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# Challenges and Opportunities of Patient Safety Event Reporting

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**Abstract.** The World Health Organization (WHO) announced the first-ever World Patient Safety Day on September 17, 2019, which remarks a global campaign to create an awareness of patient safety and urges people to show their commitment to making healthcare safer. Reporting medical incidents or patient safety events (PSE) has been recommended as an effective approach for the detection of patterns, discovery of underlying factors, and generation of solutions. It is believed that PSE reporting systems (e-reporting) could be a good resource to share and to learn from the reporting if the event data are collected in a properly structured format. Unfortunately, the prevalence of underreporting and low quality of the reports have become barriers to ultimately achieve the goal of preventing and reducing medical incidents. This chapter describes the efforts that have been made to improve e-reporting through informatics approaches, including a review of PSE taxonomies and conceptual frameworks, studies of medication events, patient falls, and PSE involved in health information technologies, as well as discussions of design requirements for future e-reporting systems.

**Keywords.** patient safety, event reporting, healthcare quality

## 1. Why Patient Safety Event Reporting?

Medical error is one of the leading causes of death in the US [1] and many other countries in the world [2]. The reduction of medical errors and patient safety events has become a major concern in healthcare today [3–5]. It is believed that patient safety event reporting (e-reporting) systems could be a good resource to share and to learn from the errors. When the event data are collected in a properly structured format, the reports could be useful for the detection of patterns, discovery of underlying factors, and generation of solutions [6,7]. Effectively gathering information from previous lessons and timely informing the subsequent action are the two major goals for the design, development, and utilization of such a system [8].

To achieve the goal of preventing and reducing medical errors, e-reporting systems should be secure, easy to use, and effective [9], that is, confidential or anonymous, with excellent user acceptance, and used in a meaningful way. Being able to facilitate learning from past mistakes is critical to e-reporting systems to eventually decrease recurring incidents. Unfortunately, common issues of e-reporting mainly focus on underreporting and low-quality reporting. The quality of voluntary reports is just as significant as the

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number of submissions [10].

## 2. Barriers of Event Reporting

Lack of instructions and training in event reporting, event analysis, and use of reporting systems undermines the motivation of reporters, accounting for under-reporting and low-quality [11].

At the organization level, the culture of blame and resistance to sharing have been identified as barriers to e-reporting [12]. Likewise, the management policy on mandatory and non-confidential reporting of medical incidents, in fact, discourages front-line clinicians from reporting internally [13]. Last, but not least, the psychological stress that healthcare staff experience while discussing mistakes with their supervising managers, such as fear of embarrassment and loss of reputation or job [11,12], should not be ignored.

At the technology level, current e-reporting systems were not built based on a consensus of conceptual frameworks. In some cases, underreporting can occur just as a result of reporters unable to identify a proper classification or definition[10]. Several medical incidents, patient safety event taxonomies, or conceptual frameworks are available for the development of e-reporting systems [14]. Unfortunately, in practice, so many taxonomies that lack consistency may impede the interoperability among different e-reporting systems at a larger scope. Selecting "other" or "miscellaneous" as an incident category is a common problem and posed barriers for computerized analysis [10]. Classification and definition used in e-reporting systems play a key role in assuring the quality of reports and may even determine whether an event is recognized or ignored [15,16].

Furthermore, existing e-reporting systems are mainly template-based, with a combination of open-ended and structured questions, aimed at maximizing the consistency and minimizing the variation in the level of details. Inevitably, it may have the unintended effect of homogenizing incident descriptions with a loss of details [8]. As a result, most e-reporting systems cannot synthesize incident data to generate actionable knowledge [10], [12,17]. In our systematic review of peer-reviewed publications and publicly accessible web pages, none of the reviewed reporting systems have any features that facilitate learning from mistakes or provide actionable feedback to reporters [8]. Despite numerous studies suggest instituting a "just culture" that encourages learning, non-punishment, few studies have investigated system difficulty and inefficiency regarding ease of use, ease of understanding, and their relations with the level of details in reporting [11] and it is rare to find research investigating data-driven learning features in e-reporting[17][18][19].

### *2.1. Learning Purpose of Event Reporting*

Since 2000, numerous e-reporting systems have been developed based on the recommendations from the IOM's report. Nevertheless, most of the systems just function as a primary data repository of the reported events with little or extremely limited evidence to show that event reporting can improve patient safety, and how much influence it can make remains unclear [20]. Therefore, learning from errors is still an intuitive way to avoid the recurrence of errors. Root cause analysis (RCA) cannot be carried out unless an occurrence of safety events has been reported in detail, based on which further actions of improvement will become possible.

