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Report of the Evidence on Health IT Safety and Interventions

Final Report

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US Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
330 C Street SW—Mary Switzer Building, Mailstop 7033A
Washington, DC 20201

Prepared by

Mark L. Graber, MD, FACP
Douglas Johnston, MTS
Robert Bailey
RTI International
3040 E. Cornwallis Road
Research Triangle Park, NC 27709

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1. BACKGROUND

This *Report of the Evidence on Health IT Safety and Interventions* is intended to summarize recent evidence in this rapidly expanding field, to identify areas where research is needed, and to encourage the development or refinement of existing tools or interventions to enhance the safety and increase the safe use of health IT. This report has been constructed with a view that, in the event stakeholders find sufficient value in this report, it could serve as the foundation of a series of evidence summaries that update its findings regularly or that delve more deeply into specific areas than is feasible in this initial, broad survey.

This report focuses on three specific areas:

- Research on the types, severity, and frequency of health IT-related events, and related methodology, findings, and classification issues;
- Research on usability, interoperability, and other targeted areas related to health IT safety; and
- Identification and evaluation of tools and interventions intended to avoid or mitigate risks of health IT or that use health IT to make care safer.

The next segment of this report is focused on source research methodology, including analyses of health IT research databases and relevant conferences.

2. SOURCES AND METHODS

This report summarizes evidence on the major advances in health IT safety since the publication of the Institute of Medicine's (IOM) landmark report in 2011: *Health IT and Patient Safety: Building Safer Systems for Better Care*.⁽¹⁾

Evidence on specific health IT safety topics was compiled from MEDLINE searches using topic-appropriate keywords and medical subject headings (MeSH) terms. For Sections 3.1 and 3.2 of this report, an initial search of the MEDLINE database was conducted to identify health IT-related review articles retrieved for the interval January 2012 to April 2015 (US based, English only) using the MeSH headings "electronic health records" and "medical informatics" (which include key terms such as health information technology and clinical informatics, and cross-reference other MeSH headings such as Health Information Exchange). Studies specific to health IT safety were then identified from these reviews, and from references identified in the AHRQ Health IT Bibliography (available at: <https://healthit.ahrq.gov/health-it-tools-and-resources/health-it-bibliography>). Additional articles were identified from reference lists found in the initial searches, and by MEDLINE listings of similar articles and articles in which the reference articles were cited.

Articles on specific health IT safety topics reviewed in Section 3.3—including usability, interoperability, alerts, and trigger tools—were identified through this initial search, and

through additional MEDLINE and Web search engines using the terms “patient safety” and “health information technology” combined with these key words (i.e., usability, interoperability, alerts, trigger tools, etc.). Finally, the health IT safety tools and interventions summarized in Section 3.4 were identified using the same results from prior searches, and refined by including appropriate additional search terms such as tools, guidelines, best practices, and risk mitigation. Additional tools and resources were also identified from the reference lists found in these initial searches.

Documents reviewed included peer-reviewed publications, presentations at major health informatics conferences (Healthcare Information and Management Systems Society—HIMSS, American Health Information Management Association—AHIMA, American Medical Informatics Association—AMIA), and reports issued by the Office of the National Coordinator for Health Information Technology (ONC), the Agency for Healthcare Research and Quality (AHRQ), and other organizations.

This report includes major studies and literature directly related to health IT safety—the development and use of electronic health records (EHRs), for example—as well as resources focused on improving the safety and safe use of health IT.

A complete list of sources reviewed is provided in the References section at the end of this report. The various findings are referenced in detail in the sections below.

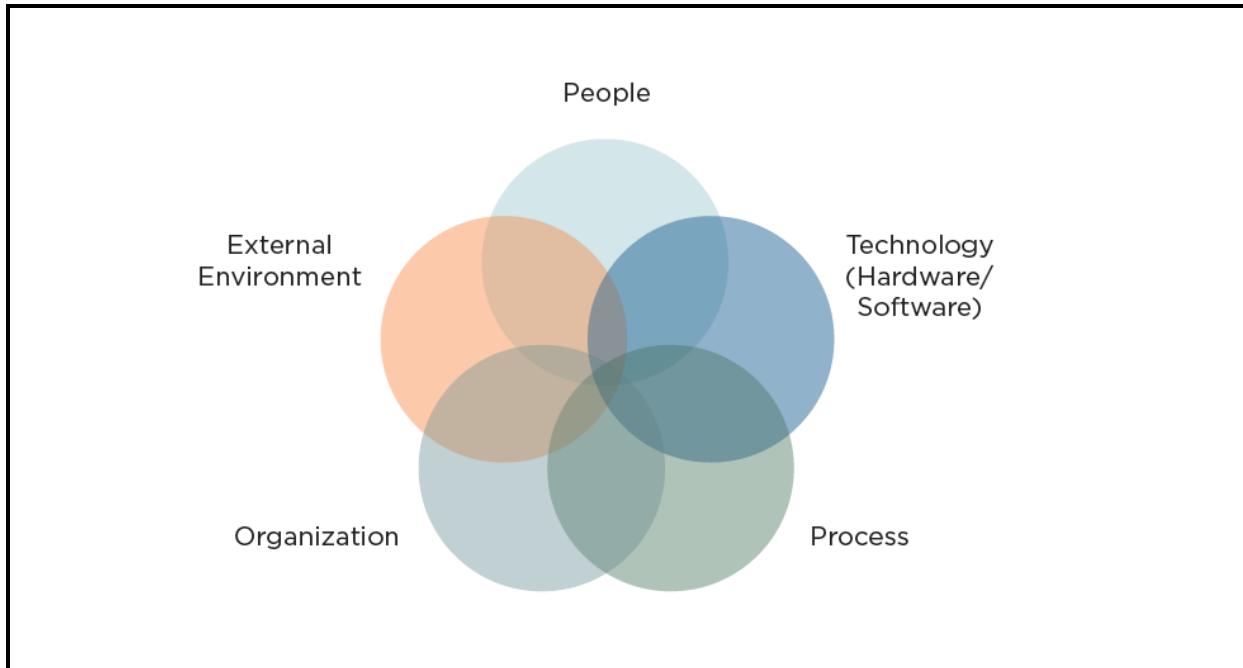
3. FINDINGS

3.1 Research on Methodology and Classification

Over the past several years, various models, frameworks, and classification schemes have been developed to better characterize health IT safety risks and errors that need attention. The IOM adopted a sociotechnical overview of health IT that proposed five major domains: people, technology, process, organization, and the external environment (see **Figure 1**).⁽¹⁾

The IOM framework synthesized concepts from several earlier models, and several remain popular: Sittig and Singh proposed an eight-dimensional sociotechnical model that centered on health IT users, but also included work-related and environmental factors that influence successful implementation and usage.⁽²⁾ In contrast, the framework of Magrabi et al. focused on human users and their computer systems, and the interface between the two, and divided these into 36 distinct dimensions.^(3, 4) Schiff et al. recently reported an additional taxonomy developed to analyze errors related specifically to physician order entry that distinguished 25 different categories for errors and an additional 25 codes that explained why an order entry error occurred.⁽⁵⁾

Figure 1. Sociotechnical Model of Health IT



To support national reporting of patient adverse events, AHRQ developed the Common Formats. (6) Now widely used by national Patient Safety Organizations (PSOs), version 1.2 of the Common Formats includes questions on identifying health IT-related events or unsafe conditions.(7) AHRQ also funded development of the Health IT Hazard Manager, whose ontology is organized around a four-phase health IT hazard life-cycle: discovery, causation, impact, and hazard mitigation. It includes factors related to usability, data quality, decision support, vendors, implementation, and others.(8)

PSOs themselves have adapted existing reporting tools or developed their own taxonomies for characterizing health IT safety risks and hazards. The ECRI Institute, for example, developed an enhanced version 1.2 of AHRQ’s common definitions and formats to help identify, classify, and analyze health IT safety events.(9) The Controlled Risk Insurance Company (CRICO), a medical liability insurer and PSO, developed its own propriety taxonomy for categorizing and analyzing malpractice claims involving health IT.(10) Finally, The Joint Commission(11), which accredits hospitals, employed a unique framework that included sentinel event reports, root cause analysis, and a sociotechnical model to identify the top health IT factors contributing to sentinel events.(12)

In 2016, the National Quality Forum (NQF) released a report on *Identification and Prioritization of Health IT Patient Safety Measures*, which included a conceptual framework, key measurement areas, suggested measure concepts, and other details on measuring health IT safety. Based on ONC’s SAFER Guides(13), the NQF report described a three-

domain health IT quality and safety model: Domain 1—safe health IT; Domain 2—using health IT safely; Domain 3—improving patient safety (using health IT). These domains correspond to the IOM’s original goals of making health IT safer and using health IT to improve patient safety. Moreover, the model incorporated prior work on EHR-specific patient safety goals and other health IT safety frameworks addressing: data availability, integrity and security (Domain 1); system usability; organizational planning, preparation and governance; complete and correct system usage; surveillance and monitoring (Domain 2); safety improvements; and patient engagement (Domain 3).(14)

Creating models, frameworks, taxonomies, and other categorization schemes is typically the first requirement in any new field to develop common terminology and organize further thought. The proliferation of methods to organize health IT-related safety events is a valuable contribution and reflects the intense interest to address these concerns. The diverse approaches that now exist create problems, however, in aggregating data or comparing the incidence of error types across studies. Inconsistent usage is another problem: even when organizations use the same reporting method, such as the AHRQ Common Formats, how and when this resource is used vary substantially among health care organizations. The field could benefit from an analysis that compares these different methods of organization to identify their strengths and weaknesses, and that could serve as a basis to help reach consensus about the best approach(es) to capture and classify health IT events.

The next segment of the report analyzes the range of existing sources that provide information on health IT-related events, to include a comparative analysis of their similarities and differences.

