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Design of a User-Centered Voluntary Reporting System for Patient Safety Events

Hong Kang, Yang Gong

School of Biomedical Informatics, The University of Texas Health Science Center at Houston, Houston, Texas, USA

Abstract

As the third leading cause of death in the U.S., patient safety events (PSE) are difficult to control due to multiple inputs from healthcare providers, systems, or even patients. Inspired by the success of reporting systems in other fields, PSE reporting systems could be a good resource to share and to learn from previous cases. However, the success of such systems in healthcare is yet to be seen due to the low report quality and the lack of interoperability and communication. A knowledge-based and user-centered PSE reporting system is needed to organize the scattered knowledge and improve user-friendliness. We described the development of a knowledge base for patient falls, the most frequent PSE. Based on the knowledge base, user-centered design features were incorporated into the system to improve the reporting accuracy, completeness, and timeliness. This prototype holds promise in improving PSE reporting quality and facilitating human-computer communication.

Keywords:

Patient Safety; Medical Errors; Knowledge Base; Medical Informatics

Introduction

A patient safety event (PSE) is an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient [1]. An estimated number of 15 million PSEs occurred in U.S. hospitals each year, as high as 40,000 per day, which exceeds the combined number from motor and air crashes, suicides, poisonings, and drownings [2]. With more than 251,000 annual deaths which are about 9.5% of all deaths, PSE, the third leading cause of death in the U.S. closely following heart disease and cancer, costs more than 9 billion dollars every year [3; 4]. Although most patients do not die from PSEs, they suffer from the PSEs for a long period of time or even the rest of their lives [5]. For example, patients may get a fracture after a serious fall in hospital or have a worsening medical condition by taking the incorrect dose of medications. PSEs, including near misses or close calls that are recognized before they actually occur, may be related to systems, operations, drug administration or any clinical aspect of patient care [6]. In the latest version of Common Definitions and Reporting Formats Version 2.0 (Common Formats, CFs) released by Agency for Healthcare Research and Quality (AHRQ), PSEs were categorized into nine subtypes including 1) blood or blood product, 2) device or medical/surgical supply including health information technology, 3) fall, 4) medication or other substance, 5) perinatal, 6) pressure ulcer, 7) surgery, 8) anesthesia, and 9) venous thromboembolism [7]. Different from diseases, which could be effectively controlled in accordance with clinical procedures, PSEs are difficult to control due to multiple inputs including healthcare providers, systems, or even patients [8]. Therefore, PSE is a major threat to the healthcare quality.

Event reporting has been proven effective by many high risk industries such as aviation, nuclear, and rail industry, for improving safety and enhancing organizational learning from errors. In healthcare fields, PSE reporting systems would enable safety specialists to analyze events, identify underlying factors, and generate actionable knowledge to mitigate risks [9-11], Dozens of PSE reporting system have been established based on this purpose. In the U.S., the Institute of Medicine (IOM) recommended using patient safety reporting systems (PSRS) [12] to evaluate why patients are harmed by health care [13]. AHRQ created the CFs [7] to help healthcare providers uniformly report PSE. Since 2000, at least 30 other PSE reporting systems have been established in the U.S., the initiatives to improve patient safety based on the common belief that data supports further learning and actionable knowledge. However, the success of such systems in healthcare is yet to be seen due to the identified barriers such as low report quality and the lack of interoperability and communication [14].

In addition to the no-blame no-shame safety culture that needs to be further enhanced, a lack of effective and efficient human-computer interaction (HCI) may largely account for the issues of low user acceptance and low-quality data currently confronting the PSE reporting systems [15]. Improved HCI in the systems may include individualized interfaces according to the user roles and requirements, increased sensitivity to the needs of the current clinical scenario, or even patient interfaces to enhance the patients' self-efficacy and awareness and thereby reduce PSEs. Our previous work indicated that the retrospective think-aloud user testing method is a useful usability evaluation method by which multidimensional measures can be synthesized to gain an insightful understanding of the usability in a voluntary patient safety reporting system [16]. However, generic PSE systems do not incorporate user-centered design (UCD), which is a major barrier to collect event data from frontline practitioners and to learn from previous events.

