Promoting Patient Safety Through Effective Health Information Technology Risk Management

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Preface

This research report was sponsored by the U.S. Office of the National Coordinator for Health Information Technology (ONC). It summarizes a project conducted by RAND Health, ECRI Institute, the University of Texas, and Baylor College of Medicine. The project facilitated the identification of safety risks associated with health information technology (IT) by 11 organizations (hospitals and ambulatory practices) and the implementation of risk management activities in each organization. The project also evaluated the implementation effort through site visits and phone interviews. This report summarizes the implementation process, six case studies, and recurring themes from the case studies that offer lessons for risk management of health IT in hospitals and ambulatory practices. The report will be of interest to federal and state policymakers, health care organizations, health IT developers, health services and health policy researchers, and others with responsibilities related to designing and implementing health IT and health IT risk management policies and programs.

The research was conducted under contract #HHSP23320095649WC with ONC. The Contracting Officer's Representative for the project is Kathy Kenyon. We thank the Contracting Officer's Representative for her guidance and review of this report; however, we note that the material contained in the report is the responsibility of the research team and does not necessarily reflect the beliefs or opinions of the Contracting Officer's Representative, ONC, or the federal government.

This research was conducted in RAND Health, a division of the RAND Corporation. A profile of RAND Health, abstracts of its publications, and ordering information can be found at www.rand.org/health.

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Executive Summary

Health information technology (IT) safety has several dimensions: using health IT to make care safer, ensuring that health IT is itself safe, and ensuring that health IT is used safely. The potential for health IT to improve the safety of health care delivery has been appreciated for decades, but the role of health IT in introducing safety risks has been recognized only more recently. As the use of health IT has grown, users have begun also to observe its fallibility. Hardware and software can malfunction. Data can be lost or corrupted during transmission. Deploying complex technologies in a complex organizational environment can introduce new hazards and safety risks. Identifying and mitigating health IT safety risks is a relatively new undertaking for most health care organizations. The introduction of health IT safety improvement initiatives could be expected to face many of the challenges that accompany introduction of any change to clinical practice. Introduction of new tools and practices can require substantial organizational effort.

Acknowledging the need for better information on the experience of organizations attempting to manage the risks posed by health IT, the U.S. Office of the National Coordinator for Health Information Technology (ONC) contracted with a team at the RAND Corporation (RAND), a nonprofit research organization; ECRI Institute (ECRI), a nonprofit research organization and patient safety organization (PSO); and health informatics research experts at Baylor College of Medicine and the University of Texas to develop and evaluate a prototype approach for engaging hospitals and ambulatory practices in health IT safety risk identification and mitigation projects. The project had the following goals:

1. Explore the challenges organizations face in deciding whether to participate in health IT safety risk identification and mitigation.
2. Test a simple diagnostic approach that participating organizations could use to identify health IT safety risks.
3. Assist organizations in developing and carrying out a short-term project intended to identify and reduce health IT safety risks.
4. Evaluate the results of the projects.
5. Evaluate the governance and management approaches used by organizations to manage health IT safety risks.
6. Identify barriers and facilitators to health IT risk identification and mitigation in hospitals and ambulatory practices.

Implementation of Health IT Safety Projects

The recruitment of sites and facilitation of process improvement projects were led by ECRI. The evaluation was led by RAND. Health informatics research experts at Baylor College of

Medicine and the University of Texas provided expert input throughout. From a sample of 44 hospitals and ambulatory practices, 12 hospitals and nine ambulatory practices completed a survey of their EHR capabilities, and seven hospitals and four ambulatory sites were invited and agreed to participate. During a nine-month period, each participating site undertook a process improvement strategy led by ECRI that included assembling a project team; selecting a safety risk topic area; prioritizing practices within that area; specifying a work plan, including risk management activities, measures, and a monitoring plan; implementing the work plan; and monitoring progress and adapting the work plan as needed. The hospitals and ambulatory practices had access to several resources, including technical assistance. They also tested reporting safety events related to health IT using the standardized definitions and reporting forms developed by the Agency for Healthcare Research and Quality (AHRQ) Common Formats.

Evaluation

To learn about the sites' experience with the process improvement strategy, including the resources and safety event reporting, an evaluation team from the RAND Corporation conducted in-person and telephone interviews with representatives of six of the hospitals and ambulatory practices. The evaluation team used a semi-structured interview protocol to elicit information about the sites' experiences with identifying risks and implementing new health IT safety practices, as well as their experiences with the AHRQ Common Formats. The evaluation data were analyzed thematically and described in case study reports. A comparative analysis was performed to identify differences and similarities in sites' implementation experiences; to develop a series of lessons learned; and to offer recommendations that may be useful to hospitals and ambulatory practices seeking to manage safety risks posed by health IT, policy makers, electronic health record (EHR) developers, and other stakeholders.

The 11 participating sites were geographically diverse and encompassed both large and small hospitals and ambulatory practices. The sites varied widely in their Health Information Management Systems Society (HIMSS) scores, which reflect health care organizations' level of EHR adoption. Four of the seven participating hospitals already reported to a PSO before beginning the health IT risk mitigation project; none of the four ambulatory practices did so before the project. The interviews revealed the diversity of sites' experiences with and commitment to patient safety and risk management, as well as their allocation of staff and other resources to health IT projects and improvement efforts. In ambulatory sites, IT staff often had non-IT responsibilities, limiting their availability for IT projects.

Most project leaders came from the risk management, quality, and IT departments. All sites selected a topic area (e.g., clinician communication, computerized provider order entry) and specific risk mitigation activities. Some sites drew from material in the draft Safety Assurance Factors for EHR Resilience Guides (SAFER Guides), which were released by ONC in their final

forms after the implementation phase of this project. All sites selected or developed metrics for measuring implementation progress, and most sites engaged in adverse event reporting to a PSO using the AHRQ Common Formats.

Most of the participating organizations found it difficult to identify and modify health IT safety risks within the nine-month project period, even with the resources and technical assistance available. Even though several organizations narrowed the focus of their projects, they encountered significant barriers at every stage of the process.

Lessons from the Pilot Project

"Readiness" to Conduct Health IT–Related Risk Identification and Mitigation Projects

Health care organizations may have limited capacity to join an externally initiated health IT risk management initiative and to sustain participation over time. Only a third of the hospitals and ambulatory practices invited to participate in the study agreed to volunteer. Among organizations that were contacted but decided not to join, "[poor] alignment with current and planned projects" was a commonly cited reason for declining to participate.

Organizations with the highest level of readiness to engage in detecting and mitigating health IT risks have in-house expertise and prior experience in conducting organizational quality improvement and risk management projects. In those sites that achieved their project objectives, we observed a preexisting and relatively sophisticated patient safety improvement infrastructure that included an adverse event reporting system and routine monitoring and analysis of patient safety-related events.

Alignment of Health IT Safety Projects with Other Quality, Safety, and Information Technology Initiatives

"Previously known problems" were more likely to be selected as targets of intervention than were problems identified through a diagnostic assessment. Each site completed a standardized diagnostic assessment designed to assist the staff in identifying potential targets for risk mitigation, but most sites selected intervention targets on the basis of known problems with safety, quality, attesting to meaningful use (MU) criteria (the demonstration of "meaningful use" of EHR so as to qualify for an incentive payment), or a combination of these items.

Similarly, projects appeared more likely to progress if they were aligned with the organization's priorities and current initiatives. Most of the sites faced the task of identifying health IT–related risks in the context of competing institutional priorities. Competing (or synergizing) priorities included business growth, meeting MU criteria, and addressing recent adverse event "near misses" or quality of service issues.

Projects also seemed more likely to succeed if they were aligned with current federal policy directives. Federal MU policy was an important driver for organizations in selecting and prioritizing initiatives. Organizations tended to view health IT safety through the lens of their efforts to meet MU standards.

Importance of Organizational Leadership

The case studies made clear the importance of organizational leadership to achieving success. Organizations whose project teams had close involvement of executive leadership were more likely to make progress in identifying and mitigating safety risks. In any organization, executive leadership sets priorities, allocates resources, directs the attention of staff to specific issues, creates accountability structures, and manages competing external demands. Disconnects and miscommunication between hospital or ambulatory managers and front line clinicians seemed to impede several steps in the identification, selection, and conduct of projects.

Challenges in Identifying Health IT Safety Risks

Organizations tended to view health IT as a solution to patient safety problems, while overlooking the potential of health IT to contribute to safety problems or to create new types of safety risks. Organizations installing, expanding, or upgrading EHRs are focused on ensuring that systems are operational and support necessary functions and that staff have sufficient training to use EHRs meaningfully. While these concerns clearly have implications for patient safety, the new safety risks associated with the implementation and use of health IT, especially EHRs, were not perceived in general as requiring focused effort.

Ambulatory practices encountered greater challenges than hospitals in identifying and addressing health IT safety risks. Resource constraints in ambulatory practices, particularly smaller practices, limited the ability of leadership to prioritize (or in some cases even recognize) health IT safety problems. None of the ambulatory practices we studied had full-time risk management staff.

Challenge of Matching Project Scope and Resources to the Demands of a Health IT Safety Project

Perhaps the most important determinant of project success was the availability of resources to commit to the health IT safety project. The most frequently cited barrier to and facilitator of successful implementation of projects was the timely and adequate allocation of staff effort and other resources to the project. Successful conduct of a risk mitigation project frequently required a substantial effort by project leaders, many of whom took on this effort in addition to a full-time job as clinician or practice manager. Risk management staff, quality and safety officers, and IT staff had to redirect attention and resources from current operations and health IT projects with looming deadlines (such as accomplishing meaningful use certification or planning for the

International Classification of Diseases, 10th Revision, Clinical Modification transition) to pursue these risk mitigation projects.

Mismatch between the selected scope of the project and the available staffing sometimes led to poor project design (even when substantial expertise was available within the organization). Because health IT risks are sociotechnical in nature, they involve individuals conducting highly complex workflows that interact with complex technologies. This is an inherently challenging analytic problem. Furthermore, organizations may struggle with determining the best approach for engaging front line clinicians who both possess the knowledge of workflow challenges and may have to make changes to workflow in order for a safety risk mitigation project to succeed.

Practical Tools to Identify and Address Health IT Safety Risks

Health care organizations, and in particular small ambulatory practices, need tools to help them identify and address safety risks attributable to health IT. The challenges noted by each of the lessons above suggest the need for practical, easy-to-use tools that can help organizations identify health IT–related risks and set priorities for addressing them. Development of several of these tools (diagnostic assessment, the SAFER Guides, and metrics used by the participating organizations) began during this project, but these are prototypes that need additional refinement.

Staff at the hospitals and ambulatory practices reported that they found navigating the AHRQ Common Formats for reporting patient safety events to be burdensome. The series of steps used to arrive at the reportable risk seemed unnecessarily complex to many. Even when data were drawn from hospital adverse event reporting systems or EHRs, staff had to complete forms manually to submit them to the PSO, in part because of misalignment between the Common Format categories and the categories used in participants' event reporting systems.

Discussion

The challenges and lessons identified in this pilot project point to several opportunities to increase the safe use of health IT systems. We draw several conclusions about the current state of health IT safety risks:

1. With few exceptions, awareness of the safety risks introduced by health IT is limited.
2. The traditional departmental "silos" between risk management, IT, and quality and safety management may impede the ability of organizations to recognize and respond to health IT safety risks.
3. External facilitation appears to be important to hospitals and practices; however, the model for providing consultation and technical assistance requires further elaboration.
4. Most ambulatory practices lack the risk management, IT, and quality and safety expertise that is available in hospitals.

5. There is an urgent need for tools and metrics to enable project teams in hospitals and ambulatory practices to detect, mitigate, and monitor health IT safety risks.
6. The current structure of the EHR marketplace, and the low awareness of the risks introduced by health IT systems, lead to weak incentives for EHR developers and providers to invest in the type of joint effort required to reduce health IT safety risks.

Given the current situation, we saw several opportunities to make progress on safe use of health IT:

Awareness

To raise awareness of the health IT safety issue, two steps are necessary and closely related: to integrate and align the health IT safety agenda with the broader patient safety agenda and to engage front line clinicians in identifying and mitigating risk. A campaign built on the model established by the patient safety movement could very effectively alert front line clinicians to health IT as an important component of patient safety.

Fostering Collaboration Among Departments and Disciplines

Health IT safety is a cross-cutting area that creates an opportunity for risk management staff, safety staff, and IT staff to collaborate. Each disciplinary perspective contributes distinct knowledge to the detection, analysis, and mitigation of health IT safety risks. Several enablers of collaboration could support future initiatives: (1) disseminating best practices (case study examples of organizations that have successfully tackled a particular problem) and project templates (step-by-step project guides for specific problems or checklists); (2) providing staff from distinct disciplines with training in core terminology and methods related to safe use of health IT; and (3) developing a cadre of experts who can provide consultation through regional extension centers (RECs), PSOs, or other organizations and can facilitate training programs. The SAFER Guides provide a valuable tool for multidisciplinary, multifunctional teams to optimize the safety and safe use of health IT, EHRs in particular.

Strengthening External Facilitation and Consultation

Often hospitals and ambulatory practices lack the size and scale to support in-house expertise sufficient to carry out effective detection and mitigation of health IT safety. There will undoubtedly be a need for external facilitation and consultation, especially among rural hospitals and small ambulatory practices. Organizations likely to be engaged in this role include RECs and PSOs. PSOs are obvious candidates to support adverse event reporting; this project demonstrates that adverse event reporting is possible with the right data collection infrastructure but currently is often done manually. Finally, ensuring safe use of health IT will require that staff are trained on a mix of the retrospective methods used to analyze patient safety events, as well as proactive

approaches designed to prevent patients safety events that may be introduced by health IT. PSOs, RECs, or other organizations could facilitate this staff training.

Supporting Ambulatory Practices

Ambulatory practices, in particular, may need more outside help if they are to succeed in identifying and mitigating health IT–related risks. Developing a "facilitator" workforce may be an opportunity to improve safety in these types of practices. Generally, facilitators receive specialized training and certification, and then serve multiple practices—providing access to the kinds of expertise and hands-on support that is typically only available to larger medical groups and hospitals.

Developing and Refining Tools and Metrics

The findings from our pilot project suggest that more work is needed to develop effective and usable tools and reporting systems. The prototype diagnostic tool we applied in the pilot was less useful to participants than hoped. An effective diagnostic approach that can be used by hospitals and ambulatory practices to identify and prioritize topics for health IT safety projects could build on and modify the tool we developed. The draft SAFER Guides that informed the implementation of the risk mitigation projects in our pilot are promising and useful. The SAFER Guides were finalized after this research project was largely complete. Further study of the SAFER Guides should evaluate their utility in practice and help to continuously improve the safety of health IT. Most organizations found reporting using the AHRQ Common Formats to be onerous and cumbersome. Revising the AHRQ Common Formats, especially for ambulatory practices, should be a high priority if adverse event reporting of health IT safety events is to be useful and guide further intervention.

