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Toward a Human-Centered Voluntary Medical Incident Reporting System

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Abstract

Voluntary medical incident reports are a valuable source for studying adverse events and near misses. Underreporting and low quality of reports in local organizations, however, have become the impediments in identifying trends and patterns relating at the local, regional and national level. Human factors on usefulness and ease of use have shown their important role in acceptance of voluntary reporting systems. To understand and identify the obstacles of quality reporting, we employed a set of human-centered analysis methods to examine one-year voluntary medical incident reports of a University Hospital. We found about 30% of the reports labeled as "miscellaneous" and "other", and their real incident types or error descriptions were identified through an in-depth recoding. Human-centered analyses show that the pre-defined reporting categories could serve well for the voluntary reporting need if reporters' tasks were better represented on user-friendly interfaces. We suggest that a human-centered, ontology based system design for voluntary reporting is feasible which could help improve completeness, accuracy, and interoperability among national and international standards.

Keywords:

Medical incident, Reporting system, Human-centered, Interoperability.

Introduction

Medical incident reporting system, where error data are collected in a properly structured format, is suggested a useful mechanism for the detection of patterns, discovery of underlying factors, and generation of solutions[1]. Such a system as a source of adverse event repository would allow patient safety researchers to categorize, trend, and analyze data, increasing knowledge about medical mistakes and generating common solutions. Voluntary incident systems are a valuable, major source for this purpose. However, there is a clear dissatisfaction with the current voluntary systems [2-5]. Incomplete and inaccurate reports are misleading and not usable for further analysis.

Despite a large amount of studies suggest instituting a "just culture" that encourages learning, non-punishment [6-15], few studies have investigated the system difficulty and inefficiency regarding ease of use, ease of understanding and their relations with the level of details in reporting[10, 16-18]. To date the research addressing the inefficiency of medical incident reporting system has been limited and fragmented, with findings not always broadly disseminated. Although general rules of human-centered design have been introduced in many other fields, currently there is a lack of design framework for medical voluntary incident reporting systems to effectively collect, catalog, and analyze the reports.

Human factors, an important role in voluntary incident reporting systems, greatly affect the reporting rate, completeness and accuracy of the incidents [19, 20]. For example, classification and definition used in incident reporting systems determine whether an event is recognized or ignored [21, 22]. The people, who report, are generally working under time critical and multi-tasking conditions, and often do not have either the time or sufficient information to create a complete and meaningful report of the incident. If "other" or "miscellaneous" is offered as an option, it is often chosen [23]. It is critical to know what the needed categories are and how they would promote the quality of reports, users' acceptance in voluntary reporting systems.

To understand the current status of voluntary reporting systems in term of completeness, accuracy and degrees of expressiveness, and to identify the technical barriers toward a human-centered design, we proposed to study a set of voluntary reports acquired from the University of Missouri Health Care System (UMHC). UMHC is one of the most comprehensive health-care networks in Missouri, with approximately 500 staffed beds and 19000 patient admissions annually, offering the finest primary, secondary and tertiary health-care services. In 2002, in response to the Institute of Medicine report[24], UMHC developed a web-based voluntary reporting system, the Patient Safety Network System (PSN), which collects adverse events, near misses reported from 5 facilities located in mid Missouri[25].

Goals, Operators, Methods and Selection rules (GOMS) have been widely applied to model user's behavior and system evaluation. As a theory of Human-Computer Interaction (HCI), GOMS models can be classified as predictive, descriptive, and prescriptive[26]. GOMS model can be used to predict the time it will take a user to perform the task. GOMS can be used to describe the way a user performs tasks on a system and can be used to prescribe because it can serve as a guide for developing training programs and help systems. Keystroke-Level Model (KLM) is a simplified version of GOMS.

KLM aggregates all perceptual and cognitive function into a single value for an entire task[27].

In particular, we are interested in those incident reports with wrong or mislabeled categories and uncovering the underlying reasons of incorrect category selection. This process may help us develop a new set of incident type or event categories to better serve reporting needs and be compatible with the Common Format(AHRQ) and International Classification of Patient Safety (WHO)[28, 29]. This paper demonstrates our process and results regarding consistency and reliability of the voluntary incident reports. Base on the analysis, we have proposed our recommendations for upgrading institutional voluntary reporting systems through a human-centered, national/international standard compatible design, and for effectively maintaining historical data.