3.2 Evidence on Types, Severity, and Frequency of Health IT-Related Events

A systematic review covering the decade 2000–2009 identified many concerns stemming from the use of a variety of health IT functionalities, including computerized provider order entry (CPOE), clinical decision support systems (CDSS), and bar coding medication administration (BCMA).(15) Recent studies proposed new taxonomies to categorize these concerns and added to the evidence base by providing data on the incidence of specific problems and their consequences. These data derived from many different sources; each provided its own unique perspective on health IT-related safety concerns. **Appendix A** provides a detailed table with more information about the following resources.

The Joint Commission searched all sentinel events reported over 3.5 years and identified 120 reports in which health IT was a factor. Because these were sentinel event reports, all involved patient harm. Problems were identified with many IT issues and functionalities; the most common were issues with the user-computer interface, identified in a third of the cases.(11)

The CRICO Malpractice Claims database. Graber et al. searched for claims in which health IT was a factor. They identified 248 cases, less than 1 percent of claims coded in 2012 and 2013. Ambulatory care was the leading site for these claims and most commonly involved medications (31%), diagnosis (28%), or a complication of treatment (31%). Over 80 percent of cases involved moderate or severe harm. Although the etiologic factors spanned sociotechnical dimensions, many recurring patterns were identified, such as risks from EHR conversions and updates, problems in copy-paste functionality and prepopulated data, and incorrect assumptions that the information in the EHR was always correct and up-to-date.(16)

The U.S. Food and Drug Administration (FDA) MAUDE database. Magrabi et al. analyzed health-IT related reports submitted over 30 months and identified 436 relevant reports. Most problems reported (96%) were computer-related and involved software issues; only 4 percent involved the machine-user interface. Authors attributed this atypical distribution to the type of reports submitted. Several new categories of error were found in reviewing these cases, expanding the author's previous taxonomy to 36 categories. Four deaths were associated with the events noted in these reports.(3, 4)

The ECRI Institute analyzed 171 health IT-related safety events reported via its PSO system over 7 weeks through a modified version of the AHRQ Common Format. The authors found that methods for completing safety reports at the local level varied widely, which hindered aggregation in many areas. Approximately 6 percent of events involved harm. Over half of the reports involved medication management systems. Using the sociotechnical categories of Magrabi et al., the authors found that just over half of the report event types were computer-related, and just under 50 percent focused on the user or the user-computer interface. Common problems included wrong input (30 examples of 211), system interface issues (33 examples), wrong record retrieval (23 examples), and software configuration problems (27 examples).(9)

A Veterans Health Administration database. Meeks et al. analyzed EHR-related safety concerns and identified 100 reports submitted over 4 years. Using the eight-dimension sociotechnical model of Sittig and Singh, they found 70 percent of reports involved two or more sociotechnical dimensions, illustrating the multiple sources of errors in almost every other type of safety investigation. Most errors resulted from unmet display needs, software changes or upgrades, system-to-system interfaces, and hidden dependencies.(17)

PSO databases maintained by the University Health Consortium (UHC) and the ECRI Institute were searched to identify reports involving health IT. Reports were submitted using AHRQ's Common Format. This search revealed that participating health care organizations did not consistently use the health IT designation in filing Common Format reports, hindering efforts to identify more health-IT related events. Conversely, closer review of reports designated as involving health IT found that almost one-third actually did

not involve it. Incidence and magnitude of harm could not be estimated. The most common problems were communications among staff (40–42%), staff inattention (33–34%), data accuracy (21–23%), and data availability (10–12%).(18)

The Pennsylvania Patient Safety Authority database. Hydari et al. studied this database to measure the impact of EHRs on reported safety events. They found that safety events declined by 27 percent after EHR implementation, including a 30 percent decline in medication error events and a 25 percent decline in reports on complications of treatment.(19) In a prior study, Pennsylvania Patient Safety Authority analysts identified nearly 3,100 EHR-related events between 2004 and 2012 in the Authority’s Pennsylvania Patient Safety Reporting System (PA-PSRS). They classified these by harm score and event type. Of these cases, 2,763 (89%) resulted in no harm, and 320 (15%) in unsafe conditions. Fifteen incidents (<1%) caused temporary harm, and one case resulted in significant harm. Further, the majority of EHR-related errors were medication errors (2,516; 81%) related to dose (missed, over, under) or errors related to procedure/treatment/test (415; 13%), in particular, laboratory test problems. Remaining events were classified as other/miscellaneous.(20)

The MEDMARX database. Schiff et al. searched more than 1 million reports of medication-related errors and identified 63,000 problems in CPOE systems over 7 years. The authors identified 21 recurring error types and tested 13 of them on 16 CPOE systems. None of the tested systems performed well; almost 80 percent of the potentially dangerous order types could be submitted either easily or with minor workarounds with no warnings.(5)

Qualitative research. RAND Health, in collaboration with the ECRI Institute and staff from the University of Texas and the Baylor College of Medicine, conducted a field study of health IT safety intervention projects at 11 institutions: seven hospitals, and four ambulatory care sites. The most common projects focused on trying to improve the transfer of information. A major conclusion was that change and improvement are difficult to achieve in a short (9-month) time, reflecting the complexity of trying to influence culture, technology, workflow, and user behaviors at the same time.(21)

3.2.1 Discussion

Comparison of the data sources and types of reports revealed several important differences. One is the type of professional staff involved. For example, reports to the MAUDE database primarily originate from pharmacists whereas reports to PSOs come from risk managers and malpractice cases that primarily involve physician and nursing staff. Another major difference is the degree of harm from events: some result in virtually no harm (on the basis of reports from safety-reporting databases on near-miss and harmful events) while others result in serious harm or death—the norm in the Joint Commission and CRICO databases. The various reporting formats and definitions also emphasize the need to use more consistent methodologies. Learning can be impeded because reporting processes,

definitions, and coding taxonomies differ, and assessments of harm are not always clearly defined or applied consistently.

In aggregate, these reports confirm that such analyses are critically important sources for learning about health IT safety and that using diverse approaches is essential to provide a balanced picture of safety problems. Another major observation gleaned from examining these different reports is no one area or functionality is most commonly linked to adverse safety outcomes: harm can potentially result from almost any health IT functionality used in health care delivery. Other health IT safety topics show a similar pattern.

3.3 Research on Other Selected Health IT Safety Topics

The numerous health-IT related safety concerns found in incident reports and claims data are remarkably diverse. A survey of members of the American Society for Healthcare Risk Management and the American Health Lawyer's Association revealed eight similarly broad issues demanding attention in no particular priority order:(22)

- Incorrect patient identification
- Extended EHR unavailability
- Failure to heed a computer-generated warning or alert
- System-to-system interface errors
- Failure to identify, find, or use the most recent patient data
- Misunderstandings about time
- Incorrect item selection from a list of items
- Open or incomplete orders

Because the above items do not provide priority areas to target, this task and report focus on the following topics from recent literature where evidence on interventions is emerging: usability, interoperability, ambulatory care, alerts, patient identification, communication and test result follow-up, and trigger tools.

3.3.1 Usability

The International Standards Organization (ISO) defines usability as "the extent to which a product can be used by specified users to achieve specified goals with **effectiveness**, **efficiency**, and **satisfaction** in a specified context of use."(23) Others define usability in more granular ways for EHRs, specifying multiple design principles that result in more usable systems.(24, 25)

Ensuring that clinicians can deliver care effectively, efficiently, and with high satisfaction through EHRs was an important focus of government and private sector health care stakeholders before the 2011 IOM report on *Health IT and Patient Safety*, and remains so today. Usability featured prominently in the IOM report: several recommendations were tied to improved patient safety through better usability and continuing research on user-centered design.(1)

Federal agencies have long supported research and development on health IT usability, particularly for EHRs. For instance, the National Institute of Standards and Technology (NIST) supported the development of the Common Industry Formats for usability testing, which help system developers and implementers conduct consistent usability evaluations of EHR systems.(26) NIST also created a companion guide to the processes approach for improving EHR system usability.(27) AHRQ supported health IT usability research, methods and tool development, a usability evaluation and use case framework,(28) interface design considerations for EHRs,(29) vendor perspectives and practices related to EHR usability,(30) and a compendium of EHR evaluation methods.(31) Through its Strategic Healthcare IT Advanced Research Projects (SHARP) grant program, ONC supported multiple projects for creating a protocol, framework, software, briefs, and guidelines for EHR usability evaluation and safety-enhanced design.(32) Recognizing the need to ensure usable certified EHR technologies, ONC included safety-enhanced design as part of Stages 2 and 3 EHR certification criteria, which required EHR vendors to use a formal user-centered design process during system development and to perform summative usability testing on their products.(33) A recent review of vendors' reported practices for 50 EHR products, however, found that less than half used ISO or NIST user-focused usability standards in their development; almost a third reported using no formal standards.(34)

Similarly, some private sector organizations have worked to address EHR usability. For instance, the HIMSS Usability Task Force created a comprehensive guide to EHR usability principles and evaluation methods,(24) and vendors have focused on developing a Common User Interface tool suite for health IT.(35) Several academic centers and commercial firms provide EHR usability evaluation services to vendors and provider organizations—conducting research, providing simulation testing and usability evaluation of existing systems, and developing prototype interfaces.