Strengthening Incentives for EHR Developers to Optimize the Safety and Safe Use of EHRs

Health IT safety is a shared responsibility of EHR developers and their clients who use EHRs in a complex sociotechnical environment. MU of certified EHR technology has the potential both to improve patient safety, if implemented and used correctly, and to introduce new sources of patient safety hazards. The participants in this research project were motivated to qualify for MU incentives, but often did not appreciate the potential of EHR systems to introduce new safety risks. MU standards and EHR certification could provide incentives for EHR developers to work with their clients to optimize the safety and safe use of their EHR products and services. Surveillance associated with certification of EHRs could be used to identify and address EHR features that may be unsafe (such as poorly constructed CPOE with clinical decision support). Finally, some EHR developer interventions could help managers and clinicians to monitor deviations from intended, safe patterns of EHR use.

Conclusion

The investment that is converting the U.S. health data infrastructure into a 21st century enterprise has the potential to improve care for patients in countless ways. However, "digitizing" the health system also has the potential for harm. In this project, we worked with 11 hospitals and ambulatory practices to evaluate a process improvement strategy and tools developed to help health care organizations diagnose, monitor, and mitigate health IT–related safety risks. While many of the health care organizations (especially the hospitals) had expertise in process improvement, we found a general lack of awareness of health IT–related safety risks (especially in ambulatory practices) and concluded that better tools are needed to help these organizations use health IT to improve care and to optimize the safety and safe use of EHRs. The SAFER Guides provide an excellent beginning, but until health care organizations have a better understanding of the safety risks posed by EHR use, tools like the SAFER Guides may not be used to their full potential. There may also be a need for additional tools and metrics (and further usability study of existing tools and metrics) to better support the needs of health care organizations as they use health IT to improve the quality and safety of patient care.

Acknowledgments

Abbreviations

ACO	accountable care organization
AHRQ	Agency for Healthcare Research and Quality
CDS	clinical decision support
CEO	chief executive officer
CMS	Centers for Medicare & Medicaid Services
CPOE	computerized provider order entry
DSH	disproportionate share hospital
ED	emergency department
EHR	electronic health record
HHS	U.S. Department of Health and Human Services
HIMSS	Healthcare Information and Management Systems Society
HIT	health information technology
HITECH Act	Health Information Technology for Economic and Clinical Health Act
HRO	high-reliability organization
ICM-10-CM	International Classification of Diseases, 10th Revision, Clinical Modification
IOM	Institute of Medicine
IT	information technology
IV	intravenous
LIS	laboratory information systems
MU	meaningful use
NCQA	National Committee for Quality Assurance
ONC	U.S. Office of the National Coordinator for Health Information Technology
PCMH	patient-centered medical home
PSO	patient safety organization
REC	regional extension center
SAFER	Safety Assurance Factors for EHR Resilience

1. Background

The potential for electronic health records (EHRs) to improve the quality, safety, and efficiency of health care delivery has been recognized since the 1960s. The 1999 Institute of Medicine (IOM) report *To Err is Human* suggested that health care delivery systems were not optimized to prevent avoidable medical errors.[1] Since the publication of that report, hospitals and other health care delivery organizations have focused on improving the reliability of processes to reduce medical errors and adverse events. EHRs have been an important cornerstone, especially because of their potential to mitigate errors through deployment of tools like clinical decision support (CDS) and computerized provider order entry (CPOE) that have been shown to reduce errors in prescribing that can lead to adverse events.[2–5] Widespread adoption of EHRs has been slow, but adoption has begun to accelerate as incentive payments authorized by the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 have enticed hospitals and clinicians to install new systems.[6, 7]

As the use of health information technology (IT) has grown, users have begun also to observe its fallibility. Hardware and software can malfunction. Data can be lost or corrupted during transmission.[8] Deploying complex technologies in a complex organizational environment can introduce new hazards and safety risks.[9] In health care, where coordination of information, decisions, and actions involving several professionals and departments must occur flawlessly in real time, health IT systems can introduce new safety risks. For example, a system outage can leave staff unable to retrieve critical information. If entered in electronic form, incorrect information about patients can be propagated quickly and widely to other staff. Staff may use health IT incorrectly, especially if they are not properly trained. Computer interfaces may be poorly designed, increasing the likelihood that tests are ordered for the wrong patient, that incorrect medication dosages are prescribed, and that the ordering of tests or medications is delayed.[10]

Recognizing the potential for health IT to introduce safety risks, the U.S. Office of the National Coordinator for Health Information Technology (ONC) asked the IOM to identify specific risks attributable to health IT and to recommend public and private actions that could diminish these risks. In 2011, the IOM published the report *Health IT and Patient Safety: Building Safer Systems for Better Care*,[8] which emphasized the importance of understanding health IT as part of a sociotechnical system in order to identify the broad range of actions that might be necessary to reduce the risks of health IT. The report also called for further research and new methods of data collection to understand safety implications and how to address them. In 2013, building on the IOM report, ONC published the *Health Information Technology Patient Safety Action & Surveillance Plan*.[7] The *Action & Surveillance Plan* identified "strategies and actions" that various stakeholders should undertake to (1) improve the safety of health care by

implementing health IT and (2) improve the safety of health IT itself (i.e., eliminate risks associated with the introduction of health IT). The ONC-funded project described in this report falls into the latter category and is described in the *Action & Surveillance Plan* under the recommendation that the U.S. Department of Health and Human Services (HHS) and its partners "support research and development of testing, user tools, and best practices related to health IT safety."

Health IT Safety Risk Identification and Mitigation

Identifying and mitigating health IT safety risks is a relatively new undertaking for most health care organizations. The introduction of health IT safety improvement initiatives could be expected to face many of the challenges that accompany introduction of any change to clinical practice. Introduction of new tools and practices can require substantial organizational effort.[11, 12] Health IT improvement poses unique challenges. Line authority over health IT–related risks within health care provider organizations is not well articulated or standardized. The multiple distinct lines of management authority over health IT, quality, and safety within organizations may create a hurdle to the systematic and coordinated identification and management of IT risk. For example, in hospitals and larger medical groups, operation of EHRs is typically managed by an IT department, efforts to improve safety may be carried out by a quality management group with a medical director and a patient safety officer, risk management is the purview of risk and liability managers, and regulatory compliance and reporting may be embedded in a compliance department. In ambulatory settings, one individual may be responsible for several of these tasks. Hospitals and ambulatory practices may be able to collaborate with health IT developers to reduce health IT–related safety risks, but it is unclear how developers and their customers should work together to identify and mitigate such risks. These and other questions suggest a need to expand the knowledge base about how hospitals and ambulatory practices can approach the identification and mitigation of health IT safety risks.

2. Implementation of Health IT Safety Risk Projects

Acknowledging the need for better information on the experience of organizations attempting to implement and improve health IT safety practices, ONC contracted with a team at the RAND Corporation ("RAND"), a nonprofit research organization; ECRI Institute ("ECRI"), a nonprofit research organization and patient safety organization (PSO);[a] and health informatics research experts at Baylor College of Medicine and the University of Texas to develop and evaluate a prototype approach for engaging hospitals and ambulatory practices in health IT safety risk identification and mitigation projects. The project had the following goals:

1. Explore the challenges organizations face in deciding whether to participate in health IT safety risk identification and mitigation.
2. Test a simple diagnostic approach that participating organizations could use to identify health IT safety risks.
3. Assist organizations in developing and carrying out a short-term project intended to identify and reduce health IT safety risks.
4. Evaluate the results of the projects.
5. Evaluate the governance and management approaches used by organizations to manage health IT safety risks.
6. Identify barriers and facilitators to health IT risk identification and mitigation in hospitals and ambulatory practices.

Conceptual Framework: Sociotechnical Context

Health IT–related safety risks occur "anytime health IT is unavailable for use, malfunctions during use, is used incorrectly, or interacts with another system component incorrectly, resulting in data being lost or incorrectly entered, displayed, or transmitted."[13] Malfunctions and downtime may be relatively easy to detect, but "incorrect use" and its consequences may be more difficult to detect. The complex interaction among machines, people, and organizations is referred to as the "sociotechnical context." Table 2.1 outlines key elements of the sociotechnical context of health IT–related risk.[13] Failure to detect these health IT risks and correct them can put patients at risk for the errors that health IT systems are meant to prevent and can also create new risks.

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[a] PSOs are organizations (or components of organizations, like ECRI Institute PSO) that—among other activities intended to improve health care quality and patient safety—analyze information provided by health care providers about patient safety events.

Table 2.1: Sociotechnical Dimensions of Health IT–Related Risk

Dimension	Description
Hardware and software	The computing infrastructure used to power, support, and operate clinical applications and devices
Clinical content	The text, numeric data, and images that constitute the "language" of clinical applications
Human-computer interface	All aspects of technology that users can see, touch, or hear as they interact with it
People	Everyone who interacts in some way with technology, including developers, users, IT personnel, and informaticians
Workflow and communication	Processes to ensure that patient care is carried out effectively
Internal organizational features	Policies, procedures, work environment, and culture
External rules and regulations	Federal or state rules that facilitate or constrain the preceding dimensions
Measurement and monitoring	Processes to evaluate both intended and unintended consequences of health IT implementation and use

SOURCE: Adapted from Sittig DF and Singh H, "Defining Health Information Technology–Related Errors: New Developments Since *To Err Is Human*," *Archives of Internal Medicine*, Vol. 171, 2011, pp. 1281–1284.[13]

Adoption of health IT is sufficiently recent in most health care organizations that the methods, practices, and management of health IT risks may be quite variable across organizations. Even those with decades of experience with health IT may not be fully prepared to manage the health IT–specific risks that can be created as they modify their systems. In hospitals, managing health IT safety risks may require collaboration across executive leadership; departments overseeing IT, risk management, and quality management; and the variety of professionals delivering care. Ambulatory practices, which frequently lack a management infrastructure, may need distinct support to successfully monitor and mitigate health IT–related safety risks. Regardless of the setting, in the absence of a deliberate monitoring and mitigation strategy, safety risks will go undetected.

The recruitment of sites and facilitation of process improvement projects were led by ECRI. The evaluation was led by RAND. Health informatics research experts at Baylor College of Medicine and the University of Texas provided expert input throughout.

Recruitment of Participants

In order to identify potential participants (hospitals and ambulatory practices) for the current project, the ECRI project team contacted members of a nationwide network of organizations it had developed through its membership and consulting programs. In the fall of 2012, these organizations were invited to participate or assist with recruitment efforts. ECRI contacted 44 hospitals and ambulatory practices by email; eleven declined to participate. ECRI engaged in recruitment calls with the remaining 33 organizations. Sites that expressed further interest in participating were provided with a link to a brief online survey that requested information about hospital or practice characteristics (including organizational structure, number of beds or patient visits, and number of physicians), information about EHR implementation (including EHR developer, date of "go live," Health Information and Management Systems Society [HIMSS] score, and meaningful use [MU] measures currently being reported), and other contextual factors (such as relationship with a PSO). Twelve hospitals and nine ambulatory practices completed the survey. The final set of participants—seven hospitals and four ambulatory sites—was a convenience sample based on sites' willingness and capacity to plan and undertake a process improvement project and participate in the evaluation within the short timeline of the project.

Standardized Process Improvement Strategy

Participants were asked to engage in a standardized process improvement strategy that was drawn from well-known quality improvement approaches (including Continuous Quality Improvement,[14, 15] High-Reliability Organizations,[16] Lean,[17, 18] Six Sigma,[19] and Business Process Reengineering[20]). An ECRI project facilitator assisted each organization throughout the nine-month project period (January through September 2013), reviewing progress, identifying resources, and providing ongoing technical assistance. Several health IT–specific inputs were also available to assist in the design of the improvement projects. These included draft materials used to develop the Safety Assurance Factors for EHR Resilience (SAFER) Guides[21] (referred to as the draft SAFER Guides hereafter).[b] The draft SAFER Guides included over 100 best practices for health IT safety organized by topic area (e.g., CPOE, EHR downtime).[c]

ECRI facilitators guided sites through the following six steps:

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[b] During the course of this project, the SAFER Guides were under development, and early drafts were made available to the ECRI facilitators and site project teams to use in designing the improvement projects. Final versions of the SAFER Guides were released in January 2014 after the individual hospital and ambulatory practice projects were complete. ONC funded the development of the SAFER Guides.

[c] The final version of each SAFER Guide contains the final best practices, as well as a status worksheet for each practice, including a rationale for the practice, suggested sources of input, examples of potentially useful scenarios, and space for staff to enter notes on needed follow-up.

1. Assembling a project team
2. Selecting one of the six topic areas of the draft SAFER Guides
3. Prioritizing specific best practices from the selected draft SAFER Guide
4. Specifying a work plan
5. Implementing a work plan
6. Monitoring progress and adapting the work plan as needed.

The first four steps were conducted over a four-month period, with five months allocated to implementation and monitoring (steps 5 and 6).

After assembling a team, sites were asked to select one of the following health IT–related safety topic areas aligned with a draft SAFER Guide: test result reporting and follow-up, EHR downtime, clinician communication, CPOE, organizational activities and responsibilities, and patient identification. To facilitate topic selection, the ECRI project team, with support from the RAND project team and the experts at Baylor and the University of Texas, developed a diagnostic assessment. The diagnostic assessment aimed to help sites evaluate their current practices for identifying and mitigating health IT–related safety risks. It began with two to three statements about current practices in each of the draft SAFER Guide topic areas. For example, the clinician communication section contained the following statement: "EHR users can see the status (e.g., pending, complete) of test orders, results, referrals, and other requests in the EHR." Respondents rated each statement on a five-point scale (from "no activity" to "fully implemented in all areas"). The diagnostic assessment then asked respondents to rank order the SAFER Guide topic areas, based on the sites' responses to the topic area–specific statements, and to identify any additional issues that did not fall into the topic areas. The next section of the diagnostic assessment asked about sites' use of health IT–related safety metrics, such as CPOE rate and alert override rate. Finally, the diagnostic assessment asked about processes for resolving safety events or mitigation risk, including the role of third parties (e.g., EHR developers, IT consultants, PSOs).

After selecting a topic area, each site's team evaluated the level of adoption of 10 to 30 best practices in the draft SAFER Guide for that topic area. The project leader and staff then conducted a feasibility and importance assessment of practices that were not yet adopted and were expected to prioritize one or more of the best practices for their project. Next, the sites specified a work plan for the project period, including activities in which they planned to engage in order to increase adoption of the best practice(s), metrics for measuring change in performance, and a monitoring plan. Finally, sites were expected to implement the work plan, measure their performance on the selected metrics over time, and adapt the work plan in response to any unexpected developments.

Resources

Sites were invited to join ECRI-led webinars (see the list in Table 2.2), each of which lasted 30 minutes to an hour and included an opportunity for questions and answers. Sites were also invited to use the resources on a web site that ECRI created for this project, containing relevant literature, recordings of the webinars, and other resources.

Table 2.2: ECRI Webinars Offered to Participating Organizations

Timing	Title
Month 1	Introduction to ECRI Patient Safety Organization (PSO)
Month 2	Implementation of PSO
Month 3	PSO Event Reporting Webinar
Month 4	Health IT PSO Deep Dive
Month 4	Electronic Health Record: A Systems Approach to Evaluation & Implementation
Month 5	Options to Improve EHR Usability
Month 6	The "Unintended Consequences" of Health Information Technology

Participating sites were also asked to report either health IT hazards (using Hazard Manager[d]) or actual adverse events associated with health IT (using the AHRQ Common Formats[e]) to ECRI Institute PSO. All sites chose to report adverse events rather than health IT hazards, so discussions of "site reporting" in the remainder of this report refer to reporting of adverse events using the AHRQ Common Formats. Reporting took place through a portal on the ECRI web site.

