee on Quality of Health Care in America. Linda Kohn, Janet Corrigan, and Molla Donaldson, Editors. "To Err Is Human: Building a Safer Health System." *National Academy Press*. 1999. Available at: http://www.nationalacademies.org/hmd/Reports/1999/To-Err-is-Human-Building-A-Safer-Health-System.aspx.

[2] Institute of Medicine Committee on Quality of Health Care in America. "Crossing the Quality Chasm: A New Health System for the 21st Century." *National Academy Press*. 2001. Available at: https://www.nap.edu/catalog/10027/crossing-the-quality-chasm-a-new-health-system-for-the.

[3] Centers for Medicare and Medicaid Services. *March 2017 EHR Incentive Program*. 2017. Available at: https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/March2017_Summary-Report.pdf.

[4] JaWanna Henry, Yuriy Pylypchuk, Talisha Searcy, and Vaishali Patel. "Adoption of Electronic Health Record Systems among U.S. Non-Federal Acute Care Hospitals: 2008-2015." *ONC Data Brief, no.35*. Office of the National Coordinator for Health Information Technology: Washington DC. May 2016. Available at: https://dashboard.healthit.gov/evaluations/data-briefs/non-federal-acute-care-hospital-ehr-adoption-2008-2015.php.

[5] Office of the National Coordinator for Health Information Technology. "Office-based Physician Electronic Health Record Adoption." *Health IT Quick-Stat, no.50*. December 2016. Available at: https://dashboard.healthit.gov/quickstats/pages/physician-ehr-adoption-trends.php.

[6] Martin Makary and Michael Daniel. "Medical error - the third leading cause of death in the US." *BMJ*. 353:i2139. 2016. Available at: http://www.bmj.com/content/353/bmj.i2139.

[7] John James. "A new, evidence-based estimate of patient harms associated with hospital care." *Journal of Patient Safety*. 9(3):122–128. 2013. Available at: http://journals.lww.com/journalpatientsafety/fulltext/2013/09000/A_New,_Evidence_based_Estimate_of_Patient_Harms.2.aspx.

[8] David Classen, Roger Resar, Frances Griffin, et al. "'Global Trigger Tool' Shows That Adverse Events In Hospitals May Be Ten Times Greater Than Previously Measured." *Health Affairs*. 30:581-9. 2011. Available at: http://content.healthaffairs.org/content/30/4/581.full.

[9] Health Grades. HealthGrades Quality Study: *Patient Safety in American Hospitals*. 2004. Available at: http://www.providersedge.com/ehdocs/ehr_articles/Patient_Safety_in_American_Hospitals-2004.pdf.

[10] Department of Health and Human Services. *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries*. 2010. Available at: http://oig.hhs.gov/oei/reports/oei-06-09-00090.pdf.

[11] Melonie Heron. "Deaths: Leading Causes for 2014." *National Vital Statistics Reports*. 65:5. 2016. Available at: https://www.cdc.gov/nchs/data/nvsr/nvsr65/nvsr65_05.pdf.

[12] Institute of Medicine Committee on Quality of Health Care in America. Linda Kohn, Janet Corrigan, and Molla Donaldson, Editors. "To Err Is Human: Building a Safer Health System." *National Academy Press*. 1999. Available at: http://www.nationalacademies.org/hmd/Reports/1999/To-Err-is-Human-Building-A-Safer-Health-System.aspx.

[13] Ibid.

[14] Alison Banger and Mark Graber. "Recent Evidence that Health IT Improves Patient Safety." *RTI International for the Office of the National Coordinator for Health Information Technology*. 2015. Available at: https://www.healthit.gov/sites/default/files/brief_1_final_feb11t.pdf.

[15] Centers for Medicare and Medicaid Services. *March 2017 EHR Incentive Program*. 2017. Available at: https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/March2017_Summary-Report.pdf.

[16] JaWanna Henry, Yuriy Pylypchuk, Talisha Searcy, and Vaishali Patel. "Adoption of Electronic Health Record Systems among U.S. Non-Federal Acute Care Hospitals: 2008-2015." *ONC Data Brief, no.35*. Office of the National Coordinator for Health Information Technology: Washington DC. May 2016. Available at: https://dashboard.healthit.gov/evaluations/data-briefs/non-federal-acute-care-hospital-ehr-adoption-2008-2015.php.

