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Goals and Priorities for Health Care Organizations to Improve Safety Using Health IT

Revised Report

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1. Background

Over the past decade, the adoption and use of health information technology (health IT) increased at unprecedented rates. Due in large part to the Centers for Medicare & Medicaid Services (CMS) Electronic Health Records (EHR) Incentive Programs (1) and the provisions of Meaningful Use (MU) (2), the vast majority of both physician practices (over 478,000, or 72% of eligible professionals) and hospitals (over 4,800, or 99% of eligible hospitals) have now adopted certified EHR technologies (3). At the same time, health IT vendors have expanded many other aspects of health IT functionality, enabling advanced decision support, telehealth, and data warehousing, which provide the foundation for quality assessment, research, and predictive analytics.

A substantial body of evidence now supports the claim that health IT improves the quality and safety of health care (4), but that health IT has not yet reached its full potential. A host of residual and emerging challenges limit the impact of health IT, including issues of usability, interoperability, and unintended consequences generally.

Health care organizations and practices interested in addressing these challenges need to know where to focus their efforts and which problems to prioritize. To facilitate that process, we surveyed relevant literature and Web sites of widely respected organizations working in health care quality and safety. The objective was to identify goals and priorities from these organizations related to health IT safety, to improve both the safety of health care delivery and the safe use of health IT. Recommendations for health care organizations originated largely from the results of studies of adverse event reports and claims reported to (or through) entities, including The Joint Commission (TJC), The ECRI Institute, the Controlled Risk Insurance Company (CRICO), the Institute for Safe Medication Practices (ISMP), the Veterans Health Administration, and the Food and Drug Administration's (FDA's) Manufacturer and User Facility Device Experience (MAUDE) database. Recommendations were also informed by the Institute of Medicine's (IOM) *Health IT and Patient Safety* report published in 2011 (5).

2. General and National Goals and Priorities for Health IT Safety

Goals for improving health IT safety began at the national level with the priorities established by the U.S. Department of Health and Human Services and its Office of the National Coordinator for Health IT (ONC). The Health Information Technology for Economic and Clinical Health (HITECH) Act, passed as part of the American Recovery and Reinvestment Act of 2009 (6), required the ONC, in collaboration with other appropriate Federal agencies, to maintain the Federal Health IT Strategic Plan, including strategies to enhance the use of health IT in improving health care quality and safety. The *Federal Health*

IT Strategic Plan 2011–2015 (7), was closely aligned with the National Quality Strategy as well as the HHS Strategic Plan and ongoing implementation of HITECH Act programs (8).

Summary IOM Health IT Safety

Recommendations to Department of Health and Human Services (HHS)

1. Publish a health IT safety action and surveillance plan.
2. Working with vendors, ensure free exchange of information about health IT safety experiences and issues; not prohibit sharing of such information, including details.
3. Make comparative user experiences across vendors publicly available.
4. Fund a new Health IT Safety Council to evaluate criteria for assessing and monitoring the safe use of health IT and the use of health IT to enhance safety.
5. All health IT vendors should be required to publicly register and list their products with the ONC.
6. Specify the quality and risk management process requirements that health IT vendors must adopt; focus on human factors, safety culture, and usability.
7. Establish a mechanism for both vendors and users to report health IT-related deaths, serious injuries, or unsafe conditions.
8. Recommend that Congress establish an independent Federal entity for investigating health IT safety events.
9. Monitor and publicly report on the progress of health IT safety annually. Direct FDA to begin developing the necessary framework for health IT safety-related regulation.
10. In collaboration with other research groups, support cross-disciplinary research toward the use of health IT as part of a learning health care system.

ONC commissioned the IOM to examine the impact of health IT on quality and safety, and provide recommendations for improvements in these areas (see text box above) (5). In 2011, IOM released its findings and recommendations in a major report: *Health IT and Patient Safety* (5). This report helped to define Federal agency priorities related to two critical goals: advancing the safety and safe use of health IT, and using health IT to make care safer. In response to the first of IOM's recommendations, the ONC devised the *Health Information and Technology Patient Safety Action and Surveillance Plan*, which described ONC's actions to advance health IT safety in three categories: learning, improving, and leading (9). The *2014 Report to Congress on Health IT Adoption and Exchange* (10) further highlighted progress in achieving the goals set in these reports, and set the stage for the next iteration of the *Federal Health IT Strategic Plan 2015–2020* (11).

ONC proposed that the future innovation and improvement in health IT safety should be coordinated at the national level through a proposed Health IT Safety Center—renamed the Health IT Safety Collaborative to emphasize the vision of it as a trusted convener of stakeholders around shared purpose in an environment of voluntary development and exchange of information driving such innovation. ONC contracted with RTI to develop a roadmap for this enterprise based on input from a wide range of stakeholders (12). As

envisioned in the report published in July 2015, the Health IT Safety Collaborative would be a nonregulatory, public-private partnership dedicated to improving health IT safety and the safe use of health IT.

As articulated in the *Health Information and Technology Patient Safety Action and Surveillance Plan* and the *Health IT Safety Center Roadmap*, the responsibility of ensuring and advancing the safety and safe use of health IT is shared across many stakeholders, including health IT developers and users as well as government agencies with coordination and oversight responsibilities. Clinician practices and health care provider organizations face specific challenges as health IT users while bearing ultimate responsibility for the safety of the care they deliver. Providers and their patients must address these challenges in complement to, and while waiting for the realization of, the vision for the health IT safety collaborative. This report focuses primarily on goals and priorities for health care organizations and practices' health IT safety improvement efforts as suggested by well-known, widely respected safety organizations' data and research. A complementary resource from the National Quality Forum is a compilation of measures relevant to health IT safety (13).