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[d] Hazard Manager, developed with funding from the Agency for Healthcare Research and Quality (AHRQ), is software that allows clinicians and staff to capture and manage information about health IT–related hazards before they result in patient harm.

[e] The Common Formats, also developed with funding from AHRQ, provide standardized definitions and reporting forms for health care organizations to report adverse events to PSOs.

3. Evaluation

A case study methodology was used to determine the extent to which the six-step process improvement strategy and associated resources were helpful to participating hospitals and ambulatory practices in identifying areas of risk, developing an improvement strategy, and ultimately mitigating risk.

Evaluation Objectives

RAND identified six objectives for its case study–based evaluation:

1. Describe the health IT safety risk areas prioritized by the individual sites and any factors associated with changes in priorities over time.
2. Describe the role of health IT in the organization and the existing organizational health IT safety and risk mitigation strategies.
3. Describe the health IT risk mitigation activities chosen by the sites and their experience in implementing those activities.
4. Identify any challenges or barriers encountered during implementation and possible root causes and solutions.
5. Collect feedback from the participating sites regarding any specific tools that were employed as part of the process improvement, including the AHRQ Common Formats.
6. Draw from the experience of the sites to describe how health IT–related risks can be best identified and prioritized, and how risk mitigation strategies might be undertaken and managed by health care organizations in the future.

Data Sources

RAND had three main data sources for its evaluation: (1) the diagnostic assessment completed by each of the 11 participating sites, (2) ECRI's "project implementation dossier" on each site, and (3) RAND site visits and interviews with six of the sites:

1. Diagnostic assessments: Site leaders and other key staff completed the diagnostic assessment, as described in the previous chapter.
2. ECRI-collected project implementation dossiers: ECRI generated a dossier of documents related to each hospital and ambulatory practice's project implementation. Documents included initial and modified work plans, conference call notes, and performance on metrics over time. Each dossier also contained an ECRI-developed implementation summary, which listed the risk that the hospital or ambulatory practice aimed to mitigate, the selected activities, selected metrics for evaluating progress, use of adverse event

reporting to ECRI Institute PSO, ECRI's assessment of barriers to success, the implementation progress over time, and a project timeline.

3. Site visits and telephone interviews: The RAND evaluation team conducted site visits to each of five participating organizations between September 2013 (nine months after project initiation) and March 2014. (For one of the smaller ambulatory sites, RAND conducted telephone interviews instead of a site visit.) In advance of the interviews, RAND developed a semi-structured interview protocol. The protocol included standard and custom topics informed by the diagnostic assessments and the implementation dossiers.

Interview Participants

The final set of project participants—seven hospitals and four ambulatory sites—were willing to plan and carry out a process improvement project and also participate in its evaluation under an unusually tight timeline. Due to these circumstances, three of the seven participating hospitals had limited engagement in the project. To maximize the lessons learned, the RAND team chose to focus on the four hospitals and four ambulatory sites that remained fully engaged in the project throughout. RAND staff reached out to each organization's project leader by phone and email. Three of the four hospitals and three of the four ambulatory sites agreed to participate in interviews.[f] The RAND evaluation team conducted interviews using a semi-structured interview protocol (described below). Interviewees included the project leader; executive leadership; leadership and staff from the risk management, quality improvement, and IT departments; clinical champions; and clinical and support staff.

Interview Protocol

Prior to the site visit (or interview), the RAND evaluation team iterated with the site project leader on the site visit agenda. RAND sent the project leader a list of possible topics and, for each, a list of positions (e.g., executive leadership, clinical champion) that would likely have knowledge of the topic. The site project leader proposed any modifications to the topics, proposed an order for the interviews, and provided names in place of the generic positions. Each site visit typically began with an interview with the project leader; this interview consisted of overview questions about the project and questions relevant to the leader's specific position within the organization and area of expertise. The visit then continued with interviews with other key informants (mostly through group interviews). The interviews were semi-structured, based on the dimensions shown in Table 3.1. Each site visit also included a roundtable discussion about

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[f] The fourth hospital refused, citing competing priorities, particularly clinical EHR conversion. The fourth ambulatory site did not respond to multiple emails and phone calls.

the institution's experience with the AHRQ Common Formats when reporting adverse events related to health IT safety to ECRI Institute PSO.

Table 3.1: Site Visit Interview Guide Evaluation Dimensions and Sample Items

Topic	Dimension	Sample Items
Agenda Topic 1	Background and context	1. Environmental factors 2. Characteristics of the organization 3. Leadership 4. Existing risk management strategies and processes 5. Existing initiatives that implement process improvement techniques 6. Other resources and initiatives
Agenda Topic 2	Health IT adoption	1. Adoption of EHR system 2. Other health IT infrastructure
Agenda Topic 3	Health IT safety and risk management	1. Status of health IT safety and risk management initiatives 2. Prioritization of health IT safety and risk management
Agenda Topic 4	Implementation: process improvement experience	1. Roles and responsibilities 2. Best practices identified as priority 3. Components of implementation plan 4. Metrics 5. Adherence/adjustments to implementation plan
Agenda Topic 5	Barriers and facilitators to health IT safety and lessons learned	1. Barriers (technical and sociotechnical) 2. Facilitators 3. Adjustments to address barriers 4. Lessons learned

Topic	Dimension	Sample Items
Agenda Topic 6	Utility of resources and process improvement strategy, and opportunities to improve strategy	1. Utility of methods used to identify priorities for process improvement 2. Perceived value and needs of third-party assistance 3. Perceived effectiveness of diagnostic assessment 4. Use and perceived effectiveness of AHRQ Common Formats 5. Perceived effectiveness of specific activities used to address health IT safety issues 6. Review of novel metrics used by sites

A team of three RAND investigators conducted the interviews. For each interview, the health IT expert was paired with one of the two senior qualitative researchers.

Theme Identification

To synthesize the large quantity of information generated by the interviews, diagnostic assessment results, and implementation dossiers, the RAND evaluation team adopted a thematic approach to data analysis. RAND began selecting possible themes after the first interview was completed, which helped to refine the data collection protocols and expedite the process of identifying cross-cutting themes. Using a comparative approach to case study data analysis, the team identified the aspects of the process improvement strategy that appeared to be associated with risk mitigation and either (a) were noted across several participating organizations (hospital versus ambulatory practice) or (b) were unique to either hospitals or ambulatory practices.

4. Results

As described in the previous two chapters, seven hospitals and four ambulatory sites completed the project, although three of the hospitals had limited engagement toward the end. Characteristics of the 11 participating sites are provided in Table 4.1. In four of the seven hospitals, projects were led by an individual in the risk management department; one of these individuals also had a position in the quality department. In two of the other hospitals, the projects were led by individuals in the quality department. The project in the final hospital was led by an individual in the IT department. The projects in the ambulatory practices were led by a diverse group: (1) an individual with various roles in the organization (managing the EHR, the billing system, and a dialysis clinic), (2) the director of practice operations, (3) a member of the parent health system's risk management team, and (4) the owner of the practice.

The 11 sites were geographically diverse and encompassed large and small hospitals and ambulatory practices. Four of the seven participating hospitals were already reporting to a PSO before beginning the health IT risk mitigation project. None of the four ambulatory practices had reported to a PSO before the project. The hospitals and ambulatory practices selected a variety of topic areas; the most common area (clinician communication) was selected by three of the practices. The hospitals and the ambulatory practices varied widely in their HIMSS scores, representing a range of levels of EHR adoption. In the hospitals, HIMSS scores ranged from Stage 3 to Stage 7; in the ambulatory practices, HIMSS scores ranged from Stage 4 to Stage 7.[g]

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[g] HIMSS's EMR Adoption Model provides an eight-stage scale (Stage 0 to Stage 7) indicating the level of EHR adoption. Stage 1 for hospitals indicates that laboratory, radiology, and pharmacy have adopted EHRs. Stage 1 for ambulatory practices indicates desktop access to clinical information, unstructured data, multiple data sources, and intra-office/informal messaging. Stage 2 signifies that a hospital or ambulatory practice has Stage 1 capabilities plus additional specified capabilities. Descriptions of each HIMSS stage can be found at http://www.himssanalytics.org/home/index.aspx.

Table 4.1: Characteristics of Participating Sites

Site Number	Participated in Site Visit/ Interviews?	Project Leader's Department	Reporting to PSO Before Project?	Selected Topic Area
Hospitals				
1	No (Limited engagement)	Quality	Yes	Organizational activities and responsibilities
2	Yes (Case Study 3)	Risk management	No	Clinician communication
3	Yes (Case Study 2)	Risk management	Yes	Test result reporting and follow-up
4	Yes (Case Study 1)	Quality and risk management	No	CPOE
5	No (Limited engagement)	Quality	Yes	Clinician communication
6	No (Refused)	IT	No	EHR downtime
7	No (Limited engagement)	Risk management	Yes	Clinician communication
Ambulatory Practices				
8	Yes (Case Study 4)	Multiple roles	No	CDS
9	No (Nonresponsive)	Operations	No	Patient identification
10	Yes (Case Study 6)	Risk management	No	Test result reporting and follow-up
11	Yes (Case Study 5)	Practice owner	No	Test result reporting and follow-up

All participating sites and ambulatory practices were required to report any health IT–related patient safety events to ECRI Institute PSO. The appendix contains ECRI Institute PSO's analysis of the reports.

As described in the previous chapter, RAND conducted site visits or phone interviews with three of the four highly engaged hospitals and three of the four highly engaged ambulatory sites.

Case Study 1: Hospital

Background and Context

This case study involved a small hospital that has an acute care license but operates primarily as a psychiatric hospital. Medical/surgical beds largely serve safety-net patients, most often providing drug and alcohol detoxification services. The hospital's chief executive officer (CEO) noted the unique stability of the hospital's business environment, with no expected major fluctuations in revenue or planned expansion of facilities. Strategically, the hospital leadership has a policy of undertaking only one major project each year; in 2012, the hospital focused on implementation of the EHR, and in 2013, the hospital focused on Joint Commission recertification.

In terms of organizational culture, both leadership and staff describe a "horizontal" organizational structure with open lines of communication among all levels of personnel, which facilitates identification and resolution of issues. Leadership and staff cited patient safety as a high priority for the institution. Current patient safety activities include an internal, paper-based adverse event and near-miss reporting process and database that is reviewed weekly by risk management staff. Each incident report is investigated to determine whether it was due to error or negligence and whether it points to the need to change standard processes.

Health IT

The hospital implemented its EHR in 2012 for all products necessary for MU. The CEO stated explicitly that MU incentives were the exclusive motivation for implementing an EHR system. Leadership emphasized that meeting MU criteria and "truthful [MU] attestation" were high priorities for the hospital, which is evidenced by the resource allocations made for health IT staffing, beginning with the EHR rollout. The hospital has an EHR committee that meets weekly. Its membership includes the CEO, the director of risk management and quality improvement, pharmacy management, the medical staff director, the nurse educator, IT staff, and a different member of "line staff" selected each week. Fifty percent of the weekly EHR committee meeting time is devoted to MU, and it also publishes a "Tips of the Day" email to help educate staff on EHR features. Clinical staff has generally accepted the EHR. A physician stated that the EHR had probably neither impaired nor improved productivity; nursing staff were more enthusiastic about the EHR, reporting improved efficiency of medical recordkeeping.

Both IT and risk management staff reported that they had adequate resources to achieve EHR implementation. After the EHR rollout, executives reallocated funding from the medical records department to fund additional IT staff. This shift in funding resulted in the commitment of five full-time staff to maintaining and supporting the EHR hardware and software, including one full-

time employee in the role of EHR technical support. This employee is primarily tasked with facilitating EHR use, including shadowing and training clinicians to promote safe and effective use of the EHRs. In addition, the secretary for each hospital unit is trained on new EHR features and serves in the role of "on the ground" technical support. Hospital personnel are paid for up to two hours per week of EHR proficiency training.

Health IT Safety and Risk Management

The EHR committee described above reviews near miss and adverse event reports related to health IT and, if necessary, makes remediation plans (e.g., to educate staff or adapt technology). The quality improvement and risk management director leads a team of staff dedicated to reporting, issue analyses, and resolution processes. This group maintains a database of quality measure results, adverse event reports, and near-miss reports.

In addition to the clinical processes targeted in this project (described below), the EHR committee has identified several other important issues, all related to accessibility and timeliness of critical information to staff using the EHR. Some of these issues are related to interoperability and interface problems (e.g., external lab reports not being delivered as HL7 messages, a specification that allows for interoperability, and "terminology drift," which results from lab system updates being out of sync with the EHR terms and requires updates to code maps). In addition, the EHR committee identified a lack of appropriate follow-up on a radiology report that was not readily retrievable using the EHR. One of the physicians pointed out in the site visit that these types of information gaps have traditionally been filled by use of verbal or paper communications. He raised the concern that the increasing use of the EHR as the primary communication mechanism among clinicians for noncritical results is leading to both "complacency" and "distraction" that are introducing additional patient safety risks related to failure to follow up on abnormal results.

Project Implementation

As noted above, participation in this project was concurrent with EHR implementation, which could have been either beneficial or detrimental (depending on how time- and resource-intensive the EHR implementation was for IT and other hospital staff). In this case, participation in ECRI activities (including webinars, work plan development, and measurement and reporting activities) fit with the organization's change management plans for its EHR rollout. As staff described it, they were health IT "neophytes" at the beginning of EHR rollout and therefore gratefully received the tools and assistance provided by ECRI.

Project Leader. The director of risk management and quality improvement was the project leader and appeared to have good rapport with staff. The project team included the informatics director, a member of IT staff, the facility's nurse educator, and an assistant.

Selected Topic Area and Safety Practices. The project team selected CPOE as its topic area in part because of concern over an event that preceded this project. The event involved a patient fall with a subsequent abnormal radiology result (a broken arm) that was not reviewed by a physician before the patient was returned to the psychiatric unit. The patient was subsequently discharged. After completing the diagnostic assessment, the project team identified the order entry system as a contributor to the failure to review radiology and other laboratory results, selecting CPOE as the topic area. The project team selected the following best practices from the draft CPOE SAFER Guide: "EHR users need to be able to view the status (pending, completed) of test orders, results, referrals, and other requests in the EHR," and "Verification and completion of computer-entered orders for Laboratory and Radiology can cause communication issues between providers."

After reviewing EHR use patterns, the project team chose to focus on the specific safety risk of nurses failing to acknowledge new tasks and orders in the hospital's EHR system. "Tasks" include such items as reviewing results, medication administration, and following up on orders and labs. Tasks are often used as a means to communicate when the clinical process involves coordination across multiple individuals. The hospital's EHR system notifies staff that a new task or order is available and requires acknowledgement that the task message has been received. This initial notification is displayed in the EHR's landing page, which opens by default when a patient's record is accessed. However, once a nurse clicks on the notification in the main task dashboard, the notification is removed from the more visible landing page; accessing open tasks requires navigation to "deeper" parts of the EHR. This practice introduced risks because nurses did not know to look for the results of orders, especially after shift changes. As a workaround, nursing staff would often leave the tasks and orders unacknowledged so they could be viewed by nurses on future shifts in the landing page. However, this widespread workaround also introduced risks because nursing staff could not easily understand the status of a given task, only that at some point the task had been created.

