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A human factors and survey methodology-based design of a web-based adverse event reporting system for families

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ABSTRACT

Purpose: Adverse event reporting systems allow healthcare institutions to detect and prevent recurrence of avoidable patient harm. It is known that standard reporting systems, which are initiated by clinicians, detect only a minority of chart-documented adverse events. The objective of the study was to develop a web-based system, the Family Reporting System (FRS), to elicit adverse event reports from families of children admitted to hospital through survey methodology and human factors engineering techniques.
Measurements: Face validity and usability were measured via standardized survey instruments. Utility was measured via the rate, typology, degree of harm, likelihood of recurrence, quality of information, and inter-rater agreement analysis of the reported events.
Results: The FRS has good face validity, excellent usability, and good clinical utility.
Conclusion: The application of survey and human factors methodologies to the design of an electronic system is an effective means of developing an electronic adverse event reporting system for the use of families of pediatric patients.

1. Introduction

Recent reports indicate that adverse events[1] during hospital stay result in more deaths per year than deaths from breast cancer, motor vehicle accidents or AIDS [1]. Of these events, approximately half have been judged preventable [2], thus the identification of potential or real risks to patients is essential for improving patient safety.

Currently, most healthcare facilities use adverse event reporting systems to gather information about safety problems. These systems require healthcare providers to initiate

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[1] An adverse event is an injury caused by medical management rather than the patient's underlying disease. Adverse events can be either preventable or unpreventable. A Medical Error is the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. A near miss is an error that could have caused harm but did not reach the patient because it was intercepted [18].

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safety reports. However, many opportunities for improvement are lost because healthcare provider-initiated reports significantly under-represent the true adverse event rate [3]. Previous research has shown that events detected by patients can provide valuable learning opportunities not reported by healthcare providers or documented in patients' medical records [4–14].

The objective of the study was to develop a web-based system, the Family Reporting System (FRS), to elicit adverse event reports from families of children admitted to hospital. It was hypothesized that the FRS would capture the types of adverse events typically experienced at the study hospital and would achieve human-centric goals (face validity and usability), while providing good utility.

1.1. *Presentation of the problem*

Since *To Err is Human*, released in 2001, reported that as many as 100,000 Americans may die each year due to medical errors [1], a huge international effort has been undertaken to identify and reduce harm due to medical care [15]. From the Canadian perspective, an adverse event occurs in approximately 7.5% of hospital admissions [2], a rate similar to other developed countries, such as the United States where approximately 70,000 children experience an adverse event annually [16]. Families and loved ones suffer by association. Accordingly, there is an urgent need to provide insight into the nature of adverse events and to develop mechanisms by which they can be systematically reduced on a large scale. Addressing this safety deficiency has become a priority for many researchers and providers, who have emphasized information technology as a means to tackle this challenge [17].

1.2. *Discovering patient safety opportunities for improvement: giving patients and families a voice*

To increase the reporting of adverse events, several institutions have shifted their focus and have given adult patients and their families the opportunity to report adverse events directly [4–14]. These approaches have identified more adverse events more successfully than traditional techniques [9,10]. Patient reports have also been shown to possess good reliability and validity, indicating their potential usefulness in healthcare generally [9,10,12]. However, there are no published investigations of a system designed to allow patient or surrogate reporting of adverse events in the pediatric population. In order to address this gap in patient safety, a web-accessible system, which families can use to report patient safety concerns, the FRS, has been developed.

1.3. *Research objectives*

The aim of this project was to develop a system enabling families to routinely identify adverse events and near misses. Research efforts were divided into the following four separate goals: (1) relevance: the FRS design and structured taxonomy would be based on the adverse events reported to the current healthcare provider reporting system, from the study ward, during the 1 year prior to the commencement of the study; (2) face validity: clinical experts and parents/guardians of pediatric patients would judge the event categories and language to be suitable to the task of reporting adverse events; (3) usability: families would find the FRS easy to use; (4) utility: a representative sample of adverse events reported by parents would be judged to be clinically useful.