Thanks to the advancement of machine learning and web programming techniques, increasing UCD features have been incorporated into PSE reporting systems, such as spreadsheets, keyword searching, and automatic error correction. Nevertheless, investigating and learning from the reported events still largely rely on manual approaches due to the lack of an integrated view of PSE [17]. Developing a PSE knowledge base is necessary because it could acquire, organize and integrate PSE information and connect reported events to potential solutions. More importantly, the knowledge base would enable the users to view the system with an open and receptive mind. The story of *the blind men and the elephant* [18] is often told to PSE reporters. In the story, each man had touched only a part of the elephant thus making it impossible for him to know the whole animal. The same is true for

unintegrated reporting systems. The PSE knowledge base holds promise for organizing PSE knowledge and supporting advanced UCD features toward shared learning.

In our preliminary study [14], we developed a PSE similarity searching model by utilizing the semantic similarity measures on the PSE datasets of AHRQ WebM&M (Morbidity and Mortality Rounds on the Web) [19] and CFs [7]. Based on this model, we proposed a novel schema which can process the comparison tasks for PSEs and provide the reporters pertinent suggestions about solutions and prevention options for their cases. Patient falls, a subtype of PSEs, was chosen to assess the schema. As a follow-up study, this paper focused on the development of PSE knowledge base and UCD features. We developed a knowledge base for fall events, based on which we incorporated multiple UCD features into the reporting system.

Methods

Prototype a PSE knowledge base

The PSE knowledge base we prototyped was the collection of PSE reports, solutions, and the potential connections among them (Figure 1).

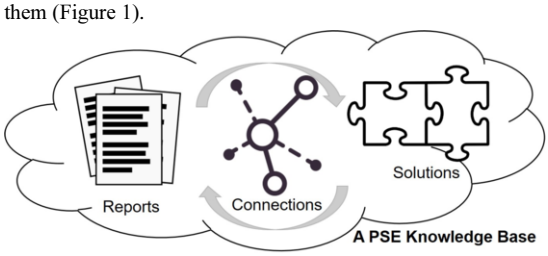

Figure 1– An infrastructure of PSE knowledge base

The knowledge base establishment was started from the most common PSE subtype, patient falls. In our preliminary study, we collected more than 7,000 fall reports from an institute from Patient Safety Organization (PSO) and developed a similarity searching model based on semantic similarity methods to make connections among reports, among solutions, and between reports and solutions [14]. To enrich the knowledge base for patient falls, we identified solutions for patient falls from multiple authoritative resources, such as the AHRQ WebM&M [19], Joint Commission Center for Transforming Health Care's Targeted Solutions Tool [20], Pennsylvania Patient Safety Authority [21], National Safety Council and National Patient Safety Agency's Patient Safety Observatory report [22], and synthesized them by building a connection between the entry-based solutions and the AHRQ CFs. These solutions were summarized and grouped into two types: general solutions (for all patient fall event reporters) and specific solutions (customized according to the reporting contents). We also initiated a survey with the Missouri Center for Patient Safety to evaluate and extend our solution entries. In the survey, we provided a text box following each solution for experts to comment on the adequacy of the solutions to the corresponding questions and answers in CFs. Five experts who are familiar with PSE reporting process and patient safety data participated in the survey. The contents of the solutions and their connections to the CFs were improved according to the expert comments.

Review current PSE reporting systems

To figure out the status quo of PSE reporting systems and propose an improved reporting system toward high-quality reporting, we investigated the current systems from peer reviewed publications and publicly accessible web pages. Resources for publications included three databases: Ovid MEDLIINE, PsycINFO, and Health and Psychological Instruments. Keywords including "patient safety event", "medical error/incident/event", "report/reporting system", "electronic report", "healthcare", "information system" were applied with different combinations to all field search (title, abstract, keywords, etc.). As this strategy may include articles with high sensitivity and low specificity, we set restrictions on the MeSH Subject Heading to match such term clusters as "Risk/Safety Management"/ "Quality of Health Care"/ "Quality Assurance" and "Patients or Medical Records Systems"/ "Computerized or Hospital Information Systems". We used Google search engine to identify publicly accessible PSE reporting systems and other information sources that contain substantial system descriptions (e.g., screen shots or demonstration videos) as supplemental information. Results from these additional materials were merged into the results of the literature review. Two domain experts filtered the initial results and generated a finalized review list.