Risk Mitigation Activities. The hospital project team decided to engage in two activities aimed at decreasing the common behavior among nursing staff of not acknowledging tasks and orders: (1) evaluating and standardizing the workflow for verification and completion of laboratory and radiology orders and (2) educating nursing staff in the medical/surgical unit about utilizing the "Quick View" tab, which gives an overview of tasks performed, recent orders, and laboratory and radiology results.

Selected Measures. The project team selected two measures: (1) rates of accessing the "Quick View" tab and (2) rates of unacknowledged tasks. The EHR committee evaluated performance on these measures by selecting patient charts at random for audit. Results were reviewed and discussed with nursing staff in order to identify education opportunities. Aggregate scores were posted in the medical/surgical unit.

Results. At the time of RAND's case study interviews, accession of the newly introduced "Quick View" screen was reported to have increased. Even so, a high number of unacknowledged tasks remained.

Barriers and Facilitators

The most substantial barrier to accomplishing the project goals was the need to split the hospital's focus and energy between this project and Joint Commission reaccreditation. As described above, the hospital's strategy is to undertake only one major initiative each year, and this project was more closely related to the prior year's focus on EHR implementation. While this division of focus and energy was a barrier to maintaining and delivering reports to ECRI, it does not appear to have interfered with the adoption of the new risk management practice (use of "Quick View").

Some nurses who had started using "Quick View" expressed concern that downstream staff would continue to rely on the original workaround. This fear contributed to the persistence of leaving tasks open. Project staff indicated that one barrier to changing behavior was that no formal accountability mechanism had been established that would place the burden of responsibility for checking task status through the correct channel ("Quick View") on downstream users. Thus staff could not assume that downstream users would check "Quick View" rather than relying on workaround communications. Additionally, "Quick View" is not the default view, and a number of mouse-clicks are required to access the task status in the "Quick View" tab. At the time of the site visit, the EHR committee had already identified some of these issues with the EHR developer for future updates. Other barriers to accomplishing project goals included staff turnover, delays in training, and the fact that no incentives (positive or negative) were in place to change existing practices, other than publicly posted feedback in the unit.

Several facilitators were important. The project benefited from strong executive-level leadership and the corresponding allocation of resources and dedicated staff. IT and other staff were well trained and were accustomed to producing performance measures. The timing of the project—it took place the year after the hospital converted its EHR and was concurrent with full implementation of EHR—was a fortuitous and important project facilitator. Another facilitator was the EHR developer's responsiveness to the hospital's need for EHR changes to improve staff

experience, provide timely updates, and respond to other concerns. Because the hospital is primarily a psychiatric treatment facility, the EHR's features have been customized to fit the staff workflow.

Utility of Resources and Process Improvement Strategy

Members of the project team agreed that all phases of ECRI's implementation process were helpful and increased their institution's attention to health IT safety issues. At the time of the site visit, the project team was planning to review project materials when it moved forward with developing MU risk assessments.

Two issues were raised in discussion of the AHRQ Common Formats reporting tools. The first was difficulty logging on to the PSO online reporting system. The second was related to the AHRQ Common Formats taxonomy and skip logic. Facility staff reported that a "cumbersome" series of steps were required to report an event. This reporting was inconsistent with—and more complex than—the facility's internally used protocol for characterizing safety events.

Case Study 2: Hospital

Background and Context

This case study involved a midsize teaching hospital that is part of a larger health system that includes a multihospital system, an employed physician group, and independent providers. The health system has a "system office" that manages several operational areas, including risk and loss management strategy, IT, and financial operations across the hospitals and ambulatory sites. The organization has a strong commitment to patient safety, demonstrated by both leadership buy-in and local practice. According to risk management leadership, the health system uses a standardized process for selecting risk management and safety projects: First, priority areas are selected based on analysis of data, driven primarily by complaints and or malpractice claims. After priority areas are identified, a team of project managers and a steering committee is formed. The team develops a systemwide policy statement that describes the protocols and the measures of policy compliance and then conducts measurement. A team contacts providers who are not compliant with the policy in order to better understand barriers to compliance and to create and monitor an action plan. As an additional incentive for practice change, providers compliant with the policies receive a premium discount on malpractice insurance. To date, this model has been replicated in three projects. Other examples of the organization's commitment to safety and risk management include the use of root cause analysis as part of regular operations and the use of the "learning from defects" approach.

Health IT

Within the health system, hospitals—including the one that participated in this project—use a different EHR system from the ambulatory practices, and the EHR systems have limited interoperability. In general, health IT has had minimal support from the organization, especially from executive leadership. Accordingly, the organizational priority related to health IT is meeting the minimum requirements for MU incentives. Site visit interviewees, including residents and project leadership, indicated that few resources are devoted to EHR development. In fact, the former chief of staff of the hospital was described as an "active opponent" of electronic systems. (He was recently replaced with a chief of staff who, according to site visit interviewees, has a more neutral attitude, but is by no means a health IT champion.) Interviewees also noted that an influential medical executive committee has been reluctant to support health IT–based improvements, perhaps due—in part—to the suboptimal initial rollout of the EHR system ten years ago, after which the EHR system was actually retracted and the hospital returned to a paper-based system until needed improvements could be made. There are open channels of communication about EHR problems, and project leadership communicated that staff are generally vocal with suggested improvements.

Health IT Safety and Risk Management

The organization's commitment to safety and risk management extends somewhat to health IT. Informatics staff participate occasionally in root cause analyses to better understand health IT factors that might contribute to causes or to future solutions. An event reporting system preceded this project, and any events that are clearly related to health IT are brought to the attention of the local clinical informatics staff. Providers receive incentives for event reporting.

Project Implementation

This project occurred in the context of a hospital with a strong dedication to risk management and patient safety but a reluctance to engage in health IT development.

Project Leader. The project was led by the director of risk management for the entire health system. The project team included the participating hospital's chief medical information officer, director of risk management, director of clinical informatics, and nurse-liaison between informatics staff and clinicians.

Selected Topic Area and Safety Practices. On the basis of the diagnostic assessment and with support from an ECRI facilitator, the project team selected test result reporting and follow-up as the project's topic area. The project team selected the following best practice from the draft Test Result Reporting and Follow-Up SAFER Guide: "Workflows related to high-risk scenarios (i.e., those vulnerable to handoff problems) are identified, and back-up procedures (i.e., fail-safe, cascade, or escalation systems) are used to communicate results." The project team noted that patients are at high risk of information loss during patient handoffs or signouts. This risk of information loss was thought to be due, in part, to the multiple information management systems, including a sensor monitoring system, the hospital EHR, the whiteboard, paper charts, verbal communications, and implicit protocols. The project team decided to focus on obstetrics handoffs because this issue had been identified by the organization's existing risk management analyses. In addition, based on their perception that younger staff would be more engaged in changes to health IT, project leadership decided to target a system used by the obstetrics residents.

Risk Mitigation Activities. Based largely on feasibility and synergy with existing priorities, the project team aimed to implement a custom interface in the EHR that would facilitate obstetrics handoffs between shifts.

Selected Measures. The project team decided to measure the utilization rate of the handoff tool at signout.

Results. The project team educated obstetrics residents on use of the handoff tool. However, two months after this education took place, limited utilization of the tool was found. The project team then planned and executed a reeducation process, which was conducted two months after limited utilization had been discovered. One month after reeducation, utilization of the handoff tool by obstetrics residents had not increased.

Barriers and Facilitators

The handoff tool was not widely adopted by obstetrics residents. A key barrier was the existence of multiple, complex existing systems for documentation and information management, to which the handoff tool contributed an additional layer of complexity. Another major barrier was that the new handoff tool was not integrated well into the existing workflow. For example, obstetrics residents collaborate closely with nursing staff, who primarily use a separate health IT system (not the EHR). This issue raises questions about the level of involvement of the obstetrics residents in selecting the tool and the extent to which established workflows can be changed.

A key facilitator was the organization's dedication to risk management and patient safety, including the organization's systematic measurement and prioritization practices. Given the low level of adoption by clinicians, utilization of the new handoff tool might have been expected to lead to a premature termination of the project, but the active efforts of the risk management team enabled the project to continue through the end of the implementation period. In the context of this project, the risk management leadership and the informatics team forged a closer working relationship, suggesting that such projects can serve as a stimulus for interdepartmental collaboration. In the future, this collaborative relationship may enable greater attention on the role of health IT in risk management.

Utility of Resources and Process Improvement Strategy

Like several other participating sites, the hospital based its project selection on synergy with existing initiatives rather than on the diagnostic assessment or other tools. During site visit interviews, several interviewees noted other needs that the selected project did not seem to address. Among these needs were interoperability, system integration, and user interface issues, particularly with respect to ordering and laboratory systems. Interviewees noted difficulty in undoing erroneous EHR actions even if the mistake was discovered right away. Many of these issues were represented in practices included in draft SAFER Guides other than the SAFER Guide that informed the hospital's project, suggesting that selecting a topic area first was not an effective approach for this site.

The hospital implemented its own approach to reporting in the AHRQ Common Formats. The health system's director of risk management reviewed the AHRQ Common Formats and identified those fields that matched fields in the organization's existing reporting product. This exercise allowed a risk manager at the hospital to develop filters that could be applied to the hospital's existing reports by searching for health IT–based categories and then manually filtering out reports that were not health IT–related. The manually filtered report could then be passed to the hospital's director of clinical informatics, who would categorize events in accordance with the AHRQ Common Formats. The AHRQ Common Format information would then be manually abstracted back into the reporting forms. While this process involved several steps, it did leverage existing systems in a way that enabled the department to classify reports using the AHRQ Common Formats.

Case Study 3: Hospital

Background and Context

This case study involved a midsize hospital belonging to a large health system that is growing through acquisitions and mergers with a goal of becoming an accountable care organization (ACO) for contracting purposes. During the site visit interviews, staff and leadership were consistent in identifying system growth, health IT adoption, and building population management capabilities as key priorities. According to leadership, the health system is also currently participating in dozens of studies related to health services and translational research. Multiple interviewees emphasized the system's "culture of safety." Leadership at the health system has demonstrated a commitment to risk management and safety, particularly at the hospital level, filling risk management roles with staff distinct from those that handle claims and encouraging a proactive approach by standardizing reporting and analysis practices for adverse events and near misses. The health system began participating in PSO activities before the project.

Health IT

The hospital was a relatively early adopter of health IT: It initially implemented an EHR over a decade ago. It was in the process of switching EHR developers during this project. The health system to which the hospital belongs has procured predictive modeling software to identify patients in the commercially insured pool that are at risk for high utilization or readmission. Use of the software is limited to the commercially insured individuals because the health IT developer charges a fixed price per patient; however, a more affordable, claims-based system is being procured for risk identification in the rest of the patient population.

Health IT Safety and Risk Management

The health system has invested significantly in information systems for safety reporting and tracking. A legacy system for handling staff reports of unusual occurrences has been combined with metrics generated from the EHR to assist staff with identification of near misses and adverse events. The hospital recently invested in risk management software that includes adverse event tracking and reporting capabilities. The new software, which will replace the legacy reporting system but had yet to be implemented at the time of the site visit, has a streamlined, user-friendly interface that generates reports in the AHRQ Common Formats that can be both viewed internally and submitted to external safety programs.

Project Implementation

Project implementation was concurrent with the hospital's transition to a new EHR developer, which—as is noted in another case study report—could have been either beneficial or detrimental (depending on how time- and resource-consuming the EHR developer transition was for IT staff and other hospital staff, and given organizational priorities). In this case, competing priorities impeded the measurement of project implementation progress because IT staff had limited availability.

Project Leader. The project team was highly centralized in the risk management department. The project leader, the director of risk management for the health system, has responsibility for limiting liability and addressing grievances. Other project team members included the director of informatics and the chief information officer.

Selected Topic Area and Safety Practices. Using the diagnostic assessment, and with support from an ECRI facilitator, the hospital selected clinician communication as the topic area for the project. The hospital did not select specific practices from the draft Clinician Communication SAFER Guide, but focused on the risk of increased use of verbal orders as the hospital transitioned to a different EHR system. Verbal orders pose known risks to patient safety because of the potential for miscommunication, misunderstanding, and delayed documentation. Verbal orders also limit clinicians' ability to take advantage of safety features that come with electronic CDS that trigger alerts for drug interactions and allergies. Project leadership indicated that MU criteria and HIMSS targets contributed to the site's selection of use of verbal orders as a project focus. MU criteria for CPOE promote limits on verbal orders by offering incentives for increasing direct use of CPOE by licensed professionals. Informatics staff noted that CPOE compliance is a HIMSS Stage 7 target and that the informatics team follows MU compliance metrics closely.

Risk Mitigation Activities. The hospital decided to monitor providers' use of verbal orders, beginning at the time the new EHR system was implemented. The hospital planned to (1) create a verbal order utilization report to run monthly, (2) review the verbal order report and identify outliers by specialty and individual provider, and (3) notify the chief medical officer and management staff of the clinical areas in which providers had high rates of using verbal orders.

Selected Measures. Given a goal of reducing reliance on verbal orders and increasing reliance on CPOE, the project team constructed a metric that would assess reliance on verbal orders among physicians who met a minimum threshold for the number of orders given during a time frame. The intent was to identify physicians who gave verbal orders almost all of the time. Specifically, the verbal order utilization report contained the following metric: the percentage of

all providers with more than 25 orders in a month, for whom more than 90 percent of the orders were verbal.

Results. The project leader and site project team successfully ran the verbal order utilization report for four consecutive months, reviewing the results and identifying the physicians who relied almost exclusively on verbal orders. In the first month, 11.2 percent of providers had more than 90 percent of orders made verbally. In the second, third, and fourth months, 3.3 percent, 3.5 percent, and 4.6 percent of providers met the threshold, respectively. Among the specialties, gastroenterology and psychiatry had the most providers who had high rates of verbal orders for two or more months. Although the percentage of providers utilizing verbal orders had a small increase in the third month and a slightly larger increase in the fourth month, the hospital project team communicated at the site visit that they believed that the measurement and internal reporting had reduced reliance on verbal orders. The project team also believed that the uptick in the fourth month was due to the hiring of new staff who had to be trained on CPOE.

The project team planned to continue to work on the project after the official implementation end date and, as of the site visit, had decided to meet with each provider who appeared on all four reports to discuss noncompliance. The team also decided to establish a threshold of acceptability (perhaps 2.5 percent of all providers) that they would target in the coming months.

Barriers and Facilitators

Key barriers were the limited availability of informatics staff to generate reports and insufficient time and resources for clinical staff to adapt to new roles and workflows required by the new EHR. The concurrent implementation of the new EHR was both a facilitator and a barrier. It drew leadership and staff attention to health IT issues and increased staff capability and readiness to work on such issues. At the same time, it required significant resources and staff time and was a higher priority than this project. At the time of the site visit, the IT staff was having difficulty with managing the backlog of existing EHR-related requests.

A major facilitator was the hospital leadership's commitment to the project and to safety generally. Leadership facilitated involvement in the project. Clinical and administrative staff were highly engaged and motivated to improve information systems and workflow. Because verbal order rates are part of MU criteria, order rates—the selected metric—were automatically generated by the new EHR developer's data warehousing system. Selecting a metric that was already available in the EHR facilitated measurement.