2. Methods

2.1. *Selection of sites and subjects*

The study was conducted at British Columbia Children's Hospital, an academic tertiary care facility located in Vancouver, British Columbia, Canada. Ethics approval was received from the relevant Institutional Review Boards. The relevance phase of the study did not require subject recruitment. For face validity studies, members of the hospital's Family Advisory Committee, and collaborators who were unfamiliar with the FRS were recruited. For the usability and utility studies, parents and guardians of children admitted to the general surgical ward at the hospital were recruited. Parents and/or guardians were included only if they provided written informed consent.

2.2. *Intervention: development of the FRS*

The process of developing the FRS began with a literature review of all English language publications concerning patient or family-initiated adverse event reporting [18]. A list of adverse events obtained from the papers produced by this review, and the current hospital critical incident reporting application (Datix Software, London, UK) produced an initial list of 44 example adverse event items. These were subsequently grouped into six main categories of possible incidents: (1) medication problems, (2) complications of care, (3) equipment problems, (4) communication problems between hospital staff, (5) communication problems between family and staff, and (6) other concerns.

2.3. *Integration into the provider–patient safety learning system*

The commercial web-based patient safety learning system (Datix Corporation, London, UK), currently deployed in the hospital for provider-based reporting, was adapted to provide the web interface for this study. The FRS design is based on a systems perspective of adverse events and near misses. The interface is a web page that respondents use via a series of drop-down lists and pop-up boxes. The web page was designed to include introductory information (Fig. 1), links to further details (such as the study information sheet), and instructions for use.

Respondents did not require a log in name, received no training in how to use the system, and were recruited and consented by a Research Assistant. Respondents are presented with a specific question used to identify, from the six categories of errors, the types of adverse events that may have occurred during hospitalization. Each category is explained using a concise definition and clarifying examples. Respondents must respond to each of the six items by indicating if a safety problem had occurred or if it was

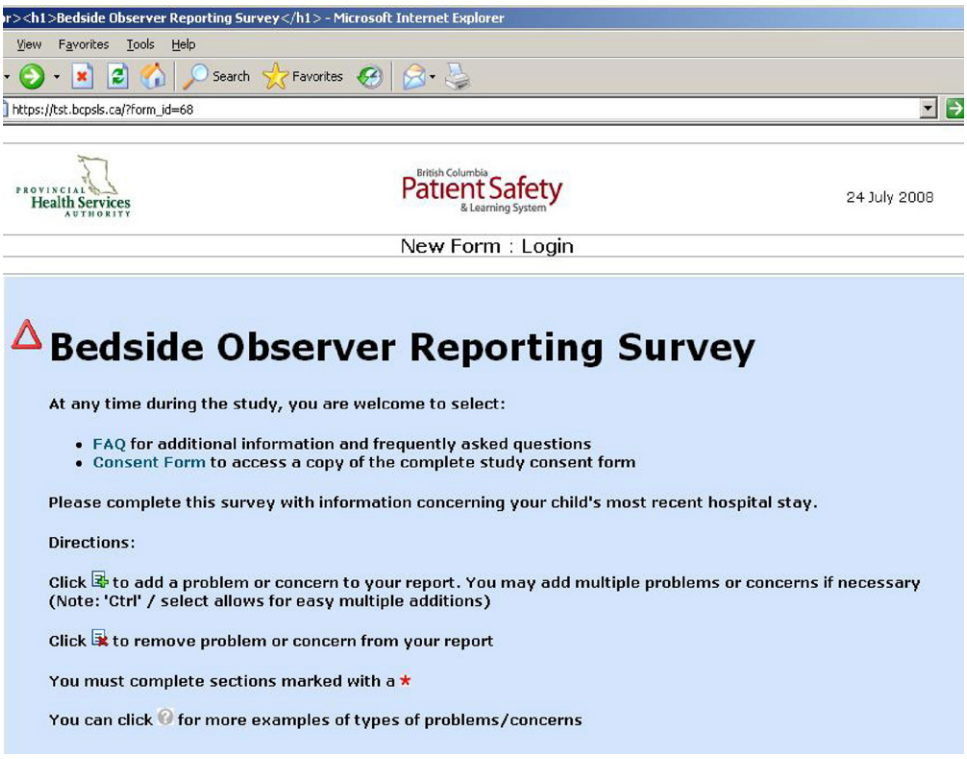

Fig. 1 – Introductory screen for family-initiated adverse event reporting system.