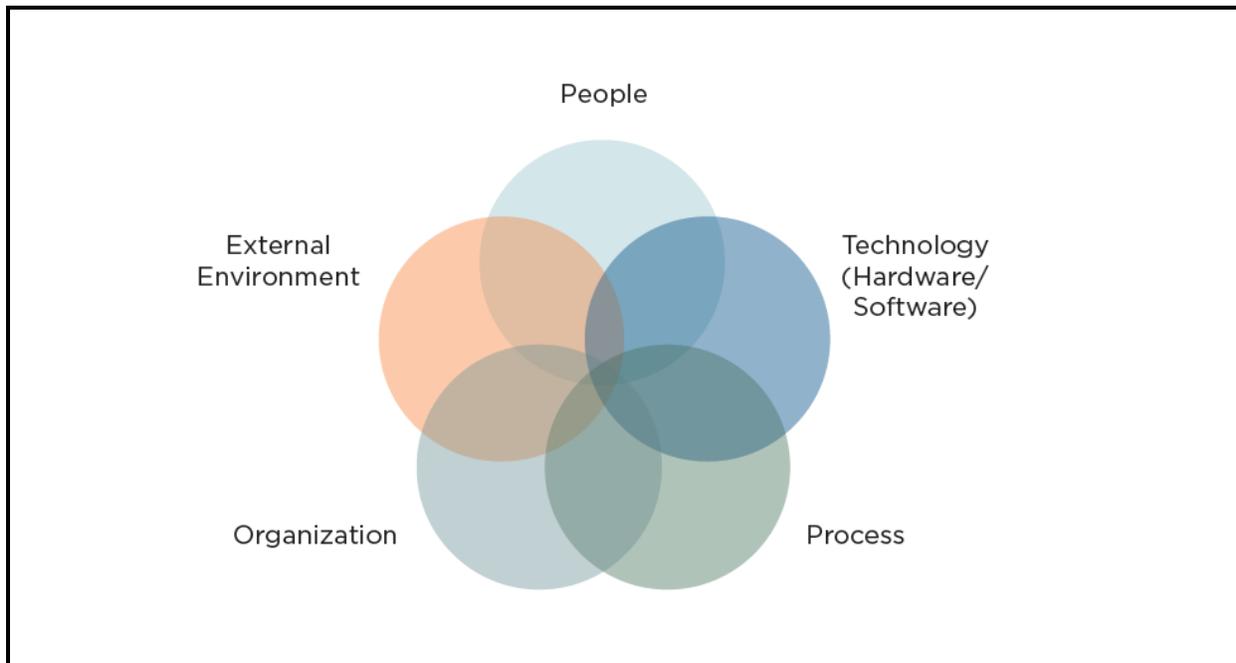
3. Goals and Priorities for Health Care Organizations and Practices

Health care providers are interested in how health IT can improve the safety of health care, and at the same time ensure that the unintended consequences, usability, and interoperability issues of health IT are addressed (14-16). A study sponsored by the American Medical Association cited current EHR technology as a major source of dissatisfaction among providers (17), with a host of issues awaiting resolution, including: limited interoperability and challenging user interfaces and software design that can degrade efficient clinician workflow and that seem to serve administrative priorities rather than quality medical care (14-16).

Of particular concern are the examples of unintended consequences of health IT that detract from the safety of health care or from the use of health IT itself. These concerns derive from case reports (18), claims databases (19), reports through patient safety organizations (20, 21), electronic surveillance (event triggers) (22), and adverse and sentinel event reports to TJC (23, 24) and the Department of Veterans Affairs (VA) (16).

According to sociotechnical models developed to categorize health IT safety evidence, many technical and nontechnical factors can contribute to increasing safety risks, hazards, and the resulting safety events (25, 26). The IOM adopted a sociotechnical framework of health IT that proposed five major domains: people, technology, process, organization, and the external environment (**Figure 1-1**) (5).

Figure 1-1. IOM Sociotechnical Model of Health IT



Using the IOM’s sociotechnical model as a guide, we reviewed reports and guidance on safety-related priorities as well as recent analyses of health IT events. Many of these studies categorized events according to some form of sociotechnical framework or hazard model. Although dimensions of these models are similar, most have been adapted or customized to suit a particular purpose or setting. In addition, many studies included data from a wide range of sources and formats, such as narrative safety event reports, malpractice claims, and sentinel event data. As such, we found a lack of consistency and agreement across sources; no clear consensus emerged on which health IT safety goals were most important and which risks and hazards most deserved prioritization.

This report aims to help health care organizations learn from other stakeholders in setting their own health IT safety goals and priorities. The lack of consistent goals and priorities across sources we reviewed is perhaps due to the nascent state of health IT safety research, which makes it challenging to recommend areas of focus. To help translate this existing evidence into action, we structure the remainder of this report as follows:

1. We discuss summaries of recent studies of health IT safety events, noting recommendations that surface from analyses of risks and hazards associated with EHRs and other systems.
2. We sort the specific goals, priorities, and recommendations found in these resources into two broad categories:
 - Part A – Intended to guide or inform the process of adoption and implementation; and
 - Part B – Intended to guide or inform use of EHRs and health IT in practice.