Studies on e-reporting systems have been limited and fragmented. Most of them were based on qualitative studies [21][22][23]. Thus, it has been equivocal regarding how to build an effective event reporting system to assist in overcoming the technical barriers and achieving the expected learning effect. The barriers identified are worth an extensive discussion so that timely knowledge support could be offered and reporting motivation could be enhanced [24]. In addition, it has been unclear in terms of long-term evaluation strategies based on the event reporting systems, triggering the uncertainty about the real effect of the systems. There have been questions regarding how to mitigate or resolve these issues, and accordingly, design a set of learning-oriented and user-centered features to enhance reporting motivation.

### *2.2. Design Features of E-reporting Systems*

A systematic review of reporting systems introduced the systems implemented between the years 2000-2011 in healthcare institutions across the world, including the United States, Netherlands, Canada, United Kingdom, Germany, Australia, China, and Japan. The use of e-reporting systems was not limited to a particular clinical area. For example, some of them focus on general patient safety events and some others focus on specific areas, such as anesthesia events and radiation oncology events. The system design features were identified as 'widgets', i.e. drop-down lists, checkboxes, or radio buttons used to replace plain text input for users' convenience when appropriate, other features include 'anonymity or confidentiality', 'validator', 'reference', 'review notification', and 'hierarchy'[8]. Similar to the evolvement of paper charts to electronic health records (EHR), the features show a trend of the advancement of user-centered design. The designs in the early stages (stages 0–2) simply transformed paper forms into e-forms where the features ensuring data quality (stages 3–6) were not pervasive. It was found that 12 out of all 48 (25%) identified e-reporting systems were actually electronic copies of paper-based reporting forms rather than interactive systems.

### *2.3. Data Quality of E-reporting Systems*

Data quality in general regarding accuracy, completeness, and timeliness has been the main concern in event reporting, meaning flaws in terms of functionality and usability that could be treated per the user-centered perspectives. Data quality in an e-reporting system is defined as a multidimensional concept, including accuracy, completeness, and timeliness. We define the three data quality dimensions as follows:

- Accuracy: the degree of proximity of a given patient safety event report to corresponding real-world occurrences. The reporting accuracy is subject to user errors and cognitive limitations in memory and reasoning, including but not limited to typographical errors, memory decay, causal attribution, and hindsight biases. The accuracy of e-reporting could be improved if these contributing factors are incorporated into design considerations with good usability and functionality.
- Completeness*:* the degree to which a given patient safety event report includes necessary information describing the corresponding real-world event to be sufficiently valid for the purpose of analysis and generation of intervention. The completeness could be enhanced if its criteria are explicitly delineated and properly represented to the reporters with the help of interface features.

- Timeliness: the degree to which a patient safety event is reported on time for root cause analysis and the generation of real-time intervention. The timeliness could be enhanced by improving the efficiency of the reporting process and offering a smooth review process to generate actionable knowledge.

The quality and rate of event reporting can be greatly affected by the user interface associated with human factors [10,25]. It was argued that an effective design of e-reporting systems should support the social-cognitive process of potential reporters [16,26], meaning e-reporting systems should guide a reporter to go through the reporting details step-by-step without costing additional time and efforts. A well-designed system tends to generate data of high quality. Likewise, a well-designed e-reporting system could serve as a facilitator to enhance data quality for understanding and trending the data about patient safety events. Unfortunately, by far, the design features of e-reporting systems have been addressed in a fragmented way across studies.

## 3. Taxonomy for Event Reporting

Despite the potential of e-reporting systems, narrative reports are severely under-utilized. The current classifications for event reporting are difficult for reporters to understand and utilize, which constrains the quality of reports and may result in misleading and wrong information in the reports. Moreover, the high workload of clinical duties, also known as competing priorities, spares less time for clinicians to complete reports of high quality. Last but not the least, e-reporting systems do not provide timely feedback to reporters as a regular system function, such as process of reporting, analysis of the cases, and recommended interventions [11,24].

Taxonomies, classifications, and terminologies can be used to determine the spectrum of data elements. The International Classification for Patient Safety (ICPS) [27] of the WHO and the Common Formats of the Agency of Healthcare Research and Quality (AHRQ) [6] provide widely accepted concepts, terms, and frameworks for patient safety. The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) [28] developed a comprehensive Taxonomy of Medication Errors which defines terms with high granularity in all dimensions of medication errors. These medication error reporting tools serve as trustworthy resources for the determination of necessary data elements and the construction of the model for narrative reports.