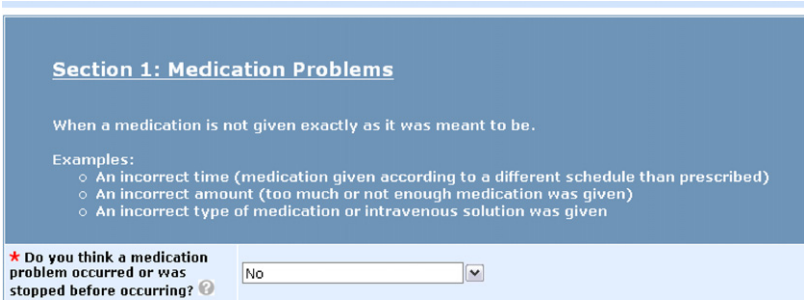

Fig. 2 – Medication problems interface.

stopped before occurring (a "near miss" or "close call"). An example of the medication problems category is shown in Fig. 2.

Responses to each question are mandatory. Selecting 'Yes' from the drop-down box provides a list of follow-up questions that provide additional information about the identified problem (Fig. 3).

Selecting 'No' from the drop-down box allows for a quick exit from that category. The questions asked and their corresponding response method is indicated in Table 1. Respondents could report problems in more than one category.

Respondents had the option of including identifying information (name, contact information, relationship to the patient, and willingness to participate in efforts to prevent

Table 1 – Design of patient safety problem interface.

Question	Response method
Medication problems that occurred:	Pop-up box
Medication problems that were stopped before occurring:	Pop-up box
If any other medication problems occurred which were not listed above, or if you would like to provide more information on one you observed, please list the details here:	Free text field
Was staff aware of this problem or concern?	Drop-down list (yes/no)
If you discussed this problem or concern with staff, did the discussion meet your needs?	Drop-down list (yes/no)
Did you or your family receive an apology from staff?	Drop-down list (yes/no)
If you think staff could do anything to prevent this from happening to patients, please select from the list:	Pop-up box