Design a user-centered voluntary reporting system for PSE

The input quality of PSE reporting system relies on the UCD since UCD has been proven effective in user acceptance [16; 23]. Guided by the reporting quality-related factors derived from the review of current PSE reporting systems, we applied UCD to our reporting system with the support of the PSE knowledge base.

Results

A PSE knowledge base for patient falls

32 general and 137 specific solution entries for patient falls were determined after the survey results were analyzed. The survey also helped us assess the mapping rules between reports and solutions. Each specific solution entry will be displayed to the reporter only when the corresponding condition is met. The condition consists of combinations of users' answers to the 13 questions in the fall event CFs. Table 1 shows an example of the activation condition of a specific solution S_i.

Table 1– The activation condition of solution S_i

Solution S_i is activated when	
	The hth answer of Question Q_{j1} is selected
AND	The kth answer of Question Q_{j2} is not selected

i=1,2,…,137; j=1,2,…,13

Three data quality dimensions for PSE reporting systems

48 unique PSE reporting systems in the United States, Netherlands, Canada, United Kingdom, Germany, Australia, China, and Japan were identified and reviewed by domain experts. Based on which, three data quality dimensions were defined as follows.

- Accuracy: the degree of proximity of a given PSE report to corresponding real world occurrences. The reporting accuracy is subject to user error and cognitive limitations in memory and reasoning, including but not limited to typographical errors, memory decay, casual attribution and hindsight biases. Accuracy of reporting could be improved if these contributing factors are incorporated into design consideration with good usability and functionality.
- Completeness: the degree to which a given PSE report includes necessary information describing the corresponding real world event so as 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 PSE is reported in a timely manner for root cause analysis and generation of real time intervention. It can be enhanced by improving the efficiency of the reporting process and offering a smooth process to generate actionable knowledge as soon as the report is identified by reviewer.

A user-centered PSE reporting system

To improve the accuracy, completeness, and timeliness of PSE reporting systems, a set of UCD features determined in our preliminary studies [24; 25] were developed and incorporated into our system. Table 2 shows a summary of the available and under-development UCD features in our reporting system.

Table 2– UCD features of the proposed PSE reporting system toward high-quality reporting

UCD Features	Accuracy	Completeness	Timeliness
• Validator	√	√	√
• Knowledge support and user feedback	√	√	
• User-friendly layout		√	√
• *Role-based reporting and learning*		√	√
• *System interoperability*	√		√
• *Instant communication*	√		√

(Features in an *italic* font are under development)

Validator

Multiple validators were incorporated into the reporting system. For example, the completeness validator can check whether all necessary fields have been filled by the reporter before the final submission to ensure the completeness of the report (Figure 2a). The spelling validator can identify spelling mistakes to avoid unnecessary accuracy loss during the similarity searching (Figure 2b). We initialized a terminology list in patient safety domain to standardize the words and phrases which may be applicable for reporters to choose from during reporting. The spelling validator was further improved toward text prediction based on the terminology list. Over time of individual and group use, nonstandard inputs are expected to be identified by this validator, and the possible standard terms will be prioritized for further selection (Figure 2b), which holds promise in improving the reporting accuracy, consistency and efficiency. Furthermore, the system can track new terms and update their frequencies to inform the system administrator periodically. The terms with high frequencies will be reviewed by domain experts and then put into an updated terminology list to enhance data entry quality.

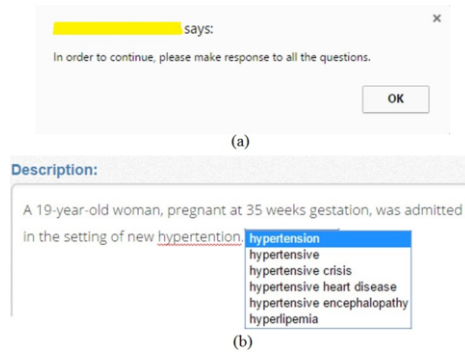

Figure 2– Screenshots for the validators. (a) Completeness validator (the IP address of local server was de-identified); (b) Validator for spelling and text prediction.