Utility of Resources and Process Improvement Strategy

Members of the hospital project team perceived the tools and technical assistance provided by ECRI to be of very high value. Several lessons emerged from the hospital project team's use

of these resources. First, the selection of the topic area and specific risk mitigation activities were not guided by the tools alone. The hospital project team expressed uncertainty about how best to assign responsibility for completing the diagnostic assessment (which could be completed by members of the management team, front line staff, or both groups) and how to assign responsibility for the work plan. The use of the diagnostic assessment led the hospital project team to question whether the health IT risk priorities identified by hospital staff were consistent with those identified by risk management leadership. They noted that the feasibility of a project to improve practice may have been evaluated differently by these two groups. Discussions about priorities during the site visit illustrated this disconnect. Staff identified EHR configuration and medication list management as high priorities, but given the available IT resources, any interventions requiring additional application development would likely not be feasible. The selection of a topic area and specific risk mitigation activities was concurrent with the introduction of a new EHR system, so the relevance of the project to health IT safety issues that might arise after transition to the new EHR was unclear.

The information systems used by the health system for handling event reporting included a legacy system that leadership has long considered inadequate because of low specificity of event descriptions. As described above, the hospital recently invested in risk management software that will replace the legacy system. During the current project, the health system piloted PSO reporting with the AHRQ Common Formats. The risk management department found the AHRQ Common Formats too burdensome, considering several items irrelevant or too detailed for risk management staff to complete without the assistance of an "eyewitness" to the event. For example, the health IT safety form addresses both health IT–associated events and medical device–associated events, so the questions about medical device–associated events were not relevant to the risk management staff completing the AHRQ Common Formats. The implementation team shortened the forms and simplified the logic for ease of use.

Case Study 4: Ambulatory Practice

Background and Context

This case study involved a large multispecialty medical group that includes both partners and salaried physicians. It competes with multiple small practices and a few other medical groups. Currently, the medical group has a number of strategic objectives, including building additional clinical capacity, adding new salaried physicians, and developing a strong market position to enable the group to deliver "value-based" care without sacrificing its profitability in fee-for-service. The general approach was summarized as "invest in infrastructure in the short term and invest in [changing the] culture in the long term." The practice's leadership anticipates that this approach will enable them to adapt to changing market conditions (having seen the "writing on the wall") and/or to increase their practice's potential value in an acquisition deal.

The medical group does not have an established quality improvement infrastructure, and there is no feedback of performance metrics to the physicians, with the exception of feedback about financial productivity, which the group reviews frequently with all physicians. Consensus among the partners on new initiatives, such as a health IT project, can be difficult to achieve.

Health IT

The medical group implemented an EHR system in 2008, and because MU incentives were not yet available, initial purchase and implementation represented a significant investment. The EHR platform had to be customized to accommodate the practice's specialists, and some specialists still use paper forms. The practice's leaders believe that adoption of EHR has led to efficiencies, pointing to elimination of support staff (medical coder positions). The next planned health IT–related implementations include a patient portal (an ongoing health IT project) and the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) update.

The medical group has a health IT "champion" (one of the managing partners is an active proponent of health IT). However, IT staffing currently consists of a single staff person with no administrative support who manages the EHR system and also has responsibilities for billing and administration of the dialysis clinic. Resources to develop additional clinical applications and/or performance reports are very limited. Interviewees indicated that the practice could benefit from additional IT staff, but resources are currently inadequate to hire personnel.

Health IT Safety and Risk Management

Interviewees reported that they have no formally established protocol or channels for communicating about adverse events or near misses. Addressing safety issues related to health IT

is not currently a priority for the practice, except as it relates to other, higher priorities around building capacity and strengthening the group's market position for delivering value-based care. When queried about health IT risk management during the evaluation site visit, those in leadership positions tended to focus on privacy and data protection. Beyond information security, interviewees did not conceive of health IT as a risk factor related to patient safety, despite participation in the facilitated activities of the project (webinars and telephone calls).

Project Implementation

The medical group's implementation of the process improvement strategy was challenged by competing priorities, lack of resources, and the staff's own lack of awareness of the risks to patient safety associated with health IT. Despite ECRI's efforts, at the time of the site visit by RAND investigators, no interviewee from the medical group (including its project leader) identified health IT safety as the main focus of this project.

Project Leader. The project leader has a number of roles within the medical group, including managing the EHR, the billing information system, and a dialysis clinic. Others on the project team were the medical group's executive director and a newly hired operations manager.

Selected Topic Area and Safety Practices. The medical group selected CDS as its topic area for the project. During the site visit, interviewees communicated that CDS was selected as the topic area for the project because of its relationship to MU priorities, not because they perceived an ineffective implementation as a high risk to patient safety.

Risk Mitigation Activities. The project team decided to implement three rules/alerts in the EHR for diabetic patients. This process was to involve several steps: creating a governance team, developing a governance plan for CDS, building out the rules/alerts, building out the capacity for custom reports to support each rule, training providers on workflow to support CDS, and monitoring and providing feedback to physicians. If carried out, these steps are critical to ensuring safe implementation of CDS.

Selected Measures. The site was expected to select metrics that would be used to indicate progress on adoption and implementation of the new CDS alerts. However, the selected metrics were actually process measures for diabetes care, which may or may not be related to CDS. Two of these are part of the MU measure set that EHR developers are required to support as part of MU certification. The medical group communicated during the site visit that they chose to report quality measures for diabetes that were based on foot exams and lab tests because that documentation was easier to access than some other diabetes-relevant indicators, such as documentation of retinal exams. Performance on these measures was reported for three providers to the project facilitator with some regularity.

Results. The medical group drafted a governance plan but was otherwise unable to adopt any new risk mitigation practices during the project period. At the time of the RAND site visit, the implementation of the CDS alerts had been stalled by technical challenges.

Barriers and Facilitators

Site visit interviews suggested that leadership and staff at the medical group began the project without a well-formed framework for thinking about the impact of health IT on patient safety, and instead developed a clinical care improvement project that involved health IT. We also observed limited convergence of motivation to participate among the medical group's staff, which presented a major barrier to successful process improvement. The executive director viewed this project as an opportunity for the project leader to develop additional EHR management skills. Others viewed it as a project designed to improve patient outcomes or improve practice efficiency. None of the leadership or project team members interviewed perceived the focus of the project to be managing risks associated with health IT.

Another barrier was that the project was not perceived as a high priority or in alignment with existing priorities. Health IT is generally not a high priority for the medical group, and because interviewees did not have consistent perceptions of the project's purpose, they did not perceive it as aligned with any other projects that the medical group was undertaking. Furthermore, with only one staff member assigned to health IT (among other responsibilities), few internal resources were allocated to the project, and progress was slow.

Finally, in selecting a health IT safety risk topic area, the group appeared not to have identified its most pressing health IT safety problems. The topic area selected as the top priority at the outset of the project was not a high priority at the end of the project. Instead, interviewees identified several new health IT safety issues, including problems with identity management and chart duplication. The group was experiencing ongoing problems with clinical information integrity, as support staff were duplicating charts and not adhering to workflows.

Utility of Resources and Process Improvement Strategy

The medical group had no prior experience with measuring or reporting adverse events or near misses. They found the reporting process using the AHRQ Common Formats burdensome and poorly matched to their local needs. The site project lead perceived the AHRQ Common Formats to be designed for hospitals and not useful for ambulatory practices; redundant around issues that interviewees perceived to have been addressed already, to the extent possible; and not resulting in actionable recommendations for the practice to implement.

Case Study 5: Ambulatory Practice

Background and Context

This case study involved a small pediatric specialist practice located in a highly competitive market. The practice priorities are set by its owner, who is the sole physician and decisionmaker. The ambulatory practice's business strategy focuses on raising its profile through high levels of patient satisfaction achieved by increasing care quality and conducting patient education and outreach activities. For example, as an educational outreach, the practice has distributed digital recordings about common pediatric complaints. The practice leader is known in the field as a frequent presenter at national professional meetings and organizes workflow training for local hospital staff.

Health IT

This practice installed the first version of its EHR system about five years before this project. The practice leader had implemented several patient and referral tracking systems that predated EHR implementation and might be considered an EHR "super user." After testing about half a dozen different EHR systems, he decided to install an EHR system that was developed and customized by a friend, who often relies on the practice leader for suggesting and beta testing new features.

When the EHR system was initially installed, it had to be customized significantly for pediatric and specialty use. The process of selecting modules for implementation and customizing was intensive: Several fields and features that are required for pediatric practices, such as immunizations and well-care visits, were hidden to facilitate the use of the system for specialty care. Some features, like e-prescribing modules, were not implemented because of cost and/or insufficient need (e.g., the practice has a relatively low volume of prescriptions). Additional customizations were implemented to facilitate the creation of visit reports and other records.

This practice does not have dedicated IT personnel or contractors; most of the IT support and technical issues, including hosting and maintenance of servers, are handled by the practice leader, who also plays the IT support role for staff. Even in this small practice, levels of computer proficiency varied among staff, and there was some degree of resistance to the initial move to an EHR system.

Health IT Safety and Risk Mitigation

During the interview, the practice leader referenced several health IT safety issues, such as rare events of system downtime, entry of data into the wrong patient chart, and concerns about

the completeness of data imported from paper charts into the EHR. When queried more generally about health IT safety, the practice's leader expressed frustration with inadequate interoperability between EHRs and with the lack of a single sign-in across different hospitals' EHR systems. He viewed this lack of standardization as a significant barrier to timely access to information.

Project Implementation

Project Leader. The practice leader led the project. All practice staff—nurses and administrative staff—were either directly or indirectly involved in the project.

Selected Topic Area and Safety Practices. Using the diagnostic assessment, and with support from an ECRI facilitator, the project team selected test result reporting and follow-up as the topic area for this project. The project team did not select specific practices from the draft Test Result Reporting and Follow-Up SAFER Guide, deciding instead to focus on reducing the time it takes the practice leader to finalize prepopulated consultation reports before sending them to referring practices. Prompt submission of the consultation letters to the referring physicians may improve timeliness of implementation of the recommended care plan.

The consultation reports are created by the practice leader or the nursing staff. While the initial versions of these reports contain information automatically imported from the EHR and therefore are typically created during or soon after patient encounters, they are finalized manually, outside of the visit. Reports created by nurses are reviewed and approved by the practice leader before submission to the referring physicians. The finalized consultation reports are then transmitted by fax. Patient-centered medical home (PCMH) certification by the National Committee for Quality Assurance (NCQA) requires a turnaround time of 30 days or less, which the practice was not achieving before the project.

The project team identified the practice leader's insistence on a meticulous review process as the cause of the delays in submitting consultation reports (not a health IT issue per se). The practice leader required that the content of all consultation reports must be unambiguous, grammatically correct, and stylistically professional. Nurses indicated that they did not feel capable of meeting these standards every time. Ensuring document quality has delayed report submission to the referring physician.

Risk Mitigation Activities. The project team selected several activities to increase the time available for finalizing consultation: (1) delaying the start time of the practice leader's first appointment to 9:20 a.m., (2) using the EHR's time-in-motion studies to monitor the length of each appointment and identify opportunities to keep visits on schedule so that staff has sufficient time at the end of each day to work on consultation reports, (3) disseminating educational materials that patients can view after the appointment to shorten time allocated to patient

education during appointments, (4) investigating the value of hiring a scribe service, and (5) asking nurses to peer-review letters prior to sending to the practice leader for review and finalization.

The practice leader has also created a standardized, electronic consulting form with a "phrase library." The library contains fragments that correspond to such commonly used expressions as "patient complained of nausea" and "tests were negative" that can be quickly selected to reduce typing effort. He believed that this feature might expedite and standardize the process of completing consultation reports for non-complex patients, regardless of whether a patient was seen by the physician or a nurse. Changing this technology or how it is used was not selected as a target for the project.

Selected Measures. Two metrics were used to track and report intervention success: (1) the percentage of incomplete consultation reports, calculated by dividing the total number of incomplete consultation reports by the total number of visits in a month, and (2) the percentage of unprinted consultation reports, calculated by dividing the total number of unprinted consultation reports by the total number of visits in a month.

Results. At the start of the implementation period, 45 percent of consultation reports in the past three months had been completed and sent to the referring provider within the 30-day time frame. One month into engaging in risk mitigation activities, 54 percent of that month's reports were finalized and sent within the 30-day time frame. The next month, 56 percent of reports were finalized and sent. In the last two months, despite an increase in visits and staff vacations, 56 percent of reports were finalized and sent.

Barriers and Facilitators

The decision to implement a standardized electronic consulting form as a risk mitigation activity may have been a barrier to improving health IT safety in this practice. The interviews revealed other significant health IT–related safety issues (e.g., downtime, patient identification issues). Given that the consulting physician in this practice communicates clinically significant findings immediately by phone, the selected intervention had relatively little impact on improved patient safety. The goal of improving documentation of routine consultations using EHR functionality was largely driven by interest in achieving PCMH certification.

The most formidable barrier was the low comfort level of staff with the application as designed. The practice leader indicated that he would allocate less time to reviewing letters if the nurses were to use the standardized electronic documentation formats in the phrase library he created, especially for simple follow-up visits, but the nurses seemed to be more comfortable using free text fields. As a result, consultation reports undergo careful editing before they are

sent to the practice leader for finalization, and the practice leader allocates significant time to review.

The major facilitator of this project was the practice leader's high level of commitment to using the EHR system. By offering EHR training and troubleshooting services to his staff, the practice leader demonstrated his commitment to increasing the comfort level of his staff with the EHR, as well as improving his own ability to efficiently finalize consultation reports.

Utility of Resources and Process Improvement Strategy

Interviewees remembered the tools well and described their utility, triangulating the consultation report turnaround as an issue that fits into the test results and the clinician communication areas of risk identified in the material from the draft SAFER Guides.

This practice did not have prior experience with measuring or reporting adverse events or near misses and does not participate in any PSO reporting programs. For this project, a senior administrator and a nurse conducted event reporting using the AHRQ Common Formats. They believed that the tool was easy to use and, unlike other interviewees, did not indicate that it was inappropriate for ambulatory settings.

Case Study 6: Ambulatory Practice

Background and Context

This case study involved an ambulatory medical group that is part of a large health system that includes two hospitals and several dozen physicians practicing in ambulatory primary care and specialist practices. The health system's culture of safety is embedded in the medical group, which has a "catch of the month" award, offers a mechanism for anonymous reporting of safety issues, and assigns staff ancillary roles related to safety awareness.

Health IT

The health system to which the medical group belongs has acquired many independently operating ambulatory practices over time, resulting in several variations in EHR developers. When the health system recently selected an EHR developer for its hospitals, ambulatory sites moved to the same EHR. The health system has used a systematic prioritization process for new features and issues related to the EHR. Of note, site visit interviews (which included interviews with employees of the health system, in addition to the medical group) revealed some discordance of opinion between health system staff and medical group staff about the results of this process. Medical group staff expressed the concern that easy-to-fix IT issues receive higher priority, while more important—but more difficult to solve—issues are given lower priority.

Health IT Safety and Risk Mitigation

The ambulatory practices had no specific safeguards for mitigating health IT safety risks. In site visit interviews, clinicians expressed concern that inadequate training was introducing safety risks as newly acquired clinic sites adopted or switched to the new EHR.

Project Implementation

Project Leader. The project leader for this medical group was the director of the health system to which with the medical group belongs. Other project team members included the medical group's director of office operations and a practice manager.