These recommendations are summarized in **Tables 4-1** and **5-1** in this report.

3.1 Health IT Safety Recommendations from Current Research

RAND. ONC contracted RAND, and RAND engaged ECRI as well as health informatics experts at Baylor University and the University of Texas to partner with them, to develop and evaluate a prototype approach for engaging hospitals and ambulatory practices in health IT safety risk identification and mitigation projects. The project revealed six main issues related to providers engaging in these projects, described below (18).

1. **Readiness** to take on health IT–related patient safety issues: Two-thirds of invited sites declined to participate. Those that participated and achieved project goals had a preexisting safety improvement infrastructure and adverse event reporting system.
2. **Competing initiatives:** Sites showed a preference for projects that would help them achieve “meaningful use” objectives under the Medicare and/or Medicaid EHR Incentive Programs.
3. **Leadership:** Projects that had the involvement of executive leadership were more likely to succeed.
4. **Perception:** Site staff tended to view health IT as a solution and found it challenging to identify new safety risks being introduced. This issue was true for ambulatory practices more than for hospitals.
5. **Resources:** Risk management/mitigation projects competed for time with clinical and practice-management responsibilities.
6. **Tools:** Additional practical tools to help identify and address health IT–related patient safety risks were needed.

ONC SAFER Guides. ONC contracted for the development of a unique set of specific recommendations and self-assessment instruments for health care organizations in their use of health IT resources (27). The *SAFER Guides* were based on expert opinion, a comprehensive literature review on each topic, and field testing to ensure relevance and usability. There is a specific *SAFER Guide* for each of nine areas, and each *Guide* contains a host of individual recommendations, grouped into three phases: Phase 1, Safe Health IT; Phase 2, Using Health IT Safely; and Phase 3, Monitoring Safety. Recommended practices associated with Phase 1 address the health IT adoption and implementation stage; practices associated with Phase 2 address the use of health IT in practice. These equate roughly to the organization of specific recommendations presented in Part A and Part B of this report.

The *SAFER Guides* reflect the most comprehensive compilation of recommendations available to date and should be the first resource that organizations interested in addressing health IT safety should consult. The nine focus areas are:

1. High-priority practices
2. Organizational responsibilities
3. Contingency planning
4. System configuration

5. System interfaces
6. Patient identification
7. Computerized physician order entry
8. Test result reporting and follow-up
9. Clinician communication

CRICO. Cases that involve patient harm comprise a unique source of data on safety risks in health care. In a recent study of 248 cases of harm involving EHRs contained within the database of CRICO, a large professional liability carrier, cases were coded to identify the responsible service providing care, the profession of the clinicians involved, and both user- and system-related sociotechnical factors (28). These cases provided extensive detail on the factors underlying the harmful event, based on depositions and testimony and medical record reviews. Most cases derived from ambulatory care, involved internal medicine providers, and occurred in the setting of medication management or diagnosis. Trends emerging from this analysis identified the top priorities to target in reducing the risk of harm in using EHRs. An important observation from this study was that the likelihood of harm was high in all of the sociotechnical categories, and depended more on the particular circumstances of each patient. Prioritizing safety interventions should therefore target the ambulatory care setting and the trends identified as most problematic.

The Joint Commission (TJC). TJC accredits and advises the majority of health care organizations in the United States, using an analysis framework that encompasses all aspects of organizational performance, including quality and safety. TJC has focused on the role model that high reliability organizations (HROs) provide as a goal for health care organizations.

National Patient Safety Goals: For the 2016 hospital accreditation program, TJC listed six main patient safety goals, all of which have implications for health IT safety (29). Three of these standards (Goals 1, 3, and 7) also apply to the ambulatory care survey.

- Goal 1 - Improve the accuracy of patient identification.
- Goal 2 - Improve the effectiveness of communication among caregivers.
- Goal 3 - Improve the safety of using medications.
- Goal 6 - Reduce the harm associated with clinical alarm systems.
- Goal 7 - Reduce the risk of health care-associated infections.
- Goal 15 - The hospital identifies safety risks inherent in its patient population.

Sentinel Event Alerts: TJC outlined 13 specific suggestions for the safe use of health IT in *Sentinel Event Alert #42* (30). Further guidance on the safe use of health IT was issued in 2015 in *Sentinel Event Alert #54*, based on an extensive analysis of harmful health IT-associated adverse events reported to TJC (23). These reports include a root cause analysis

performed at the responsible health care organization. An analysis of 120 cases involving health IT found that most cases involved medication errors, wrong-site surgery, or delays in treatment (23). Of the eight sociotechnical dimensions defined by Sittig and Singh (25), these cases most often involved just three: the human–computer interface, workflow and communication problems, and problems with the medical record content. Similar to the analysis of CRICO data discussed above, this analysis of TJC sentinel event data suggests that, although the fraction of the cases that involve health IT is relatively small—less than 5 percent of all cases—these cases can provide many important lessons for improving the safety of health IT in the future, and identify trends that help prioritize areas to address.

The new recommendations from TJC target three areas: safety culture, process improvement, and leadership (31). The recommendations place major emphasis on organizations using the *SAFER Guides* (27) to improve safety in health care, and in using health IT in particular.