Materials and Methods

We obtained a total of 2919 de-identified, unique (duplicate copies were combined) voluntary incident reports generated in a 12-month period during 2005-2006 from the Office of Clinical Effectiveness (OCE) at UMHC. The reports are stored in MS Access and password protected on a secured server. The PSN is a web-based electronic reporting with tutorials and explanations on harm scores usage provided on the same webpage. Regardless of the choice of anonymity, each reporter must complete a factual and objective report in the PSN system immediately following an adverse or near-miss event. The OCE periodically holds a peer review process, which identifies the basic or causal factors with focuses primarily on systems and processes, not individual performance.

In this system, adverse events/incidents are defined as "any potential deviation from policies, procedures and standards regarding patient care, or a clinically related adverse or unexpected event causing injury or the potential for injury to any person"[30]. This could include an unexpected adverse outcome related to the natural course of the patient's condition or an outcome unrelated to the patient's condition. Near-miss events are defined as "an adverse event that could have resulted in an accident, injury or illness to a patient but did not through chance or timely intervention."[30]

Data Structure & Reporting Flow

The voluntary report database contains one table with 26 required fields. Each case has been automatically assigned a unique event ID. Of the data fields represented on user interface, Five (up to seven) fields, including patient age, report date, event date, patient unit ID, patient unit ID, are typed in by reporters. Report data and event date can be either typed in or selected from a calendar. Most fields require reporters to select from pre-defined menus displayed as drop down lists, radio groups, check boxes, etc. The fields displayed in predefined menus include harm score, incident type, error description and brief description. Event description is a short narrative to support the selected harm score. The harm score is a subjective rating of severity from 0(no clinical changes) to 5(death). Each harm score corresponds to a different number of items provided to reporters as a reference for evaluating the severity of events[30]. For a typical reporting process, one has to go through "answer initial questions", "event common questions", "event details", and "report summary", totally four interfaces to complete a report. For all reports, reporters may choose to report them anonymously or retain their IDs. After submission, hospital administrators, service medical directors or departmental managers review the reports and fill in the solution, review, and additional information fields. Therefore, all reports we studied were previously reviewed and responded by domain experts.

Procedure

First, we conducted a systematic content analysis on all the reports using a comprehensive coding interface which aggregates event information on one page and offers a coding space for researchers [23, 31]. Content analysis is an effective method of identifying key concepts and building up the conceptual hierarchical structure of concepts [32]. Content analysis is especially necessary in such a voluntary reporting process because there might be a great variety of term usage in reporting a case. Similarly, the selections of harm score, incident type or error description may lack consistency due to individual's understanding and therefore affect usefulness of the reports for patient safety research [33]. The content analysis was conducted by two data analysts who completed the work independently and performed a cross checking for achieving a higher consistency among harm score, incident type and error description.

Second, we further conducted an in-depth analysis on a selective type of cases (346 patient fall cases) to reveal the factors which might have caused the inconsistency and incompleteness of the reports. We selected fall cases to examine for two reasons. (1) according to the hospital policy, all falls are required in the PSN system [30]. Therefore, this type of incident has a mandatory nature within a voluntary reporting system. (2) Patient fall, as a typical category in voluntary reporting systems, represents the quality and taxonomy granularity in the current system. Fall cases are usually more frequently reported in incident reporting systems than in patient charts. This is in consistency with other group's study [5]. In our study, fall is defined as a sudden, unintended, uncontrolled downward displacement of a patient's body to the ground or other object (such as bed or commode) at a lower level. The fall excludes the falls resulting from a purposeful action or violent blow [34].

Third, for exploring the feasibility of transforming the hospital on-site reporting categories into a compatible format recommended by WHO International Classification of Patient Safety(ICPS) [29] and AHRQ Common Formats [28], we developed a prototype using a set of questions with a step-by-step structure for fall incident reporting. The reporting categories were mapping results between the PSN fall terminology and the national/ international standards. We then compared the estimated execution times of two interfaces between the PSN and our prototype by using KLM, which predicts task execution time from a specific design and specific task scenario. Following Kieras's method [27], two experienced reporters conducted KLM analysis of reporting a typical fall case based upon two interfaces.