Selected Topic Area and Safety Practices. Using the diagnostic assessment, and with support from an ECRI facilitator, the project team selected test result reporting and follow-up as its topic area for the project. The project team did not select specific practices from the draft Test Result Reporting and Follow-up SAFER Guide, but focused on the risk of delayed clinician access to results as the medical group transitioned to a different EHR system. In the new system, test

results are sent through the EHR—along with other messages—to a clinician's "in-basket." In interviews, leadership and staff both pointed to a grievance[h] that had been submitted to the patient advocacy department shortly before the project: A clinician had failed to contact his patient regarding a serious test result before it was automatically released to the patient's view of the health record (seven days after it was released to the clinician). This grievance contributed to the project team's selection of risk mitigation activities.

Risk Mitigation Activities. The medical group decided to monitor the timeliness of clinicians' review of in-basket messages. The group planned to create an in-basket message report, select a random day each month on which to run the report, identify any clinicians with more than three unread in-basket messages received more than three days before, and notify the management staff of the individual clinicians and clinical areas with high rates of unread in-basket messages.

Selected Measures. The medical group created an in-basket message report with the following metric: the percentage of all providers who have more than three unread in-basket messages that were received more than three days before (the audit date).

Results. The project leader and team ran the in-basket message report monthly for a three-month period, reviewing the results and identifying providers who had high rates of unread messages. In the first month, 24.7 percent of providers had more than three unread in-basket messages. In the second and third months, the results were 29.7 percent and 33 percent, respectively. Of the providers with more than three unread messages for all three months, about half were from the psychiatry department, and about a quarter were family practice physicians.

Barriers and Facilitators

A primary barrier to the medical group's health IT–related project was the higher priority assigned to acquiring new ambulatory sites and expanding use of the EHR relative to changes to current health IT processes. The health system's acquisition strategy and EHR growth has resulted in high demand for training of new clinical staff to use the EHR. Ambulatory practice managers and clinicians pointed in particular to the limited time available to train clinicians at newly acquired sites and specialists in the use of the EHR. While some training was provided during the switch to the new developer for sites that were already part of the health system, newly acquired clinics did not have sufficient training.

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[h] Grievances are complaints that patients or their representatives make to hospitals about the patients' care. All hospitals that participate in Medicare/Medicaid must have processes for resolving grievances promptly.

A major facilitator was the health system leadership's commitment to the project and to safety generally. Leadership facilitated involvement in the project. A related facilitator was a "culture of safety" that has been promoted by leadership for years, including assigning staff risk management roles and provisioning awards for identification of safety risks. Clinical and administrative staff were highly engaged and motivated to improve information systems and workflow.

Utility of Resources and Process Improvement Strategy

The medical group project team found ECRI tools and technical assistance to be of high value but found the AHRQ Common Formats reporting too burdensome to implement within the medical group. Interviews with the leadership suggested that the selection of the health IT safety project was not guided by the diagnostic assessment and list of SAFER Guide best practices, but by a grievance submitted previously to the patient advocacy department. For this group, tools that could be used as part of clinical staff training might have overcome the significant challenge of bandwidth available to focus on health IT safety in the context of a rapid expansion of EHR across ambulatory practices.

5. Lessons from the Pilot Project

Health care organizations in the United States are on an unprecedented pace to introduce and expand the use of new health IT systems in response to federal payment incentives. Strong evidence shows that health IT systems reduce some types of risks to patient safety. On the other hand, health IT also has the potential to introduce new types of patient safety risks, especially if poorly designed, implemented, or used. Given the effort to install and operate these health IT systems and their relative novelty, identifying and managing these new risks may be an afterthought for many organizations. The protocols for detecting and mitigating such risks are not yet well defined.

In this pilot, a PSO-based team developed and tested a standardized approach designed to help hospitals and ambulatory practices identify, prioritize, select, and mitigate safety risks attributable to health IT. The participating organizations agreed to design and implement a health IT–related risk improvement project during a nine-month time frame. This chapter summarizes the lessons learned by the participants, with special emphasis on the six case studies involving hospitals and ambulatory practices.

Two overarching observations about this pilot are notable:

1. The majority of the participating sites focused in one way or another on improving the reliability of information transfers using the EHR. The targeted health IT–related practices involved distinct types of information (lab results, orders, tasks, patient status), but the effective transfer and retrieval of this information was at the root of the project team initiatives. This focus on achieving timely and accurate information transfer may indicate that technical assistance and support focused on information transfers during transitions (or "handoffs") may be particularly germane to organizations. Tools that focus on assisting organizations with improving data interfaces, test result review and follow-up, or order entry may be in high demand.
2. Participating organizations found it difficult to identify and modify health IT safety risks within the nine-month project period. Even though several organizations narrowed the focus of their projects, they encountered significant barriers at every stage of process improvement. The health IT safety risks identified by hospitals and ambulatory practices required complex changes involving clinical staff, workflow, and processes related to health IT. This complexity and the short time frame for accomplishing measurable progress may have contributed to difficulty achieving endpoints.

The lessons below are necessarily preliminary and subject to several limitations. This project involved a fairly rapid recruitment phase. The hospitals and ambulatory practices that were

approached and volunteered to participate agreed to initiate and complete projects in a relatively short time frame and without funding for additional personnel. This may have limited the options that they were able to consider, given other organizational priorities that may have been set for the year and the need to respond to the demands of MU. While we are confident that many health care providers and organizations will see some of their own experiences in these case studies and that this may validate the observations of this report, several additional lessons might emerge from a larger project involving more hospitals and ambulatory practices.

1. "Readiness" to Conduct Health IT–Related Risk Identification and Mitigation Projects

Health care organizations may have limited capacity to join an externally initiated health IT risk management initiative and to sustain participation over time. Only a third of the hospitals and ambulatory practices invited to participate in the study agreed to volunteer. Among organizations that were contacted but decided not to join, "[poor] alignment with current and planned projects" was a commonly cited reason for declining to participate. Attrition occurred among the 14 selected for participation: Three dropped out after selecting topic areas from the draft SAFER Guides. Eleven sites sustained participation through the first few months of the project period, but three of those 11 became less engaged as the nine-month project period unfolded. Among the 11 organizations that participated actively, most were unable to complete risk mitigation projects that they designed and attempted to implement, citing competing priorities and the lack of time to devote to such initiatives. This outcome suggests that even organizations with good intentions may be unable to achieve the goal of implementing a health IT safety project within a short time frame—even with technical assistance from an outside organization.

Organizations with the highest level of readiness to engage in detecting and mitigating health IT risks have in-house expertise and prior experience in conducting organizational quality improvement and risk management projects. In those sites that achieved their project objectives, we observed a preexisting and relatively sophisticated patient safety improvement infrastructure that included an adverse event reporting system and routine monitoring and analysis of patient safety–related events. For example, one hospital that achieved its project goals already had a robust internal adverse event and near-miss reporting process. Before the project started, risk management staff had been reviewing the adverse event database weekly. The project succeeded in large part because implementation was consistent with the hospital's standard operating procedures. Also, in the more successful projects, individuals with prior experience led the implementation team, and staffing was adequate for need. In contrast, the smaller ambulatory practices typically had a very limited quality improvement infrastructure in place. Project leaders in those practices found it difficult to achieve project milestones because

they were often serving several different and unrelated roles (for example, in one medium-size medical group, the quality improvement staff member also had responsibility for billing and administration of the dialysis clinic). The medical group did not have protocols for reporting or tracking adverse events or near misses or an established quality improvement strategy.

Beyond expertise and infrastructure for quality improvement, staff at several sites emphasized the need for a "culture of safety" within the organization. A culture of safety (or "just culture") implies that an organization treats error as an opportunity for improvement rather than cause for individual blame. Indicators of a culture of safety include a system for encouraging and rewarding staff for identifying risks and reporting adverse events and a non-punitive approach to addressing medical error.[22] Participants from half of the hospital and ambulatory practices that participated in site visits described their organization as having a culture of safety that predated this project and suggested that this culture contributed to their organizations' engagement with the project.

2. Alignment of Health IT Safety Projects with Other Quality, Safety, and Information Technology Initiatives

"Known problems" were more likely to be selected as targets of intervention than were problems identified through use of responses to a diagnostic assessment. While each hospital and ambulatory site completed a standardized diagnostic assessment designed to assist the staff at hospitals and ambulatory practices as they sought to identify potential targets for risk mitigation, most sites selected intervention targets on the basis of known problems with safety, quality, MU criteria, or a combination of these items. One hospital selected its target based on having recently experienced a serious safety event related to health IT, and this event drove their selection of risk mitigation activities. Two other sites focused on recently identified quality-of-service issues, which were loosely related to patient safety, in spite of the project emphasis on health IT–related safety risks. The remaining sites selected targets for intervention that were related to MU criteria or reportable quality measures. Only one of the participants identified system downtime as a priority for risk mitigation. In the future, a diagnostic assessment might specify a menu of common problems in health IT safety from which organizations could select topics for improvement.

Projects aiming to reduce safety risks of health IT are more likely to succeed if they are aligned with the organization's priorities and current initiatives. Most of the sites faced the task of identifying health IT–related risks in the context of competing institutional priorities. Competing (or synergizing) priorities included business growth, meeting MU criteria, and addressing recent adverse event near misses or quality of service issues. This focus on existing institutional priorities may have come at the expense of addressing more critical safety issues

that had not yet come to the attention of the organization's leadership. A lack of identification of more critical issues may have been a missed opportunity—particularly in ambulatory practices, where health IT safety risks are not as easily observable. For example, an ambulatory practice decided to focus on expediting the submission of consultation reports to the referring physicians, even though the cause of these delays was not related to health IT per se and these delays did not pose a significant patient safety risk (because the information was also provided by telephone). In contrast, a hospital that was able to align the risk mitigation project with its EHR implementation was able to achieve many of its project milestones.

Initiatives that aim to reduce the safety risks of health IT are more likely to succeed if they are aligned with current federal policy directives. Federal MU policy was an important driver for organizations in selecting and prioritizing initiatives. Organizations tended to view health IT safety through the lens of their efforts to meet MU standards. To the extent possible, organizations sought to align health IT safety risk mitigation metrics with those needed to achieve MU standards. For example, one hospital selected rates of verbal orders as the metric of implementation progress, in part because it was automatically generated by the EHR developer's data warehousing system in response to MU (measuring and reducing verbal orders is an MU certification and attestation criterion).

3. Importance of Organizational Leadership

Organizations whose project teams had close involvement of executive leadership were more likely to make progress in identifying and mitigating safety risks. In any organization, executive leadership sets priorities, allocates resources, directs the attention of staff to specific issues, creates accountability structures, and manages competing external demands. The ownership, governance, and management of health care organizations are highly diverse. Disconnects and miscommunication between hospital or ambulatory managers and front line clinicians seemed to impede several steps in the identification, selection, and conduct of projects. In these environments, the attentiveness and responsiveness of organizational leadership to concerns of front line clinicians played a critical role in several of the projects.

Leaders enabled the projects in several ways. First, by their nature, health IT risk mitigation projects require coordination across distinct departments or functional units, including IT, quality improvement, regulatory compliance, and risk management. Each of these departments or functional units has its own priorities, and risk mitigation projects often require new collaborations between IT staff and quality or safety managers. Coordination of midlevel managers or leaders is critical for health IT safety initiatives to make progress. In two of the cases we observed, this was the first time that IT staff had collaborated with safety managers.

This lack of prior experience in coordination across IT and quality improvement, regulatory and risk management departments is a recurring theme in projects that were less successful.

Second, leaders enable projects by setting direction. Inevitably, a new initiative aimed at reducing health IT safety risks will have to compete with the priorities and ongoing initiatives of several departments within an organization. To enable these distinct departments to reset or modify priorities and to work together successfully, executives or leaders at higher levels of the organization have to engage in setting direction. To the extent that executive leadership was engaged in the projects we observed, project staff were better able to achieve project objectives. Where hospital leaders were committed to the project—and to safety generally—clinical and administrative staff were highly engaged and motivated.

4. Challenges in Identifying Health IT Safety Risks

Organizations tended to view health IT as a solution to patient safety problems, while overlooking the potential of health IT to contribute to safety problems or to create new types of safety risks. Organizations installing, expanding, or upgrading EHRs are focused on ensuring that systems are operational and support necessary functions, and that staff have sufficient training to use EHRs meaningfully. While these concerns clearly have implications for patient safety, the new safety risks associated with the implementation and use of health IT, especially EHRs, were not perceived in general as requiring focused effort. In part, this seemed to be due to a perception that health IT was infrequently seen as a cause of patient safety problems. In part, this may be due to the lack of a policy framework or reporting systems that would reveal health IT as a contributing factor in patient safety events. This perception was even more pervasive in small ambulatory practices, where patient safety risks are less obvious in general.

Ambulatory practices face greater challenges than hospitals in identifying and addressing health IT safety risks. Resource constraints in ambulatory practices, particularly smaller practices, limited the ability of leadership to prioritize (or in some cases even recognize) health IT safety problems. Resource allocation for safety and risk management in hospitals is substantially greater than in ambulatory clinics because of the size of the institutions and the fact that workflow in hospitals is significantly more complex. None of the ambulatory practices we visited had full-time risk management staff; only the largest of the three ambulatory practices planned to recruit a director of risk management in coordination with the larger health system.

5. Challenge of Matching Project Scope and Resources to the Demands of a Health IT Safety Project

Perhaps the most important determinant of project success was the availability of resources to commit to the health IT safety project. The most frequently cited barrier to and facilitator of successful implementation of projects was the timely and adequate allocation of staff effort and other resources to the project. Successful conduct of a risk mitigation project frequently required a substantial effort by project leaders, many of whom took on this effort in addition to a full-time job as clinician or practice manager. Risk management, quality and safety officers, and IT staff had to redirect attention and resources from current operations and health IT projects with looming deadlines (such as accomplishing meaningful use certification or planning for the ICD-10-CM transition) to pursue these risk mitigation projects. Projects that required a significant amount of attention from health IT staff were more likely to be delayed because of capacity constraints. Monitoring of progress toward goals was a key component of each health IT safety project, so availability of staff to generate regular reports tended to be an important bottleneck in both the hospital and ambulatory practice projects.

Mismatch between the selected scope of the project and the available staffing sometimes led to poor project design (even when substantial expertise was available within the organization). Because health IT risks are sociotechnical in nature, they tend to be associated with teams of individuals and highly complex workflows interacting with complex technologies. Furthermore, organizations may struggle with determining the best approach for engaging front line clinicians who both possess the knowledge of workflow challenges and may have to make changes to workflow in order for a safety risk mitigation project to succeed.

To illustrate, the project team at one hospital identified a problematic workflow related to coexisting independent and incompatible information systems. In targeting this problem for risk mitigation, the team decided to introduce a custom interface to the EHR to facilitate handoffs between residents (trainees) at shift changes. Although the project team provided educational support to the residents, they rejected the new tool because it added another layer of complexity to an already bifurcated electronic documentation system (an EHR for physicians and a separate health IT documentation system for nurses) and because it could not be integrated well into the existing workflow (which also included whiteboard and paper processes). Modifying existing workflows, even when they are suboptimal, is often difficult, as this case study illustrated. More closely involving the front line clinicians in the selection and design of the health IT risk mitigation project might have been difficult for several reasons, but doing so could have identified the barriers to the project earlier and prompted either a revisiting of the target area or an improved design before the team invested effort in an ultimately unsuccessful project.