ECRI Deep Dive: Health Information Technology. To specifically identify safety concerns related to health IT, ECRI identified and reviewed 171 adverse safety events reported to their Patient Safety Organization (PSO).

ECRI identified a number of health IT problem areas, including: inadequate data transfer from one health IT system to another; data entry in the wrong patient record; incorrect data entry in the patient record; failure of the health IT system to function as intended; and configuration of the system in a way that can lead to mistakes. They concluded that health IT must be considered in the context of the environment in which it operates during the three phases of any health IT project: planning for new or replacement systems, system implementation, and ongoing use and evaluation of the system. Shortsighted approaches to health IT can lead to adverse consequences.

MAUDE Database—Analysis of Adverse Events. Magrabi et al. reviewed 46 adverse events associated with patient harm identified in the MAUDE database maintained by the FDA (32). Events were classified as medication problems, clinical process problems, exposure to radiation, and surgery problems. Forty-one percent (a total of 19) of the 46 events were related to medication problems. In 63 percent of these, computerized provider order entry (CPOE) interface issues resulted in overdoses. One-third of the events related to clinical process problems. Issues included data entry errors, network problems causing specimen analysis and treatment delays, and system usability issues causing data misinterpretation, for example. Fifteen percent of events were associated with radiation exposure. A variety of problems in obtaining, storing, and retrieving images caused imaging procedures to be repeated, resulting in re-exposure to radiation. Eleven percent of events were associated with surgery—for example, old data, image output issues, and poor user interfaces resulting in unnecessary surgery, surgery on the wrong site, and surgery on the wrong patient.

U.S. Department of Veterans Affairs (VA). Meeks et al. investigated the safe use of health IT in the VA system by analyzing 100 cases reported voluntarily to a national incident event reporting network over 4 years. Using the eight-dimension sociotechnical model of Sittig and Singh, they found that 70 percent of reports involved two or more sociotechnical dimensions, illustrating the multiple sources of errors in almost every other type of safety investigation. Most errors resulted from unmet display needs, software changes or upgrades, system-to-system interfaces, and hidden dependencies. (16)

ECRI and University Health Consortium (UHC). Researchers at ECRI and UHC, in collaboration with RAND and Westat, analyzed structured and narrative data associated with adverse event reporting to better understand the use of the Agency for Healthcare Research and Quality's (AHRQ) Common Formats and health IT-related patient safety events. They found that these reports provided value, but missing data and incorrect coding of events limited their utility. For example, they found that 30 percent of events coded as health IT-related were not health IT-related and 1.2 percent of events coded as non-health IT-related actually were health IT-related. Since the proportion of non-health IT-related events was very large, 25 percent of all health IT-related events were not coded as health IT-related. The researchers made a number of observations suggesting areas for future research, with the goal of reducing variation in the implementation and use of the Common Formats to increase the value of the reports and to facilitate data aggregation and analysis (20).

4. Part A. Specific Recommendations for Adoption and Implementation

Safety issues have been identified at all phases in the adoption and use of health IT. Because this report is intended to help health care organizations learn from other stakeholders and set their own health IT safety goals and priorities, in this section we organize findings across sources' reviews according to six areas related to the safe use of health IT during adoption and implementation. These six categories (defined below) emerged from the population of measures identified during our research and proved useful for grouping the identified goals, priorities, and recommendations for further analysis (**Table 4-1**).

1. **Leadership:** Leadership involves establishing a vision for an organization and sharing that vision so that others will follow willingly; providing the information, knowledge and methods to realize that vision; and coordinating and balancing the conflicting interests of all members and stakeholders.
2. **Culture and Engagement:** High-reliability organizations maintain a commitment to safety at all levels, from frontline providers to managers and executives. This commitment establishes a culture of safety that helps ensure engagement, creates blame-free environments, and encourages collaboration to address patient safety problems.

3. **Planning and Readiness:** “Assess your practice readiness” and “plan your approach” are steps 1 and 2 of ONC’s step-by-step guide to EHR implementation (33). The assessment phase is a foundation for all other EHR implementation steps, and involves determining if the practice is ready to make the change from paper records to EHRs or to upgrade to a new version. The planning phase clarifies and prioritizes implementation tasks and helps ensure clear communication about tasks to the entire team involved with the change process.
4. **Installation:** Step 4 of ONC’s guide to EHR implementation is “conduct training and implement an EHR system.” [EHR implementation](#) involves the installation of the EHR system and associated activities, such as mock “go-live” and pilot testing. Configuration and pilot testing must involve clinicians familiar with the workflows in clinical practice. The EHR implementation plan and schedule are executed during this phase.
5. **Training and Proficiency Support:** Also part of Step 4 in ONC’s guide, EHR implementation involves the execution of a training plan that includes practice-specific goals and needs. Proficiency support acknowledges that transitioning from paper records to an EHR, or incorporating new or different health IT products into the user’s workflow, is an ongoing learning process. Providing recurring and ongoing learning opportunities (sometimes called retraining) supports users in achieving true proficiency with the health IT so they can more fully and efficiently use the system and resolve questions that arise after initial use of new systems.
6. **Upgrades and Conversions:** Upgrades and conversions often present specific challenges that require change control processes, testing, and specific attention to users so that they are thoroughly trained and supported in achieving proficiency on the new system.