On another front, several professional associations have recommendations for improving EHR usability. For instance, in response to increasing evidence of health IT safety issues, AMIA convened a task force on usability to examine evidence, identify critical issues, and provide recommendations. In four broad areas (research, policy, industry, and end users), AMIA's recommendations reflected the range of stakeholders involved with—and contributing to—EHR usability issues. Accordingly, their recommendations were aligned by type of stakeholder; for instance, suggesting that industry (EHR vendors) develop a common user interface style guide for EHR functions. Patient safety was a strong theme throughout these recommendations, summarized in **Figure 2**. Many recommendations emphasized the relationship to patient safety-sensitive EHR functions or focused on supporting advances to health IT safety measurement, reporting, and education.(36)

Figure 2. Summary of AMIA Usability Task Force Recommendations

- | |
|---|
| <p>1. Usability and human factors research agenda in health IT</p> <ul style="list-style-type: none"> a. Prioritize standardized use cases. b. Develop a core set of measures for adverse events related to health IT use. c. Research and promote best practices for safe implementation of EHRs. <p>2. Policy recommendations</p> <ul style="list-style-type: none"> a. Ensure that EHR systems are standardized and interoperable and address usability concerns. b. Establish an adverse event reporting system for health IT and voluntary health IT event reporting. c. Develop and disseminate an educational campaign on safe, effective use of EHRs. <p>3. Industry recommendations</p> <ul style="list-style-type: none"> a. Develop a common user interface style guide for select EHR functionalities. b. Perform formal usability assessments on patient-safety sensitive EHR functionalities. <p>4. Clinical end-user recommendations</p> <ul style="list-style-type: none"> a. Adopt best practices for EHR system implementation and ongoing management. b. Monitor how IT systems are used and report IT-related adverse events. |
|---|

In 2013, research on factors affecting the professional satisfaction of physicians found that concern about EHRs, especially poor usability, was a common source of dissatisfaction.(37) Building upon this finding, the American Medical Association (AMA) convened an Advisory Committee on EHR Physician Usability that identified eight priorities to ensure more usable EHRs (see **Figure 3**).(38) These priorities reflected

Figure 3. AMA’s Eight EHR Usability Priorities

- | |
|---|
| <ul style="list-style-type: none"> 1. Enhance physicians’ ability to provide high-quality patient care. 2. Support team-based care. 3. Promote care coordination. 4. Offer product modularity and configurability. 5. Reduce cognitive workload. 6. Promote data liquidity. 7. Facilitate digital and mobile patient engagement. 8. Expedite user input into product design and post-implementation feedback. |
|---|

the challenges physicians face in using certified EHR technologies. They were based on an understanding that usability is a complex issue involving system interface design, system implementation, physician training, organizational policies and practices, and other factors. Moreover, the AMA focused usability improvement efforts squarely on supporting clinical care processes and delivering safe care.

Another challenge is that EHRs designed and implemented for specific care settings may have unique usability concerns. NIST convened an expert panel to develop recommendations to improve EHR usefulness, usability, and patient safety for pediatric care delivery. In contrast to AMIA’s and the AMA’s more general recommendations, the NIST panel recommendations had nine critical user interaction categories (see **Figure 4**)—relative to specific stakeholders: EHR developers, small-group pediatric medical practices, and children’s hospitals.(39)

Many studies and reviewed articles on health IT and EHR usability evaluation methods were published prior to the 2011 IOM report. Since then, researchers have continued to summarize the evidence in this area. Notably, Yen and Bakken published a systematic review of health IT usability study methodologies. Using the systems development life cycle (SDLC) framework, the authors categorized and assessed over 300 studies according to their relevance to various developmental stages. Based upon their assessment, the authors developed a guide to the selection of theoretical models, outcome measures, and evaluation methods appropriate for evaluating usability at a given stage of development.⁽⁴⁰⁾ The assessment and categorization of qualitative and quantitative usability evaluation methods using the SDLC underscores the need for usability evaluation across the entire process of developing, implementing, and supporting systems.

Figure 4. NIST Nine Critical User Interaction Categories

1. Patient identification
2. Medications
3. Alerts
4. Growth chart
5. Vaccinations
6. Labs
7. Newborn care
8. Facilitate digital and mobile patient engagement.
9. Privacy
10. Radiology

Some studies, however, focused on emerging or discrete aspects of health IT and EHR usability evaluation. For example, with the proliferation of mobile technologies, EHRs have increasingly become cross-platform systems. Accordingly, EHR usability issues and evaluations should include mobile form factors and applications. In one study, researchers assessed the appropriateness of the Health IT Usability Evaluation Model (Health-ITUEM) for evaluating the usability of mobile health technology. While not applied to EHR functions on mobile devices, this model was found to be helpful in conducting usability assessments on mobile platforms. The model included usability principles such as error prevention, completeness, memorability, information needs, flexibility/customizability, learnability, performance speed, competency, and other measures.⁽⁴¹⁾

Using medical simulation centers to conduct EHR usability assessments allows designers to detect and fix usability problems before EHRs are implemented in health care delivery. Typically, EHR usability studies are conducted by experts trained in usability evaluation and human factors assessment methods using specialized equipment and software. The value of simulation testing is that it allows users and evaluators to identify the unintended consequences of using health IT applications without actually causing any real harm. The disadvantage is that some unintended consequences only become apparent when health IT systems are put into everyday use, a strong argument for end users to supplement these studies with further safety evaluation in actual practice.⁽⁴²⁾ More realistic simulation studies may also provide valuable information; a team of informatics researchers reported successfully integrating an EHR into an existing simulation center, “which may provide

realistic environments for usability testing, training, and evaluation of human–computer interactions.”(43)

3.3.2 Interoperability

Interoperability is the ability of different information technology systems and software applications to communicate, exchange data, and use the information that has been exchanged.(44) Growing evidence shows that interoperable health information exchange (HIE) has value to stakeholders and can improve care quality, efficiency, and safety by improving the timeliness and completeness of important patient health information such as medical test results, medications, diagnoses, preventive care measures, and allergies.(45-50) Improving interoperability has been identified as one of the top health IT safety priorities.(51-53)

Interoperability also provides the opportunity for unintended consequences, summarized in a 2012 study prepared for ONC that identified several challenges including incomplete, inaccurate, or untimely data; poor data presentation and data overload problems; and other issues.(51) These and other HIE-related safety risks are discussed in more detail below.

Incomplete, Inaccurate, or Untimely Data Provided by HIE

Unintended consequences can result from:

- Incorrect patient matching, where some or all data retrieved via HIE relate to a different (and incorrect) patient. Such errors can happen because of flawed matching algorithms used for HIE.
- Data quality issues, such as incomplete data on the patient, duplicate patient records, or data entry errors, can propagate through HIE increasing the potential for adverse safety events.
- Loss of data integrity during transmission, for example, if the HIE process changes the meaning of the data or errors in translation occur between different systems, reflecting differences in vocabularies. Integrity loss may be caused by the structure of the data; for instance, data fields may be dropped or truncated due to mismatched expectations of structure between sending and receiving systems. Errors may also occur in data representation because of mismatched terminology expectations. Completely eliminating data errors and data integrity problems is difficult—and without care, these errors can possibly be propagated and perpetuated as data are shared more widely.
- Technical limitations such as when a participant in HIE may not be able to provide a certain type of data (e.g., data from specific ancillary systems) consistently. How HIE is implemented technically, such as batching requests rather than immediate data sharing in real-time, may limit the data’s timeliness. Moreover, if the HIE degrades EHR or other system performance, critical delays in accessing HIE data can result.

HIMSS and AHIMA have developed resources to support patient matching for HIE.(56, 57) AHIMA recommends standardizing data capture by using existing national standards, increasing the number of primary data elements, and incorporating secondary data

elements to accurately identify participants in HIE.(58) HIMSS developed a Patient Identity Integrity Toolkit with resources to enhance understanding of patient identity integrity and the many issues involved in reliably and safely matching patient identity across systems.(57)

One patient-matching solution is the Veterans Health Administration's (VHA's) "no risk" model for data exchange between VA providers and its HIE partners, where both the exchange partner and VHA's systems performed independent tests that confirmed the positive match. Each exchange partner used an independent matching algorithm that strictly considers various demographic traits and only allows a match when both systems agree.(50)

Problems Related to Data Presentation, Including Data Overload

These unintended consequences can result from:

- The large volume of data the HIE makes available, which can dwarf the amount of data in the clinician's EHR and be difficult to process cognitively; and
- Design shortcomings of the systems that present the HIE data to the clinician. Many EHRs are not optimized to manage HIE data. Furthermore, many do not employ user-centered design principles in presentation of data. Clinicians may be unsure what data are present or missing from the HIE system. Data presentation issues can negatively impact clinicians' workflow and their ability to use HIE information to provide and coordinate care.(51, 59)

A recent evaluation of the VHA HIE program identified potential improvements to data presentation based on stakeholder input. For example, HIE data should be automatically integrated with the user's local data, along with clear identification of the date and information sources. A suggested workflow improvement included data reconciliation or adjudication support (e.g., highlight or remove duplicate data from multiple sources and sort by date).(50)

Novel techniques for HIE data adjudication are being developed to improve HIE data presentation and usage. The University of Utah, for example, developed an adjudication approach that goes beyond passively accepting HIE data and incorporating that data into an organization's own EHR. The approach applies a decision support infrastructure to adjudicate HIE data on the basis of consistency, compatibility, completeness, and timeliness. For example, the technique assesses whether an external result has all of the mandatory information, the value has physiological compatibility (is within possible range), and whether it should be stored in a receiving system (if it is redundant with other data). This approach creates the opportunity for local autonomy in setting standards for clinical data integrity, as opposed to relying on HIE organizations, which may be limited by consensus decisions and potentially by the lowest quality source of data.(59)

The *Strengthening Health Information Exchange* report identified many potential tools and solutions that would help mitigate these risks and unintended consequences of HIE, such as best practices for optimizing patient matching. This report also suggested other tools and solutions to mitigate data presentation risks, to ensure that HIE-enabled EHRs incorporate user-centered design, and to help identify and highlight important clinical data.

