Health Information Technology Adverse Event Reporting: Analysis of Two Databases

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Executive Summary

Fifteen years ago, the landmark report by the Institute of Medicine, *To Err is Human*, raised awareness that the primary cause of medical errors and injuries was a flawed medical care system rather than flawed individual providers. As a result, the comprehensive deployment of health information technology (IT) in the US health care system was promoted to eliminate medical errors and the cost of adverse events. While health IT has improved quality and safety in some ways, health IT can negatively affect patient care and safety if it is not designed, implemented, and used appropriately. The Patient Safety and Quality Improvement Act of 2005 (PSQIA) authorized the Agency for Healthcare Research and Quality (AHRQ) to develop Common Formats for patient adverse event reporting and to enable aggregation across healthcare organizations. Patient Safety Organizations (PSOs) can use these Common Formats in working with the provider community to understand, monitor and reduce safety events.

The purpose of this study was to answer several questions about the use of the Common Formats to capture information about health IT-related safety events, and to analyze both structured data and narrative descriptions of these events to better understand their patterns and impacts. The specific objectives of the study include:

1. To provide basic descriptive information about health IT-related events compared to non-health IT-related events using Common Formats structured data fields in areas such as event type, level of harm, preventability, patient demographics, and contributing factors.
2. To conduct a more in-depth analysis of the types of clinical events and processes involved in health IT-related events using PSO proprietary taxonomies.
3. To conduct a more in-depth analysis of the types and characteristics of health IT-related safety events based on manual review of event narratives.
4. To estimate the positive predictive value (PPV) and the negative predictive value (NPV) of the Common Formats structured data elements that indicate health IT involvement in a safety event relative to the information in the event narrative. The PPV is the percentage of events reported as health IT-related in the structured data, which are found actually to be health IT-related based on manual review of the event narrative. In contrast, the NPV is the percentage of events reported as <u>not</u> health IT-related in the structured data, which are found actually to be not health IT-related based on manual review of the event narrative.
5. To assess the overall sufficiency of the information in the structured data elements and in the event narratives for classifying and analyzing health IT-related safety events.

Westat collaborated with two large PSOs, UHC and the ECRI Institute, to conduct this analysis. In addition to collecting data elements from the Common Formats from participating providers, each of these PSOs collects additional data elements that allow for more detailed analysis. Both UHC and ECRI categorized the health IT-related events in their samples according to the data elements in the Common Formats, Version 1.2, as well in the Magrabi (2012) classification.

Findings

Objective 1: ECRI and UHC analyzed the structured data from the Common Formats in their reporting systems. In the ECRI database, only 4% of reported events had a response to the questions regarding health IT involvement in the event, thereby limiting analyses of reported adverse

events related to health IT. In the UHC PSO database, the Common Formats question indicating health IT involvement was answered approximately half the time, providing a larger set of records for analysis. Based on the analysis of Common Formats structured data in the UHC database, medication-related events were the most common health IT-related event type, accounting for about one-third of these events, although more than half of the health IT-related events were categorized in the "other" report category making it difficult to determine the clinical problem involved in these events from these data. About 60% of the events involving health IT were categorized as an incident (i.e., they reached a patient although they may not have resulted in harm to the patient), 14% as near miss event and 26% as an unsafe condition. The most common contributing factors to health IT-related events were communication among staff and team members (40-42%), staff inattention (33-34%), accuracy of the data (21-23%), and availability of data (10-12%). These factors were more frequently identified in health IT-related events than in events that were not health IT-related. Overall, incidents involving health IT were less likely to result in harm when compared to those events that were not health IT-related.

Objective 2: UHC used the coded data in its proprietary taxonomy to illuminate the types of events in the Other category. The largest subset of these events fell in the medical record or patient identification group. This includes patient identification issues and incomplete or incorrect chart or order entries. Other large groups include care coordination and communication issues and laboratory test issues. Infrastructure failures include information system problems leading to a lack of availability of IT systems.

Objective 3: The approach to the third objective relied on manual review of a sample of narrative descriptions of events that were coded as health IT-related in the Common Formats structured data. Clinical documentation systems, computerized provider order entry (CPOE), and laboratory information systems are among the types of IT most commonly involved in safety events. Health IT-related issues were common in the interfaces between different software components that make up health IT systems. Interface issues occurred between CPOE and other software such as the clinical documentation, laboratory, radiology, medication, and blood management information systems. Health IT-related errors occurred at nearly every stage of the care delivery process. Some were computer-related, while others relate to the human-computer interface as detailed in the report.

Objective 4: Based on the UHC analysis, the PPV of the health IT indicator in the Common Formats was 69 percent, indicating that over 30 percent of the events coded as health IT-related were not found to be health IT-related based on review of the event narrative. The NPV was nearly 99 percent, indicating that approximately 1.2 percent of the events coded as not health IT-related actually were health IT-related. Because a high percentage (95 percent) of the events were coded as not health IT-related, this suggests that approximately 25 percent of the actual cases may have been misclassified as not health IT-related. In summary, an estimated 31 percent of the events coded as health IT-related were not actually health IT-related, and over 25 percent of the events that actually were health IT-related were not coded as such.

Objective 5: The selection and number of cases analyzed in this study, combined with the thoroughness of the manual review and classification provide useful exploratory information about the nature of these events. Overall, the Common Formats structured data elements provide useful, but necessarily limited information on the nature of the event and its causes. The findings from this study show that the event narratives often provide additional details useful for classifying and analyzing these events, but the narratives do not provide all of the potentially relevant information.

The level of detail in the narratives may also vary due to the perspective of the adverse event reporter and their health IT background.

While the analysis demonstrated some value in the Common Formats structured data and event narratives with regard to understanding health IT-related events, there are important qualifications, many of which could apply to reporting of all adverse events. These include limitations of event reporting systems, limitations of voluntary systems, limitations of PSO implementation of the AHRQ Common Formats, limitations of event narratives, and the variety and non-standardization of event reporting systems. This study was not designed to explicitly evaluate the use of provider safety event reporting systems. However, the findings and our observations suggest several important implications, and the need for further research, related to standardized, large-scale safety event reporting and monitoring programs:

- There appears to be a great deal of variability in how the Common Formats are implemented across providers. Providers often choose to customize data collection screens so that only certain data elements are readily available for input, and definitions and coding options may vary from the Common Formats. Thus, it appears that often the Common Formats are not implemented as they were designed to be used.

- Some PSOs have legacy event reporting taxonomies and definitions that differ from the Common Formats. The interest and value in maintaining historical data series complicate efforts to revamp data collection systems.

- Many providers and PSOs appear to use data mapping techniques as a way to convert data elements collected in the historical manner to the Common Formats data elements. This mapping is technically complex, costly, unique for each provider, and inherently limited in effectiveness.

- The Common Formats, as a tool for collecting information on adverse events, are not uniformly incorporated into usual clinical workflows or into safety investigations. This variability in roles and expectations is an important cause of the variability in the data that are available.

- Providers face multiple and variable safety event reporting expectations including regulatory reporting to states and other jurisdictions, internal health system requirements, and the need for information to guide safety investigations within the facility, complicating efforts to collect uniform data on safety events to guide safety improvement efforts.

- The skill and training of the reporters who conduct adverse event investigations and complete the Common Formats questions may significantly affect the quality and variability in both the structured data and event narratives, especially related to identifying and describing the role of health IT.

As the pace of health IT adoption and use increases and matures, understanding its role in, and contribution to, patient safety events will support strategies to achieve the objectives of the Health Information Technology Patient Safety Action & Surveillance Plan -- to use health IT to make care safer and to continually improve the safety of health IT. AHRQ's Common Formats are intended to enable aggregation and analysis of adverse events across healthcare organizations, including those

in which health IT is a contributing factor. They are a potentially powerful tool for understanding and, therefore, improving quality and safety in healthcare. These analyses of the UHC and ECRI PSO databases point to challenges in implementing the AHRQ Common Formats, in particular with regard to health IT-related events. Additional research is required to understand the processes by which patient safety events are reported based on the Common Formats. Additional study will inform potential refinements to the AHRQ Common Formats and make it easier for providers to report patient safety events to PSOs. While the analyses of the UHC and ECRI data suggest that work must be done to make the Common Formats a more useful tool for aggregating and understanding adverse events in healthcare, they are necessary for learning across healthcare organizations about the complex factors, including the role of health IT, that contribute to patient safety.