Table 4-1. Goals, Priorities, and Recommendations on the Safe Use of Health IT during Adoption and Implementation

	Leadership	Culture and Engagement	Planning and Readiness	Installation	Training and Proficiency Support	Upgrades and Conversions
RAND (18)	Projects that have the involvement of executive leadership are more likely to succeed	<ul style="list-style-type: none"> ▪ Align health IT patient safety with the broader patient safety environment ▪ Engage clinicians in identifying and mitigating risk ▪ Engage regional extension centers and patient safety organizations in facilitation 	<ul style="list-style-type: none"> ▪ Develop a facilitator workforce ▪ Develop a cadre of experts ▪ Continue to develop and refine tools ▪ Align event reporting systems with Common Formats to simplify the task 		<ul style="list-style-type: none"> ▪ Disseminate best practices ▪ Provide training 	
ONC SAFER Guides (27)	Many — example: an effective decision-making structure exists for managing and optimizing the safety and safe use of health IT	Many — example: practicing clinicians are involved in all levels of EHR safety-related decision making that impact clinical use	Many — Example: Workflow analysis to map how work is actually done is conducted regularly	Many— example: clinical applications and interfaces are tested individually and as-installed before go-live	Many — example: EHR training and support are assessed regularly to optimize complete and safe use of the EHR	Many — example: after system changes, the data and data presentations are reviewed to ensure accuracy and completeness
CRICO (28)					Keep clinicians abreast of changes	Target adoption and conversion phases
TJC (34)	High-reliability organizations have excellent leadership					
TJC Alert 42 (30)		Actively involve frontline staff in all assessment and improvement activities	Carefully plan health IT implementations	Monitor for emerging problems after implementation	Extensively train staff on health IT use <ul style="list-style-type: none"> ▪ Use formal risk assessment approaches 	
TJC Alert 54 (31)	Target leadership to improve safety in health care	<ul style="list-style-type: none"> ▪ Achieve safety culture to improve safety in health care ▪ Create and maintain an organizational-wide culture of safety, high reliability, and effective change management 	Target process improvement to improve safety in health care			

(continued)

Table 4-1. Goals, Priorities, and Recommendations on the Safe Use of Health IT during Adoption and Implementation (continued)

	Leadership	Culture and Engagement	Planning and Readiness	Installation	Training and Proficiency Support	Upgrades and Conversions
ECRI Deep Dive (21)	Enlist leaders' commitment and support for the organization's health IT projects	Involve health IT users in system planning, design, and selection	<ul style="list-style-type: none"> ▪ Conduct a review of workflow and processes to determine how they must be modified ▪ Evaluate the ability of existing IT systems within the organization to reliably exchange data with any health IT system under consideration 	Conduct extensive tests before full implementation to ensure that the health IT system operates as expected	<ul style="list-style-type: none"> ▪ Provide user training and ongoing support ▪ Educate users about the capabilities and limitations of the system 	<ul style="list-style-type: none"> ▪ Evaluate the ability of existing IT systems within the organization to reliably exchange data with any health IT system under consideration ▪ Introduce alterations to a health IT system in a controlled manner
VA (16)				Target "hidden dependencies" of the EHR		Focus on problems related to software upgrades or replacements

4.1 Leadership

RAND. Leadership was one of the six main issues identified by investigators. They noted that “projects that had the involvement of executive leadership were more likely to succeed” but did not develop specific leadership challenges or solutions (18).

ONC SAFER Guides. Most Phase 1, safe health IT, recommendations address adoption and implementation issues. Many checklists address best practices for organizational leadership. Two examples of recommended practices from the organizational responsibilities checklist include: “An effective decision-making structure exists for managing and optimizing the safety and safe use of the EHR” and “The highest-level decision makers (e.g., boards of directors or owners of physician practices) are committed to promoting a culture of safety that incorporates the safety and safe use of EHRs” (27).

TJC. TJC emphasizes several consistent characteristics of high-reliability organizations, including having excellent leadership (23). Leadership is needed to guide organizations as they progress through the four stages of adoption specified by the high-reliability framework, which culminate in safely adopted IT solutions integral to sustaining improved quality.

TJC’s *Sentinel Event Alert #54*, issued in 2015, was based on an extensive analysis of health IT–associated adverse events resulting in harm and reported to TJC (31). The new recommendations target three areas, including leadership as well as safety culture and process improvement. The recommendations place major emphasis on organizations using the *SAFER Guides* (27) to improve safety in health care, and in using health IT in particular.

ECRI Deep Dive: Health Information Technology. One of ECRI’s key recommendations is to enlist leaders’ commitment and support for the organization’s health IT projects (21).

4.2 Culture and Engagement

RAND. Investigators defined six challenges and mapped them to broadly defined solutions requiring future development. Two of the six address culture and engagement: “Awareness of health IT patient safety issues is limited” and “Additional facilitation is needed but consulting models need elaboration.” Two solutions were suggested regarding the awareness challenge: “Align health IT patient safety with the broader patient safety environment” and “Engage clinicians in identifying and mitigating risk.” One solution was suggested regarding the facilitation challenge: “Engage Regional Extension Centers and Patient Safety Organizations in facilitation” (18).

ONC SAFER Guides. Many of the checklists address best practices for ensuring engagement and creating a culture of patient safety. A recommended practice in the checklist for organizational responsibilities is: “Practicing clinicians are involved in all levels of EHR safety-related decision making that impact clinical use.” An example from Phase 2,

Using Health IT safely, is found on the checklist for Computerized Provider Order Entry (CPOE) with Decision Support: “Clinicians are engaged in implementing, reviewing, and updating” clinical decision support (CDS) (27).