HIE Data Semantic Interoperability

The *Strengthening Health Information Exchange* report did not specifically discuss semantic interoperability, e.g., the ability of health information systems to unambiguously share and use data. Semantic interoperability ensures that the context of clinical data is preserved; that data are not only understandable in their original context, but also capable of supporting clinical decision making and other uses in different care settings.(44) Failure to have semantic interoperability impacts the first two contributors to unintended consequences and patient safety issues—the HIE data quality, accuracy, and completeness and the data presentation.

Heterogeneity of Use of HIE capability

Heterogeneity in implementation and use of HIE can result in suboptimal use of HIE capability, which in turn can contribute to safety risks. Low or suboptimal use may be due to:

- Workflow and provider preferences not considered in design / implementation of the HIE capability; for example, in how the clinician accesses the information (e.g., separate portal, not integrated with EHR);
- Lack of confidence in the data, which typically come from providers who are not known to the user;
- Data not considered reliable, e.g., complete and accurate, and meeting the intended purposes. Clinicians may not consider a reported medication allergy from another provider to be reliable, for example.
- Lack of financial drivers or an acceptable value proposition; and
- Lack of an adequate, trained workforce to support HIE use (e.g., administrative, technical, clinical leadership).

Shapiro et al. explored aspects of HIE relevant to emergency medicine and offered guidance for the use and promotion of emerging HIE technology. Their research provided emergency medicine-focused recommendations to HIE organizations, policymakers, and professional groups to demonstrate the value of HIE in this setting.(60)

Interoperability of Medical Devices

Medical errors can occur when hospital medical devices such as infusion pumps, electronic health records, and pulse oximeters are not interoperable. It would not be unusual for a patient in intensive care to be connected to 10 or more devices. Nurses, for example, have

to program and monitor the devices and often spend a significant time transcribing data by hand because the devices are not designed to share information. Manual transcription from one device to another increases the risk of medical errors.(61)

Fostering the development of interoperable products and systems, in part, requires the creation, validation, and recognition of common standards across product categories. The Medical Device Plug and Play Interoperability Program is an interdisciplinary, multi-institutional program committed to advancing medical device interoperability to improve patient safety and health care efficiency. This program supports the widespread clinical use of medical data and enables medical device integration to produce complete and accurate EHRs, create error-resistant systems, and reduce health care costs. More information about this program is available at: <http://www.mdnp.org/>.

3.3.3 Ambulatory Care

Although most studies of health IT safety have focused on inpatient settings, research is rapidly expanding to study ambulatory care, where most medical care takes place. Tejal Gandhi emphasized the challenges of studying safety in this setting because care is widely distributed, episodic, and encounters with no safety concerns vastly outnumber the incidence of true errors.(62) Moreover, many safety concerns may go undetected from a learning perspective, because ambulatory care settings typically fall outside of the quality and risk management programs that now focus primarily on inpatient care. Achieving the maximal potential of health IT to improve safety in the future depends on the ability to learn from and address the health-IT related issues in ambulatory care.

In an AMIA-sponsored review of ambulatory care safety publications over 10 years, the most common safety concerns fell into a few categories, and health IT was a central issue in each of these, detailed below.(63)

Medication Errors

Medication errors are the leading cause of adverse safety events in health care, and the majority of these occur in ambulatory settings.(64) Most physicians and pharmacies now use e-prescribing,(65) and recent reviews have highlighted the evidence that e-prescribing reduces medication error rates substantially.(66) Abramson et al., for example, studied prescribing errors before and after implementation of e-prescribing in an ambulatory clinic, and found a reduction from 41 percent down to 4 percent 2 years after implementation.(67) Besides reducing prescribing errors, e-prescribing contributes substantially to cost savings by avoiding adverse drug events, promoting use of less costly formulary drugs, and improving medication adherence. The challenge now for health IT is:

- to address the residual problems with electronic prescribing and dispensing,
- to continue development of tools that use electronic data and algorithms to detect and prevent prescribing errors, and

- to improve the other many aspects of medication management.

Diagnostic Errors

Singh et al. estimated that one in 20 ambulatory patients will experience a diagnostic error every year, and a substantial fraction of these result in harm.(68) This statistic is the basis for the recent IOM conclusion that most patients will experience one or more diagnostic errors in their lifetimes.(69) The IOM report on diagnostic errors also emphasized that health IT has profoundly affected every aspect of the diagnostic process; these effects have improved the timeliness and accuracy of diagnosis.(70, 71) EHRs improve access to key information about patients, enable decision support, assist in finding and analyzing diagnostic data, and contribute to effective collaboration and coordination. At the same time, EHRs can contribute to degradation of diagnostic processes because of the ubiquitous misuse of copy-paste functionality and design features intended to optimize coding and billing rather than support clinical reasoning.(72) Important priorities for next-generation systems to support more timely and accurate diagnosis include: improved problem lists, use of electronic trigger tools to detect patients at risk for harm related to diagnostic error, and ways to engage patients more directly in their own care.(73, 74)

Patients in Transition

Recently discharged patients are particularly vulnerable to adverse drug events. Roughly one in five recently discharged patients experiences an adverse drug event,(75) and these patients are also at risk for diagnostic error. Follow-up is deficient on 20–61 percent of laboratory tests pending at discharge(76), including cancer-related biopsy results, a variety of actionable microbiology results, and other critical findings, such as abnormal lead levels. Automated alerts(77), emails(78), and improved electronic discharge summaries(79, 80) are some of the interventions being tested to improve communication about pending results.

An automated tool to improve the handling of tests pending at discharge was found to increase physician awareness of the results of tests pending at discharge, potentially mitigating this unresolved patient safety issue. An estimated 41 percent of patients leave the hospital before all test results are reported, and almost 10 percent of these are judged to be actionable.(81)

3.3.4 Alerts

Clinical decision support (CDS) can help clinicians monitor patient-specific concerns and can provide evidence-based suggestions or other information at the point of care.(1) CDS encompasses tools to enhance decision making in the clinical workflow, including computerized alerts and reminders to both care providers and patients. Common types of alerts are:

- Various basic medication-related alerts, such as drug-drug interactions (DDI; where one drug potentiates or reduces the efficacy of another drug), drug duplication alerts, dosing alerts, and formulary-specific alerts.
- More sophisticated medication-related alerts where a medication is assessed in relation to some other parameter in the EHR, such as drug-laboratory, drug-disease, drug-allergy, and drug-age alerts.
- Reminders that preventive services are due.
- Reminders to perform patient-appropriate screenings and counseling.

The IOM *Health IT and Patient Safety* report documented some potential benefits of these CDS and alerts, including reductions in relative risk of medication errors, toxic drug levels, time to therapeutic stabilization, prescriptions of non-preferred medications, and improved monitoring and alerting clinicians of adverse outcomes.(1) Safety concerns include widely varying rates of detecting DDIs among different vendors, and high override rates of computer-generated alerts to clinically significant risks due to high rates of alerts of low clinical value that lead to alert fatigue.

Recent Studies Identify Approaches to Reduce Alert Fatigue

Since the 2011 IOM report, additional studies have reported problems in the usability and effectiveness of CDS, particularly concerning alert fatigue and overrides.(82-92) Alert fatigue occurs when a provider, after receiving too many alerts or reminders (some or many of which may be irrelevant to that provider), overrides or ignores further alerts without attending to them, which can decrease the care improvements expected from the tools and pose patient safety risks.

In a 2014 study of medication alerts in outpatient settings, Nanji et al. found that providers overrode about half of CDS alerts and about half of these overrides were classified as inappropriate. The alert override rate varied by alert type, ranging from formulary substitution (85%) and age-based suggestions (79%) to drug-drug interactions (24%). This study suggests that refinement of alerts can improve the relevance of alerts and reduce alert fatigue.(86)

Improving the usability of CDS is important because patient safety is compromised when clinicians perceive safety alerts as unimportant (due to poor presentation or lack of relevance). Recently, a DDI CDS Conference Series produced a set of recommendations for medication-related alerting strategies about DDIs. A workgroup of 24 clinical, usability, and informatics experts representing academia, health IT vendors, health care organizations, and ONC developed principles to convey drug information effectively while reducing clinicians' cognitive effort to improve medication safety.(88) These recommendations addressed the following questions:

- What, how, where, and when should DDI decision support be displayed?

- Should presentation of DDI decision support vary by clinician?
- How should the effectiveness of DDI decision support be measured?

The workgroup recommended that seven elements be included with DDI decision support, and that DDI information should be presented to all clinicians. Among the recommendations are:

- Seriousness category, using consistent terms and definitions to indicate the potential seriousness of the DDI and aid clinician interpretation across all CDS Systems;
- Interacting drugs involved, clearly identified, using name ordered as well as generic ingredient names;
- Clinical consequences and frequency for patients taking interacting drugs, allowing the clinician to balance the risks and benefits;
- Mechanism of interaction to help clinicians choose therapeutic alternatives;
- Contextual information/modifying factors, including predisposing factor information such as comorbidities, age, diseases, and drug regimen to be included in the alerting logic or display;
- Recommended action, or guidance to mitigate potential harm;
- Consistent terminology and brevity to promote semantic clarity and improved speed of processing the information.

Areas for future research to improve DDI decision support were also identified. Resources including white papers from the Conference Series are available at:

<https://sites.google.com/site/ddiconferenceseriessite/>.

Selected recent findings, developments, and novel approaches to improve and refine alerts are summarized below.