Background and Purpose

Health IT and Patient Safety

Fifteen years ago, the landmark report by the Institute of Medicine, *To Err is Human*, raised awareness that the primary cause of medical errors and injuries was a flawed medical care system rather than flawed individual providers (Kohn, Corrigan, & Donaldson, 1999). As a result, the comprehensive deployment of health information technology (IT) in the US health care system was promoted to eliminate medical errors and the cost of adverse events (Kohn, Corrigan, & Donaldson, 1999; Bates & Gawande, 2003; Leape & Berwick, 2004). While health IT has improved care quality and safety in some ways, health IT can negatively affect patient care and safety if it is not designed, implemented, and used appropriately (Schneider et al., 2014; IOM, 2012).

The analyses of the ECRI and PSO databases described in this report were not designed to answer the question of whether adoption of health IT has improved safety and quality. However an earlier analysis by UHC of its database showed significant reductions of 25–35 percent in medication errors following the introduction of CPOE in seven organizations (Williams, Szekendi, Thomas 2013; UHC 2013). ECRI, which operates the Pennsylvania Patient Safety Authority's adverse event database, recently worked with researchers on a study which showed an overall reduction of adverse events by 27% and a reduction of medication errors by 30% after adoption of advanced electronic health records (Hydari, Telang, and Marella 2014). These studies and others provide increasingly strong evidence that health IT, especially advanced EHRs, have improved quality and safety, and provide a potentially powerful platform for far greater improvements in the future. The UHC and ECRI study findings presented in this report were designed, in part, to help PSOs, healthcare providers, EHR developers, and others understand how to better design, implement, and use health IT to make care safer and improve quality.

Integrating health IT into health care brings an additional layer of complexity to clinical encounters (IOM, 2012). The safety risks of health IT have been categorized by several notable researchers according to a sociotechnical framework with several dimensions, including: 1) the technology (hardware, software), 2) the people (clinicians, patients), 3) the clinical implementation (processes, workflow), and 4) organizational and external policies (IOM, 2012; Sittig, 2010). For example, three issues have commonly been identified as affecting health IT safety: sub-par user interface design; inefficient and suboptimal workflow design; and lack of interoperability preventing information from being used in a timely manner in medical decision making (IOM, 2012; McGowan et al., 2012).

Patient safety concerns often occur across several sociotechnical dimensions rather than in only one. For example, a human-related problem (e.g., data entry errors) may be compounded by technology-related problems (e.g., poor interface design), organizational factors (e.g., slow network), and clinical implementation (e.g., out of date software) (Meeks et al., 2014; Wallace et al., undated). Several concerns have impeded progress in health IT safety risk reduction including: lack of awareness of health IT patient safety risks, lack of risk assessment tools and metrics, lack of transparency by health IT vendors, and lack of collaboration and alignment of priorities across those charged with managing health risks, health IT, and quality (Schneider et al., 2014).

The PSQIA, PSOs, and Common Formats

The goal of the Patient Safety and Quality Improvement Act of 2005 (PSQIA) was to improve patient safety by encouraging voluntary and confidential reporting of events that adversely affect patients. The Act created Patient Safety Organizations (PSOs), a new type of entity, to help health care providers improve patient safety. By conferring privilege and confidentiality protections on providers who work with Federally-listed PSOs, the Act was intended to promote shared learning to enhance quality and safety nationally. The Agency for Healthcare Quality and Research (AHRQ) was given the responsibility for implementing and administering the provisions relating to PSO operations. The first PSOs were approved and listed by AHRQ in late 2008.

One key PSO activity is to collect information on adverse events. The PSQIA authorized AHRQ to develop Common Formats for reporting information on adverse events that the PSOs can use in working with the provider community. Using these Common Formats, health care providers can capture and send information on adverse events to PSOs in a standardized way, including incidents, near misses, and unsafe conditions, using common definitions and reporting formats. To develop the Common Formats, AHRQ reviewed existing patient safety event reporting systems from a variety of health care organizations, and released Version 1.0 for hospitals in September 2009. The Common Formats are designed with a modular structure; certain modules apply to all types of events and other modules collect detail about specific types of events (e.g., medication events, falls, pressure ulcers, device-related events). To allow valid aggregation and analysis across health care organizations, the Common Formats were designed to be the primary reporting language and tool for monitoring adverse events, although healthcare organizations were expected to use additional elements of special concern in their clinical setting. Use of the AHRQ Common Formats is voluntary; organizations are not required to use them. Following a public comment process, AHRQ release Version 1.1 of the Common Formats in March 2010. In Version 1.1, the Summary of Initial Report (SIR) Form included the question "Was health information technology (HIT) implicated in this event?", with the response choices Yes, No, and Unknown.

In conjunction with the Food and Drug Administration (FDA), the Office of the National Coordinator for Health Information Technology (ONC), and a workgroup of federal representatives with experience in patient safety monitoring, AHRQ revised the module for device-related events available in Common Formats Version 1.1 to include additional information on patient safety events related to health IT. The revised module, entitled Device or Medical/Surgical Supply including HIT Device (Version 1.2), was released in April 2012. A health IT device was defined as hardware or software that is used to electronically create, maintain, analyze, store, or receive information to aid in the diagnosis, cure, mitigation, treatment, or prevention of disease and that is not an integral part of an implantable device or an item of medical equipment. In Version 1.2 of this module, HIT device was added as a response option to the question "What type of device was involved in the event or unsafe condition?" If the

respondent answers Yes, then there are additional questions regarding the type of health IT device involved in the safety event. The Common Formats also have the capability to capture narrative descriptions of events for analysis by PSOs. In keeping with the voluntary nature of the program, PSOs had the flexibility to offer providers the use of Version 1.1 or Version 1.2 of the Common Formats. Thus information on health IT-related safety events was collected in different ways by different PSOs.

Objectives

The purpose of this study was to answer several questions about the use of the Common Formats to capture information about health IT-related safety events, and to analyze both structured data and narrative descriptions of these events to better understand their patterns and impacts. The specific objectives of the study include:

1. To provide basic descriptive information about health IT-related events compared to non-health IT-related events using Common Formats structured data fields in areas such as event type, level of harm, preventability, patient demographics, and contributing factors.
2. To conduct a more in-depth analysis of the types of clinical events and processes involved in health IT-related events using PSO proprietary taxonomies.
3. To conduct a more in-depth analysis of the types and characteristics of health IT-related safety events based on manual review of event narratives.
4. To estimate the positive predictive value and the negative predictive value of the Common Formats structured data elements that indicate health IT involvement in a safety event relative to the information in the event narrative.
5. To assess the overall sufficiency of the information in the structured data elements and in the event narratives for classifying and analyzing health IT-related safety events.

Methods

Data Sources

Westat collaborated with two large PSOs, UHC and the ECRI Institute to conduct this analysis. In addition to collecting data elements from the Common Formats from participating providers, each of these PSOs collects additional data elements that allow for more detailed analysis.

UHC, an alliance of 118 academic medical centers and 299 of their affiliated hospitals, represents the nation's leading academic medical centers. UHC's Safety Intelligence® database is one of the largest repositories of patient safety event data with almost 3 million event reports collected nationally since its inception in 2002. UHC Safety Intelligence® PSO was one of the first 10 AHRQ-listed PSOs. Currently, over 100 organizations submit adverse event data using the AHRQ Common Formats (since 2010) and UHC's proprietary taxonomy of over 400 patient safety event types. Of these participating organizations, 40 organizations in the United States were participating in the UHC Safety Intelligence® PSO at the time of this analysis, including academic medical centers, community and specialty hospitals, community health centers, group practices, and clinics. UHC integrated Common Formats Version 1.1 into its incident reporting tool in 2010. Organizations working with UHC have the option of making some Common Formats questions optional or removing certain questions. About 20 organizations in these datasets did not have the health IT question turned on at

the time of this analysis, so that data element is missing from data submitted by those organizations as described in the results for objective 1.