TJC. One of the 13 specific suggestions for the safe use of health IT outlined in *Sentinel Event Alert #42* is that organizations actively involve frontline staff in all assessment and improvement activities (30). *Sentinel Event Alert #54* includes new recommendations that target three areas, including safety culture (31). It also includes a specific recommendation regarding safety culture: “Create and maintain an organizational-wide culture of safety, high reliability and effective change management, with a collective mindfulness focused on identifying, reporting, analyzing and reducing health IT–related hazardous conditions, close calls or errors.”

ECRI Deep Dive: Health Information Technology. One of ECRI’s key recommendations is to involve health IT users in system planning, design, and selection (21).

4.3 Planning and Readiness

RAND. Investigators defined six challenges and mapped them to broadly defined solutions requiring future development. One of these six was “readiness to take on health IT–related patient safety issues.” Pilot sites that participated and achieved project goals had a preexisting safety improvement infrastructure and adverse event reporting system. Solutions suggested to improve readiness and address challenges include: “Develop a cadre of experts,” “Develop a facilitator workforce,” and “Continue to develop and refine tools” (18).

ONC SAFER Guides. Many of the checklists address best practices for planning and ensuring readiness. Recommended practices for organizational responsibilities include: “Workflow analysis to map how work is actually done is conducted regularly.” Selected examples of the 10 recommended practices for contingency planning include: “Hardware that runs applications critical to the organization’s operation is duplicated,” “An electric generator and sufficient fuel are available to support the EHR during an extended power outage,” and “Paper forms are available to replace key EHR functions during downtimes” (27).

TJC. One of the 13 specific suggestions for the safe use of health IT outlined in *Sentinel Event Alert #42* is: “Carefully plan health IT implementation” (30). *Sentinel Event Alert #54* included a recommendation regarding process improvement: “Develop a proactive, methodical approach to health IT process improvement that includes assessing patient safety risks” (31).

ECRI Deep Dive: Health Information Technology. Two of ECRI’s key recommendations are to: “Conduct a review of workflow and processes to determine how they must be

modified,” and “Evaluate the ability of existing IT systems within the organization to reliably exchange data with any health IT system under consideration” (21).

4.4 Installation

ONC SAFER Guides. Best practices for system configuration include seven recommendations. Selected examples include: “There are an adequate number of EHR access points in all clinical areas,” “The EHR is hosted safely in a physically and electronically secure manner,” and “The organization’s information assets are protected using strong person authentication mechanisms” (27).

TJC. One of the 13 specific suggestions for the safe use of health IT in *Sentinel Event Alert #42* is: “Monitor for emerging problems after implementation” (30).

ECRI Deep Dive: Health Information Technology. One of ECRI’s key recommendations is: “Conduct extensive tests before full implementation to ensure that the health IT system operates as expected” (21).

VA. Analysis of health-IT related safety incidents using the VA’s EHR system found four major types of problems related to: 1) display of information, 2) software use in the process of care, 3) information flowing inappropriately or incorrectly with the EHR, including interoperability problems, and 4) hidden dependencies, for example, users were unaware that medication orders and lists were not accurately transferred from one setting of care to another. (16) Mitigating strategies were proposed to address each of these issues.

4.5 Training and Proficiency Support

RAND. One of the six challenges RAND defined was: “Communication often occurs in silos.” Solutions developed to address training challenges include disseminating best practices, providing training, and developing a cadre of experts (18).

ONC SAFER Guides. The checklist for organizational responsibilities contains training recommendations and best practices, including: “EHR training and support are sufficient for the needs of EHR users and readily available,” “EHR training and support are high quality, provided by qualified trainers, and appropriately tailored to specific types of users’ needs,” and “EHR training and support are assessed regularly to optimize complete and safe use of the EHR.” An example from Phase 2, *Using Health IT Safely*, is found on the CPOE with Decision Support checklist: “Clinicians are trained and tested on CPOE operations before being issued login credentials” (27)

CRICO. A key recommendation is to keep physicians abreast of changes to reduce the risk of harm and mitigate the dangers inherent in the adoption phase of a new EHR, converting to a new one, or using a hybrid system of paper and electronic records (28).

TJC. One suggestion from the *Sentinel Event Alert #42* (30) for the safe use of health IT is to extensively train staff on health IT use.

ECRI Deep Dive: Health Information Technology. Two of ECRI's key recommendations are to provide user training and ongoing support, and to educate users about the capabilities and limitations of the system (21).

4.6 Upgrades and Conversions

ONC SAFER Guides. Recommended practices on the system interfaces checklist include: "Changes to hardware or software on either side of the interface are tested before and monitored after go-live." Recommended Phase 2 practices on this checklist include: "The organization notifies people involved in maintenance or use of system interfaces when changes are made that affect the content of the standard data files or allowable values transmitted via the interface." Recommended practices on the test results reporting and follow up checklist include: "After system changes in components or applications related to CPOE and diagnostic services, the data and data presentation are reviewed to ensure accuracy and completeness" (27).

CRICO. Top priorities to target in reducing the risk of harm in using EHRs include dangers inherent in the adoption phase of a new EHR, converting to a new system, or using a hybrid system of paper and electronic records (28).