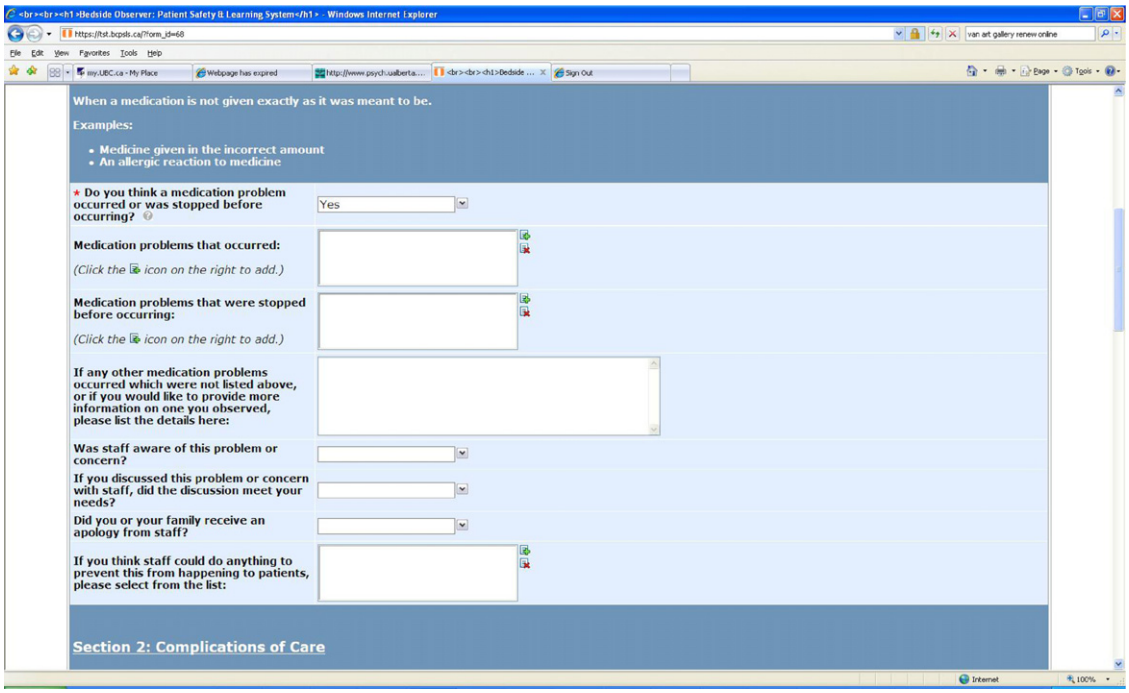

Fig. 3 – Additional questions displayed after a positive response to one of the six initial question items.

similar occurrences) following the completion of the six question items. This was done so that contacting the parent to obtain further information about a reported event would be a possibility; and for the recruitment of a parent liaison committee to represent families during hospital efforts to prevent future adverse events. A recent Canadian study performed in a similar pediatric tertiary care center revealed that most of their parent population had internet access (95%), and that 70% did their banking online. In this population, 42% had at least a university education, and 63% had a family income greater than $50,000 Canadian dollars [19].

2.4. *Relevance*

To ensure that the FRS would be relevant, de-identified provider reports of adverse events from the study ward for the 1-year period, prior to the study period were obtained from the Department of Quality, Safety and Risk Management. Each report was matched to one of the six initial questions and subsequent question items on the FRS by investigators AK and JMA. In the event of a disagreement, consensus was reached. The number of reports that did not map to an FRS category was counted. Revisions were made to the design to include unsuccessfully mapped adverse events.

2.5. *Face validity*

To establish the face validity of the FRS, five patient safety experts were selected to assess the validity of the wording used in the FRS (89 items). An online survey application (built using www.SurveyMonkey.com, Oregon, USA) was used to collect feedback on the validity of each question or statement used in the FRS, according to the Nevo technique [20]. All components rated as inadequate or unsuitable were reviewed by a panel of three of the investigators. Modifications and improvements were then made to the questions statements and language used in the FRS to improve its validity. This procedure was repeated with 15 members of the hospital Family Advisory Committee (non-patient safety experts) and additional modifications were made to improve validity of questions, examples and statements.

2.6. *Usability*

To ascertain usability of the FRS, parents of children ($n = 15$) who were being discharged from the surgical ward, were recruited for the task of using the FRS to report any patient safety problems that had occurred during their stay. After the participants completed this task, the Lewis Computer System Usability Questionnaire was administered [21]. Any aspect of the FRS that scored below a four on the seven point scale and/or had negative comments was reviewed and revised.

2.7. *Utility*

To determine the utility of the FRS, all adverse event reports obtained between November 1, 2008 and January 31, 2009 from parents of children hospitalized on the study ward were analyzed. Parents were consented and allowed to interact with the FRS via laptop on the mornings of the day they were discharged from hospital. Two clinician reviewers reviewed and classified the reported events in terms of their degree of harm, their likelihood of recurrence, and information quality. Degree of Harm options were:

- Not a patient safety issue.
- Near Miss: Harm almost occurred but was avoided through chance or timely action.

- Minor Harm: Minor, but temporary, injury occurred to the patient.
- Moderate Harm: Moderate, but temporary, injury occurred to the patient.
- Severe Harm: Serious injury, altering hospital stay and/or requiring additional treatment.
- Death.