[17] Office of the National Coordinator for Health Information Technology. "Office-based Physician Electronic Health Record Adoption." *Health IT Quick-Stat, no.50*. December 2016. Available at: https://dashboard.healthit.gov/quickstats/pages/physician-ehr-adoption-trends.php.

[18] Committee on Patient Safety and Health Information Technology. "Health IT and Patient Safety: Building Safer Systems for Better Care." *Institute of Medicine.* National Academy Press. 2011. Available at: http://nap.edu/13269.

[19] Public Law No: 112-144 (2012). Food and Drug Administration Safety and Innovation Act. Available at: https://www.congress.gov/112/plaws/publ144/PLAW-112publ144.pdf.

[20] Bipartisan Policy Center. *An Oversight Framework for Assuring Patient Safety in Health Information Technology*. 2013. Available at: https://bipartisanpolicy.org/library/oversight-framework-assuring-patient-safety-health-information-technology/.

[21] Food and Drug Administration. "FDASIA Health IT Report: Proposed Strategy and Recommendations for a Risk-Based Framework." 2014. Available at: https://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhreports/ucm391521.pdf.

[22] Public Law 114-255 (2016). 21st Century Cures Act. Available at: https://www.congress.gov/114/bills/hr34/BILLS-114hr34enr.pdf.

[23] Spencer Jones, Robert Rudin, Tanja Perry, and Paul Shekelle. "Health Information Technology: An Updated Systematic Review with a Focus on Meaningful Use." *Annals of Internal Medicine*. 160:48-54. 2014. Available at: http://annals.org/data/journals/aim/929584/0000605-201401070-00008.pdf.

[24] Melinda Buntin, Matthew Burke, Michael Hoaglin, and David Blumenthal. "The Benefits of Health Information Technology: A Review of the Recent Literature Shows Predominantly Positive Results." *Health Affairs*. 30(3):464-71. 2011. Available at: http://content.healthaffairs.org/content/30/3/464.full.pdf.

[25] Caroline Goldzweig, Ali Towfigh, Margaret Maglione, and Paul Shekelle. "Costs and Benefits of Health Information Technology: New Trends from the Literature." *Health Affairs*. 28(2):w282-w93. 2009. Available at: http://content.healthaffairs.org/content/28/2/w282.full.pdf.

[26] Basit Chaudhry, Jerome Wang, Shinyi Wu, Maglione M, Mojica W, Roth E, et al. "Systematic Review: Impact of Health Information Technology on Quality, Efficiency, and Costs of Medical Care." *Annals of Internal Medicine*. 144:742-52. 2006. Available at: http://annals.org/data/journals/aim/20115/0000605-200605160-00125.pdf.

[27] Alison Banger and Mark Graber. "Recent Evidence that Health IT Improves Patient Safety." *RTI International for the Office of the National Coordinator for Health Information Technology*. 2015. Available at: https://www.healthit.gov/sites/default/files/brief_1_final_feb11t.pdf.

[28] Janet Marchibroda. "Health Policy Brief: Interoperability." *Health Affairs*. 2014. Accessed at: http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_122.pdf.

[29] Dean Sittig and Hardeep Singh. "Electronic Health Records and National Patient-Safety Goals." *New England Journal of Medicine*. 367;19. 2012. Available at: http://www.nejm.org/doi/full/10.1056/NEJMsb1205420#t=article.

[30] David Classen, Roger Resar, Frances Griffin, Frank Federico, Terri Frankel, Nancy Kimmel, John Whittington, Allan Frankel, Andrew Seger, and Brent James. "Global Trigger Tool Shows that Adverse Events in Hospitals May be Ten Times Greater Thank Previously Measured." 2011. *Health Affairs*. 30, No. 4. Available at: http://content.healthaffairs.org/content/30/4/581.abstract.

[31] Institute for Healthcare Improvement. "Introduction to Trigger Tools for Identifying Adverse Events." Available at: http://www.ihi.org/resources/Pages/Tools/IntrotoTriggerToolsforIdentifyingAEs.aspx.