The ECRI Institute is a nonprofit applied science research organization that focuses on the assessment of procedures, devices, drugs, and health care processes involved in patient care. It is an AHRQ-designated Evidence-Based Practice Center as well as a listed PSO. The ECRI Institute PSO Reporting System is based on the AHRQ Common Formats and also incorporated the National Quality Forum's (NQF) serious reportable events. This system also includes some additional event types (e.g., Laboratory/Radiology, Security, Emergency Services) as well as other fields related to medical devices, contributing factors, and others. ECRI used Version 1.1 of the Common Formats through March 18, 2012. Starting on March 19, 2012, ECRI implemented Version 1.2 of the Common Formats, although the binary question regarding health IT involvement in a safety event from Version 1.1 continued to be available to providers using the ECRI reporting system. Thus all of those data elements were potentially available to reporting providers, although there was significant missing data as described in the results for objective 1.

Event Selection

For the analysis of the Common Formats structured data elements, UHC selected all reported events with an event date from January 1, 2011 through June 30, 2013. UHC has two databases for analysis—PSO and non-PSO organizations. The PSO database included approximately 450,000 events from 40 organizations that were members of the PSO, and the combined data that included a total of approximately 925,000 events from 81 organizations. This includes the 40 organizations in the PSO plus an additional 41 organizations that participate in the event reporting system, but are not members of the PSO.

For the manual review and classification of the event narratives, UHC selected events that had been coded as health IT-related in the PSO database in nine of the most common and relevant categories:

Event Category	Total health IT-tagged events in category	Sample size (# events reviewed)	Sample size as a % of total events.
1. Medication-related	3,206	300	9
2. Medical records/patient identifications†	1,224	300	25
3. Care coordination/communication†	1,036	300	29
4. Laboratory test†	1,036	300	29
5. Device/supply	306	300	98
6. Radiology/imaging†	242	242	100
7. Omissions/errors in diagnosis, assessment and monitoring†	218	218	100
8. Blood/Blood Product	151	151	100
9. Infrastructure failure†	149	149	100
Other Event Categories Reviewed*			
Falls	280	50	18
Surgery or anesthesia	196	50	25

†These event types were captured using UHC's proprietary taxonomy, but would map to "other" category in Common Formats.

*These were event types assumed to have a high rate of false tagging; therefore, a small sample was reviewed to ensure important information was not overlooked in these categories.

The event categories Medication-related, Device/supply, and Blood/Blood Product coincide with the Common Formats event categories. The others fall with the Common Formats "Other" event category. For event categories with less than 300 events, UHC manually reviewed the narrative for all of the events coded as health IT-related. For event categories with more than 300 events, UHC reviewed a random sample of 300 events. In addition, UHC reviewed a random sample of 50 health IT-related events in the Common Formats Surgery or Anesthesia category, plus 50 events in the Common Formats Fall category to ensure that important information was not overlooked in these categories, which were expected to have a low rate of actual health IT involvement.[1]

To address the question of false negative tagging of health IT events in the Common Formats, UHC selected a random sample of 500 events in which the answer was "no" to the question "Did this event involve health IT?" The random sample was derived from the same 9 categories listed above. To assist in rapidly identifying possible health IT-related events, UHC developed a list of health IT-related words or combinations of words, and then searched the narratives of the random sample of 500 events for these terms. The search words included: help desk, electronic medical record, EMR, electronic health record, EHR, CPOE, computer, alert, IT and help or assist, software, hardware, network, malware, upgrades, interface, system and down, downtime, wired, wireless, programming, corruption, internet, technology, information system, information exchange, HIE, E-prescribing, data, and override. UHC read the event narratives where there were matches on these terms to assess actual health IT involvement. Narratives that did not match on any of these terms were assumed to be correctly classified as not health IT-related.

The ECRI Common Formats structured data analysis included over 300,000 events in the PSO database with event dates from October 10, 2009 through March 29, 2014. To select records for manual review of the event narratives, ECRI identified a set of events likely to be health IT-related by searching the narratives for a series of terms that were likely to indicate health IT involvement. That search returned 10,717 event reports. ECRI narrowed down the list by filtering for events that contained the terms ('order' AND ('record' OR 'document')). This filter returned 1,202 unique events which were then manually reviewed.

Classification of Health IT-related Safety Events

Both UHC and ECRI categorized the health IT-related events in their samples according to the data elements in the Common Formats, Version 1.2, as well in the Magrabi (2012) classification. There is significant overlap between the two classification systems, as well as areas of difference. For example, both classifications include categories for the following concepts, although the level of detail in the available classification terms varies:

- Hardware or network failure or unavailability
- Software interface with device or other software
- Software design, configuration, or functionality
- Data output or display
- Data entry

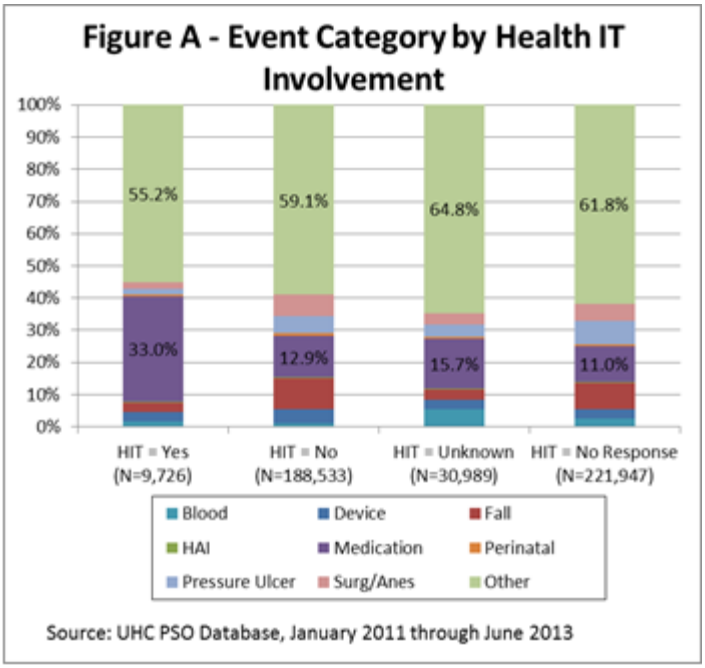
[1] The Common Formats also include event categories for Healthcare-associated Infections, Perinatal, and Pressure Ulcer. There were few events in these categories coded as health IT-related in the structured data. Therefore UHC did not conduct manual review on these event types.

The Common Formats include details not found in the Magrabi classification on software maintenance issues and the types of health IT systems involved in an event. Magrabi includes information on contributing factors related to human actions that are not found in the Common Formats. By using concepts from both classification systems to categorize the event narratives, the UHC and ECRI researchers were able to produce rich metadata for analysis.

Results

Objective 1 – Analyze Health IT Safety Event Structured Data

ECRI and UHC analyzed the structured data from the Common Formats in their reporting systems. In the ECRI database, in almost 96% of all events reported (n=299,241 out of 312,881), there was no response to the question, "Was Health IT implicated in the event?" Of the 13,640 reports that did include a response to the question, 10,280 (75%) indicated that health IT was not involved, 2,605 (19%) were unsure whether health IT had contributed to the event, and only 755 (5.5%) reports indicated that health IT did play a role in the event. Of the 755 reported health IT events, 513 (68%) were classified as incidents, 110 (15%) as near misses, and 132 (18%) as unsafe conditions. The low completion rate for the health IT questions limited the ability to conduct more in-depth analysis of these events.