Likelihood of recurrence was ranked on a five point scale between 0 and a 100% (<1%, 1–10%, 11–50%, 51–90%, >90%). Quality of information was judged on a three point scale (inadequate, adequate and excellent). Percent agreement between reviewers was determined.

2.8. *Analysis*

The proportion of adverse events that did not map to the FRS class-taxonomy and the number of revisions required for correction were analyzed to gauge relevance. The proportion of all items ranked in need of review (having a score of three or less on a five point scale), and the number of corrective changes made to the FRS were used to determine the face validity of FRS. For usability, the average rating in each usability aspect was calculated. To estimate utility, the rate, typology, degree of harm, likelihood of recurrence, quality of information, and inter-rater agreement of the reported events and their classification was determined.

3. Results

3.1. *Relevance*

Two hundred and eighty-five reports paper-based reports were completed (from between November 1, 2008 and January 31, 2009). Seventy-two percent (205) of the reports mapped to only one FRS category, however, 72 reports (25%) mapped to two or more categories. Nine reports (3%) could not be mapped before changes to the classification scheme were made. Eight of these events involved documentation errors. The problem category distribution is given in Table 2.

Table 2 – Number of reports mapped to each category.

Category	Number of reports	Percentage
Medication problems	157	55%
Miscommunication between staff	42	15%
Complication of care	32	11%
Equipment problem	32	11%
Other concerns	16	6%
Miscommunication between your family and staff	6	2%
Total	285	100%

3.2. *Face validity*

3.2.1. *Expert face validity review*

Experts ranked 52 items as in need of review (58% of total). Of the 52 items ranked by the expert reviewers as needing review, 65% were flagged by only one reviewer, and 33% were flagged by two reviewers. No items were flagged by four or more experts. A panel consisting of three of the investigators reviewed the 52 items, and made changes to 33 items (63%) to reduce ambiguity and required reading level. An example of an adverse event item changed after review is "medicine given in the incorrect amount" which reads at a Grade 10 level (Flesch-Kincaid Readability Statistic, Microsoft Word 2007, Redmond, Washington), which was replaced by the two separate items "too much drug given" (Grade 1 readability) and "too little drug given" (Grade 4 readability). Another item changed was "intravenous or arterial line did not work correctly" (Grade 11 readability), which was replaced by the two items "intravenous line did not work" and "Arterial line did not work", both of which have Grade 5 readability. Additionally, all of the experts' comments were reviewed, and an additional 17 changes to the FRS were made (19% of total items). A summary of the results is given in Table 3.

3.2.2. *Non-expert face validity review*

Parents ranked 45 items as in need of review (58% of total). Of the 45 items ranked by the non-expert reviewers as needing review, 26% were flagged by only one reviewer, 19% were flagged by two reviewers, and 18% were flagged by three reviewers. Additionally, one item was flagged by four review-

Table 3 – Summary of expert reviewers' validity feedback.

Section	Items considered per section	Items judged as needing review	Items revised after review	Changes due to expert comments
Medication problems	19	6	2	3
Complications of care	16	11	7	0
Equipment problems	12	4	2	2
Miscommunications between staff	10	7	5	1
Miscommunication between you and staff	11	7	7	4
Other concerns	12	11	5	4
Follow-up questions	2	2	2	1
Preventative actions	7	4	3	2
Total	89	52	33	17

Table 4 – Summary of family member reviewers' validity feedback.