Knowledge support and user feedback

With the support of the PSE knowledge base, the user can either choose an existing case or report a new PSE as a query, and the system will retrieve similar cases and customized solutions for promoting shared learning.

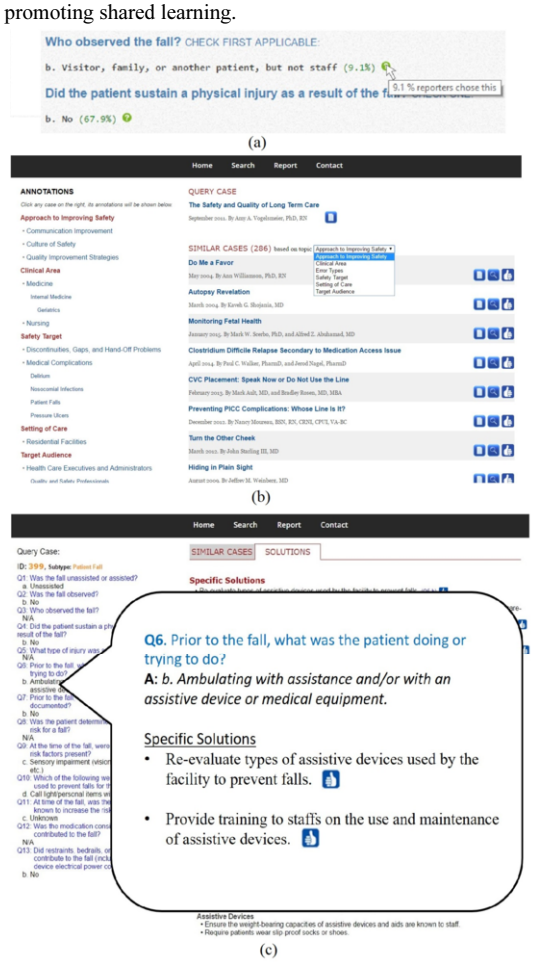

Figure 3– Screenshots for the knowledge support and user feedback. (a) Timely statistical analysis during reporting; (b) Providing similar cases for a new report; (c) Providing customized solutions based on user's reporting.

As shown in Figure 3, the knowledge support and user feedback are offered for fall events in our system. Reporters can receive timely notifications about the distribution of each answer option during reporting (Figure 3a), as well as similar cases (Figure 3b) and actionable solutions (Figure 3c) after reporting. The similar cases provide previous experiences and evidence-based suggestions from healthcare experts to prevent the potential consequences of the query event. The customized and actionable solutions can offer an interactive way to solve the current event. Users are allowed to send their feedback by clicking the thumb-up buttons to let the system know their preferences. The weights of the selected similar cases and solutions will be automatically enhanced in the similarity matrices. Therefore, the knowledge support is expected to become more precise enhanced by increasing number of user feedback.

User-friendly layout

The layout of user interface was an important factor we considered during the development. A user-friendly layout could improve the reporting system in terms of completeness and timeliness. For example, the hierarchical question layout during reporting reduces reporters' memory load for the particular task operation and decreases the likelihood of skipping correct answers.

Role-based reporting and learning

To provide customized solutions according to the various roles of healthcare providers (e.g., managers, clinicians, and staff) or even patients, we are classifying the solution entries into 3 categories: direct actions (for clinical staff to make specific actions), principles (unspecific actions, may be actionable for managers) and patients (patient actions). The system will retrieve similar cases and customized solutions based on the query and the reporter's role.

System interoperability

Lacking considerations on system interoperability and communication indicates a poor integration of event reporting procedure into clinicians' work flow, organizational quality control, and risk management process. Interfaces with other clinical applications (e.g., drug-drug interaction system) are under development.

Instant communication

Timeliness could be enhanced by instant communication between reporter and expert, and feedback access or notification. Both internal message module and live chat module will be developed to facilitate such communication.