[32] Christine Sammer, Susanne Miller, Cason Jones, Antoinette Nelson, Paul Garrett, David Classen, and David Stockwell. "Developing and Evaluating an Automated All-Cause Harm Trigger System." *The Joint Commission Journal on Quality and Patient Safety*. 43:155–165. 2017. Available at: http://www.jointcommissionjournal.com/article/S1553-7250(17)30010-7/pdf.

[33] Institute of Medicine Committee on Quality of Health Care in America. Linda Kohn, Janet Corrigan, and Molla Donaldson, Editors. "To Err Is Human: Building a Safer Health System." *National Academy Press*. 1999. Available at: http://www.nationalacademies.org/hmd/Reports/1999/To-Err-is-Human-Building-A-Safer-Health-System.aspx.

[34] Gerard Castro, Lisa Buczkowski, Joanne Hafner, Stacey Barrett, Ken Rasinski, and Scott Williams. "Investigations of Health IT-related Deaths, Serious Injuries or Unsafe Conditions." Prepared for the Office of the National Coordinator for Health Information Technology. 2015. Available at: https://www.healthit.gov/sites/default/files/safer/pdfs/Investigations_HealthIT_related_SE_Report_033015.pdf.

[35] Erin Sparnon and William Marella. "The Role of the Electronic Health Record in Patient Safety Events." *Pennsylvania Patient Safety Authority*. 9(4):113-21. 2012. Available at: http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2012/Dec%3B9%284%29/Pages/113.aspx.

[36] Mark Graber, Dana Siegel, Heather Riah, Doug Johnston, and Kathy Kenyon. "Electronic Health Record-Related Events in Medical Malpractice Claims." *Journal of Patient Safety*. 2015. Available at: http://journals.lww.com/journalpatientsafety/Citation/publishahead/Electronic_Health_Record_Related_Events_in_Medical.99624.aspx.

[37] Gerard Castro, Lisa Buczkowski, Joanne Hafner, Stacey Barrett, Ken Rasinski, and Scott Williams. "Investigations of Health IT-related Deaths, Serious Injuries or Unsafe Conditions." Prepared for the Office of the National Coordinator for Health Information Technology. 2015. Available at: https://www.healthit.gov/sites/default/files/safer/pdfs/Investigations_HealthIT_related_SE_Report_033015.pdf.

[38] Derek Meeks, Michael Smith, Lesley Taylor, Dean Sittig, Jean Scott, and Hardeep Singh. "An analysis of electronic health record-related patient safety concerns." *Journal of the American Medical Informatics Association*. 21:105301059. 2014. Available at: https://academic.oup.com/jamia/article-pdf/21/6/1053/9517899/21-6-1053.pdf.

[39] Mark Graber, Douglas Johnston, and Robert Bailey. "Report of the Evidence on Health IT Safety and Interventions." *RTI International*. 2016. Available at: https://www.healthit.gov/sites/default/files/task_8_1_final_508.pdf.

[40] Mark Graber, Dana Siegel, Heather Riah, Doug Johnston, and Kathy Kenyon. "Electronic Health Record-Related Events in Medical Malpractice Claims." *Journal of Patient Safety*. 2015. Available at: http://journals.lww.com/journalpatientsafety/Citation/publishahead/Electronic_Health_Record_Related_Events_in_Medical.99624.aspx.

[41] Gerard Castro, Lisa Buczkowski, Joanne Hafner, Stacey Barrett, Ken Rasinski, and Scott Williams. "Investigations of Health IT-related Deaths, Serious Injuries or Unsafe Conditions." Prepared for the Office of the National Coordinator for Health Information Technology. 2015. Available at: https://www.healthit.gov/sites/default/files/safer/pdfs/Investigations_HealthIT_related_SE_Report_033015.pdf.

[42] Russ Mardon, Lois Olinger, Marilyn Szekendi, Tammy Williams, Erin Sparnon, and Karen Zimmer. *Health Information Technology Adverse Event Reporting: Analysis of Two Databases*. Prepared for the Office of the National Coordinator for Health Information Technology. 2014. Available at: https://www.healthit.gov/sites/default/files/Health_IT_PSO_Analysis_Final_Report_11-25-14.pdf.