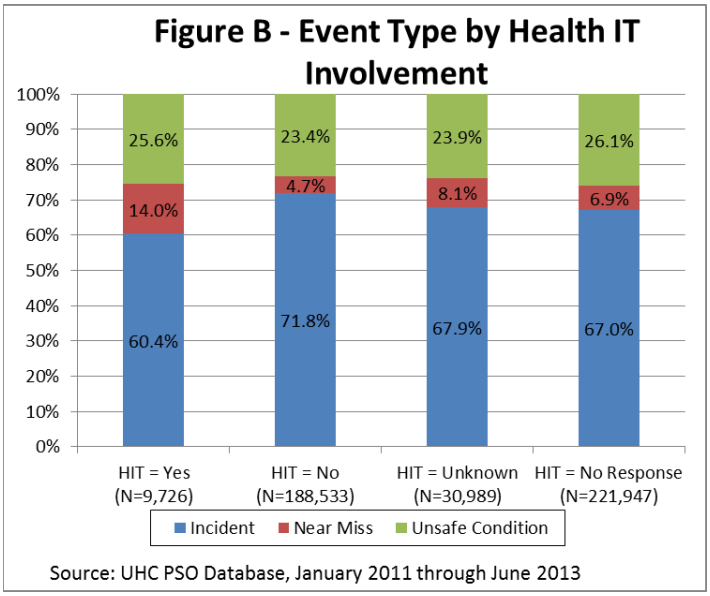


In the UHC PSO database, the Common Formats question indicating health IT involvement was answered approximately half the time, providing a larger set of records for analysis. Specifically, this question was answered for 229,248 events in the PSO data and for 438,568 events in the combined data. In the PSO data, 9,726 events involved health IT, representing 4.2% of events for which the health IT question was answered. In the combined data, 20,758 events involved health IT, representing 4.7% of the events for which the health IT question was answered. The rest of the results related to the analysis of structured data in this section are from the UHC data.

As shown on Figure A, about 55% of all events identified as health IT-related in the structured data were entered under the "other" report category, making it difficult to determine the clinical problem involved in these events from these data. Of the 9 Common Formats categories, medication-related events were by far the most common health IT-related event in the PSO data and in the combined data, accounting for 33% (n=3,206) and 36% (n=7501) of events respectively, more than double the percentage for non-health IT-related events. Devices and/or Medical/Surgical Supplies were involved in about 3% of health IT-related events in both UHC datasets (n=306, n=686). Patient falls accounted for about 3% of health IT-related events (n=280, n=641), surgery and anesthesia for about 2%, blood and blood

products for about 1-2%, and pressure ulcer for about 1%. The remaining event type categories accounted for less than 1% of health IT-related events.

Figure B shows that about 60% of the events involving health IT were categorized as an incident (i.e., they reached a patient although they may not have resulted in harm to the patient), 14% as near miss event and 26% as an unsafe condition in both UHC datasets. There was more near-miss reporting in health IT-related events compared to events that did not involve health IT. The categories of health IT-related events that were more likely to be incidents than near misses or unsafe conditions were blood/blood product events, medication events, and surgery/anesthesia events; whereas device/supply events less commonly reached the patient.



Health IT-related incidents and near misses by contributing factor

Contributing factors were identified in 4,522 health IT-related PSO reports (62% of incidents and near misses) and 10,105 health IT-related reports in the combined data (66% of incidents and near misses) as shown in Figure C. In both UHC databases contributing factors were identified for about five to six percent more health IT-related cases than for the non-health IT-related cases. The Common Formats do not collect contributing factors for unsafe conditions. The most common contributing factors to health IT-related events in both UHC datasets were communication among staff and team members (40-42%), staff inattention (33-34%), accuracy of the data (21-23%), and availability of data (10-12%). These factors were more frequently identified in health IT-related events than in events that were not health IT-related. Managers identified issues with data accuracy and availability approximately 5 times more often in health IT-related events. Communication among staff and inattention issues were about 1.5 times more common in health IT-related events.

Figure C - Leading Contributing Factors*

HIT-Related Events

- Communication Among Staff (40.0%)
- Inattention (33.8%)
- Data Accuracy (20.7%)
- Data Availability (11.7%)
- Data, Other (9.9%)
- Communication, Staff to Patient (9.5%)
- Physical Surroundings (9.4%)
- Equipment/Device Function (6.1%)

Non-HIT-Related Events

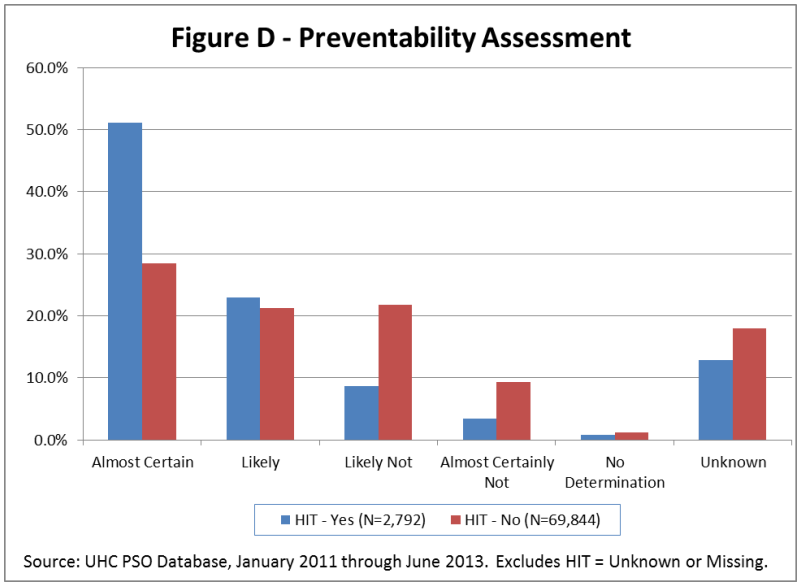
- Communication Among Staff (24.8%)
- Inattention (21.7%)
- Physical Surroundings (12.5%)
- Communication, Staff to Patient (9.3%)

*Percentages are based on cases where at least one contributing factor was identified. Percentages add to more than 100% since more than one factor may be identified per event.

Source: UHC PSO Database

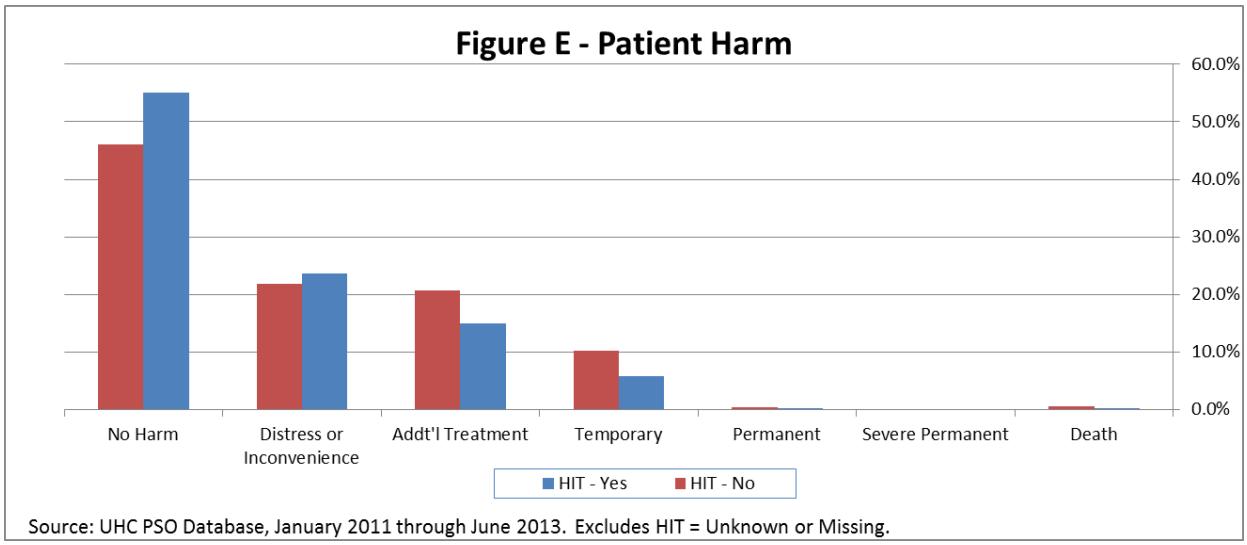
Health IT-related incidents by preventability

In the Common Formats, reporters of incidents are asked to assess the incidents' preventability. This question is not applicable to near misses or unsafe conditions. In both UHC datasets, health IT-related incidents were more commonly identified as almost certainly or likely to be preventable (74%-76%) compared to about 50%-54% of incidents that were not health IT-related as shown in Figure D. For more than half of incidents the preventability question was not answered.