6. Practical Tools to Identify and Address Health IT Safety Risks

Health care organizations, and in particular small ambulatory practices, need tools to help them identify and address safety risks attributable to health IT. The challenges noted by each of the lessons above suggest the need for practical, easy-to-use tools that can help organizations identify health IT–related risks and set priorities for addressing them. Additional tools are needed by project teams to support the projects. A diagnostic assessment tool designed by our team, the SAFER Guides developed and refined by others during this project, and metrics developed by participating organizations might serve as models for this type of tool development.

The diagnostic assessment tool designed to assist participating hospitals and ambulatory practices in identifying safety risk topics did not live up to expectations. None of the project teams mentioned the assessment at the time of the interviews, and when it was mentioned to them, few interviewees reported that it had influenced their planning in a significant way. Several problems may have contributed to this. First, the diagnostic assessment starts with having a respondent choose a priority area and then identifies specific practices within a risk area. While this seemed intuitively appealing, sometimes the result was to narrow the organization's focus prematurely. Had project teams seen the full menu of draft SAFER Guide topics and practices, they might have recognized more salient project targets at the outset. Some sites chose projects that were more closely related to quality or service improvement than safety per se. For example, during two of the site visits, project staff indicated that two health IT–related risk areas—patient identification and managing duplicate charts—were issues in their institutions, but those areas of focus were not identified using the diagnostic assessment.

The SAFER Guides were not a focus of this evaluation because they were still under development when the project teams began their work. Nevertheless, material included in the SAFER Guides proved useful to some organizations in the context of this project. Participants reported that browsing the specific practices in the SAFER Guides and other materials raised awareness of health IT safety risks. Further development and testing of the role of the SAFER Guides in future projects may offer lessons about the degree to which organizations may successfully carry out health IT safety projects on their own and what degree of technical assistance or consultation is necessary to support project teams working on different types of safety projects.

Metrics that can be used in health IT safety projects are another key tool. The evaluation found that metrics that were easy to generate were more likely to be used than metrics that might be more useful but more difficult to collect and report. Ease of measurement was a driver not only for selection of the metrics but also for selection of the risk mitigation target for the project. The salience of metrics associated with MU was aligned with the tendency of participants to

prioritize MU-related initiatives. Additional health IT safety metrics for tracking and reporting might be of value to identify and monitor sources of risk that can be feasibly captured in EHR data.

Many participants found the AHRQ Common Formats reporting forms difficult to integrate into workflows, particularly in ambulatory settings. Representatives of most of the hospitals and ambulatory practices that we visited reported that they found navigating the AHRQ Common Formats reporting forms for reporting patient safety events to be burdensome: The series of steps used to arrive at the reportable risk seemed unnecessarily complex to many. Staff had to manually complete the forms to submit them to the PSO, drawing data from their adverse event reporting systems or EHRs, in part because the categories are inconsistent with the categories used in their own event reporting systems. None of the sites were able to populate the AHRQ Common Formats electronically—although one hospital project director noted that the developer for their web-based adverse event reporting system did offer an AHRQ Common Formats–compatible interface. A decision about whether to upgrade to that compatible interface will depend on the availability of resources and whether other institutions moved in that direction. The site that had the most ease with the AHRQ Common Formats devoted some effort to harmonizing the categories in their existing adverse event reporting system with the AHRQ Common Formats so that reporting did not require duplicative data entry. Two of the three ambulatory practices noted that the forms were designed for use by hospitals and were not well suited to issues that surfaced as part of routine ambulatory care. Most sites did report at least one event, and two sites reported the majority of total events reported (see the appendix). Most events were associated with the EHR, specifically CPOE and CDS.

6. Discussion

It is a well-known systems engineering paradox that technical solutions designed to address safety problems frequently introduce new types of safety problems. The EHR that alerts physicians to trivially abnormal lab results may breed complacency and therefore cause them to miss serious abnormal lab results. As hospitals and ambulatory practices have been moving forward aggressively to implement health IT, this core paradox has not been prominently featured in their implementation plans. The introduction of health IT may be planting the seeds of a new set of patient safety risks, but awareness of these risks has been limited. This suggests the need for a deliberate strategy that can bring health IT–related safety risks to the attention of health care leaders and front line clinicians and the development of policy, tools, and metrics that can help them address these new risks. The goal is to reap the safety benefits of health IT while minimizing the new risks that health IT can introduce.

The challenges and lessons identified in this pilot project point to several opportunities to increase the safe use of health IT systems. We draw several conclusions about the current state of health IT safety risks:

1. With few exceptions, awareness of the safety risks introduced by health IT is limited. Many organizations sense that health IT is difficult to implement successfully, and some have experienced significant patient safety events, but organizations vary in their appreciation of the connection between those difficulties and events and their health IT installation. At the current time, engagement of front line clinicians in detecting and mitigating health IT–related safety risks appears to be limited.
2. The traditional departmental "silos" between risk management, IT, and quality and safety management may impede the ability of organizations to recognize and respond to health IT safety risks. This is especially the case in hospitals. For some hospitals, this project represented the first time that staff from these different departments had worked in collaboration with one another.
3. External facilitation appears to be important to hospitals and practices, but the model for providing consultation and technical assistance requires further elaboration. This model has to account for wide variation in the capabilities of most hospitals and ambulatory practices to take on health IT risk mitigation projects.
4. Most ambulatory practices lack the risk management, IT, and quality and safety expertise that is available in hospitals. Ambulatory practices have limited staff capacity to address health IT safety, given the more pressing challenges of maintaining a financially viable ambulatory practice in a rapidly changing health care market.

5. There is an urgent need for tools and metrics to enable project teams in hospitals and ambulatory practices to detect, mitigate, and monitor health IT safety risks. Tools available to project teams during this project were not adequate to fully support the needs of the organizations participating in this pilot project.

6. The current structure of the EHR marketplace, and the low awareness of the risks introduced by health IT systems, lead to weak incentives for EHR developers and providers to invest in the type of joint effort required to reduce health IT safety risks. Because of that market failure, certification and standards will continue to be an important mechanism for ensuring that EHR products are designed to minimize the introduction of new safety risks.

Given these challenges, there are several opportunities to advance the field and reduce the health IT–specific risks to patients.

Awareness

To raise awareness of the health IT safety issue, two steps are necessary and closely related: to integrate and align the health IT safety agenda with the broader patient safety agenda and to engage front line clinicians in identifying and mitigating risk. Since the IOM's landmark report *To Err Is Human*, hospitals and other health care organizations have been on a journey to prioritize patient safety—focusing on the development of a culture of patient safety within their organizations, on identifying and reporting adverse events and near misses, on identifying the root causes of patient safety events, and on taking a preventive approach to mitigating risks. Similarly, a campaign built on the model established by the patient safety movement could very effectively alert front line clinicians to health IT as an important component of patient safety. Integrating the messages of this campaign with current patient safety programs and initiatives would leverage the existing awareness of patient safety and engagement among front line clinicians. This alignment might also reduce the risk that health IT safety is lost in the competition among initiatives and departments for scarce resources.

Fostering Collaboration Among Departments and Disciplines

Health IT safety is a cross-cutting area that creates an opportunity for risk management staff, safety staff, and IT staff to collaborate. Each disciplinary perspective contributes distinct knowledge to the detection, analysis, and mitigation of health IT safety risks. Improvement projects will benefit from interdisciplinary collaboration and coordination because front line clinicians are less likely to engage in several related initiatives that are poorly coordinated, whereas a single well-designed initiative may leverage their effort more effectively.

Several enablers of collaboration could support future initiatives:

Best Practice Examples and Project Templates. Health IT safety risks are common across organizations even though the local implementation of risk mitigation strategies may require customization. Best practices (case study examples of organizations that have successfully tackled a particular problem, such as ensuring review of abnormal lab test results) and project templates (step-by-step project guides for specific problems or checklists) can accelerate implementation of risk mitigation projects by helping team members implement strategies that draw on their unique expertise without having to "reinvent the wheel."

Training Selected Staff to Promote Cross-Disciplinary Collaboration. Providing staff from distinct disciplines with training in core terminology and methods related to safe use of health IT can encourage more effective dialogue in the project-specific context. These training programs might vary from brief introductory modules (e.g., IT safety basics for quality and safety managers) to short-term fellowship programs that deliver an advanced curriculum and certify an individual clinician or manager as having cross-disciplinary expertise in the analysis, planning, and conduct of health IT safety projects. Such individuals could become project leaders in hospitals or ambulatory practices.

Developing a Network of Experts Who Can Provide Consultation and Facilitate Health IT Safety Training. Efforts to develop a cadre of experts who can provide consultation through regional extension centers (RECs), PSOs, or other organizations and can facilitate training programs would have several benefits. Such experts could raise awareness nationally. They could also provide a bridge between the EHR developer community and the hospital and ambulatory practice leaders, managers, and practicing clinicians, assisting collaborative efforts across the traditional silos.

Strengthening External Facilitation and Consultation

Often, hospitals and ambulatory practices lack the size and scale to support in-house expertise sufficient to carry out effective detection and mitigation of health IT safety. There will undoubtedly be a need for external facilitation and consultation, especially among rural hospitals and small ambulatory practices.

Regional Extension Centers (RECs) and Patient Safety Organizations (PSOs). Several organizations may be well situated to provide triage and referral services between hospitals and ambulatory practices and experts or other practice leaders who are capable of analyzing workflow and adapting solutions to the circumstances of a facility or ambulatory practice. RECs and PSOs seem especially suited to this role. The emerging profession of "quality facilitator," which helps small practices with limited resources adopt better measurement and quality improvement strategies, may be of value for health IT safety as well.[23]

Reporting. PSOs are obvious candidates to support reporting. As the appendix demonstrates, adverse event reporting is possible with the right data collection infrastructure. However, as the project interviews demonstrate, current reporting is often done manually. Developing safety event tracking software products that are integrated into EHRs could enhance reporting and better support analysis of events. Electronic standards are emerging. Just as billing software and EHR software have been converging onto shared (or interoperable) standards and translations, the same opportunity exists for adverse event reporting software products.

Training. Ensuring safe use of health IT will require that staff are trained on a mix of the retrospective methods used to analyze patient safety events (e.g., examining an adverse event or a patient grievance to identify contributing factors), as well as proactive approaches designed to prevent patients safety events that may be introduced by health IT (e.g., querying front line clinicians and training them to recognize that health IT can be a contributing factor to adverse events and errors). PSOs, RECs, or other organizations could facilitate this staff training.

Supporting Ambulatory Practices

Ambulatory practices, in particular, may need more outside help if they are to succeed in identifying and mitigating health IT–related risks. Developing a "facilitator" workforce may be an opportunity to improve safety in these types of practices. Generally, facilitators receive specialized training and certification and then serve multiple practices—providing access to the kinds of expertise and hands-on support that is typically only available to larger medical groups and hospitals. As noted above, the RECs and PSOs may provide the best setting for these individuals.

Developing and Refining Tools and Metrics

The findings from our pilot project suggest that more work is needed to develop effective and usable tools and reporting systems. The prototype diagnostic tool we applied in the pilot was less useful to participants than hoped. An effective diagnostic approach that can be used by hospitals and ambulatory practices to identify and prioritize topics for health IT safety projects could build on and modify the tool we developed. The draft SAFER Guides that informed the implementation of the risk mitigation projects in our pilot are promising and useful. Further study of the SAFER Guides should evaluate their utility in practice and help to continuously improve the safety of health IT. The pilot experience reflected in the appendix demonstrates that reporting of health IT–related adverse events to a PSO is feasible and their analysis informative, but most organizations found reporting using the AHRQ Common Formats to be onerous and cumbersome. Revising the AHRQ Common Formats and forms for reporting, especially for ambulatory practices, should be a high priority if adverse event reporting of health IT safety events is to be useful and guide further intervention.

Strengthening Incentives for EHR Developers to Optimize the Safety and Safe Use of EHRs

Health IT safety is a shared responsibility of EHR developers and their clients who use EHRs in a complex sociotechnical environment. MU of certified EHR technology has the potential both to improve patient safety, if implemented and used correctly, and to introduce new sources of patient safety hazards. The participants in this research project were motivated to qualify for MU incentives, but often did not appreciate the potential of EHR systems to introduce new safety risks. MU standards and EHR certification could provide incentives for developers to work with their clients to optimize the safety and safe use of their EHR products and services.

Surveillance associated with certification of EHRs could be used to identify and address EHR features that may be unsafe (such as poorly constructed CPOE with CDS). The government could also require specific design procedures. For example, a testing protocol, the Test Procedure for "safety-enhanced design," was added to the 2014 certification requirements.[24] While it is an important acknowledgement of the safety risks of health IT, the current Test Procedure does not include tests for the types of complex workflow and information transfer problems that our study participants most frequently cited as safety risks.

Some EHR developer interventions could help managers and clinicians to monitor deviations from intended, safe patterns of EHR use. For example, if developers built metrics that enabled monitoring of the use of their current EHR products along with reporting functionality, managers and clinicians could analyze these reports to identify risky patterns of health IT use before they can harm patients. Policymakers might evaluate the feasibility and value of measuring additional patterns of unsafe use with EHRs before serious events occur and might consider incorporating these metrics and reporting requirements into policy.

Conclusion

The investment that is converting the U.S. health data infrastructure into a 21st century enterprise has the potential to improve care for patients in countless ways. However, "digitizing" the health system also has the potential for harm. In this project, we worked with 11 hospitals and ambulatory practices to evaluate a process improvement strategy and tools developed to help health care organizations diagnose, monitor, and mitigate health IT–related safety risks. While many of the health care organizations (especially the hospitals) had expertise in process improvement, we found a general lack of awareness of health IT–related safety risks (especially in ambulatory practices) and concluded that better tools are needed to help these organizations use health IT to improve care and to optimize the safety and safe use of EHRs. The SAFER Guides provide an excellent beginning, but until health care organizations have a better understanding of the safety risks posed by EHR use, tools like the SAFER Guides may not be

used to their full potential. There may also be a need for additional tools and metrics (and further usability study of existing tools and metrics) to better support the needs of health care organizations. ONC could additionally support efforts in this area by strengthening incentives for EHR developers to make safer health IT products and to participate with providers in risk mitigation.

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Appendix: ECRI Institute PSO Adverse Event Analysis

Authors: ECRI Institute Implementation Team

ECRI Institute PSO conducted a review of health IT–associated events reported by the project sites. The events were submitted between April 2, 2013, and November 15, 2013. (Though the project's official end was in September, some sites continued to work on the project and engage in event reporting through November.) During that period, a total of 515 individual events were reported by a total of 10 facilities. One acute and one ambulatory site provided the majority of the events reported.

Sites were instructed to submit each event to ECRI Institute PSO using AHRQ Common Formats version 1.1 for the main reporting forms; AHRQ Common Formats version 1.2 for the Device or Medical/Surgical Supply, Including Health Information Technology (HIT), form; and ECRI enhanced forms for providing information about events that are not covered by the AHRQ Common Formats main reporting forms. This approach enabled ECRI Institute PSO patient safety analysts to review events entered by participating facilities and apply the AHRQ Common Formats health IT taxonomy if not provided by the participants.