[43] Gordon Schiff, Mary Amato, Tewodros Equale, Jennifer Boehne, Adam Wright, Ross Koppel, et al. "Computerized physician order entry-related medication errors: Analysis of reported errors and vulnerability testing of current systems." *BMJ Quality and Safety*. 24(4):264-71. 2015. Available at: http://qualitysafety.bmj.com/content/early/2015/01/16/bmjqs-2014-003555.full.

[44] Committee on Patient Safety and Health Information Technology. "Health IT and Patient Safety: Building Safer Systems for Better Care." *Institute of Medicine. National Academy Press*. 2011. Available at: http://nap.edu/13269.

[45] Mark Friedberg, Peggy Chen, Kristin Van Busum, Frances Aunon, Chau Pham, John Caloyeras, Soeren Mattke, Emma Pitchforth, Denise Quigley, and Robert Brook. "Factors Affecting Professional Satisfaction and Their Implications for Patient Care, Health Systems, and Health Policy." *RAND Corporation*. 2013. Available at: http://www.rand.org/content/dam/rand/pubs/research_reports/RR400/RR439/RAND_RR439.pdf.

[46] AmericanEHR Partners and American Medical Association. "Physicians Use of EHR Systems 2014." 2015. Available at: http://www.americanehr.com/research/reports/Physicians-Use-of-EHR-Systems-2014.aspx.

[47] Committee on Patient Safety and Health Information Technology. "Health IT and Patient Safety: Building Safer Systems for Better Care." *Institute of Medicine. National Academy Press*. 2011. Available at: http://nap.edu/13269.

[48] Janet Marchibroda. "Health Policy Brief: Interoperability." *Health Affairs*. 2014. Accessed at: http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_122.pdf.

[49] Bipartisan Policy Center. "Challenges and Strategies for Accurately Matching Patients to their Health Data." 2012. Available at: https://bipartisanpolicy.org/library/challenges-and-strategies-accurately-matching-patients-their-health-data/.

[50] Office of the National Coordinator for Health Information Technology. "SAFER Guides." 2017. Available at: https://www.healthit.gov/safer/safer-guides.

[51] Committee on Patient Safety and Health Information Technology. "Health IT and Patient Safety: Building Safer Systems for Better Care." *Institute of Medicine. National Academy Press*. 2011. Available at: http://nap.edu/13269.

[52] Ibid.

[53] Institute of Medicine Committee on Quality of Health Care in America. Linda Kohn, Janet Corrigan, and Molla Donaldson, Editors. "To Err Is Human: Building a Safer Health System." *National Academy Press*. 1999. Available at: http://www.nationalacademies.org/hmd/Reports/1999/To-Err-is-Human-Building-A-Safer-Health-System.aspx.

[54] Public Law No: 109-41 (2005). Patient Safety and Quality Improvement Act of 2005. Available at: https://www.congress.gov/109/plaws/publ41/PLAW-109publ41.pdf.

[55] The Joint Commission. "Patient Safety Systems Chapter, Sentinel Event Policy and RCA2." 2017. Available at: https://www.jointcommission.org/sentinel_event.aspx.

[56] Carrie Hanlon, Kaitlin Sheedy, Taylor Kniffin, and Jill Rosenthal. "2014 Guide to State Adverse Event Reporting Systems." National Academy for State Health Policy. 2015. Available at: http://www.nashp.org/sites/default/files/2014_Guide_to_State_Adverse_Event_Reporting_Systems.pdf.

[57] Food and Drug Administration. "MedWatch: The FDA Safety Information and Adverse Event Reporting Program." 2017. Available at: https://www.fda.gov/safety/medwatch/.

[58] Food and Drug Administration. "MedSun: Medical Product Safety Network." 2017. Available at: https://www.fda.gov/medicaldevices/safety/medsunmedicalproductsafetynetwork/.

[59] Food and Drug Administration. "Manufacturer and User Facility Device Experience (MAUDE)." 2017. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM.

[60] Federal Register. "ONC Health IT Certification Program: Enhanced Oversight and Accountability." *Health and Human Services Department*. October 16, 2015. Available at: https://www.federalregister.gov/documents/2016/10/19/2016-24908/onc-health-it-certification-program-enhanced-oversight-and-accountability.