Health IT-related incidents by AHRQ harm score v.1.1

In the Common Formats, reporters of incidents are asked to assess the harm to the patient based on a seven-level scale. Overall, incidents involving health IT were less likely to result in harm when compared to those events that were not health IT-related as indicated in Figure E. Events that were not health IT-related were about 1.5 times likely to be categorized as needing additional treatment or resulting in temporary harm. A difference was also seen in high harm events where 0.5-0.6% of health IT-related events resulted in permanent harm or death compared to 0.9%-1.0% of events that did not involve health IT, although the number of cases was small.



Health IT-tagged incidents by age group, gender, race, and ethnicity of patients involved

Patients 18-65 years old were most commonly involved in health IT-related event (54%-56%, as reflected in both UHC datasets), followed by mature adults age 65-74 years old (12%-13%), and

older adults age 75-84 years old (8%-9%). Neonates and infants were involved in about 6%-7% of events, followed by children age 1-12 years old (6%-5%). Little difference in the age distribution was noted in health IT-related events when compared to those that did not involve health IT, and the frequency of health IT-related events did not vary greatly by age group. The distribution of males (47%-48%) and females (50%-49%) affected by health IT-related events was similar to non-health IT-related events. The race (80%-83%) and ethnicity question (83%-84%) was commonly not answered in these event reports. Of the health IT-related incidents that had the patient's race identified, 76% were white and 22% were black or African American. No difference was seen compared to events that did not involve health IT.

Objective 2 - Categorize Events Coded as "Other" In the Common Formats

In the UHC analysis of the structured data in the PSO database described above, fully 55 percent of the events fell into the Common Formats Other category. One-third of these events fell into the Medication or Other Substance category. The remainder of the Common Formats categories accounted for 3 percent of the events or less. The large number of events in the Other category may be due in part to the design of the Common Formats event types around the impact, or potential impact, on patients. Some of the events in the Other category in this analysis may contribute to subsequent events that impact patients more directly and which are explicitly distinguished in the Common Formats.

To address objective 2, UHC used the coded data in its proprietary taxonomy to illuminate the types of events in the Other category. Table 1 provides a more detailed look at the distribution of the 5,370 health IT-related events in the Common Formats Other category based on the UHC taxonomy. The largest subset of these events fell in the medical record or patient identification group. This includes patient identification issues and incomplete or incorrect chart or order entries. Other large groups include care coordination and communication issues and laboratory test issues. Infrastructure failures include information system problems leading to a lack of availability of IT systems.

Table 1: Health IT-Related Events in the Common Formats "Other" Category, Classified According to the UHC Proprietary Taxonomy

UHC Proprietary Taxonomy Category	Number of Events
Medical records or patient identification issues	1,224
Care coordination/communication issues	1,036
Laboratory test issues	1,036
Radiology/imaging	242
Omission/errors in diagnosis	218
Infrastructure Failure	149
Behavioral	79
Food/Nutrition	53
Respiratory care	46
Other	531
All other events combined[2]	696

Source: UHC PSO Database

[2] All other event types with lower number of events (< 1%) tagged as health IT-related were combined.

Objective 3 – Understand Health IT-related Safety Events by Analyzing Event Narratives

Our approach to the third objective relied on manual review of a sample of narrative descriptions of events that were coded as health IT-related in the Common Formats structured data. This manual review allowed for a more complete coding of the aspects of the event related to health IT. ECRI and UHC independently classified and analyzed event narratives for a sample of events that involved health IT. The sample selection and event classification methods were similar, but also had important differences as described in the Methods section. Hence, we present the results for each PSO separately rather than aggregating or comparing the results.

ECRI analysts identified 671 events as health IT-related out of the total sample of 1,202. These events were then classified by the reviewers into both the Common Formats Version 1.2 health IT categories and the categories from the Magrabi (2012) based on the information in the event narrative. The results for the Common Formats are shown in Table 2. This table includes columns for the Medication or Other Substance and Laboratory Test/Radiology subsets as well as for the full set of 671 events. These were the only subcategories for which there were a sufficient number of health IT-related events for analysis. The most common EHR components involved in these events were CPOE, eMAR, and clinical documentation systems. Data entry or selection issues were the most common problem for all health IT reports, and for events related to medication-related processes and diagnostic services.

Table 2: Common Formats Classification of Health IT-Related Safety Events

Error Type	ALL health IT-related reports (N=671)	Medication or Other Substance (N= 307)	Laboratory Test/Radiology (N=104)
Involve medication/ substance	305	260	2
Type of health IT Device			
Component of Administration/ Billing			
Master Patient Index	5	1	
Registration/Scheduling	23	1	1
Coding/billing	0		
Unknown Administration/ Billing	0		
Other Administration/ Billing	0		
Automated dispensing	36	35	
EHR/Component of EHR			
CPOE	354	178	48
Pharmacy	75	68	
eMAR	194	167	2
Clinical documentation	211	50	33
CDS	0		
Unknown EHR	4	2	1
Other EHR	3	2	
User interface Device	0		
Lab Information System	40		23
Radiology/imaging/PACS	16		9
Other Component	22	3	14

Table 2: Common Formats Classification of Health IT-Related Safety Events, Continued

Error Type	ALL health IT-related reports (N=671)	Medication or Other Substance (N= 307)	Laboratory Test/Radiology (N=104)
Circumstances			
Incompatibility	8	4	
Equipment/ device function			
Loss or delay of data	23	9	4
Data does not match patient	32	7	6
Image measurement/ corruption issue	1		1
Image orientation incorrect	0		
Incorrect test results	5		3
Incorrect software programming calculation	1		
Incorrect/ inappropriate alert	3		
Other Equipment/device	3		1
Equipment/ device maintenance	0		
Hardware failure or problem	4	1	1
Network failure or problem	2		2
Ergonomics or User Interface Issues			
Hardware Location (e.g., awkward placement)	0		
Data entry or selection	434	212	70
Information display or presentation	14	5	
Alert/ alarm fatigue	0		
Other Ergonomics or User Interface	0		
Security virus or other malware issues	2		
Unexpected software design issue	8	7	
Unknown Circumstance	4	2	1
Other Circumstance	3	1	

Source: ECRI Institute PSO Database

The distribution of health IT-related events in the ECRI database according to the Magrabi classification is shown in Table 3. Commonly occurring categories include failure to communicate or carry out a task, missing data, failure to update data, and wrong input.

Table 3: Magrabi Classification of Health IT-Related Safety Events

Error Type	ALL health IT-related reports (N=671)	Medication or Other Substance (N= 307)	Laboratory Test/Radiology (N=104)
1.1 Data Capture Down or Unavailable	2		
1.2.1 Wrong input	125	50	18
1.2.1.1 Wrong input- Units Error	6	6	
1.2.1.2 Wrong input- Wrong fields	13	6	2
1.2.2 Missing Data- Entry	157	71	27
1.2.3 Fail to Update Data	153	77	18
1.2.4 Fail to communicate/carry out task	180	86	36
2.1 Network Down or slow	1		1
2.2 System Interface Issues	11	5	
3.1 Output device down or unavailable	2	1	
3.2 Record Unavailable	24	7	2
3.3 Output/display error	2	1	
3.4.1 Wrong record retrieved	21	7	3
3.4.2 Missing Data (did not look at complete record)	16	10	
3.4.3 Didn't look	19	9	1
3.4.4 Not Alerted	4	1	
3.4.5 Misread/misinterpret	10	4	1
4.1 Computer system down or too slow	9		2
4.2 Software Not Available	4	1	
4.3 Unable to Login	1		
4.4.1 Software issue- functionality	6	4	
4.4.2 Software issue- system configuration	15	7	3
4.4.2.1 Software issue- system configuration- Default	5	3	
4.4.3 Software issue- Device Interface	1		
4.4.4 Software issue- Network configuration	0		
4.5 Data Loss	6	1	2
5.1 Contributing factors- Staffing/training	9	4	2
5.2.1 Contributing Factor- Cognitive Load- Interruption	1		
5.2.2 Contributing Factor- Cognitive Load- Multi-tasking	1		1
5.3.1 Contributing Factor- Failure to carry out duty-Failure to log off	9	4	1
Contributing Factor- Paper vs EHR Mismatch	14	7	1

Source: ECRI Institute PSO Database

The UHC analysis identified the type(s) of health IT involved in each event. These results, shown on Table 4, indicate that clinical documentation systems in the EHR are the most frequently identified type of health IT involved in safety events (42.1 percent of events), followed by CPOE (30.0 percent), and laboratory information systems (10.2 percent), although there were a significant number of events associated with other types of health IT, including administrative IT associated with practice management, registration, and appointment/scheduling systems (9.5 percent). Health IT types indicated with a * are included in the Common Formats.