Similar to the role of the International Classification of Diseases (ICD) in EHR systems, a taxonomy for event reporting plays an important role in terms of event analysis, data integration, data quality assessment, data quality improvement, and shared learning. In our preliminary project, we reference to the prevailing patient safety taxonomies that support event reporting in broad scopes:

- The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) [28];
- The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Patient Safety Event Taxonomy (PSET) [29];
- a Preliminary Taxonomy of medical errors in Family Practice (PTFP) [30];
- Cognitive Taxonomy of Medical Errors (COG) [31];

- Taxonomy of Medical Errors for Neonatal Intensive Care (NIC) [32];
- Pediatric Patient Safety taxonomy (PED) [33];
- Taxonomy of Nursing Errors (TNE) [34];
- The FDA Safety Information and Adverse Event Reporting Program the FDA's medical product safety reporting program for health professionals, patients and consumers (MedWatch) [35];
- International Classification for Patient Safety (ICPS) [27];
- AHRQ Common Formats [6].

The creation and development of the taxonomies can be guided by the strategies of top-down, adopting focus groups, expert panel discussion, or Delphi method, etc., and by the strategies of bottom-up, employing case analysis, inductive reasoning[29] which can be assisted by natural language processing and machine learning technologies.

A variety of taxonomies have been employed in homegrown or commercialized e-reporting systems. The taxonomies have the advantageous features for offering categorical information on reporter interface, prioritizing or trending events per pre-defined categories. Over the years, issues of taxonomy application in e-reporting systems have drawn the attention of researchers.

- Low utilization of taxonomies from reporters who often choose "other" or "miscellaneous" as a confident classification;
- Lack of unified taxonomy to cover various domains and aspects of patient safety events in large healthcare organizations, which leads to poor interoperability;
- Appending categories or subcategories to an established taxonomy per unsystematic approach often resulted in overlaps between categories, redundant subcategories, and reporters' confusion that can exacerbate the low utilization of taxonomies;
- Taxonomies are not well integrated with e-reporting systems and analysis, upgrading homegrown e-reporting systems poses challenges in adopting a new taxonomy without losing connection to the old one, merging entire events for trending and learning purposes.

Therefore, a compatible taxonomy could help solve the problems that currently pose barriers to data integration, system interoperability, and transition from data repositories to intelligent systems [36]. To overcome the barriers and improve the quality of reports, researchers have developed an ontology for e-reporting based on the WHO ICPS and AHRQ Common Formats, which helps user-centered design by providing data entry support as well as feedback upon reporting to ensure data quality [37].

### *3.1. Evolution of Patient Safety Taxonomies*

There is a long-standing need for controlled language for patient safety. The Australian Patient Safety Foundation (APSF) originally reported the Australian Incident Monitoring System in 1987. Later, in 1993 and 2000, respectively, APSF expanded the system twice [38]. As shown in figure 1, a cognitive taxonomy was developed in 2004 to categorize major types of human error contributing to medical errors [31]. Other taxonomies or standards such as JACHO patient safety event taxonomy [29], national coordinating council for medication error reporting and prevention (NCC MERP)'s taxonomy of medication errors [28], neonatal intensive care system (NIC) [39], pediatric patient safety taxonomy (PED) [33], preliminary taxonomy of medical errors in family practice (PTFP)[30], a taxonomy of nursing errors (TNE) [34], adverse event reporting ontology

(AERO) [40], and the ontology of adverse events (OAE) [41] shared insights in several specific domains.

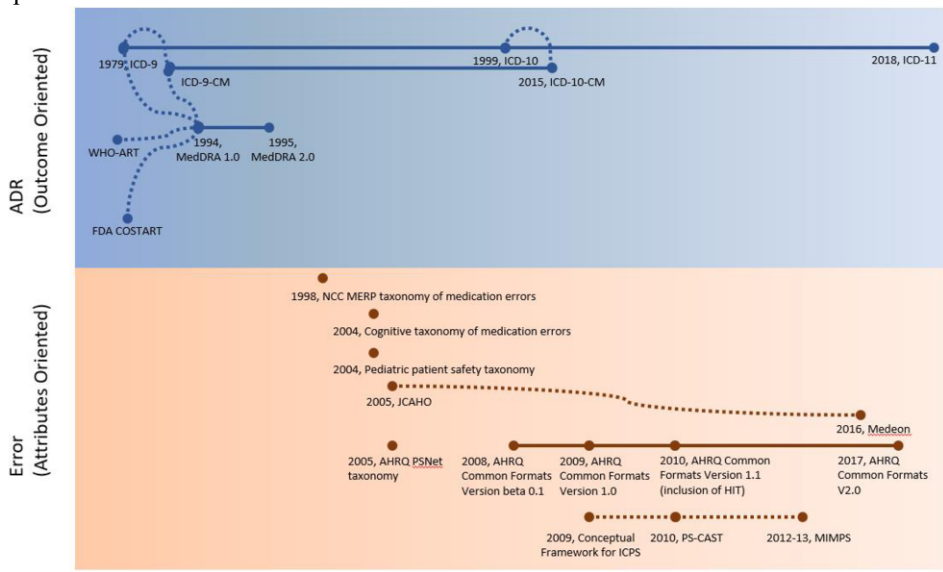


**Figure 1**. Evolution of taxonomies for patient safety.
Solid lines: updates of the same taxonomy;
Dotted lines: new taxonomies developed based on existing taxonomies.