ECRI Deep Dive: Health Information Technology. Two of ECRI's key recommendations are: "Evaluate the ability of existing IT systems within the organization to reliably exchange data with any health IT system under consideration," and "Introduce alterations to a health IT system in a controlled manner" (21).

VA. The VA identified three issues that account for over 90 percent of the health IT safety concerns examined. In addition to "hidden dependencies" mentioned in Section 4.4 above, another key issue is: "Problems related to software upgrades or replacements" (16).

5. Part B. Specific Recommendations for Use in Practice

To further support health care organizations, we categorize goals, priorities, and recommendations for the safe use of health IT in practice. As with the categories used to aggregate findings that applied to adoption and implementation, we distilled these five categories (defined below) from the population of measures identified during our research. They allow us to aggregate and compare our findings across the diverse sources reviewed (see **Table 5-1**).

1. **Clinical Documentation:** In the context of health IT, we use clinical documentation to mean patient identification, prepopulated fields, and practice-specific metrics and reporting. Goals, priorities, and recommendations address

policies, procedures, and practices that ensure the accuracy of practice-level data and reduce the risk of error.

2. **Data:** Goals, priorities and recommendations address methods to ensure the accuracy, availability, and timeliness of patient-level data, and to identify errors and missing data.
3. **Workflow:** Integrating health IT into clinical workflows properly helps ensure the timely and effective use of health IT. Goals, priorities, and recommendations included here address issues such as ease of system use as well as overriding alerts and similar system workarounds.
4. **Communication:** We use this term to mean communication between clinicians. Goals, priorities, and recommendations included here address methods to ensure effective communication about critical information. With the large body of data available for viewing in an EHR, the most critical information in system displays should be made prominent; distractions in the display should be minimized and in-person communication should not be replaced or reduced by existence of the system.
5. **Medication Management:** We use this term to mean system-based functionalities such as decision support to prevent adverse medication interactions and improve medication safety, manage order fulfillment, and reduce medication problems.

Table 5-1. Goals, Priorities, and Recommendations on the Safe Use of Health IT in Practice

	Use In Practice				
	Clinical Documentation	Data	Workflow	Communication	Medication Management
ONC SAFER Guides (27)	Many — example: policies and procedures ensure accurate patient identification	Many — example: when test results are amended, the change is clearly visible in the EHR and printed reports	Many — example: the status of orders can be tracked in the system	Many — example: EHR displays time-sensitive, time-critical information more prominently than less urgent information	Many — example: the EHR can facilitate both cancellation and acknowledgment of orders
CRICO (28)	Target copy/paste, prepopulated fields	Target delayed missing or incorrect data	Target alert overrides and workarounds	Preserve person-to-person communication	
TJC (35)	<ul style="list-style-type: none"> ▪ Reduce the risk of health care associated infections ▪ Improve the accuracy of patient identification 	Report critical results of tests and diagnostic procedures on a timely basis	Reduce the harm associated with clinical alarm systems	Improve the effectiveness of communications among caregivers	Improve the safety of using medications
TJC Alert 42 (30)		Employ a graduated system of alerts		Minimize distractions	Employ decision support to improve medication safety
ECRI Deep Dive (21)	<ul style="list-style-type: none"> ▪ Monitor the system's effectiveness with metrics established by the organization ▪ Require reporting of health IT-related events/near misses 	Conduct thorough event analysis and investigation to identify corrective measures	Closely monitor the system's ease of use and promptly address problems encountered by users		
MAUDE (26)		Use manual, automated error checking to reduce clinical process problems			Improve user interfaces to reduce medication problems
VA (17)		Focus on problems with transmission or access to data needed for appropriate patient care			
Encinosa and Bae 2014 (36)					Adopt MU requirements for safe medication use and obtain end-user buy-in

5.1 Clinical Documentation

ONC SAFER Guides. Recommended practices on the High Priority checklist include: “Processes and procedures ensure accurate patient identification at each step in the clinical workflow.” Many recommended practices for Phase 2, Using Health IT Safely, address use-in-practice issues. For example, seven additional recommended practices for patient identification are included under Phase 2 on the Patient Identification checklist (27).

CRICO. Top priorities in reducing the risk of harm while using EHRs include the inherent risks of using copy/paste functionality and prepopulating data fields (28).

TJC. The National Patient Safety Goals promoted by TJC include: Goal 2.3 — Report critical results of tests and diagnostic procedures on a timely basis; and Goal 7 — Reduce the risk of health care associated infections (35).

ECRI Deep Dive: Health Information Technology. Two of ECRI’s key recommendations are to: “Monitor the system’s effectiveness with metrics established by the organization” and “Require reporting of health IT-related events and near misses” (21).

5.2 Data

ONC SAFER Guides. Recommended practices to employ during Phase 2, Using Health IT Safely, found on the Test Result Reporting and Follow-up checklist, include: “When test results are amended, the change is clearly visible in the EHR and printed reports.” Another example of a data best practice from the CPOE with Decision Support checklist is: “There is minimal use of free-text order entry. Orders are entered and stored in standardized, coded form” (27).

CRICO. Top priorities in reducing the risk of harm in using EHRs include the dangers of delayed, missing, or incorrect data, services, or actions; and routing problems (28).

TJC. The National Patient Safety Goals promoted by TJC include: Goal 1—Improve the accuracy of patient identification (35). Another example from the 13 specific suggestions for the safe use of health IT outlined in *Sentinel Event Alert #42* is to: “Employ a graduated system of alerts” (30).