Participants in the project were provided training and collateral materials related to understanding what constitutes a health IT event, as well as information on how to submit health IT events through the AHRQ Common Formats, including the Device or Medical/Surgical Supply, Including HIT, form. Submitted events were reviewed by analysts on an ongoing basis in order to provide timely feedback related to event completion and thoroughness. Despite ongoing educational efforts, only 33.3 percent (566 out of 1,698) of the required fields in the Device or Medical/Surgical Supply, Including HIT, form were completed by the participants. Due to this low rate, the incomplete fields were manually populated by analysts after review of the event report.

Event Types

When submitting events, sites were able to classify them into more than one type. Of the 515 events reported, 478 events had one event type selected, 34 events had two event types, and three events had three event types classified, for a total of 555 event types. Events categorized as related to a device or medical/surgical supply, including HIT, were the most frequently occurring type (68 percent, or 375 events). The remaining event types in the top five list were other (10 percent, or 55 events), medication or other substance (8 percent, or 46 events), laboratory test/radiology (7 percent, or 40 events), and health IT hazard (5 percent, or 25 events). (See Table A.1.)

Table A.1: Number of Events by Type

Event Type	Number of Events	Percentage
Device or medical/surgical supply, including HIT**	375	68%
Other event	55	10%
Medication or other substance	46	8%
Laboratory test/radiology*	40	7%
HIT hazard*	25	5%
Blood or blood products	5	1%
Security/safety*	4	1%
Emergency services*	3	1%
Perinatal	1	0%
Surgery or anesthesia	1	0%
* ECRI enhanced form. * AHRQ Common Formats version 1.2 form.		

A few of the sites indicated that the health IT event affected other processes by selecting a second or third event type in addition to device or medical/surgical supply, including HIT. These types were medication use, services related to blood or blood products, emergency services, laboratory test/radiology, perinatal, safety and security, surgery and anesthesia, and other. Alternatively, some sites did not select device/HIT as an event type, and 140 were categorized under another event type. Twenty-five of these events were categorized under the event type HIT hazard. An example of multiple selections: The results for a laboratory test were delayed because of an issue related to the interface between the laboratory information system and the EHR; this caused a delay in ordering the correct medication dose for a patient. The event types selected for this example included device/HIT, laboratory test/radiology, and medication use.

AHRQ Common Formats Device or Medical/Surgical Supply, Including HIT, Form

For the AHRQ Common Formats version 1.2, Device or Medical/Surgical Supply, Including HIT, form, the reporter is asked to answer the following questions about the health IT system involved in the event:

- Which of the following best characterizes the type of HIT device related to the event or unsafe condition (e.g., administrative/billing system, electronic health record [EHR], laboratory information system, and picture archiving and communications system)?

- Which type or component of the EHR (e.g., order entry, pharmacy, clinical decision support)?/Which component of the administrative/billing system?
- Which of the following describes the circumstances involving the HIT device in the event or unsafe condition (e.g., system incompatibility, network failure, hardware failure)?
- Which problem(s) resulted from the equipment/device function problem (e.g., lost or delayed data, incorrect alert, incorrect test results)?
- Which ergonomics or human/device interface issue(s) (e.g., difficulty with the information display, alarm fatigue, wrong data entry selection)?

Health IT Devices Involved in Events

As part of the analysis, the types of health IT devices identified in events were examined (see Table A.2). The majority of events (58 percent, or 299 events) were associated with EHR systems. Second most common were events related to administrative/billing or practice management systems (12 percent, or 64 events), followed by laboratory information systems (LIS) including microbiology and pathology systems (8 percent, or 42 events). Ten percent of the events were not classified for the following reasons: unable to determine if it was a health IT–related event (7 percent, or 36 events) and unable to classify the type of health IT event (3 percent, or 18 events), due to insufficient information provided in the event report.

Table A.2: Number of Events by Health IT Device

HIT Device	Number of Events	Percentage
EHR	299	58%
Administrative/billing or practice management system	64	12%
Laboratory information system (LIS)	42	8%
Other	19	4%
Radiology/diagnostic imaging system (picture archiving and communication system)	15	3%
Human interface device	14	3%
Automated dispensing system	8	2%
Unable to determine if HIT event	36	7%
Unable to classify type of HIT event	18	3%

Further analysis provided additional breakdowns of the events associated with EHR systems and administrative/billing or practice management systems.

EHR system events: Of the 299 events associated with EHR, 46 percent (138 events) involved CPOE systems. About 30 percent or 90 events involving EHR systems were associated with clinical documentation systems, such as progress notes or test results. The remaining 71 events were associated with other devices/systems (8 percent), pharmacy systems (7 percent), electronic medication administration records (4 percent), unknown (3 percent), and clinical decision support systems (1 percent). (See Figure A.1.) An example of a CPOE-related event that was submitted during this project was when a physician entered a nursing communication note regarding a change in medication frequency instead of changing the actual medication order. The nursing communication was not reviewed until after the medication was administered.

Figure A.1: Events Associated with EHR Systems
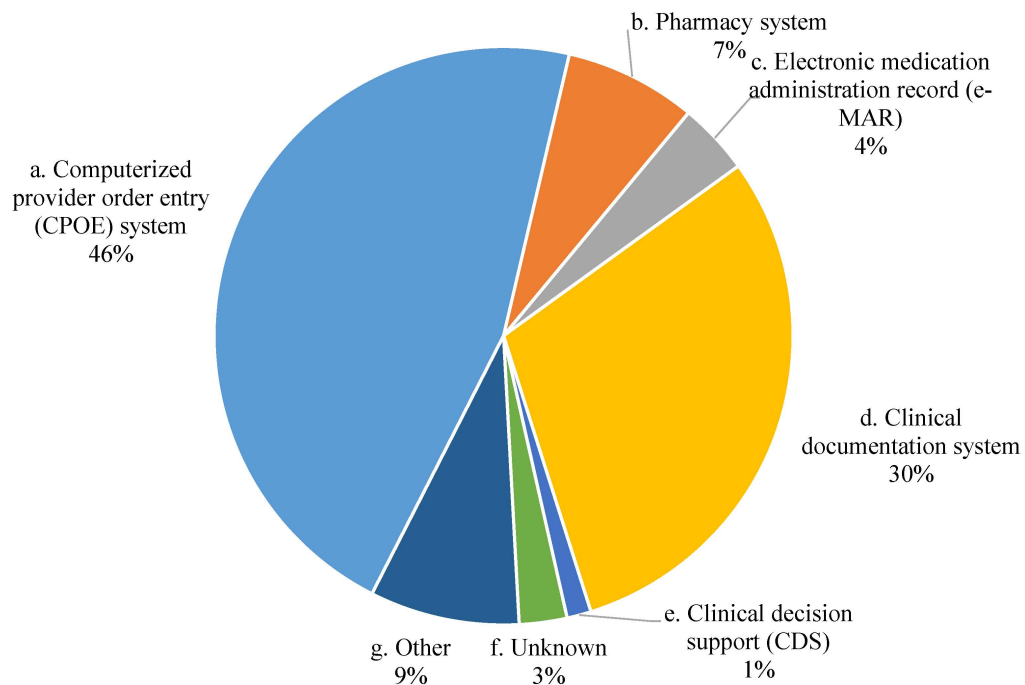
Administrative/billing or practice management events: Within the category of the administrative/billing or practice management system, the majority of events (84 percent, or 54 events) were associated with registration/appointment scheduling systems (see Figure A.2). One example of such an event that was submitted during this project was when a patient had a hyphenated last name containing too many characters for the computer field, resulting in the patient's first name on a blood bank specimen label being truncated and printed out as "Louis," not "Louise." The name mismatch deviated from the blood bank policy and procedure.

Figure A.2: Events Associated with Administrative/Billing Systems
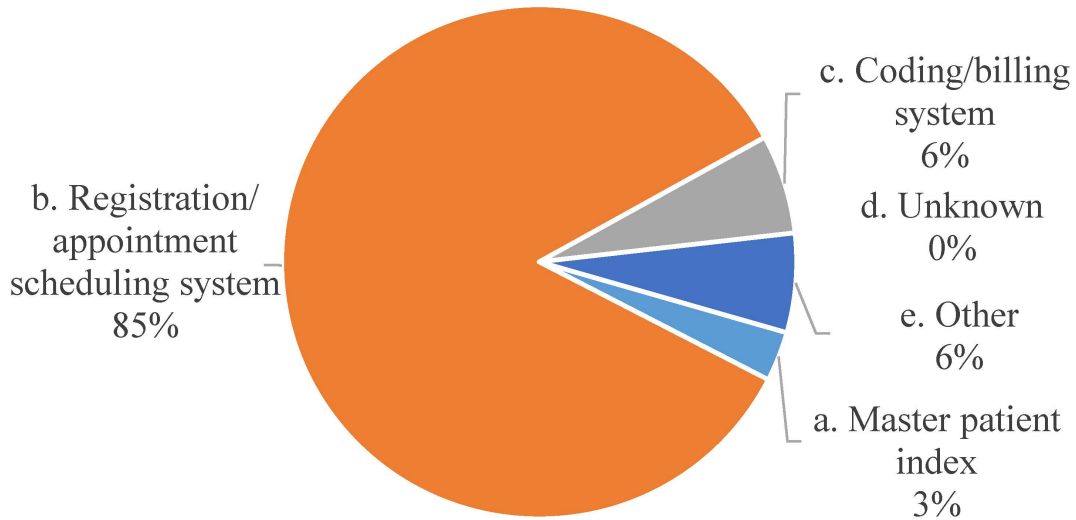
Another example submitted during this project was a registration/appointment scheduling system event in which a patient's chart had another patient's information merged into it. The following information was found in the patient information screen: two sets of parents in the contacts, incorrect address, and incorrect phone number.

Circumstances Involving the Health IT Device

Analysis of the circumstances involving the health IT device revealed that a majority of the events (40 percent, or 209 events) involved ergonomics, including human/device interface issues. Unexpected software design issues (21 percent, or 113 events) and equipment/device function (16 percent, or 84 events) were the next most common. (See Table A.3.)

Table A.3: Circumstances Involving the Health IT Device

Circumstances Involving the HIT Device	Number of Events	Percent
Ergonomics, including human/device interface issues	209	40%
Hardware location	0	0%
Data entry or selection	189	90%
Information display or interpretation	7	3%
Alert/alarm fatigue	3	1%
Other	10	5%
Unexpected software design issue	113	21%
Equipment/device function	84	16%

Circumstances Involving the HIT Device	Number of Events	Percent
Loss or delay of data	61	73%
Incorrect or inappropriate alert	7	8%
System returns or stores data that does not match patient	4	5%
Incorrect test results	4	5%
Incorrect software programming calculation	4	5%
Other	4	5%
Image measurement/corruption issue	0	0%
Image orientation incorrect	0	0%
Unknown	39	7%
Network failure or problem	32	6%
Incompatibility between devices	23	4%
Hardware failure or problem	11	2%
Other	11	2%
Equipment/device maintenance	5	1%

Further analysis provided additional breakdowns of the events associated with ergonomics, including human/device interface issues and equipment/device function. Nearly all of the events related to ergonomics were associated with data entry or selection (90 percent, or 189 events). For the events related to equipment/device function, loss or delay of data was the largest category (73 percent or 61 events).

The following are examples that were submitted during this project of circumstances involving a health IT device:

- Equipment/device function—Loss or delay of data: A procedure was delayed when the results of an EKG were unable to be accessed in the EHR.
- Ergonomics, including human/device interface issue—Data entry or selection: A floor registered nurse moved a patient from the emergency department (ED) to an assigned room in the EHR, and the ED staff were unable to complete their documentation for the patient.

Harm and Severity

Sites indicated events' level of harm to the patients. To do so, they used the National Coordinating Council for Medication Error Reporting and Prevention's Index for Categorizing Medication Errors.[23] Although originally designed for medication events, the index is often used for non-medication-related events.

A majority of the events, 70.3 percent (362), were classified as error, no harm, and 5.2 percent (27) were classified as no error. A total of 23.5 percent (121) were not classified with a harm score because harm could not be determined from the information provided.

Four of the events (0.8 percent) caused patient harm, ranging from temporary harm that required intervention to prolonged hospitalization, and one event (0.2 percent) contributed to patient death.

An example of an event that caused harm and was submitted during this project: A patient had a fatal adverse drug reaction to intravenous (IV) contrast material that resulted from allergy information not being available in the radiology information system when the order was transmitted.

Observations

- Identification of health IT–related events: The impact of health IT on events may be difficult to detect and identify, especially from the front line staff point of view. Near miss and unsafe conditions are not recognized as an "event."
- Review of health IT–related events: Reviews should be undertaken by an interdisciplinary committee with involved stakeholders. Stakeholders should include but not be limited to front line, clinical, risk management/quality/patient safety, information technology, and informatics staff. The inclusion of EHR developers should be considered.
- Usability of reporting systems: Many commercially available systems do not have taxonomy or the ability to flag an event in which health IT is considered to be the cause or a contributing factor of the event.
- AHRQ Common Formats version 1.2:
  - The HIT category, included within the Device/Medical and Surgical Supply taxonomy, may have caused confusion for reporters.
  - Answers to question 21 and subquestions 22 and 23 of the Device or Medical/Surgical Supply, Including HIT, form are currently formatted for single selection. Answers should be changed to check all that apply. Health IT–related events can have an effect on more than one type of health IT device (see Figure A.3).
  - The list of devices does not include such ancillary systems as barcode technology, smart IV pumps, and clinical monitoring interoperability, such as EKG and telemetry documentation. This list would be improved by including these systems.

Figure A.3: AHRQ Common Formats Questions About Type of Health IT Device

21. Which of the following best characterizes the type of HIT device related to the event or unsafe condition?
    CHECK ONE:
    a. ☐ Administrative/billing or practice management system
    b. ☐ Automated dispensing system

    22. Which component of the administrative/billing system?
        CHECK ONE:
        a. ☐ Master patient index
        b. ☐ Registration/appointment scheduling system
        c. ☐ Coding/billing system
        d. ☐ Unknown
        e. ☐ Other: PLEASE SPECIFY
        _____

    c. ☐ Electronic health record (EHR) or component of EHR
    d. ☐ Human interface device (e.g., keyboard, mouse, touchscreen, speech recognition system, monitor/display, printer)
    e. ☐ Laboratory information system (LIS), including microbiology and pathology systems
    f. ☐ Radiology/diagnostic imaging system, including picture archiving and communications system (PACS)
    g. ☐ Other: PLEASE SPECIFY
       _____

    23. Which type or component of the EHR? CHECK ONE:
        a. ☐ Computerized provider order entry (CPOE) system
        b. ☐ Pharmacy system
        c. ☐ Electronic medication administration record (e-MAR)
        d. ☐ Clinical documentation system (e.g., progress notes)
        e. ☐ Clinical decision support (CDS) system
        f. ☐ Unknown
        g. ☐ Other: PLEASE SPECIFY
        _____

Limitations

- Event data were voluntarily reported by sites participating in the project.
- Information about the health IT events submitted to ECRI Institute PSO was limited to the brief narratives and information provided in the AHRQ Common Formats version 1.2 Device/Medical and Surgical Supply, Including HIT, form.
- Event classification of the health IT–specific questions, if not completed by the facility, was performed by consensus of two project analysts. Inter-relater reliability was not assessed.