These vocabularies have been recognized as a necessary element for facilitating communication, health data collection, knowledge representation, and exchange, etc. [42,43]. Nevertheless, research interest in the development of these vocabularies has been primarily focusing on whether sufficient vocabulary terms are employed to cover the intended domain. In recent years, the emerging need for nationwide incident reporting, the adoption of e-reporting systems, large-scale error analysis, and the ever-growing knowledge of patient safety problems call for a highly competent method to represent the vocabulary for patient safety.

### *3.2. Patient Safety Ontology Supporting Intelligent e-Reporting Systems*

Ontologies were explored to enable a number of needed functions of controlled vocabulary for patient safety, including computerized linguistic representation, semantic reasoning, and advanced data analysis, such as biomedical Natural Language Processing (NLP). A publication reported the development of an ontology for medical errors by using refined concepts and semantic relations stemmed from UMLS Metathesaurus and Semantic Network [44]. The other ontological approach is reported to model patient safety incidents knowledge from the ICPS [45–47]. Recent progress has been reported to develop a patient safety ontology to underpin incident reporting regulated by the AHRQ Common Formats [37,48] and incident analysis using NLP [49,50].

In addition to meeting the fundamental information need for patient safety reporting and analysis, ontologies also serve as a cornerstone for developing patient safety intelligent systems. Although the application of intelligent systems in health care is not recent, such an application in patient safety is still at the conceptual stage. The global or national strategies for patient safety improvement require large-scale incident reporting

and timely analysis. To meet these requirements, a specialized intelligent e-reporting system is indispensable for providing timely information service and decision support during incident reporting and analysis. A uniformed patient safety ontology is regarded as the key requirement for building such a system for the following reasons [51].

First, ontology is a promising approach to enhancing knowledge requirements for various communication gaps, especially in the patient safety domain. For example, communication in health care requires commonly shared knowledge [52]. Such knowledge consists of different medical terminologies, persons, locations, temporal information, and intricate relations and constraints among entities. Ontologies written by highly expressive languages, e.g., Web Ontology Language (OWL), allow the formal representation of various entities and relations.

Second, the 'ontology language' is computer understandable [53]. This feature largely improves the automation of patient safety knowledge management, particularly tasks involving narrative medical incident data [37].

Third, ontologies hold the potential to inform new knowledge from retrospective data. One approach is to perform semantic reasoning tasks based on predefined entities and relations [54]. Another approach is to perform various machine learning tasks where the ontology can provide rich linguistic features to improve the feature space in machine learning tasks.

In sum, the development of ontologies to support e-reporting would promote the revolution from the data repository of patient safety events to intelligent systems in e-reporting.

## 4. Medication Events

Medication event is one of the most significant threats to patient safety in hospitals[45], it could cause severe patient harm even death. The Institute for Safe Medication Practices (ISMP) has defined high-alert medications as drugs that have higher risks of causing [56]significant patient harm in the medication events [57]. The ISMP's high-alert medications list contains 19 categories of drugs, which are updated based on the opinions of patient safety experts, the error reports submitted to ISMP, and related literature [57]. Among all categories of drugs, the Institute for Healthcare Improvement (IHI) identified four types of drugs that may cause the greatest harm to patients and have great opportunities for improvement[58]. The four types of drugs include narcotics and opiates, anticoagulants, insulins, and sedatives, which are associated with adverse drug reactions such as hypotension, bleeding, hypoglycemia, delirium, lethargy, and oversedation [56]. Opiates are identified as the most common specific cause of adverse drug event outcomes, which account for 5.6% of all inpatient events [59].

Medication error reporting is an essential way of controlling the occurrence of medication errors and developing strategies for error prevention. The Joint Commission in the USA has been collecting and analyzing error reports from accredited hospitals, and issuing alerts and recommendations based on the results of integrated data analysis [29]. Also, the Food and Drug Administration (FDA) has launched the FDA Adverse Event Reporting System (FAERS) since 1997 to collect medication error reports. Many Patient Safety Organizations (PSO) in the USA and individual healthcare facilities also established their reporting programs to manage medication errors. These error reporting programs hold the potential to improve the quality of patient care and to further understand the nature of medication errors [50,60,61].