The way that alerts are presented to clinicians can impact their use. Scheepers-Hoeks et al. studied the effect of four alert presentation methods on alert compliance in a hospital intensive care unit (ICU): pharmacy intervention, physician alert list, EHR section, and pop-up alerts. Clinicians were surveyed to determine their preferred method of alerting. In this ICU, the most common alert was drug dosing during decreased renal function and potassium disturbances. The rate of alerts leading to action consistent with the aim of providing the alert was highest for recommendations provided in pop-up alerts (41%), followed by pharmacy intervention (33%), the physician alert list (20%), and the EHR section (19%). Clinicians preferred the pharmacy intervention and pop-up alerts, if applied correctly. They did not consider the physician alert list and EHR section suitable for CDSS. Active alerts such as pop-ups and pharmacy intervention were found to be more effective than passive alerts, which do not automatically appear during clinical workflow.(93)

Prescribing potentially hazardous drugs is common when treating patients with renal impairment. Czock et al. analyzed critical drug prescriptions in a university-based nephrology clinic to evaluate the effect of two different alerting strategies on the alert burden. One strategy generated alerts whenever drug-specific information was available; the other generated alerts only when the estimated glomerular filtration rate of a patient fell below a drug-specific value. This study found that alerting strategies using patient- and drug-specific information to generate more specific alerts have the potential to reduce the alert burden by more than 90% and could facilitate a more critical individual evaluation of drug prescriptions that should be avoided in patients with renal impairment.(94)

In addition, advances are occurring in the use of Natural Language Processing (NLP) to reduce alert fatigue. NLP can extract information from free-text clinical notes that can then be used to improve decision support for medication prescribing and management.(95)

3.3.5 Patient Identification

Providing care to the wrong patient is a longstanding concern in patient safety, prompted The Joint Commission's very first Patient Safety Goal: "Improve the safety of patient identification." Recently, better ways to measure the incidence of the problem have been identified, and research has begun to clarify why these errors happen and how they can be prevented.

Adelman et al.(96) developed a tool to identify wrong-patient orders, a "retract-and-reorder" trigger, which identified instances where the same order was placed on a different patient within a 10-minute period. Based on interviews that same day with the ordering providers, the tool was estimated to have a positive predictive value of 76 percent, identifying 170 wrong-patient orders in a 3-month period. These researchers estimated that 14 wrong patient orders were placed every day, all detected by the ordering provider, which translated to an incidence of 58 wrong-patient selections for every 100,000 orders. The figure was very similar to a previous estimate of 51 wrong-patient notes/100,000.(97)

The most common reason for a wrong-patient order was interruption while writing the order.(98) Other contributing factors included incorrect entry of the patient's name or number, small font sizes, failure of one provider to exit the system before another provider logs on, and juxtaposition opportunities, where the next patient is chosen from a list. The importance of the user-interface design in both enabling and preventing wrong-patient selections has been emphasized.(99) Many cultural and workflow issues were also involved, such as desire to avoid inconveniencing the patient.(100) These errors create opportunity for harm. An analysis of reports to the National Practitioner Databank from 1990 to 2000 identified 27 cases of wrong-patient surgery,(101) and the Joint Commission receives over 100 wrong-patient, wrong-site, or wrong-procedure event reports every year.(100)

The intervention recommended by The Joint Commission is to always check two different patient identifiers. Scant experimental evidence exists about the impact of this approach, although one study of eye-tracking during order entry found that providers rarely checked a second identifier when choosing patients from patient rosters, even when there were many similar names.(102)

Several novel, alternative interventions have been proposed that seem promising:

- In a pediatric neonatal ICU that was experiencing wrong-patient problems with as-yet-unnamed infants, an intervention that included the mother's name (Wendy Jackson's baby girl) reduced the misidentification rate by 36 percent.(96)
- In an emergency department, the self-reported wrong-patient selection rate was 1.3 percent. Staff believed that introducing a large watermark of the patient's room assignment would be highly effective in reducing this rate.(103)
- An electronic surveillance system linked to the patient's problem list was effective in intercepting 32 wrong-patient selections over a 6-year period.(104)
- In one study, an electronic verification screen, requiring the user to verify the patient selected after a 2.5-second delay, reduced wrong-patient orders by 30 percent.(105) A similar but slightly different approach in another study reduced these errors by 60 percent.(98)
- Incorporating the patient's picture on the selection screen substantially reduced wrong-patient selections in one small study.(106) Similarly, including a facial photograph taken at the time of medical imaging provided a way to detect wrong-patient errors in radiology images by radiologists.(107, 108)

3.3.6 Communication and Test Result Follow-Up

Communication breakdowns are the most common system-related factor in all adverse events, and EHR systems are rapidly replacing face-to-face communication as the default way health care providers exchange information and discuss problems and plans. How well EHRs function in enabling communication is a critical safety concern.

One unintended side effect of using electronic communication is loss of direct conversations about and with patients. For example, frontline clinicians now rarely speak directly with peers in diagnostic radiology or the clinical laboratory, and spending time with data entry and EHRs has reduced time spent in bedside or clinic interactions with patients.(72)

Another significant problem is the communication of test results, both from the clinical laboratory and medical imaging departments. Lapses in test result follow-up can lead to missed or delayed diagnoses, failure to recognize important medication side effects, and other problems that create risks for patient harm and liability.(109) These risks of communication breakdowns apply not only to critical values but also to abnormal but non-life-threatening test results. A systematic review of evidence quantified the extent of failure to follow up on test results and the impact for ambulatory patients. This review found wide variation in test results follow-up, ranging from 6.8 percent to 62 percent for laboratory

tests and from 1 percent to 36 percent for radiology.(110) A lack of follow-up of test results for inpatients ranged from 20 percent to 62 percent and for emergency department patients ranged from 1.0 percent to 75 percent when calculated as a proportion of tests.(76)

Although EHR systems have been shown to improve test result communication, problems can still occur even in organizations using mature EHRs.(76, 110) Singh et al. found that in one such setting, 10 percent of alerts for abnormal laboratory test results went unread by providers, and a large proportion of patients did not receive timely clinical follow-up. The investigators found similar results in an analysis of follow-up of alerts for abnormal imaging results.(111, 112) Their recommendations for communicating abnormal test results included requirements for policies that specify the ownership responsibility for each test ordered, clear policies on what results need to be communicated verbally, and fail-safe practices that close the loop.(113)

A useful risk mitigation tool is the *Test Results Reporting and Follow-Up SAFER Guide*, which identified recommended safety practices to optimize the safe use of processes and EHR technology for electronic communication and management of diagnostic test results. The SAFER Guide can help assess whether those aspects of the EHR associated with communication of diagnostic test results (and related processes) work as they should, are used correctly, and are designed and implemented to minimize the potential errors.(114)

3.3.7 Using Health IT to Find and Prevent Harm (Trigger Tools)

Interesting ways to use health IT to find and prevent harm from adverse events have recently been developed. Novel algorithms, often called “trigger tools,” extract data of interest from electronic records to identify cohorts of patients at risk. Singh et al. used an algorithm that identified patients admitted within 2 weeks of a primary visit to identify patients at risk for diagnostic error. The incidence of identified errors was 20 percent in this cohort versus 2 percent in randomly selected outpatients.(115) Similarly, Kanter and colleagues used electronic data to detect patients with red-flag conditions (for example, positive fecal occult blood, very elevated PSA levels) who did not have a scheduled follow-up visit. The intervention identified large numbers of such patients, and facilitated appropriate actions by their primary care providers.(116) The IHI Trigger Tool, developed by the Institute for Healthcare Improvement (IHI), has become the gold standard for detecting adverse events in health care settings; in one study, the IHI Trigger Tool found 10 times as many adverse safety events as were detected using the standard approaches based on incident reporting and related methods.(117)

3.4 Tools and Interventions to Avoid or Mitigate Risks Associated with the Use of Health IT or That Use Health IT to Make Care Safer

A review of available tools and interventions produced since the 2011 IOM report identified various resources supported by ONC and AHRQ as well as those developed by private sector stakeholders. We summarize many of the main tools and resources produced by Federal agencies, notably ONC and AHRQ, by industry associations, and by accreditation and patient safety organizations. Foremost among the many resources identified are the *SAFER Guides* produced under contract to the ONC, available at <https://www.healthit.gov/safer/>.

3.4.1 The SAFER Guides

The *SAFER Guides* include nine checklists, organized by topic, designed to help those adopting, implementing, or using health IT by describing best practices and providing the rationale for and guide to using these practices to mitigate risks. Checklists are grouped into three main categories: foundational guides, infrastructure guides, and clinical process guides. Within most checklists, best practices are grouped according to phases. Phase 1 is *Safe Health IT* and is intended to address safety concerns unique to EHR technology. Phase 2, *Using Health IT Safely*, is intended to optimize the safe use of EHRs. Phase 3 is *Monitoring Safety* and addresses best practices using EHRs to monitor and improve patient safety. **Table 1** provides a summary of each guide and its checklist.