Table 4: Types of Health IT Involved in Safety Events

Type of Health IT Involved	Number of Events†
*Administrative - Master patient index	20
*Administrative - Practice management, Registration/appointment scheduling system	148
*Administrative - Other	0
*Automated Dispensing Machine	14
*Billing - Coding/billing system	3
Blood Management System	38
Cardiovascular Information System (CVIS)	4
*EHR - Clinical decision support system	8
*EHR - Clinical documentation system	657
*EHR - Computerized Prescriber Order Entry - Medication	171
*EHR - Computerized Prescriber Order Entry - Other	296
*EHR - Electronic medication administration record (eMAR)	83
EHR - Entire system	16
*EHR - Other	2
*EHR - Pharmacy system	45
*Human interface device (e.g., hardware, keyboard, mouse, touchscreen, speech recognition system, monitor/display, printer)	26
*Laboratory information system (LIS), including microbiology, and pathology systems	159
Operating Room Information System	6
*Radiology Information System (RIS), including picture archiving and communication system (PACS)	79
Total Health IT-related Events	1,559

Source: UHC PSO Database.

†More than one type of health IT could be identified in an event, so the total of the technology types is greater than the number of health IT-related events.

*Categories in the AHRQ Common Formats Version 1.2.

Similar to ECRI, UHC also applied codes from the Common Formats Version 1.2 and the Magrabi classification, as well as selected other codes suggested by the data. These results are shown in Table 5. Categories or subcategories indicated with (M) are from the Magrabi classification while those with a * are from the Common Formats. Results for the event-type subsets in the UHC sample such as medication, patient identification, care coordination, laboratory testing, radiology/imaging, and others were completed, but are not shown on the table.

Table 5: Classification of Health IT-Related Safety Events

Category	Subcategories	Total
Computer-Related		*1350*
(M) Data output/ display error (n=392, 25.1%)	Data not displaying/*Delay in receiving data/(M) Record unavailable	184
	Incomplete/incorrect display of order, treatment, medication, or procedure	104
	(M)*Loss of data	53
	*Incomplete/incorrect display test results	21
	Incomplete/incorrect display patient information or diagnosis	15
	*System returned or stored data that does not match patient	13
	*Image orientation/display of markers incorrect (flipped) or *image measurement/corruption issue	1
	Other output/display error	1
(M) Software functionality or configuration Issue (n=274, 17.6%	Does not function as intended, information inaccurate, or not updated	93
	(M) Alerts not programmed or clinical decision support inadequate	45
	Necessary fields/selections not available	40
	Order format inflexible	24
	*Incorrect software programming calculation / incorrect display of dosing information (e.g. dose rounding, incorrect unit of measure)	17
	Other functionality/configuration issue	12
	Change in order not connected to previous order (duplicate orders)	10
	Order/medication canceling ambiguity	10
	*Alert incorrect or inappropriate	8
	Procedure-linked medication/treatment issue (e.g. treatment not held before, resumed after or discontinued after procedure)	8
	Auto-product selection resulting in wrong product	4
	One time order remains on active list after completed	3
(M)*Issue in the interface between software (n=247, 15.8%)		247
(M) Computer/system/software down/unavailable/slow (n=187, 12%)		187
(M)*Issue in software interface with a device (n=169, 10.8%)	Bedside monitor (including remote monitoring)	58
	Bar code scanner	42
	Printer issues (Inconsistencies in printed version and display of data, delays, not printing, wrong printer)	37
	Point of care testing (e.g., glucose, lab tests, EKG)	26
	Other (e.g. IV pump)	6
(M)*Network failure/problem (n=31, 2.0%)	Failure/problem with wired or wireless	16
	Network issue, not specified	15
*Problem associated with maintenance or upgrades (n=24, 1.5%)		24
*Hardware failure/problem (n=22, 1.4%)		22
*Security, virus, or malware issue (n=4, 0.3%)		4

Table 5: Classification of Health IT-Related Safety Events, Continued

Category	Subcategories	Total
Human-Computer Interface		***1676***
(M)*Data entry/retrieval error (n=827, 53%)	*Entered for or retrieved from the wrong patient	246
	(M)*Data not entered/incompletely entered	166
	*Entry incorrect patient information(demographic/clinical) for correct patient	98
	*Entry incorrect medication, treatment or procedure for correct patient	96
	*Entry incorrect test or test results for correct patient	75
	Duplicate entry of patient accounts, orders, tests, or treatments	44
	Failure to update data or download data	43
	Entered in wrong place in record	23
	Deletion of information (e.g. orders for tests)	14
	Records unintentionally merged	7
	*Entry incorrect diagnosis for correct patient	7
	*Other incorrect entry for correct patient (e.g., wrong doctor, encounter)	8
Missed/overlooked information (n=199, 12.8%)	Orders	146
	Other clinical information	31
	Laboratory/test results	22
Did not review /seek out info in record (n=138, 8.8%)		138
(M)*Design of user interface/display of information/interpretation (n=56, 3.6%)		56
Access issue (e.g., unable to log in, multiple user issue) (n=39, 2.5%)		39
User ignored or overrode an alert (n=12, 0.7%)		12
Total Health IT-Related Events		**1559**

Source: UHC PSO Database.
*Categories in the AHRQ Common Formats Version 1.2.
(M) Categories in the Magrabi (2012) classification.
Note: An event can be assigned to more than one category, so the sum of the categories is more than the total number of events.

The narrative descriptions of events in UHC's data provided rich information about the types of computer-related and human-computer interface issues in HIT-related events and when health IT-related issues occurred in the course of care. Health IT-related errors occurred at nearly every stage of the care delivery process. For example, in the medication process, errors occurred during ordering, transcribing, dispensing, administration, and monitoring. In laboratory, blood, or radiology processes, errors occurred during ordering, collecting specimens or administering treatment or tests, and interpreting or reporting results.

Computer-Related

Data output or display errors were the most common computer-related issue found in the data, representing 25% of computer-related events reviewed. Almost 50% of these incidents involved data that did not display, delays in receiving data, or records that were unavailable. In device events, failures occurred in the transmission of data from bedside monitors and point of care testing to the clinical documentation system. Medication orders did not display in the pharmacy system or the electronic medication administration record (eMAR), and medication errors occurred when the eMAR was filtered by time and medications were not in the view. In laboratory events, orders did not cross over to the laboratory information system and results did not display in the clinical documentation system or the prescriber's basket. Radiology orders, images or reports did not display or were lost. Problems occurred in the display/availability of data (orders, other clinical information, or the entire record) during transitions in care between units and settings and when patients were

discharged in error. In about one-fourth of data display issues, information—mostly involving orders and treatment—displayed incompletely or incorrectly. Orders were missed by laboratory personnel when they combined with another order.