### *4.1. Challenges in Reporting Medication Events*

Several factors make the reporting of medication events a challenging task in clinical settings. The medication event has one of the highest rates among all patient safety events [62]. The relationship between medication errors and adverse drug events [63–65] could cost a large amount of time to report all the events. Medication event is an umbrella concept that clinicians may have a different understanding of it. Thus, clinicians may have biases when reporting the medication events. There are several concepts related to medication events, such as medication error, adverse drug event (ADE), adverse drug reaction (ADR), etc. According to the NCC MERP, a medication error is defined as any preventable event that may cause inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer [66]. It may happen at any stage of the medication distribution process in hospitals, starting from a clinician who prescribes a medication to the end the patient takes the medication. An ADE is an injury caused by the use of any medication. The medication error and ADE have some overlaps. Only a portion of medication errors could result in ADEs, and not all ADEs are caused by medication errors. The ADEs that are not caused by medication errors are called non-preventable ADEs. Non-preventable ADEs do not have any errors until the medications are taken and related harm identified [67], it is usually due to the patient's pathophysiological factors. The near-misses, a subset of medication errors, refer to those identified before they reach the patients. However, the near misses hold similar learning values compared to other medication errors. Among all the medication error reports, those describe the medication errors, including the near misses, are key for healthcare facilities to identify error causes and create processes to reduce the risk of errors [68]. At the current stage, the ADEs and medication errors are usually not differentiated, and all regarded as medication events in many reporting systems.

Moreover, multiple personnel are likely to be involved in medication events, such as physicians, nurses, which could make the events complicated. The various types of medication events also make it challenging to report. Since the patient needs to receive the right drug, in the right dose, at the right time, and in the right way [69], any compromise during the procedure will lead to different types of errors. And for a certain type of error, there may be different causes. For example, if a patient receives a wrong dose of a drug, it may be due to a wrong prescription by a physician, or due to wrong administration by a nurse. Thus, during medication error reporting, the events may need more elaborated narratives to restore the key information in the events.

### *4.2. Related Taxonomies of Medical Errors*

In order to systematically study the medication errors, guide the medication error reporting and promote the safe use of medications, it is important to build a taxonomy for medication error. The NCC MERP has developed a comprehensive medication error taxonomy that aims to record, track, categorize, and analyze medication errors [66]. The effectiveness of medication error reporting and the resulting analysis of the error reports are highly dependent on the amount and the quality of the data collected by medication error reports. Thus, how to design and build the medication error reporting mechanism within healthcare facilities remains a challenging problem. The NCC MERP taxonomy provides healthcare facilities with a framework to collect adequate information for recording medication errors. The taxonomy is in a tree structure and contains 454 items organized in 5 levels, which covers detailed information about the patient involved in the

error, the medication involved in the error, the context of the error, the type, cause, and contributing factors of the error, and the patient outcome. And it still has the potential to be expanded. Considering the complexity of medication error and the information needed for its reporting, the taxonomy has great potential to improve the efficiency and efficacy of medication error reporting if it is integrated into the error reporting system. In order to maximize the application of the taxonomy, the reporting system should collect as much information as the taxonomy required (NCC MERP). In most cases, if the error is reported under the framework of the taxonomy, it could avoid using the time to conduct retrospective audits to collect the needed information. The taxonomy also suggests that the information related to the medication error should be collected and reported as soon as possible, the reporting mechanisms within healthcare facilities should set regulations to keep the timeliness of the information.

The NCC MERP Medication Error Index was proposed in 1996 and revised in 2001. Several authors advocate that it is the most adequate method. However, more data from different institutions needs to be collected in a methodologically similar fashion so that comparisons can be made with the data presently available [70][71].

### *4.3. Medication Events Often Involved with HIT Components*

In recent years, the implementations of health information technology (HIT) in healthcare facilities have increased rapidly. It has been proved that HITs, such as EHR, CPOE, and CDSS, are playing important roles in preventing medication errors and improving patient safety [72]. However, the use of HIT to improve patient safety has led to new and unexpected types of errors [73]. According to the statistics from the Joint Commission, the typical medication errors related to HIT were attributed to the human-computer interface, workflow and communication in healthcare settings, and clinical content [74]. The HIT-related errors could happen during every step of the medication-use process, especially during the prescribing, transcribing, and administering stage[73].