ECRI Deep Dive: Health Information Technology. One of ECRI’s key recommendations is to: “Conduct thorough event analysis and investigation to identify corrective measures” (21).

MAUDE. Analysis of events in this database conducted by Magrabi et al. suggests that manual and automated error checking could reduce clinical process problems (26).

VA. The VA identified three issues that account for over 90 percent of the health IT safety concerns examined. One issue is: “Problems with the transmission or access to data needed for appropriate patient care” (16).

5.3 Workflow

ONC SAFER Guides. Recommended practices to employ during Phase 2, Using Health IT Safely, found on the CPOE with Decision Support checklist, include: “The clinician is informed during the ordering process when additional steps are needed to complete the order being requested.” Recommended Phase 2 practices from the Test Result Reporting and Follow-up Checklist include: “The EHR is able to track the status of all orders and related procedures;” and “Workflows that are particularly vulnerable to mishandling of test results, especially critical ones, are identified, and back-up procedures ensure test results are received by someone responsible for the affected patient’s care” (27).

CRICO. Top priorities to target in reducing the risk of harm in using EHRs include the inherent risks of overriding alerts and employing workarounds (28).

TJC. The National Patient Safety Goals promoted by TJC include: Goal 6 — Reduce the harm associated with clinical alarm systems (35).

ECRI Deep Dive: Health Information Technology. One of ECRI’s key recommendations is to: “Closely monitor the system’s ease of use and promptly address problems encountered by users” (21).

5.4 Communication

ONC SAFER Guides. The Clinician Communication Checklist includes 12 best practice recommendations, seven of which apply to Phase 2 and are therefore relevant to use in practice. A few examples include: “The EHR displays time-sensitive and time-critical information more prominently than less urgent information;” “The EHR facilitates accurate routing of clinician-to-clinician messages and enables forwarding of messages to other clinicians;” and “Electronic message systems include the capability to indicate the urgency of messages” (27).

CRICO. Top priorities in reducing the risk of harm while using EHRs include the dangers of overreliance on the EHR, assuming that all the information is correct and included, and believing that use of the EHR eliminates the need for person-to-person communication (28).

TJC. The National Patient Safety Goals promoted by TJC include: Goal 2 — Improve the effectiveness of communications among caregivers (34). Another example from the 13 specific suggestions for the safe use of health IT outlined in *Sentinel Event Alert #42* is to: “Minimize distractions” (30).

5.5 Medication Management

ONC SAFER Guides. The CPOE with Decision Support Checklist includes many best practice recommendations for medication management that apply to use in practice. Selected examples include: “CPOE is used for ordering all medications, diagnostic tests, and procedures for which CPOE is available;” “Drug-allergy interaction checking occurs during the entry of new medication orders and new allergies;” “Drug-condition checking occurs for important interactions between drugs and selected conditions;” “Drug-patient age checking occurs for important age-related medication issues;” and “Dose range checking (such as maximum single dose or daily dose) occurs before medication orders are submitted for dispensing” (27).

TJC. The National Patient Safety Goals (34) promoted by TJC include: Goal 3–Improve the safety of using medications. “Employ decision support to improve medication safety” is another example from the 13 specific suggestions for the safe use of health IT outlined in *Sentinel Event Alert #42* (30).

MAUDE. Analysis of events in this database conducted by Magrabi et al. suggests that safer user interfaces could reduce medication problems (26). Most medication-related errors reported to the FDA were related to deficiencies in the design and use of CPOE systems. Improved availability and use of decision support were cited as potential solutions to many of these errors.

Encinosa and Bae evaluated the impact of the five core medication-related MU requirements and clinician buy-in on the incidence of adverse drug events in Florida hospitals (36). With adoption of the five core Stage 1 MU requirements (CPOE, ability to exchange data with outside providers, decision support for drug-drug interactions, medication-related allergy tracking, and lists of current medications), adverse drug events were reduced 52 percent at facilities that described clinician buy-in, but rose 14 percent at facilities that described overall clinician resistance (36).

6. Summary and Conclusions

Many health care organizations face similar struggles in their initial adoption and implementation of health IT. The process of selecting and implementing an EHR, training users, and managing workflow changes often pose significant challenges. Along the path to improving health care quality and maximizing safety through EHRs, health care organizations need to avoid or resolve any unanticipated problems associated with these technologies. This report aims to help health care organizations become more informed about emerging health IT safety-related goals and priorities.

At the national level, the IOM and the Department of HHS have set ambitious goals and priorities for improving the safety and safe use of health IT. Doing so will require a

collaborative effort between health IT vendors and end users to improve existing products and develop new functionalities. At the local level, health care organizations need to decide for themselves what aspects of health IT safety need attention. Our review of the recommendations offered by leading organizations identified a wide range of opinions and suggestions to provide guidance. Other valuable resources include reviews of the safety reports for specific areas; each case offers the opportunity to ask whether the same problem could happen “here” at a local institution. At this point in the adoption and implementation of increasingly interoperable health IT—including but not limited to EHRs—across the health care system, there is great value in learning from others and leveraging the experience from the field to solve local problems.

Safe care is created locally by the individuals who carefully consider the challenges at each step and make wise choices in adopting, implementing, and using health IT. The information provided in this guide will hopefully serve as a starting point for organizations interested in using health IT safely to achieve better care and healthier people.

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