Functionality and configuration issues were found in 18% of computer-related events. The software program was not updated or accurate, did not have necessary fields, or did not function as intended in its design or integrate well into clinical workflow. Restrictions or dependencies programmed into the software resulted in the need for workarounds when the conditions were not met, for example, when medications were not administered on time and dropped from the eMAR. Upgrades or code changes led to unintended problems with previous configured functions. Serious but infrequently reported events involved incorrect calculations and unit of measure or dose rounding issues. Incorrect or inappropriate alerts were noted in some events; however, inadequate alerts or clinical decision support were found more commonly. Alerts or clinical decision support may have prevented errors when entries were incomplete, medication orders were expiring, dosing or weights were out of range, duplicate orders were entered, and treatment or tests were contraindicated.

In 12% of computer-related events the computer, system, or software was down/unavailable or slow. Staff concerns and/or frustration was apparent in some of the event descriptions when technology was down, unavailable, slow or they couldn't get access, because they were unable to access or enter information which impeded patient care.

Human-Computer Interface

Over 50% of the health IT-related reports related to the human-computer interface involved some type of human data entry or retrieval error. Errors mainly involved the incorrect entry of patient demographic or clinical information (e.g., weight, height, or medical history) or entry of the wrong medication, treatment, procedure or test, or test results. Entry errors frequently occurred when orders were entered, but also occurred in the administrative software during registration/scheduling. Other entry errors were associated with the creation of duplicate orders or patient records, which led to tests that were repeated unnecessarily, extra doses of medication, and historical clinical information that was unavailable or missed.

Despite national efforts, wrong patient errors were among the most common human-computer interface issue—described in 15% of all health IT-related events associated with the human-computer interface. Wrong patient errors were common in radiology- and laboratory-related events, and were reported more often in the emergency department and outpatient clinics. These errors occurred during encounters with clinicians, at the time of registration or appointment scheduling, or when orders or results were entered. The wrong patient often had the same or similar name or was a relative. Other factors contributing to entries into the wrong record include: clicking and bar code scanning errors, selecting the wrong record when two or more were open; failing to log off so that record remains open to the next user; hitting the wrong key (e.g. enter) on the keyboard causing advancement to another record; labeling errors; inattention; and distractions/interruptions. The vast majority could have been prevented by use of two patient identifiers, but this strategy has not been effective in eliminating human errors.

Health IT-related issues were common in the interfaces between software systems, involving 16% of all events. Interface issues occurred mainly between CPOE and other software such as the clinical documentation, laboratory, radiology, medication, and blood management information systems. Other human-computer interface errors occurred because staff missed, overlooked, did not review

or seek out information in the record. Sometimes, staff had difficulty interpreting information because of the design and display of information in the software. These issues were mainly described in the display of transfusion orders and the clinical documentation, medication in the e-MAR, and abnormal laboratory results, and when obtaining information for medication reconciliation. Another significant finding involved failures in communication between team members and departments when staff relied on the transmission of electronic data as the sole means of communication, highlighting the need for verbal communication in error-prone situations. Other factors that frequently contributed to health IT-related safety events involved lack of knowledge training, or experience, failure to carry out a necessary task, and staff inattention.

Objective 4 – Positive and Negative Predictive Values of Health IT Involvement Indicator

Objective 4 was to estimate the positive predictive value (PPV) and the negative predictive value (NPV) of the Common Formats structured data elements that indicate health IT involvement in a safety event relative to the information in the event narrative. These are measures of the consistency between the structured data and the event narrative regarding health IT involvement. The PPV is the percentage of events reported as health IT-related in the structured data, which are found actually to be health IT-related based on manual review of the event narrative. Of the 2,260 events in the UHC sample, all of which were reported as health IT-related in the structured data, UHC analysts categorized 1,559 of these as actually health IT related upon manual review of the event narrative. This yields a PPV of 1,559/2,260 = 69.0 percent.

In contrast, the NPV is the percentage of events reported as not health IT-related in the structured data, which are found actually to be not health IT-related based on manual review of the event narrative. To assess the NPV, UHC selected a random sample of 500 events coded as not health IT-related. To efficiently locate events in this sample that might be health IT-related, UHC first electronically searched the narrative to flag events where one or more of the words on the list in the Methods section appeared. Events for which none of these terms appeared in the narrative were assumed to be correctly classified as not health IT-related and were not reviewed further. The text search yielded 15 events where one or more of the terms appeared. These 15 events were manually reviewed to determine if they actually were health IT-related. Of these 15 events, 6 involved health IT based on manual review of the event narrative. Thus 6 out of 500, or 1.2 percent of the random sample, were falsely coded as "not HIT-related" for a negative predictive value of 494/500 = 98.8 percent. These misclassified events involved orders not displaying or displaying incorrectly in the software interface, inability to access the EHR, entry error involving the wrong patient, and downtime.

The PPV and NPV can be used to estimate the extent of incorrect health IT coding in the full database. Applying the estimates of the PPV and NPV to the UHC PSO database implies that out of 9,726 events coded as health IT-related, an estimated 69 percent, or approximately 6,700, were correctly coded as health IT-related. The remaining 3,000 events were coded incorrectly as health IT-related. Conversely, out of 188,533 events coded as not health IT-related, approximately 1.2 percent, or 2,260 events were likely actually health IT-related. This means that in the database there were an estimated 8,960 health IT-related events, 6,700 which were coded as health IT-related and 2,260 which were coded as not health IT-related. Thus 2,260 out of 8,960, or 25.2 percent, of the health IT-related events may have been incorrectly tagged as not health IT-related. In summary, an estimated 31 percent of the events coded as health IT-related were not actually health IT-related,

and over 25 percent of the events that actually were health IT-related were not coded as such. Thus there was a meaningful level of misclassification in both directions. The results suggest that there is significant room for improvement in implementation and use of Common Formats questions to identify whether health IT is involved in reported events.

This study did not explore the rate of actual health IT-involvement for the events coded as unknown health IT involvement, or the large number of events where the Common Formats health IT question was not answered.

Because of the low completion rate for the Common Formats health IT indicators in the ECRI sample, it was not possible to estimate their positive or negative predictive values from those data.

Discussion of Findings and PSO Analysis using Common Formats

This study provided rich information for assessing the use of the Common Formats for analysis of health IT-related safety events, understanding patterns of those events, and weighing the implications of the findings for safety event reporting system implementation.

Objective 5 - Sufficiency of Common Formats for Understanding Health IT-related Safety Events

The fifth objective of the study was to assess the overall sufficiency of the information in the Common Formats structured data elements and event narratives for classifying and analyzing health IT-related safety events. This analysis indicates that the answer is a qualified yes. Clearly, there are limitations to the data on health IT-related events collected by the UHC and ECRI PSOs to-date, as described below. In the ECRI data approximately 96 percent of the events had missing data regarding health IT involvement; and in the UHC data, approximately half of the events were missing this information. Furthermore, an estimated 31 percent of the events coded as health IT-related in the UHC data were not actually health IT-related, and over 25 percent of the events that actually were health IT-related were not coded as such. Thus there was a meaningful level of misclassification in both directions. UHC did not analyze the cases where health IT involvement was reported as unknown or where the health IT-involvement indicator was not reported at all, so the analysis does not address those cases. UHC and ECRI both have longstanding relationships with many providers, and proven track records of working with providers to analyze, understand, and address safety problems. The implications for safety event reporting system utilization that are suggested by this study likely affect other PSOs as well, perhaps even more strongly.

While the analysis demonstrated the value of the data in the Common Formats structured data and event narratives, there are important qualifications. These fall into several categories:

- **Limitations of event reporting systems** – Safety event reports are designed to provide timely information on safety problems as they are discovered, but they have inherent limitations related to the accuracy of the categorization of the event and the thoroughness and exactness of the information contained within the event report, including whether the root cause of the IT issue was identified. Staff entering the information at the time of the event may not be aware of the IT issue, and the cause may not have always been entered in the report once determined.

- **Limitations of voluntary systems** – The voluntary nature of the reporting to PSOs makes it impossible to assess the representativeness and comprehensiveness of the health-IT safety events included. In addition, the large number of events for which the health IT data fields were not completed further calls into question the representativeness of the data.