Section	Questionnaire items considered per section	Questionnaire items judged as needing review	Questionnaire items revised after review	Questionnaire items revised due to comments alone
Medication problems	15	14	3	4
Complications of care	14	7	1	1
Equipment problems	9	4	2	2
Miscommunications between staff	9	4	1	0
Miscommunications between you and staff	11	4	4	1
Other concerns	8	7	4	0
Follow-up questions	3	1	0	0
Preventative actions	9	4	0	1
Total	78	45	15	9

ers, and the largest number of reviewers flagging a single item was five, which occurred once. All 45 items were reviewed and 15 changes (33% of total items) were made to reduce ambiguity and required reading level. The most common reason for not changing an item when a parent or expert had flagged it as in need of review was that no explanation was given for how the item was problematic, and the investigators could not determine this themselves. In the case where the investigators did not know the problem with the item, and it was of acceptable grade level, it was not changed. Additionally, all of the family members' comments were reviewed and 9 additional changes to the FRS (38% of total items) were made. These changes all involved reducing the grade level of statements in a similar fashion to the examples given in Section 3.2.1. A summary of the changes is given in Table 4. Totals in Table 4 do not match totals in Table 3 due to deletion of very low scoring items from a list of candidates for FRS category definitions.

3.3. *Usability*

Twelve percent of the questionnaire items were considered for further review, which resulted in a total of nine minor corrective changes to the usability of the FRS. A summary of the usability results is given in Table 5.

High usability scores (<2.0) were achieved for simplicity, learnability, productivity, and understandability. However, only moderate usability scores (2.0–2.5) for ease of use, comfort, effectiveness, recoverability, and on-screen messages were obtained, with lower usability scores for on-screen messages and likeability of using the system.

3.4. *Utility*

One hundred and three patient safety problems were reported from 180 consented discharged patients. Two hundred and thirty-two patients were eligible and approached to participate in the study, resulting in a 78% participation rate (50 parents declined to participate). These 103 safety problem reports were from 73 families as thirty families reported more than one patient safety problem. This yields a problem reported rate of 40% of discharges. The typology of the reported events is shown in Fig. 4.

The degree of harm and likelihood of recurrence of the reports is given in Tables 6 and 7.

Table 5 – Usability experiment results.

Usability statement	Average rating out of 7 (1 = max score)	Highest rating	Lowest rating
Overall, I am satisfied with how easy it is to use this system.	2.2	1	5
It is simple to use this system.	1.9	1	5
I can effectively complete my task using this system.	2.1	1	5
I am able to complete my task quickly using this system.	1.9	1	4
I am able to efficiently complete my task using this system.	2.1	1	4
I feel comfortable using this system.	2.1	1	6
It was easy to learn to use this system.	1.8	1	5
I believe I became productive quickly using this system.	1.7	1	4
The system gives error messages that clearly tell me how to fix problems.	2.9	2	4
Whenever I make a mistake using this system, I recover easily and quickly.	2.4	1	7
The information (such as on-screen messages) provided with this system is clear.	2.2	1	5
It is easy to find the information I need.	2.5	1	5
The information provided with the system is easy to understand.	1.7	1	4
The information is effective in helping me complete my task.	2.0	1	4
The organization of information on the system screens is clear.	2.5	1	5
The interface of the system is pleasant.	2.2	1	5
I like using the interface of this system.	2.8	1	7
This system has all the functions and capabilities I expect it to have.	2.0	1	4
Overall, I am satisfied with this system.	2.0	1	4

Table 6 – Degree of harm of family reports.

Degree of harm	Frequency	Number of reports by category					
		Medication problems	Complications of care	Equipment problems	Miscommunications between family and staff	Miscommunications between staff	Other
Not a patient safety issue	26%	3	0	3	5	14	10
Near miss	11%	3	1	5	6	10	2
Minor harm	0%	2	4	3	1	1	0
Moderate harm	2%	0	0	0	0	0	0
Severe harm	0%	0	2	0	0	0	0
Death	27%	0	0	0	0	0	0
Cannot evaluate	34%	10	3	3	6	3	3

Table 7 – Likelihood of recurrence of family reports.