Table 1. Summaries of SAFER Guide Checklists

Title of Guide	Checklist Summary	Topics Included
Foundational Guides		
<i>High Priority Practices SAFER Guide</i>	Identifies high-risk and high-priority recommended safety practices to optimize the safety and safe use of EHRs. It addresses at a high level the EHR safety concerns discussed in greater detail in the other eight SAFER Guides (http://www.healthit.gov/safer/guide/sg001).	<ul style="list-style-type: none"> ▪ Best practices for data and application backup ▪ Ensuring evidence-based order sets and charting templates are available ▪ Ensuring processes, procedures, and information required to accurately identify patients are in place

(continued)

Table 1. Summaries of Guide Checklists (continued)

Title of Guide	Checklist Summary	Topics Included
Foundational Guides (continued)		
<i>Organizational Responsibilities SAFER Guide</i>	Identifies individual and organizational responsibilities (activities, processes, and tasks) to optimize the safety and safe use of EHRs. This guide focuses on human behavior and relationships, and is organized by principles that apply to people responsible for patient safety rather than by the three phases used to organize other guides (http://www.healthit.gov/safer/guide/sg002).	<ul style="list-style-type: none"> ▪ Best practices for promoting a culture of safety ▪ Assigning responsibility for management of clinical decision support content ▪ Ensuring EHR training and support sufficient for the needs of EHR users
Infrastructure Guides		
<i>Contingency Planning SAFER Guide</i>	Identifies recommended safety practices for inevitable planned or unplanned EHR unavailability (http://www.healthit.gov/safer/guide/sg003).	<ul style="list-style-type: none"> ▪ Best practices to ensure electric generator and sufficient fuel are available to support EHR during extended power outage ▪ Paper forms available to replace key EHR functions during downtimes ▪ Staff are trained and tested on downtime and recovery procedures
<i>System Configuration SAFER Guide</i>	Identifies recommended safety practices for setting up EHR hardware and software (http://www.healthit.gov/safer/guide/sg004).	<ul style="list-style-type: none"> ▪ Best practices to ensure adequate number of EHR access points in all clinical areas ▪ EHR hosted safely in a physically and electronically secure manner ▪ Human-computer interface configured for optimal usability for different users and clinical contexts
<i>System Interfaces SAFER Guide</i>	Identifies recommended safety practices to optimize the safety and safe use of system-to-system interfaces between EHR-related software applications (http://www.healthit.gov/safer/guide/sg005). These practices address risks caused by the complexity of system integration.	<ul style="list-style-type: none"> ▪ Best practices to ensure EHR supports and uses standardized protocols for exchanging data with other systems ▪ System-to-system interfaces support the standard clinical vocabularies used by the connected applications ▪ Interfaces can transmit contextual information, such as units for measures or sources of information, to enable clinicians to properly interpret information

(continued)

Table 1. Summaries of Guide Checklists (continued)

Title of Guide	Checklist Summary	Topics Included
Clinical Process Guides		
<i>Patient Identification SAFER Guide</i>	Identifies recommended safety practices for identification of patients in the EHR, to ensure that the information presented by and entered into the EHR matches the correct person (http://www.healthit.gov/safer/guide/sg006).	<ul style="list-style-type: none"> ▪ Best practices to ensure enterprise-wide master patient index with patients’ demographic information, and medical record number(s) from different parts of same organization used to identify patients before importing data ▪ Clinicians’ ability to select patient records from electronically generated lists based on specific criteria ▪ Patients are registered using a centralized, common database using standardized procedures
<i>Computerized Provider Order Entry with Decision Support SAFER Guide</i>	Identifies recommended safety practices for CPOE and CDS. The implementation and use of CPOE with CDS is “complex and fragile, requiring careful planning, implementation, and maintenance to function properly” (http://www.healthit.gov/safer/guide/sg007).	<ul style="list-style-type: none"> ▪ Best practices to ensure evidence-based order sets are available in EHR for common tasks/conditions and are updated regularly ▪ EHR facilitates both cancellation and acknowledgment of receipt of orders for laboratory, radiology, and pharmacy ▪ Clinicians trained and tested on CPOE operations before being issued login credentials
<i>Test Results Reporting and Follow-Up SAFER Guide</i>	Identifies recommended safety practices to optimize the use of EHR technology for communicating and managing diagnostic test results (http://www.healthit.gov/safer/guide/sg008).	<ul style="list-style-type: none"> ▪ Best practices to ensure test names, values, and interpretations for laboratory results are stored in EHR as structured data using standardized nomenclature, predominantly text-based test reports (e.g., radiology or pathology reports) have a coded (e.g., abnormal/normal at a minimum) interpretation associated with them ▪ EHR can track status of all orders and related procedures (e.g., specimen received and collected or test completed, reported, and acknowledged)

(continued)

Table 1. Summaries of Guide Checklists (continued)

Title of Guide	Checklist Summary	Topics Included
Clinical Process Guides (continued)		
<i>Clinician Communication SAFER Guide</i>	Identifies recommended safety practices for communication between clinicians to optimize safe use of EHRs. Processes relating to clinician communication are complex and vulnerable to breakdown; breakdowns cause errors and create harm (http://www.healthit.gov/safer/guide/sg009).	<ul style="list-style-type: none"> ▪ Best practices to ensure urgent clinical information is delivered to clinicians promptly and delivery is recorded in EHR ▪ Policies and training facilitate appropriate use of messaging systems and limit unnecessary messaging ▪ EHR displays time-sensitive and time-critical information more prominently than less urgent information

3.4.2 Additional ONC Resources

ONC offers resources to help identify and mitigate risks of using health IT, detailed below.

- **How To Address Unsafe Conditions Associated with HIT.** Authored by ECRI and prepared by Westat under a task order contract with ONC, this guide provides foundational knowledge to health care organizations to help them develop rigorous processes to identify health IT hazards. It covers the following five areas:
 - Describes the many components of health IT systems and addresses their operation within a complex health care environment.
 - Identifies five common health IT problems that can occur within the context of this complex environment and contribute to the unsafe use of health IT systems, leading to potential and actual patient harm.
 - Examines the role of organization’s internal reporting systems to identify and address unsafe scenarios for health IT systems and to continually monitor health IT systems’ safety and make improvements.
 - Discusses the role of external reporting programs, such as PSOs, in helping to identify areas for health IT system improvements.

The guide is available at:

https://www.healthit.gov/sites/default/files/how_to_identify_and_address_unsafe_conditions_associated_with_health_it_2013.pdf

- **Guide to Reducing the Unintended Consequences of EHRs.** Found at <http://www.healthit.gov/unintended-consequences/>, this series of online modules represents a compilation of the known best practices for anticipating, avoiding, and addressing EHR-related unintended consequences and is intended to provide practical troubleshooting knowledge and resources for a wide range of stakeholders. To extend its utility, the developer invites users to revise tools as new systems and research findings emerge.
 - Module 1 defines and provides examples of unintended consequences.

- Module 2 provides tips and tools for avoiding unintended consequences for those selecting and implementing an EHR, including readiness assessment tools, tools for establishing and achieving organizational goals, tools for selecting an EHR, tools for assessing workflow, and a list of practices for avoiding unintended practices during implementation. Module 2 also provides tips and tools for those who have already implemented an EHR; for example, tools for identifying and assessing vulnerabilities, monitoring EHR usage, achieving meaningful use, conducting user surveys, and managing the system update process.
- Module 3 provides tools to help users understand and identify unintended consequences, including a template to establish and maintain an issues log.
- Module 4 provides tools for assessing and remediating unintended consequences after they have occurred, including a list of questions to help identify root causes, and templates for developing corrective actions and remediation plans. This module also includes tools for tracking the remediation process.
- The Appendix includes case examples, a glossary, and a compilation of all the tools provided in Modules 1 through 4.
- **ONC's SHARP C program**
 - SHARP C produced usability testing tools that cover system and user interface design principles and guidelines, test scenarios, and tutorials, and includes a detailed EHR style guide eBook. Found at <https://sbmi.uth.edu/nccd/SED/>.
 - The SHARP C research group also developed TURF, an integrated toolkit for usability evaluation, testing, measurement, and design of EHR systems. Developed to address the usability and workflow challenges of health IT, TURF provides rich data collection including audio, video, screen capture and keystroke events, and detailed evaluation templates. It allows users to generate reports following required formats. This resource is available at <https://sbmi.uth.edu/nccd/turf/>

3.4.3 AHRQ Resources

AHRQ offers tools and resources designed to help identify and mitigate risks associated with the use of health IT.

- **Health IT Hazard Manager.** The Health IT Hazard Manager, developed by researchers at Abt Associates and the Geisinger Health System, characterizes health IT hazards and identifies their potential and actual causality in adverse effects. The Hazard Manager was created to allow organizations adopting and using health IT systems to self-assess potential risks for known problems. The core of Hazard Manager 2.0 is a tab for Causation, where users can indicate the characteristics that contribute to a hazard. When combined with data from other Hazard Manager tabs, this information about hazard causes (poor usability, data quality, implementation issues, etc.) will support learning about:
 - The most common causes of health IT hazards, especially those with the potential to compromise care or harm patients.
 - How multicausal factors may combine to yield particularly dangerous hazards.
 - The relative contribution of causal factors that may be the responsibility of vendors to mitigate versus those that result from local implementation.

The beta version of the Hazard Manager Causation tab groups causal characteristics into eight categories:

1. Usability
2. Data quality
3. Software design
4. Clinical decision support
5. Implementation
6. Hardware
7. Other user characteristics
8. Other organizational characteristics

Developers envision deployment of the health IT Hazard Manager as part of a national infrastructure for monitoring and improving health IT safety.⁽⁸⁾ This resource is available at: <https://healthit.ahrq.gov/ahrq-funded-projects/health-information-technology-hazard-manager>.

- **Workflow assessment.** At <https://healthit.ahrq.gov/health-it-tools-and-resources/workflow-assessment-health-it-toolkit>, AHRQ offers a suite of tools to help those who plan, design, implement, and use health IT to understand and assess the impact of workflow on health IT use and potential patient safety implications. Tools include numerous examples and templates for benchmarking, preparing checklists, flowcharting, interviewing participants, and evaluating usability. The site includes nearly 100 tools categorized based on the following uses:
 - Data collection
 - Data display and organization
 - Idea generation
 - Problem solving
 - Process improvement
 - Process mapping
 - Project planning and management
 - Risk assessment
 - Statistical analysis
 - Task analysis
 - Usability
- **E-Prescribing toolsets.** AHRQ provides e-prescribing toolsets for implementations at physician offices and independent pharmacies at <https://healthit.ahrq.gov/health-it-tools-and-resources/implementation-toolsets-e-prescribing>. Tools for physicians are organized into 11 chapters and include, for example, tips and tools for assessing readiness, planning the implementation process, designing and managing effective workflows, and communicating with pharmacies and patients. Tools for independent pharmacies are organized into seven chapters and includes tools for answering patient questions, designing workflow and calculating cost and benefit for example.
- **Medication safety tools.** The Practice Partner Research Network conducted an AHRQ-funded primary care safety project to investigate decision support components in information systems that can help clinicians and staff improve medication safety. The authors identified 11 common strategies developed by practices to improve adherence with prescribing and monitoring indicators. Evidence-based tools, primarily tips and templates to enhance medication safety, are at: http://academicdepartments.musc.edu/PPRNet/Research/PPRNet_Medication_Safety_Toolkit.
- **EHR CPOE Flight Simulator.** The CPOE flight simulator funded by AHRQ, developed by Texas Medical Institute of Technology, endorsed by the NQF, and used by the Leapfrog Group, is intended to verify health IT system performance and identify patient safety hazards—weaknesses in system applications or their implementation—that may cause patient harm. CPOE consists of health IT-enabled safeguards such as treatment decisions supported by evidence-based clinical guidelines and adverse

drug reaction alerts. The flight simulator approach requires hospital staff to enter test patient data (age, gender, problem list, medications, allergies and test results) for 10 to 12 mock patients into the systems tested, then use those systems to order treatment sets known to contain errors. Hospital staff record alerts generated by their systems and enter them in the flight simulator web interface where they are compared with the known set of alerts that should have been generated. The tool then returns a score indicating the percentage of alerts missed, including medication errors and fatal errors. This information can alert providers to potential vulnerabilities and be used to improve system implementation, principally by “turning on” additional alerts, being careful to avoid overalerting or underalerting.(121)

3.4.4 HIMSS Library

HIMSS maintains a library that contains tools intended to enhance patient safety. Notable examples are described below.