- **Limitations of PSO implementation of the AHRQ Common Formats** – Both UHC and ECRI had established event reporting systems that predate the development of the Common Formats. Like many PSOs, they adapted these systems to include some Common Formats data elements, and created data mappings to recode other data collected through established data elements into Common Formats data elements. However, these mappings do not necessarily create data comparable to what would have been collected with a full implementation of the Common Formats. Furthermore, many providers did not make all of the possible health IT-related data elements readily available to system users, likely accounting for the large amount of missing data.

- **Limitations of event narratives** – While providing information that in some ways is richer than structured data, event narratives also have important limitations. When health IT involvement is reported by the facility in the narrative, the narrative may not contain enough information to confirm health IT involvement or allow for further classification. Analysts noted a wide variety in the length and format of free text reports in the dataset. While some comprised a single sentence describing the event, others provided detailed discussion of the event and subsequent investigation. Because many narratives indicated human error (e.g., wrong entry) as opposed to machine error (e.g., system software problems), reporters may not suspect health IT involvement. End-users may need education and training on when to suspect health IT involvement. This will be a challenge for learning more about health IT safety using text-based analysis methods.

- **Variety and non-standardization of event reporting systems** - The organizations providing the event reports used a variety of EHRs and other software products. The findings in this study are not specific to any particular products and may not be generalizable across all software products.

Overall, the Common Formats structured data elements provide useful, but necessarily limited information on the nature of the event and its causes. The findings from this study, as described in the next section, show that the event narratives often provide additional details useful for classifying and analyzing these events, but even the narratives do not always provide all of the potentially relevant information. When the narrative indicated health IT involvement, reports may have indicated the type of system involved and the type of error involved, but did not contain information about the source of the error or potential mitigating strategies that could reduce the error in the future. This observation may uncover a natural limitation of end-user reporting: additional investigation or research may not have been completed at the time of reporting, and therefore information regarding the causes or mitigating strategies of health IT events will not be captured by end-user reports. This will be a challenge for learning more about health IT safety using text-based analysis methods.

Patterns of Health IT-related Safety Events

While the limitations described above are significant, the selection and number of case in the UHC analysis, combined with the thoroughness of the manual review and classification provide useful exploratory information about the nature of these events. Key findings regarding patterns of health IT-related safety events drawn from the UHC analysis of event narratives include:

1. Data output or display errors were common and most often involved data that did not display or were incomplete or incorrect. Problems occurred in the display/availability of data (orders, other clinical information, or the entire record) during transitions in care between units and settings and when patients were discharged in error.
2. Health IT-related errors occurred at nearly every stage of the care delivery process. For example, in the medication process, errors occurred during ordering, transcribing, dispensing, administration, and monitoring. In laboratory, blood, or radiology processes, errors occurred during ordering, collecting specimens or administering treatment or tests, and interpreting or reporting results.
3. In functionality and configuration issues, the software program was not updated or accurate, did not have necessary fields, or did not function as intended in its design or integrate well into clinical workflow.
4. About 50% of the reviewed health IT-related reports associated with the human computer interface involved some type of data entry error, most often involving the incorrect entry of information. Other entry errors of concern were associated with the creation of duplicate orders or patient records/accounts.
5. Despite national efforts to reduce wrong patient errors, this type of error was the most common human-computer interface issue—described in 15% of these health IT-related events.
6. Failures in communication between team members and departments occurred when staff relied on the transmission of electronic data as the sole means of communication, highlighting the need for verbal communication in error-prone situations.
7. Staff reported problems interpreting information because of the design and display of information in the software in transfusion-related events, e-MAR medication display, medication reconciliation, and laboratory results.
8. The results highlight the need for alerts or clinical decision support when entries are incomplete; information is missed; medication orders are expiring; duplicate orders for medications and tests are entered; weights are discrepant or out of range; doses are out of range; or when there are contraindications for treatment or tests.
9. Staff concerns and/or frustration was apparent in some of the event descriptions when technology was down, unavailable, slow or they couldn't get access, because they were unable to access or enter information which impeded patient care.

ECRI did not have sufficient structured data on health IT-involvement for analysis. The reasons that may be responsible for low completion of this data element in PSO reporting systems are described in the next section on reporting system utilization and implications for event reporting. The sampling for the ECRI analysis was not designed to support inferences about the patterns of health IT-related safety events. It was designed as a methodological study to address the sufficiency of the data to support analysis. Thus we do not present a discussion of the patterns of health IT-related safety events from those data.

Reporting System Utilization and Implications for Safety Event Monitoring

This study was not designed to explicitly evaluate the use of provider safety event reporting systems. However, the study findings and our observations about how the patient safety events are reported using the Common Formats suggest several important implications and the need for further research (and potential pilot testing) for refinements to standardized, large-scale safety event reporting and monitoring programs. Some of these issues, described below, concern health IT-related events specifically, while others apply more broadly to other types of safety events.

1. While the AHRQ Common Formats were designed as a uniform reporting tool for safety improvement and monitoring, there appears to be a great deal of variability in how the Common Formats are implemented across providers. At many providers, the Common Formats are added to existing EHR or event reporting software systems after the fact, and tailored to accommodate local priorities and preferences. Providers often choose to customize data collection screens so that only certain data elements are readily available for input, and definitions and coding options may vary from the Common Formats. While this affects all types of safety events, events related to health IT may be particularly affected due to lower awareness of their impact and importance. PSOs are a resource for helping providers incorporate Common Formats data elements more uniformly, but have limited ability to influence local system design decisions.
2. In addition to variability in provider systems, some PSOs have legacy event reporting taxonomies and definitions that differ from the Common Formats. The interest and value in maintaining historical data series complicate efforts to revamp data collection systems and processes to incorporate the aspects of the Common Formats that vary from these historical approaches.
3. Given the use of legacy software systems and tools for collecting safety event reports, many providers and PSOs use data mapping techniques as a way to convert data elements collected in the historical manner to the Common Formats data elements. This mapping is technically complex, costly, unique to each provider, and inherently limited in effectiveness. It is difficult to assess the impact of mapping on the data that are available for analysis, but it is clear that they differ from what would be collected through a de novo Common Formats reporting approach.
4. Adverse event reporting using the Common Formats is not uniformly incorporated into usual clinical workflows. Each facility develops its own approach relative to the staff which gathers and enters information about safety events, and at what point in time. This variability in roles and expectations may be an important factor in the variability of data availability, and likely affects data reliability in ways that are difficult to assess.
5. Providers face multiple and variable safety event reporting expectations including regulatory reporting to states and other jurisdictions, internal health system requirements, and the need for information to guide safety investigations within the facility. Often these requirements arise independently and are not aligned with each other or with the structure of the Common Formats. In the ideal world, the data would be collected once and used to satisfy all of the multiple regulatory, quality improvement, and analytic needs for the data. In the real world, reporting to the PSOs using the Common Formats is often limited because of its voluntary nature and the importance of other requirements.
6. The quality and consistency of adverse event reporting using the Common Formats (or any other reporting system) depends on the training and skill of the front line reporters and the staff who conduct follow-up investigations. For health IT-related events, in particular, the clinical

staff who frequently have the responsibility for reporting and investigations may need additional training and IT support.

As the pace of health IT adoption and use increases and matures, understanding its role in, and contribution to, patient safety events will support strategies to achieve the objectives of the Health Information Technology Patient Safety Action & Surveillance Plan -- to use health IT to make care safer and to continually improve the safety of health IT. AHRQ's Common Formats are intended to enable aggregation and analysis of adverse events across healthcare organizations, including those in which health IT is a contributing factor. They are a potentially powerful tool for understanding and, therefore, improving quality and safety in healthcare. These analyses of the UHC and ECRI PSO databases point to challenges in implementing the AHRQ Common Formats, in particular with regard to health IT-related events. Additional research is required to understand the processes by which patient safety events are reported based on the Common Formats. Additional study will inform potential refinements to the AHRQ Common Formats and make it easier for providers to report patient safety events to PSOs. While the analyses of the UHC and ECRI data suggest that work must be done to make the Common Formats a more useful tool for aggregating and understanding adverse events in healthcare, they are necessary for learning across healthcare organizations about the complex factors, including the role of health IT, that contribute to patient safety.

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