Likelihood of recurrence	Frequency	Number of reports by category					
		Medication problems	Complications of care	Equipment problems	Miscommunications between family and staff	Miscommunications between staff	Other
>90%	26%	0	4	6	13	23	11
51–90%	11%	0	0	3	2	4	3
11–50%	0%	2	0	1	0	0	0
1–10%	2%	6	1	0	0	0	0
<1%	0%	4	0	1	0	0	0
Cannot evaluate	27%	6	5	3	3	1	1

The quality of information in the reports was deemed to be adequate or excellent in 73% of the reports for judging degree of harm; but inadequate 27% of the time. Report information quality was estimated to be adequate or excellent 80% of the time for judging likelihood of recurrence; but inadequate 20% of the time. An example of an FRS report judged to be adequate for estimating both its degree of harm and its likelihood of recurrence was "The nurse miscalculated the pain medicine and gave half the dose". An example of an FRS report judged inadequate to estimate both its degree of harm and its likelihood of recurrence was "Not sure of dose of medication and was confusing". On average, two reviewers agreed 83% of the time on report classification.

3.5. *Additional examples of FRS reports*

Additional examples of reports submitted to the FRS in each category are given in Table 8. The reader may note that the example.

4. Discussion

4.1. *Significance*

Several studies of patient reporting adverse events have been published. These studies used a wide range of methods

Table 8 – Examples of reports submitted by domain.

Domain	Example
Medication errors	"Patient developed an itchy rash all over abdomen and thighs"
Complications of care	"Child had to have his shunt surgery redone because first one failed"
Equipment errors	"The scale to weigh child did not work. It said he was losing weight when he was actually gaining. We were in hospital for a few extra days because of it!"
Miscommunications between staff	"Test was repeated because not enough blood was drawn the first time. It ended up that an additional vial of blood was required, but the nurses did not double-check the amount required until after the first procedure was completed."
Miscommunications between family and staff	"I thought I was sent to my son's room to wait for him. The recovery room nurse thought I'd be waiting somewhere else. We all finally connected and it turned out ok. Clearer instructions from less people would help."
Other	"When we arrived in urgent care, we provided a lot of information to the nurses (4 pages total), but had to constantly repeat ourselves and provide the same information over and over to the other nurses and doctors. Is this information not already available? This was complicated by the fact that our English is not good."

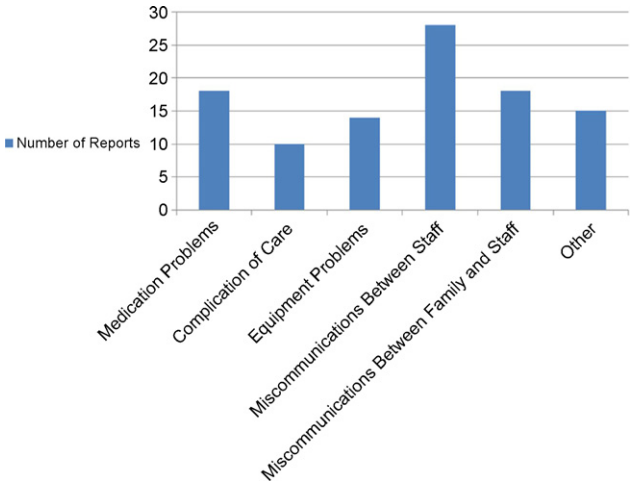

Fig. 4 – Typology of FRS reports.

and were performed in diverse settings [4–14]. Consequently, definitive comparisons and conclusions about the optimal method for acquiring these reports are not possible. This study has described the successful use of survey methodology and human factors techniques [22] in developing an electronic system intended to be used by families of pediatric patients to report patient safety problems. Reviewing the literature on patient initiated patient safety reporting shows that less than 25% of published initiatives used web-based technology [4,5,23,24], and none of them reported system metrics for the reader to evaluate the quality of their electronic system. Without describing the systems' face validity and usability, the reader cannot determine the effect of the electronic system itself on the outcome measurements. It is this neglect of human factors considerations that is often at the root of failed, yet well-intentioned electronic systems put into place in healthcare [25].