- **Patient Identity Integrity Toolkit** provides resources that describe the many issues involved in reliably and safely matching patient identity across systems. Found at: <http://www.himss.org/library/healthcare-privacy-security/patient-identity>, the toolkit includes resources to improve understanding of patient identity integrity, interface protocols, and key performance indicators (KPIs) for patient identity management. Additional tools include:
 - Model Data Practices for Patient Identity Integrity,
 - Literature and Publications on Accurate Patient Records Matching,
 - Patient Identity Integrity Resources and References,
 - Patient Identity Integrity Glossary of Terms, and
 - Information for Executives.
- **EHR Usability Toolkit:** The *EMR Usability Evaluation Guide for Clinicians’ Practices* provides small, medium, and large ambulatory practices with sample clinical scenarios, test tasks, potential tasks, and benchmarking examples (<http://www.himss.org/ResourceLibrary/GenResourceDetail.aspx?ItemNumber=41486>). Also included is a sample patient safety checklist and a spreadsheet that maps the design principles to the clinical scenarios.
- **The EHR Association (EHRA) Developer Code of Conduct 3** defines principles to which member companies commit. Topics covered include accurate communication about functionality, patient safety, interoperability and data portability, clinical and billing documentation, privacy and security, and patient engagement. In particular, patient safety principles include:
 - using quality management systems;
 - using user-centered design methodologies, recognized standards, and guidelines;
 - participating with PSOs in reporting, review, and analyses of health IT-related patient safety events;
 - sharing best practices with customers;
 - notifying customers when software issue that could affect patient safety are identified; and,

- maintaining fair and reasonable intellectual property protections to keep from limiting customer discussions of patient safety issues.

3.4.5 The Joint Commission

The Joint Commission's Sentinel Event Alert #54 examines the sociotechnical factors that impact the safe use of health IT and suggests actions centered on safety culture, process improvement, and leadership (http://www.jointcommission.org/assets/1/18/SEA_54.pdf).

Safety culture recommendations emphasize three areas:

- A collective mindfulness focused on identifying, reporting, analyzing, and reducing health IT-related hazardous conditions, close calls, or errors.
- Comprehensive systematic analysis of each adverse event causing patient harm to determine if health IT contributed to the event.
- Shared involvement and responsibility for the safety of health IT among the health care organization, clinicians, and vendors/developers.

Process improvement recommendations for health care organizations include:

- Develop a proactive, methodical approach to health IT process improvement that includes assessing patient safety risks, and refer to the *SAFER Guides* checklists.
- Make the use of health IT by clinicians, staff and patients safe and appropriate.
- Use health IT to monitor and improve safety.
- Enlist multidisciplinary representation from leadership and support in providing leadership and oversight to health IT planning, implementation, and evaluation, particularly in workflow, systems selection, and change management.

3.4.6 ECRI Institute: Partnership for Health IT Patient Safety

Designed as a multistakeholder collaboration that began in 2013, this Partnership provides a common place where providers, health IT developers, PSOs, safety researchers, insurers, patient advocates, and others to gather, identify pressing health IT safety issues, and jointly develop solutions to those issues. The first issues include developing safe practices for copy-and-paste functions in EHRs and for patient identification in these systems. The Partnership convenes quarterly meetings and invites participants from the public and private sectors. In addition, it will offer public access to health IT safety solutions and best practices developed by the Partnership as these resources become available. To access the Partnership, go to: <https://www.ecri.org/resource-center/Pages/HITPartnership.aspx>.(123)

4. ANALYSIS AND RECOMMENDATIONS

The 2011 IOM report on *Health IT and Patient Safety* concluded that health IT safety emerges within a larger sociotechnical context, and that understanding that context was the key to improving the safe use of health IT, and the use of health IT to improve safety more

broadly.(1) The IOM report viewed health IT safety as a shared responsibility and called for public and private stakeholders to mount coordinated effort to identify solutions.

This report summarized major research evidence published in the years since the 2011 IOM report. The authors found substantial evidence for progress on key issues identified in the IOM report. New ways to describe the sociotechnical environment related to health IT were proposed, and these models have been applied effectively to understand the role of health IT in specific areas; for example:

- **Usability**—Research on usability methods and identification of safety-related usability issues took place before the IOM report and continued to be extensively explored after its publication. Concerns about the usability of health IT grew along with the rapid increase in EHR adoption fostered by the Medicare and Medicaid EHR Incentive Programs. Since the 2011 IOM report, several public and private sector efforts have produced recommendations for how to address usability issues and advance the science and practice of usability evaluation. A significant theme in these recommendations is that, while they differ on other points, they all endorse and encourage the commitment of resources to define and address usability issues. To improve health IT safety, usability should remain an active area of public policy consideration, research, and development.(124) Progress has been realized in the identification of usability-related priority issues, as well as in more specialized topics such as the adaptation of usability evaluation methods to help ensure the safe and effective use of mobile applications.
- **Interoperability**—Safety for health information exchange and interoperability has advanced on the basis of recommendations for developing standards, improved approaches to data verification and adjudication, and the work of initiatives such as the Medical Device “Plug-and-Play” Interoperability Program (MD PnP). Novel ways to use the power of electronic data to monitor quality and safety, to find patients at risk for harm, and to enable more effective communication are further examples of recent progress.

The authors of this report found substantial diversity in the priorities for improving health IT safety. This finding is not surprising, given the different perspectives of the authors, the heterogeneity of data sources, care settings, and IT systems examined, as well as the variation in the frameworks and models used for classifying events. What is consistent, however, is the depiction of health IT safety issues as sociotechnical phenomena that typically arise from the interplay of multiple, interrelated factors.

Using and improving health IT are complex endeavors. The recent evidence reviewed suggests that the challenge is actually becoming more complex, because clinicians continue to envision new ways in which health IT can be used to improve quality and safety, and each new functionality brings with it potential unintended consequences. The growing catalogue of tools and resources available to the health IT community will certainly be helpful moving forward, but ultimately progress will depend on the extent to which each of the stakeholders can meet the priorities set for them. Individual users need to continue innovating and be vigilant in detecting, reporting, and addressing new problems. Health

care organizations need to fully commit to the culture of safety necessary to implement and use health IT solutions safely, and health IT developers must address problems that emerge while incorporating features that promote safety and safe use.(125) National agencies need to continue their efforts to support research, share learning, and provide standards, resources, and guidance. Other stakeholders, such as researchers, PSOs, professional associations, and patient advocates, must continue to help identify health IT safety issues and collaborate on their resolution.

Two very recent efforts may prove useful in discerning the path forward. One is the *Health IT Safety Roadmap* (<http://www.healthitsafety.org>), which proposed a national collaborative for health IT safety that would provide “a trusted space where stakeholders could convene to review evidence and jointly develop solutions to critical health IT safety issues.” The main charge for this collaborative would be to use health IT to make care safer and to continuously improve the safety of health IT—efforts that would inevitably involve prioritizing next steps. The second recent effort is an NQF project that developed a set of recommendations about the measurement of health IT-related safety events. After convening a multistakeholder committee to provide input and direction, the NQF published a final report in February 2016 that presents a conceptual framework for analyzing measures of safety in health IT and identifies priority measurement areas.(14)

Many sources—the 2011 IOM report, private sector health IT safety initiatives, such as ECRI’s Partnership for Health IT Patient Safety, and the recent development of the health IT safety roadmap under ONC contract—have demonstrated that public and private sector stakeholders are increasingly committed to work together to identify the most pressing health IT safety issues and develop solutions to them. As the IOM report emphasized, progress will be realized to the extent that each of the stakeholders can become part of the solution, and attention is paid to each of the sociotechnical dimensions that determine the success of health IT in active use.