Discussion

The evolution of PSE reporting systems

Similar to the evolution of electronic health record (EHR), PSE reporting systems started from an electronic copy of paper-based reporting forms. In this phase, the reporting systems can be viewed as a primitive alteration of paper-based reporting forms toward an intelligent reporting system. The use of drop-down lists, check boxes, or radio button replaces unnecessary free text boxes accelerates the electronic entry process and improves data accuracy by reducing data entry errors. The AHRQ CFs are designed to support operational systems at three levels: (1) support patient safety event reporting, which is currently a self-contained part of any EHR, (2) support surveillance based on the data derived from EHR and, (3) enhance analytics of safety and quality toward clinical decision support by linking PSE with EHR. Therefore, future PSE reporting systems should evolve toward knowledge-based and user-centered systems which could improve reporting quality by offering timely knowledge support.

A shift from quantity to quality of event reports

When the quantity of reports is the only factor addressed in a safety culture discussion, an increase in event reports might be regarded as a reflection of an improved reporting culture, while others may consider a reduction in event reports as an indication of a safer environment. Nonetheless, underreporting, low quality and fragmented reports have not been adequately addressed in event reporting. We envision that the user-centered and knowledge-based design will revolutionize the traditional event report strategy, advancing from simply counting events into a new era of understanding, trending, integrating, and resolving the events through a synchronous and collaborative platform.

A no-blame no-shame culture beyond reporting system

Patient safety is as much about behavior, value and attitudes as it is about physical action. Another challenge for improving safety is to cultivate a no-blame no-shame culture. The characteristics of a positive safety culture include communication founded on mutual trust and openness, good information flow and processing, shared perceptions of the importance of safety, and recognition of the inevitability to error, etc. More efforts should be made to help healthcare providers understand their roles in improving patient safety. The first step may be to ensure patient safety is of high priority for each healthcare organization. Opportunities have to be created for people to freely state their opinions, and this openness then needs to be transferred to systems that allow all individuals to report and discuss. A no-blame no-shame culture will allow individuals to report and discuss in a comfortable atmosphere.

Limitations

All the assessments in this project were processed through expert review since there is no gold standard for PSE similarity measurement and solution recommendation strategy. Each expert might bring a different perspective which may result in bias toward the variation among similarity scores and solution mapping rules. For example, a physician may judge the similarity between PSEs by measuring severity, while a nurse may judge the similarity based on suggested solutions. The biases are inevitable but should have been minimized based on the common understanding of safety and quality。Thereby, we provided targeted introductions before every round of expert review and use face-to-face interviews instead of questionnaires to help the experts better understand the common understanding and our research goal.

Future work

We will further develop the UCD features such as role-based reporting and learning, system interoperability and instant communication, and will incorporate other UCD features which could improve reporting quality into the proposed system. Besides patient falls, more PSE subtypes, such as pressure ulcer, medication reconciliation will be supported by the system. The effectiveness and efficiency of UCD features will be initially evaluated through usability inspection and heuristic evaluation. Then, we will conduct population-based, individual-based, and group-based evaluation through user survey [24], interview and testing [25], and focus groups respectively.

Conclusion

We prototyped a user-centered PSE reporting system based on a PSE knowledge base, which includes PSE reports, solutions, and their connections. In this system, users can either choose an existing case or report a new PSE, then the system will retrieve similar cases and customized solutions based on the query and the reporter's role (e.g., manager, clinician, staff, patient). The user preference may be diverse for different purposes. The system allows the user to click the feedback button to indicate their preferences to a certain similar case or solution. All feedback will be returned to the algorithm implementation step in order to update the weights of similarity matrices and dynamically upgrade the system performance. This mechanism, similar to the ranking strategy of the Google search engine, will gradually stabilize the similarity matrices, making them more convincing as the feedback increases. It will be a win-win situation that both users and the system keep getting benefits from each other toward the common overarching goal of improving the PSE reporting quality and patient safety.

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Address for correspondence

Yang Gong, MD, PhD
7000 Fannin St Suite 600, Houston, TX 77030, USA
Yang.Gong@uth.tmc.edu
Phone: +1 713 500 3547, Fax: +1 713 500 3907.