[61] Public Law 114-255 (2016). 21st Century Cures Act. Available at: https://www.congress.gov/114/bills/hr34/BILLS-114hr34enr.pdf.

[62] Centers for Medicare and Medicaid Services. "Partnership for Patients: About the Partnership." 2017. Available at: https://partnershipforpatients.cms.gov/about-the-partnership/what-is-the-partnership-about/lpwhat-the-partnership-is-about.html.

[63] Food and Drug Administration. "FDASIA Health IT Report: Proposed Strategy and Recommendations for a Risk-Based Framework." 2014. Available at: https://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhreports/ucm391521.pdf.

[64] RTI International for the Office of the National Coordinator for Health Information Technology. Health IT Safety Center Roadmap. 2015. Available at: http://www.healthitsafety.org/uploads/4/3/6/4/43647387/roadmap.pdf.

[65] Committee on Patient Safety and Health Information Technology. "Health IT and Patient Safety: Building Safer Systems for Better Care." *Institute of Medicine. National Academy Press*. 2011. Available at: http://nap.edu/13269.

[66] Bipartisan Policy Center. *An Oversight Framework for Assuring Patient Safety in Health Information Technology*. 2013. Available at: https://bipartisanpolicy.org/library/oversight-framework-assuring-patient-safety-health-information-technology/.

[67] RTI International for the Office of the National Coordinator for Health Information Technology. Health IT Safety Center Roadmap. 2015. Available at: http://www.healthitsafety.org/uploads/4/3/6/4/43647387/roadmap.pdf.

[68] ECRI Institute. "Health IT Safe Practices: Toolkit for the Safe Use of Health IT for Patient Identification." 2017. Available at: https://www.ecri.org/Resources/HIT/Patient%20ID/Patient_Identification_Toolkit_final.pdf.

[69] ECRI Institute. "Health IT Safe Practices: Toolkit for the Safe Use of Copy and Paste." 2016. Available at: https://www.ecri.org/Resources/HIT/CP_Toolkit/Toolkit_CopyPaste_final.pdf.

[70] Office of the National Coordinator for Health Information Technology. "SAFER Guides." 2017. Available at: https://www.healthit.gov/safer/safer-guides.

[71] National Institute of Standards and Technology. "NISTIR 8095 Electronic Health Record Design Considerations in Responding to Incidences of Highly Infectious Diseases: Clinical Workflows and Exception Handling." 2015. Available at: http://nvlpubs.nist.gov/nistpubs/ir/2015/NIST.IR.8095.pdf.

[72] National Institute of Standards and Technology. "NISTIR 7804-1 Technical Evaluation, Testing, and Validation of the Usability of Electronic Health Records: Empirically Based Use Cases for Validating Safety-Enhanced Usability and Guidelines for Standardization." 2015. Available at: http://nvlpubs.nist.gov/nistpubs/ir/2015/NIST.IR.7804-1.pdf.

[73] American Medical Association Advisory Committee on EHR Physician Usability. Improving Care: Priorities to Improve Electronic Health Record Usability. American Medical Association. 2014. Available at: https://www.aace.com/files/ehr-priorities.pdf.

[74] Blackford Middleton Meryl Bloomrosen, Mark Dente, Bill Hashmat, Ross Koppel, J. Marc Overhage, Thomas Payne, S. Trent Rosenbloom, Charlotte Weaver, and Jiajie Zhang. "Enhancing patient safety and quality of care by improving the usability of electronic health record systems: recommendations from AMIA." *Journal of the American Medical Informatics Association.* 2013. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3715367/pdf/amiajnl-2012-001458.pdf.

[75] National Center for Human Factors in Healthcare, MedStar Health. Available at: National Center for Human Factors in Health Care.

[76] International Organization of Standards. 2017. Available at: https://www.iso.org/home.html.

[77] Association for the Advancement of Medical Instrumentation. "Quality and Risk Considerations for Health Information Technology." 2016. Available at: http://s3.amazonaws.com/rdcms-aami/files/production/public/FileDownloads/WhitePaper/HITwhitepaper_0116.pdf.