And among all HIT components, the computerized physician order entry (CPOE) system, pharmacy system, and the electronic medication administration record (eMAR) are the top contributing factors to medication errors. Other components, including the clinical documentation system and clinical decision support system (CDSS), are also often involved. These HIT components could increase the complexity of medication errors. The users, such as physicians, nurses, and pharmacists, have to frequently interact with the HIT components during the medication distribution process, which may result in errors due to the design flaws of the systems, user errors, communication errors, etc. Accordingly, it will also increase the difficulty of reporting the medication events. The HIT factor has not received enough attention in medication events reporting. For instance, the AHRQ Common Format for medication events only contains one question about HIT, it cannot reflect the role of HIT factor in a medication event.

## 5. Patient Falls

Patient falls have been listed as one of the top patient safety events in hospitals [75]. Fall events have serious consequences: physical injuries, lowering the quality of life, or even death, which are common causes of psychological stress and extending hospitalization and costs incurred [76]. For example, a fall with injury adds on average 6.3 days to the

hospital stay and costs around $14,000 [77]. Different from diseases, which could be effectively controlled per clinical procedures, patient falls are difficult to control due to multiple inputs, including healthcare providers, systems, or even patients [78]. Theoretically, fall events are preventable in hospitals as most fall-related contributing factors are detectable, such as frailty, fatigue, insomnia, and functional degradation due to therapies and medications [79]. However, lacking publicly accessible fall event resources hinders the development of a fall risk detection model toward patient safety improvement. Besides, falls always appear simultaneously with other patient safety event types (e.g., medication) in the same cases, which increases the difficulty of factor identification.

Multiple fall risk assessment tools have been developed to reduce patient falls. The Pennsylvania Patient Safety Authority developed patient safety tools for risk factor measurement and post-fall investigation [80]. Centers for Disease Control and Prevention, The National Institute for Occupational Safety and Health (CDC-NIOSH) developed a tool that listed top risk factors for patient falls, including indoor and outdoor environmental conditions and improper use of equipment [81]. AHRQ WebM&M provides peer-reviewed patient safety cases and expert analysis, which can serve as a resource of patient safety event solutions. AHRQ also developed a toolkit for improving the quality of care, called Preventing Falls in Hospitals [82]. This toolkit focuses on overcoming the challenges associated with developing, implementing, and sustaining a fall prevention program. The validity of fall risk assessment tools was verified in some hospitals[83,84], however, current tools are still far away from an integrated system that could fully support the information flow within the patient fall management circle, i.e., event reporting, retrospective analysis, and prospective analysis, etc. A knowledge base is expected to provide the foundation for knowledge-based interventions if one could be developed and integrated into the routine workflow of patient risk management [85]. In such a knowledge base, the solutions for patient fall should be included, and their logical connections to the specific cases should be well established to support learning and clinical decision making.

In our previous study [66,67], we proposed a hierarchical list of contributing factors for fall event reports based on the contributing factor infrastructure released by AHRQ Common Formats 2.0. Based on the factor list, a rule-based contributing factor identification model was developed through an expert review on one-year narrative PSO fall reports to automatically identify the fall-related contributing factors from PSO reports. We identified solutions for patient falls from multiple authoritative resources, such as the AHRQ WebM&M, Joint Commission Center for Transforming Health Care's Targeted Solutions Tool, Pennsylvania Patient Safety Authority, National Safety Council, and National Patient Safety Agency's Patient Safety Observatory report, and synthesized them by building a connection between the entry-based solutions and the AHRQ Common Format. These solutions were summarized and grouped into two types: general solutions (for all fall event reporters) and specific solutions (customized according to the reporting contents). We also surveyed a PSO institute to evaluate and extend our solution entries. 20 general and 102 specific solution entries were determined through the survey[24]. All solutions were also labeled with our contributing factors of fall events, which finalized the connection between fall reports and solutions. Applying fall events as a trial, a novel patient safety event reporting and learning system was prototyped based on a knowledge-based strategy. In this system, a user can launch a learning session after determining a query that could be either an existing or a new report in any reporting format. According to the analysis of the query and the reporter role (e.g., manager,

physician, nurse, and patient), the system can provide customized learning materials, including similar historical reports and recommended solutions. The user preference may vary due to different learning purposes. Therefore, the system allows the user to provide feedback about whether he/she likes or dislikes a certain similar report or solution. All feedback returns to the algorithm implementation step in order to update the weights of similarity matrices and dynamically upgrade the system performance. This mechanism can gradually stabilize the similarity matrices and make them more convincing as the feedback increases.

Lacking management and analysis resources are the main challenges of the establishment of a knowledge-based system. The first step of future study may need to focus on identifying fall data from multiple resources to support the application of advanced information retrieval methods. Moreover, developing a knowledge-based fall reporting and learning system is only the beginning of achieving improved public health. Asking practitioners to change their ways of work to include the skillful uses of knowledge-based fall prevention interventions and asking organization leaders to change the roles, functions, and structures to more fully support the work of practitioners sends ripples throughout the public health system.