1. Choose one or more representative task scenarios.

2. Have the design specified to the point that keystroke-level actions can be listed for the specific task scenarios.
3. For each task scenario, figure out the best way to do the task, or the way that you assume users will do it.
4. List the keystroke-level actions and the corresponding physical operators involved in doing the task.
5. If necessary, include operators for when the user must wait for the system to respond.
6. Insert *mental operators* for when user has to stop and think.
7. Look up the standard execution time to each operator.
8. Add up the execution times for the operators.
9. The total of the operator times is the estimated time to complete the task.

"Click mouse", "move mouse", "move hand to mouse/keyboard", "time needed for mental preparation", "type keys" were calculated. System waiting W (how long the system takes to respond) was not considered as the system speed was great.

Results

Our content analysis shows the majority non-anonymous reporters were registered nurses (66.2%). Other reporting professionals such as unit clerks, physical therapists contributed a total of 5.0% in the reports. Figure 1 shows the percentage distribution. The inter-coder reliability was good and reached at 82% between two data analysts (κ=0.83).

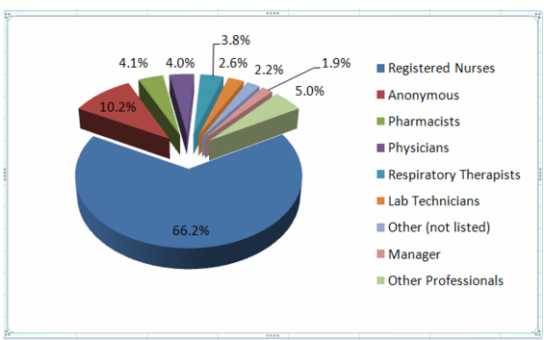

Figure 1- Distribution of Reporting Professionals in the PSN system

The incident type leads each reporter to further describe the error using predefined error descriptions and a free text entry. The major incident types are miscellaneous (32.8%), medication/IVs (23.7%), procedure/test/treatment (16.5%), fall (11.9%), equipment/device (5.9%), skin impairment (0.9%). The Error Description field is a pre-defined list designed for quickly summarizing the incident, where the major data entries were "other" (41.3%). We noticed that the field only allows reporters to select one item associated with the Incident type.

The big portion of "miscellaneous"(32.8%) in the incident type field and overwhelming percentage of "other" (41.3%) in the error description field indicate the reports lack of accuracy, completeness and affect the utility of the reporting system at large. There were 25.3% of the reports labeled with both "miscellaneous" and "other" in the two fields simultaneously. This means that the reports were completely not categorized by the original reporters. To investigate the case, investigators need to carefully examine all pieces of information and summarize out the exact category for the case.

We indentified 360 (12.3%, n=2919) fall cases among the unique 2919 medical incident reports after all the cases were cross checked and rectified for the "miscellaneous" and "other" cases. We then examined the PSN terminology used in fall reporting, which includes fell from bed/stretcher/table, fell while ambulating, sitting at side of bed, sitting in chair, toileting, transferring, unwitnessed, and other. Over one third of the cases (36.1%, n=130) belongs to unwitnessed case. This "unwitnessed", as an index for aggregating cases, does not provide more information than "miscellaneous" or "other" of other fields. As a result, we successfully revealed "unwitnessed" from reporter's free text description and replaced it with detail-oriented categories (a table not included due to space limits). We assigned "unwitnessed" as a secondary category attached to fall locations.

As shown in Table 1, the prototype with structured step-by-step questions greatly reduced the time needed for mental preparation, typing, and the total action though mouse clicks and mouse & hand moves are slightly increased. This implies that the prototype may increase reporting speed, yet it is subjected to more rigorous user testing with both new and experienced users.

Table 1- Comparison of KLM Analysis Results between the PSN system and Prototype

Action	Standard Operator	PSN system		Prototype	
		Count	Second	Count	Second
Click mouse	B (0.1 Sec)	30	3.00	34	3.40
Move mouse	P (1.1 Sec)	30	33.00	34	37.40
Move hand to mouse/keyboard	H (0.4 Sec)	11	4.40	19	7.60
Time needed for mental preparation	Tm (1.35 Sec)	139	187.65	90	121.50
Type keys	0.28 Sec/key	143	40.04	87	24.36
Total		353	238.09	264	194.26

As a result of mapping between the PSN categories and the national/international standards, seven major categories for fall were created. They are (1)sitting in chair; (2)fell while ambulating; (3)sitting at side of bed; (4)transferring(with assistance); (5)toileting; (6)location + unwitnessed; (7)fell from bed/stretcher/table, and (8)special (not included in the above situations). All the major 7 categories were clearly mapped between ICPS and Common Formats. This compatible taxonomy was used to successfully code 95.6% fall cases. Only 4.4%, coded as "special", cannot fit well in all the other six major categories.