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**Appendix A:
Summary of Major Studies of Health IT Safety-Related
Evidence: 2012–2015**

Table A-1. Summary of Major Studies of Health IT Safety-Related Evidence: 2012–2015

Organization	Organization Type	Data Sources	Safety Reports Identified as Involving Health IT	Timeframe	Issues Identified	Citation and Link
The Joint Commission	Accreditation organization	Sentinel event data	Searched 3,375 sentinel event reports; 120 identified reports involving health IT	3.5 years; January 2010 to June 2013	<p>Because of sentinel event reports, all involved patient harm. Majority of health IT sentinel event types in 3 areas: medication error (29%); wrong site surgery (19%); and delay in treatment (12%).</p> <p>This study categorized health IT events using a sociotechnical model. Most common sociotechnical issue was with the user-computer interface (33%), followed by workflow and communication (24%), content (23%), organizational policies, procedure and culture (7%), personnel (6%), hardware and software (6%), measurement and monitoring (1%), and external rules & regulations (1%).</p>	<p>Castro GM. Investigations of Health IT-related Deaths, Serious Injuries, or Unsafe Conditions. The Joint Commission, 2014. Delivered in: The Role for the EHR in Patient Safety—What does the Evidence Tell Us? Health IT Safety Webinar Series. RTI International. December 2014. Available at: http://www.healthitsafety.org/education.html</p>
CRICO	Malpractice insurer	CRICO Comparative Benchmark System (malpractice claims)	Of 12,012 coded cases, 248 cases involved EHR-related factors	3 years; January 2012 through December 2014	<p>Ambulatory care was the leading site for these claims, and most commonly involved medications (31%), diagnosis (28%), or a complication of treatment (31%). Over 80% of cases involved moderate or severe harm. Although the etiologic factors spanned sociotechnical dimensions,</p>	<p>Graber M, Siegal D, Riah H, Johnston D. EHR-related events in medical malpractice claims. Office of the National Coordinator for Health Information Technology, 2014</p>

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Table A-1. Summary of Major Studies of Health IT Safety-Related Evidence: 2012–2015

Organization	Organization Type	Data Sources	Safety Reports Identified as Involving Health IT	Timeframe	Issues Identified	Citation and Link
(continued)					many recurring patterns were identified, such as risks from EHR conversions and updates, problems in copy-paste functionality and prepopulated data, and incorrect assumptions that the information in the EHR was always correct and up-to-date.	
University of New South Wales U.S. Food and Drug Administration (FDA)	University Federal government agency	FDA MAUDE database	Of 899,768 reports, 1100 involved health IT. After removing duplicate and unrelated reports, 678 reports describing 436 events remained	2.5 years; January 2008 to July 2010	Most problems reported (96%) were computer-related involving software issues; only 4 percent involved the machine-user interface. Authors attributed this atypical distribution to the type of reports submitted. Several new categories of error were found in reviewing these cases, expanding the author’s previous taxonomy to 36 categories. Four deaths were associated with the events noted in these reports.	Magrabi F, Ong M-S, Runciman W, Coiera E. Using FDA reports to inform a classification for health information technology safety problems. Journal of the American Medical Association : JAMIA. 2012;19(1):45–53. doi:10.1136/amiajnl-2011-000369. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3240763/

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Table A-1. Summary of Major Studies of Health IT Safety-Related Evidence: 2012–2015

Organization	Organization Type	Data Sources	Safety Reports Identified as Involving Health IT	Timeframe	Issues Identified	Citation and Link
ECRI Institute	Patient Safety Organization	ECRI Common Formats (modified AHRQ Common Formats)	171 health IT-related safety events submitted to ECRI PSO	9 weeks; April 2012 to June 2012	<p>This study found that methods for completing safety reports at the local level varied widely, hindering aggregation in many areas. Approximately 6% of events involved harm. Over half of the reports involved medication management systems.</p> <p>Using the sociotechnical categories of Magrabi et al., this study found that just over half of the report event types were computer-related, and just under 50% focused on the user or the user-computer interface. Common problems included wrong input (30 examples), system interface issues (33 examples), wrong record retrieval (23 examples), and software configuration problems (27 examples).</p>	ECRI Institute: ECRI Institute PSO Deep Dive: Health Information Technology. Plymouth Meeting, Pennsylvania, December 2012.
Department of Veterans Affairs (VA)	Federal agency	VA Informatics Patient Safety (IPS) Office Reporting System (only includes health IT events)	Of 344 reported safety incidents, 100 consecutive, unique, closed investigations involving EHRs	3 years, 10 months; August 2009 through May 2013	Seventy-four investigations involved unsafe technology and 25 involved unsafe use of technology. Using the eight-dimension sociotechnical model of Sittig and Singh, they found 70% of reports involved two or more sociotechnical dimensions, illustrating the	Meeks D, Smith M, Taylor L, Sittig D, Scott J, Singh H. An analysis of electronic health record-related patient safety concerns. JAMIA. 2014;21:105301059.

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Table A-1. Summary of Major Studies of Health IT Safety-Related Evidence: 2012–2015

Organization	Organization Type	Data Sources	Safety Reports Identified as Involving Health IT	Timeframe	Issues Identified	Citation and Link
(continued)					multiple sources of errors in almost every other type of safety investigation. Nontechnical dimensions (workflow, policies, and personnel) combined with technical dimensions (software/hardware, content, and user interface) to increase safety risks. Most errors resulted from unmet display needs, software changes or upgrades, system-to-system interfaces, and hidden dependencies.	Available at: https://psnet.ahrq.gov/resources/resource/28082/an-analysis-of-electronic-health-record-related-patient-safety-concerns
Westat University Health Consortium (UHC) ECRI Institute	Contract research organization Patient Safety Organizations	PSO databases: UHC’s Safety Intelligence database (modified AHRQ Common Formats—PSOs and non-PSOs)	UHC: Of 438,568 reported events, 20,758 (4.7%) initially indicated health IT involvement	UHC—2.5 years; January 2011 through June 2013	UHC: 60% of reported health IT events categorized as incidents, 14% as near misses, and 26% as unsafe conditions. The most common problems were communications among staff (40–42%), staff inattention (33–34%), data accuracy (21–23%), and data availability (10–12%). Medication-related health IT events were most common (about one-third), although more than half of the health IT-related events were categorized as “other”, making determination of clinical problems in these events difficult.	Mardon R, Olinger L, Szekendi M, Williams T, Sparnon E, Zimmer K. Health Information Technology Adverse Event Reporting: Analysis of Two Databases. Office of the National Coordinator for Health IT. Washington, DC. November 25, 2014.

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Table A-1. Summary of Major Studies of Health IT Safety-Related Evidence: 2012–2015

Organization	Organization Type	Data Sources	Safety Reports Identified as Involving Health IT	Timeframe	Issues Identified	Citation and Link
(continued)		ECRI Common Formats (modified AHRQ Common Formats—PSOs)	ECRI: Of the 13,640 reported events, 755 (5.5%) initially indicated health IT involvement	ECRI—4.5 years; October 2009 through March 2014	ECRI: Of the 755 reported health IT events, 513 (68%) were classified as incidents, 110 (15%) as near misses, and 132 (18%) as unsafe conditions. This study revealed that participating health care organizations did not consistently use the health IT designation in filing Common Format reports, hindering efforts to identify more health-IT related events. Conversely, closer review of reports designated as involving health IT found that about one third (in UHC data) did not involve it. Incidence and magnitude of harm could not be estimated.	Available at: https://www.healthit.gov/sites/default/files/Health_IT_PSO_Analysis_Final_Report_11-25-14.pdf
Carnegie Mellon University Pennsylvania Patient Safety Authority (PSA)	University State agency	Pennsylvania PSA data sets National health care data sets	1.7 million reported safety events across 9 event categories	8 years; January 2005 through December 2012	This analysis measured the impact of EHRs on reported safety events. Safety events declined by 27% after EHR implementation, including a 30% decline in medication error events and a 25% decline in reports on complications of treatment.	Hydari MZ, Telang R, Marella WM. Saving Patient Ryan—Can advanced electronic medical records make patient care safer 2014. Available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2503702 .

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Table A-1. Summary of Major Studies of Health IT Safety-Related Evidence: 2012–2015

Organization	Organization Type	Data Sources	Safety Reports Identified as Involving Health IT	Timeframe	Issues Identified	Citation and Link
Pennsylvania Patient Safety Authority	State agency	Pennsylvania—Patient Safety Reporting System (PA-PSRS)	3,099 EHR-related events	8 years; June 2004 through May 2012	<p>Identified 3,099 events classified these by harm score and event type.</p> <ul style="list-style-type: none"> ▪ 2,763 (89%) of events resulted in no harm ▪ 320 (15%) in unsafe conditions ▪ 15 (<1%) caused temporary harm ▪ 1 case resulted in significant harm <p>Majority of EHR-related errors were medication errors (2,516; 81%) related to dose (missed, over, under) or errors related to procedure/treatment/test (415; 13%), in particular laboratory test problems. Remaining events were classified as other/miscellaneous.</p>	<p>Sparnon E, Marella WM. The role of the electronic health record in patient safety events. Harrisburg, PA: Pennsylvania Patient Safety Authority; 2012. Available at: http://www.patientsafetyauthority.org/ADVISING/SORIES/AdvisoryLibrary/2012/Dec;9(4)/Pages/113.aspx</p>
Brigham and Women's Hospital Quantros	Academic research hospital Patient Safety Organization	United States Pharmacopeia MEDMARX database	Searched 1.04 million reports of medication-related errors; identified 63,040 problems related to computerized order entry (CPOE)	7 years, 4 months; January 2003 to April 2010	<p>In a sample of 10,060 CPOE-related cases, this study identified 21 recurring error types and tested 13 of them on 16 CPOE systems. None of the tested systems performed well; almost 80% of the potentially dangerous order types could be submitted</p>	<p>Schiff GD, Amato MG, Equale T, Boehne JJ, Wright A, Koppel R, et al. Computerized physician order entry-related medication errors: Analysis of reported errors and vulnerability testing of</p>

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Table A-1. Summary of Major Studies of Health IT Safety-Related Evidence: 2012–2015

Organization	Organization Type	Data Sources	Safety Reports Identified as Involving Health IT	Timeframe	Issues Identified	Citation and Link
(continued)					either easily (28%) or with minor workarounds with no warnings (28.3%).	current systems. BMJ Quality and Safety. 2015;24(4):264-71. Available at: http://qualitysafety.bmj.com/content/early/2015/01/16/bmjqs-2014-003555.full