## 6. Application of Informatics in Patient Safety Research

Since the implementation of national reporting systems to better understand patient safety events, many countries across the world have developed a large repository of patient safety events. For example, the National Reporting and Learning System in England and Wales has accumulated over 40,000 safe events [88]. It has been a key challenge to systematically analyze and to learn from the data, which is largely represented in unstructured, free-text formats. Current analysis of patient event reports is inefficient, which often requires manual reviews at a variety of frequencies, ranging from weekly to monthly review workload for clinicians. An automated pipeline was proposed to help clinicians handle the accumulated reports, extract valuable information, and generate timely feedback from the reports [50].

Analyzing patient safety reports helps understand how and why incidents occur, which can inform policy and practice for quality improvement. Unfortunately, our capacity to monitor and respond to incident reports promptly is limited by the sheer volumes of data collected. To prioritize the incidents, one critical task of reporting analysis is to identify the severity level of the patient, which is essential for triggering risk management, identifying preventability of medical incidents, and investigating the causes and preventable actions of the harm.

It is essential to analyze the reports based on reliable and accurate assessments. A number of harm scales developed by national and international organizations are available for such purposes, including but not limited to WHO's five-level harm scale classification [27], NCC MERP's index for identifying levels of harm [66], IHI's 'Global Trigger Tools' [89], and AHRQ's five-category Harm Scale implemented within the Common Formats [90].

In a study using multiclass classification to automate the identification of incident reports via type and severity [91,92], the researchers evaluated the feasibility of regularized logistic regression, linear support vector machine (SVM), and SVM with a radial basis function (RBF) kernel to automate the identification of 10 incident types and 4 severity levels.

In United States, the harm scale from the Common Formats is suggested and widely used in hospitals. Recent studies have reported considerable deviation among clinician's judgment on patient harm when using the Common Formats harm scale, suggesting moderate to poor reliability of the tool[93,94]. Such a negative result may be related to multiple factors: (1) diverse knowledge and training of the clinician who reports incidents and submits harm scores; (2) possible equivocal definitions and descriptions of neighboring levels of harm.

One recent advance to mitigate the problem is to provide a secondary prediction of harm scores by leveraging machine learning classification and the semantic information from the description of events (free text). The best-performed classifier has achieved 0.89 on the F measure [49]. A future direction is suggested to include both human judgment and machine-learning aided prediction in the decision making.

## 7. Intelligent User-Centered Design Features

### *7.1. Intelligent Features to Promote Analysis, Aggregate, and Trending of Patient Safety Events*

When reporting a patient safety event, reporters often meet the challenges of competing priorities. Clinicians would spend more time being with patients and arrive at a high probability of proper diagnosis and treatment if data entry in reporting systems can be completed efficiently and effectively. Structured data entry is usually combined with free-text that pervades computerized patient safety event reporting systems. As a primary attempt to investigate the effectiveness of text prediction in healthcare, study findings validated the necessity of text prediction to structured data entry and laid the ground for further research improving the effectiveness of text prediction in clinical settings [16,26]. The most important knowledge in the field of patient safety is regarding the prevention and reduction of patient safety events (PSE) during treatment and care.

The similarities and patterns among patient safety events serve as a mainstay in analyzing, aggregating, and trending the events. There is an urgent need to develop an intelligent reporting system that can dynamically measure the similarities of the events and thus promote event analysis and learning effect. The similarity algorithms and scores integrated into an intelligent reporting system resulted in a high consistency with the experts' review than those randomly assigned [87]. The algorithms enable a mechanism to keep updating based on event similarity [87] and promote learning from previous events and offering timely knowledge support to the reporters.

With the knowledge base driven by similarities in the patient safety domain, the intelligent reporting system holds promise in preventing the recurrence and serious consequences of patient safety events. Further, the knowledge base in patient safety holds promise in providing personalized knowledge support based on user inputs. The learning materials (contributory factors, solutions, available toolkits, etc.) can be organized by similarities instead of merely contributing factors. Further perspectives based on the similarity will be added for developing a grouping mechanism, such as role-based, location-based, and response priority. Moreover, the user feedback module will share data with the review priority module in order to dynamically optimize the grouping mechanism to further incorporate user preferences.

### *7.2. User-Centered Features for Improving Completeness, Accuracy, Timeliness*

Narrative data entry pervades computerized health information systems and serves as a key component in collecting patient-related information in electronic health records and patient safety event reporting systems. The quality and efficiency of clinical data entry are critical in arriving at an optimal diagnosis and treatment. In patient safety event reporting, the application of text prediction has been tested effective for enhancing the human performance of data entry in reporting patient safety events [26]. The two functions of text prediction, tested via a two-group randomized design, were proven for increasing efficiency and data quality of text data entry reporting patient safety events [16,26].