Discussion

The content analysis revealed the overall status of the PSN reports in terms of consistency, accuracy and degree of expressiveness. "Miscellaneous" and "Other" cases were unmatched (mismatched) reports of incident types and error descriptions in the database. Through analyzing the short event summary, which contains the justification of harm score selection, we found that those "miscellaneous" or "other" cases usually can be coded by the categories existing in the system. This may because (1)those reporters were not experts in classification and may select the "safe" categories such as "other", "miscellaneous" due to their time limits or unfamiliarity with the classification for incident type or error description. (2) Only seven major incident types were available in the system and reporters selected "other" or "miscellaneous" when the incident could not properly fit into the description. For example, a patient fall with bleeding may be reported for both "bleeding" and "fall", since the system did not allow reporters to select more than one categories, which might result in "miscellaneous" or "other". (3) In addition, there were a few cases not fit into any existing categories, for example, an "organizational management" delay. In such a case, "other" or "miscellaneous" might be the best choice. If predefined categories do not match reporters' mental model of incident type, it may result in underreporting, incomplete or inaccurate issues. Moreover, reporters may also wish to capture varying levels of details. Therefore, each high-level category (broad concepts) ideally should contain more details through low-level categories (narrow concepts). This strategy may guide reporters to identify an optimal granularity as well as build an interoperable system at the local, regional, and national level. The reasons abovementioned direct designers of voluntary incident reporting systems to better understand the reporters' cognitive characteristics, term requirements on the interface level.

A human-centered design should fully consider both new and experienced users. In such a system, new users will not feel confused even without reading the tutorial whereas experienced users are able to find accelerators to expedite the reporting speed by using short-cuts, default values or preferred interfaces. According to the KLM analysis results, our prototype holds promise in reducing time needed for mental preparation and total steps. For example, (1) the current system requires users choose between "anonymous" and "un-anonymous" radio buttons. Since most reporters use "anonymous" reporting (no release of their work ID), new designs should offer a check box for "un-anonymous" and thus simplify the interface meanwhile make "anonymous" a default value. (2)Auto-completion features would increase the efficiency of pull-down menu selection, which is not offered in the current system. This is especially true when hundreds of names are listed in the menus. (3)Since most cases were reported with 24-48 hours, some convenient time/date stamp buttons (e.g. today, yesterday) could be very useful for reporters to click, rather than manually typing in the day and time or selecting from a calendar, which is laborious and prone to typos. (4)A holistic view that contains all entries of an individual report on a single page would be easy for reporter to conduct final editing and confirmation, rather than forcing reporters to flip pages back and forth to verify. (5)A navigational bar as an indicator of progress towards the completion of a quality report should be offered. This will improve system transparency to users and allow user to estimate if time slot is adequate to finish a report.

Designers for voluntary incident reporting system should notice the balance between efficiency and expressiveness of data entry. Current voluntary reporting systems are mainly template based, which increases data entry speed. Meanwhile, it may have the unintended effect of homogenizing incident descriptions with a loss of detail. For example, rather than asking reporters to recall an entire incident and type a long, time consuming free text description. A set of procedure-based questions, with conditional skips according to previous answers, would guide reporters better through the entire recall process. Moreover, an additional free text box would be offered in case any information not included in those questions deemed valuable for reporting. We suggest an intelligent interface for voluntary reporting based on existing data repository that can predict term requirements and offer intelligent guesses during data entry.

To further our study, we will employ heuristic analysis, user testing to examine the feasibility of our prototype, and apply an ontological approach to maintaining historical data without disrupting current users or altering the meaning of historical data. This pilot study based on an institutional voluntary reporting system contributes to a human-centered framework for voluntary reporting and promotes its migration towards a unified, interoperable reporting format.

Limitations

Accessing to medical incident reports generated in other institutes would definitely increase generalizability of the results. Collaborations between institutions are highly needed. Some inaccurate, incomplete data may be further rectified and analyzed through reviewing the corresponding patient charts. Due to the anonymous and retrospective nature, we are not able to interview the original reporters.

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