[78] Office of Management and Budget. "OMB Circular A-119: Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities." 2016. Available at: https://www.nist.gov/sites/default/files/revised_circular_a-119_as_of_01-22-2016.pdf.

[79] Ibid.

[80] Public Law 104-113 (1996). National Technology Transfer and Advancement Act of 1995. Available at: https://www.congress.gov/104/plaws/publ113/PLAW-104publ113.pdf.

[81] Public Law 111-5 (2009). American Recovery and Reinvestment Act of 2009. Available at: https://www.congress.gov/111/plaws/publ5/PLAW-111publ5.pdf.

[82] Code of Federal Regulations. § 170.315. "2015 Edition health IT certification criteria." December 11, 2015. Available at: https://www.gpo.gov/fdsys/pkg/CFR-2016-title45-vol1/xml/CFR-2016-title45-vol1-sec170-315.xml.

[83] Federal Register. "2014 Edition Release 2 Electronic Health Record (EHR) Certification Criteria and the ONC HIT Certification Program; Regulatory Flexibilities, Improvements, and Enhanced Health Information Exchange." Health and Human Services Department. September 11, 2014. Available at: https://www.federalregister.gov/documents/2014/09/11/2014-21633/2014-edition-release-2-electronic-health-record-ehr-certification-criteria-and-the-onc-hit.

[84] Federal Register. "2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications." *Health and Human Services Department*. October 16, 2015. Available at: https://www.federalregister.gov/documents/2015/10/16/2015-25597/2015-edition-health-information-technology-health-it-certification-criteria-2015-edition-base.

[85] Public Law 114-255 (2016). 21st Century Cures Act. Available at: https://www.congress.gov/114/bills/hr34/BILLS-114hr34enr.pdf.

[86] Federal Register. "ONC Health IT Certification Program: Enhanced Oversight and Accountability." *Health and Human Services Department*. October 16, 2015. Available at: https://www.federalregister.gov/documents/2016/10/19/2016-24908/onc-health-it-certification-program-enhanced-oversight-and-accountability.

[87] Code of Federal Regulations. § 170. "Health Information Technology Standards, Implementation Specifications, and Certification Criteria and Certification Programs for Health Information Technology." December 11, 2015. Available at: https://www.gpo.gov/fdsys/pkg/CFR-2016-title45-vol1/xml/CFR-2016-title45-vol1-part170.xml.

[88] Raj Ratwani, Natalie Benda, A. Zachary Hettinger, Rollin Fairbanks. "Electronic Health Record Vendor Adherence to Usability Certification Requirements and Testing Standards." *Journal of the American Medical Association*. 314(10):1070-1071. 2015. Available at: http://jamanetwork.com/journals/jama/data/journals/jama/934405/jld150029.pdf.

[89] The Leapfrog Group. "Results of the 2014 Leapfrog Hospital Survey: Computerized Physician Order Entry." *2014 Leapfrog Hospital Survey Results*. 2015. Available at: http://www.leapfroggroup.org/sites/default/files/Files/2014LeapfrogReportCPOE_Final.pdf.

[90] The Joint Commission. About the Joint Commission. 2017. Available at: https://www.jointcommission.org/about_us/about_the_joint_commission_main.aspx.

BIPARTISAN POLICY CENTER

2017 marks the Bipartisan Policy Center's 10th anniversary. For a decade, BPC has worked to find actionable solutions to America's major policy challenges.

Celebrating ten years of productive partisanship.

The Bipartisan Policy Center is a non-profit organization that combines the best ideas from both parties to promote health, security, and opportunity for all Americans. BPC drives principled and politically viable policy solutions through the power of rigorous analysis, painstaking negotiation, and aggressive advocacy.

bipartisanpolicy.org | 202-204-2400
1225 Eye Street NW, Suite 1000 | Washington, D.C. 20005

@BPC_Bipartisan
facebook.com/BipartisanPolicyCenter
instagram.com/BPC_Bipartisan
flickr.com/BPC_Bipartisan

BPC Policy Areas

Economy

Energy

Finance

Governance

Health

Housing

Immigration

Infrastructure

National Security

BIPARTISAN POLICY CENTER

1225 Eye Street NW, Suite 1000 | Washington, D.C. 20005

202-204-2400 | bipartisanpolicy.org