While both groups of participants exhibited a good capacity for accomplishing the assigned task of reporting patient falls, the results from the treatment group showed an overall increase of 70.5% in text generation rate, an increase of 34.1% in reporting comprehensiveness score, and a reduction of 14.5% in the non-adherence of the comment fields. The treatment group also showed an increasing text generation rate over time, whereas no such an effect was observed in the control group.

As an attempt to investigate the effectiveness of text prediction functions in reporting patient safety events, the study findings proved an effective strategy for assisting reporters in generating complementary free text when reporting a patient safety event [16].

## 8. Learning Support

Current patient safety event reporting systems present defects that may influence the efficacy and usability of the systems. One major defect is that the systems usually do not give any feedback to users, they just collect the data about the patient safety events. Other major defects are related to the lack of learning-oriented design in the systems. The Kirkpatrick model has the potential to systematically guide the design and development of reporting and learning systems. The Kirkpatrick model is frequently used for training and performance evaluation in many areas, such as business companies, universities, and government agencies [95]. The model, comprised of four levels, could be applied to evaluate whether a training program meets the expected outcomes of both organizations and the staff[96]. The model enables the participants of the training program not only to learn what they need to know, but also to react favorably to the program. No matter in the business area or the healthcare setting, the training activities have a commonality regarding their core challenge, which is how to reach the expected outcomes through improving the staff's learning effect and applying what they have learned in daily work. Thus, the Kirkpatrick model has great potential to help improve the patient safety event reporting systems [97].

The Joint Commission Center for Transforming Healthcare has developed an online patient safety events management system, the Targeted Solutions Tool (TST), which covers four major patient safety events, i.e. patient falls, surgery, hand hygiene, and hand-off communications in hospitals. The TST tool uses a fact-based, systematic, and data-driven problem-solving approach to facilitate the hospitals to build long-term training programs to reduce patient safety events. To achieve the goal, it first defines the scope of the program and sets up plans for patient safety event management. And it provides the pragmatic reporting tool for an individual event, which could collect

detailed information about event data. Compared to other existing event reporting systems, the TST collects data describing the events and integrates the data analysis module in the tool to facilitate the process of understanding why and how the events happened. Moreover, the TST contains a knowledge base that can provide suggestions to healthcare facilities based on the analysis. Overall, the TST sets a good example of how the patient safety event reporting system can guide the healthcare facilities to identify the root causes of patient safety events and provide them with authoritative solutions that are based on specific root causes [98].

It is imperative that collecting patient safety events through reporting systems that should provide intelligent features to support the creation of accurate, complete, and timely reports. The reports are invaluable assets for us to understand, mitigate and reduce the occurrence of patient safety events and improve the safety of care.

Over the years, effects have been made in improving health information systems mainly focusing on electronic health records, yet the potential impact of event reporting systems has not been fully created. More collaborative efforts are needed for patient safety event reporting systems to deliver the expected benefits in terms of offering timely feedback, shared learning, and sustainable reduction of risks and safety events. Healthcare systems and organizations around the world have sought to create databases of patient safety events, which has paved the path toward an intelligent system supported by knowledgebase for extracting and refining actionable knowledge on patient safety events.

In addition to event reporting, the applications of the event triggering tools and machine learning approaches are complementary to e-reporting for enriching the learning experiences and to detect risk signals, prioritize safety concerns, and enhance healthcare quality.

## 9. E-reporting and Global Roadmap of Patient Safety

Improving and ensuring patient safety has been recognized as a growing challenge for health service delivery globally. Since the very first World Patient Safety Day in 2019, the WHO has been urging healthcare leaders to understand the purpose, strengths, and limitations of patient safety event reporting, which remarks a global campaign to create an awareness of patient safety and to make healthcare safer. The initiatives include the design of event reporting and learning systems on an international classification [99].

It is a long-term and worldwide effort to meet the challenges and opportunities of patient safety event reporting. Recently, a global patient safety action plan has been formulated in consultation with WHO member states, a wide range of partners, and other organizations. The global action prioritizes patient safety as an essential foundational step in designing, developing, operating, and evaluating the performance of all health care systems. The adoption of such a plan represents a remarkable milestone in global efforts to take concerted action on patient safety to reduce the burden of patient harm because of unsafe health care. It is expected that the global collaboration will facilitate the implementation of strategic patient safety interventions at all levels of health systems over the next ten years (2021-2030) [100].

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