When soliciting adverse event reports, recruiting and interviewing in-person within hospital and primary care settings increase response rates [7]. Exclusively asking for personal experiences or using open-ended questions may yield higher usability for users, but requires a more time consuming and costly analysis. Direct questions and limited response options allow for accurate analysis and provide a structure for classifying adverse events and near misses. The limited response options and the fact that a single event could be correctly classified into more than one class is a common difficulty seen with the classification of any real world complex adverse event. However, closed-ended methods do not allow patients to explain details of events, and can inhibit user freedom and satisfaction. For these reasons, a combination of closed-ended questions and open-ended narratives was used in the design of the FRS.

The approach used in the development of the FRS is consistent with the human-centered design [26] paradigm for technology development. The first step in development was to understand the user domain by analyzing the types of adverse events that had been reported to the hospital Department of Quality, Risk and Safety in the past year. This is similar to a work-domain analysis, commonly conducted in human-centered design efforts [27], but constitutes more of a problem-domain analysis. The face validity of the FRS statements was also assessed. The function of face validity measurement is to determine how relevant each item is to the intended user. The initial work, understanding the problem-domain, allowed for improved face validity ratings from users. The two-stage approach to evaluating face validity, first with patient safety experts and then with parents, ensured the FRS had adequate relevance according to both safety stakeholders. This iterative approach to the face validity testing provided an incremental improvement in design. By incorporating these checkpoints midway through the design cycle, many improvements to the FRS were made. This can be seen to be analogous to the usability engineering lifecycle [28] used in software design, and this approach, in part, is credited for the overall high usability scores obtained from user testing.

Parents' perceptions of adverse events have been shown to differ from those of healthcare providers [4], and parent feedback on some of the FRS event options was no exception. For example, several families considered language barriers to not be a safety problem, a belief that starkly disagrees with the published literature [29]. Future research into defining patients' perceptions of what constitutes a patient safety problem is warranted if their input is to be harnessed.

A continually challenging issue during the design of the FRS in regards to patient safety was terminology. There exists no consensus on terminology to be used by patient safety researchers and practitioners [30] and there are fewer than 20 articles published on the topic of family reporting of patient safety problems [18]. It is still a very nascent field, and consequently even further away from a consensus-approved lexicon for patient safety as a whole [30]. Additional challenges when developing a standardized patient safety terminology include differing levels of healthcare literacy among families [31], and provider and risk managers' fear of malpractice litigation due to the use of terms which may imply blame, such as "medical error" [32].

The FRS was shown to have good clinical utility. Its rate of detecting patient safety problems (40%) was higher than that determined by a large chart review study [16], and reports were deemed to be of useful quality on average 77% of the time. (The rate of useful reports generated by the FRS was also thereby higher than that achieved by standard detection methods.)

The typology of the patient safety problems reported was consistent with the patient safety literature, where poor communication and medication errors form a large proportion of presenting adverse events [4,33]. The FRS also performed well at identifying near-miss events, well known to be a highly valuable but very often not reported source of information in efforts aimed at improving patient safety [34].

However, 27% of the reports could not be evaluated for degree of harm, mostly due to lack of detailed information from the reporter. Thirty-four percent of FRS reports were not safety issues at all, indicating a potential limitation of the reporting system. These reports were undoubtedly associated with dissatisfaction with the healthcare service received, however. Thus, the lay public may have difficulty distinguishing between low satisfaction healthcare and unsafe

healthcare, which may reflect an inherent limitation of family reporting. Dissatisfaction in healthcare however, has been shown to be a useful predictor of adverse events [35]. Consequently, dissatisfaction-based reports may still be regarded as useful, but their value in preventing recurrence of specific patient safety problems is limited. To reduce the number of reports which could not be evaluated due to lack of detail, the FRS design could be improved to encourage more detailed information from parents through a forcing function which requires parents include a free text description of the event when submitting a report. This would assist in report evaluation.

4.2. *Limitations*

A limitation in the development of the FRS was that due to small sample sizes, we could not perform hypothesis testing, and relied instead on a more qualitative investigation than a quantitative one. Additionally, a test–retest reliability evaluation was not performed, and the Pearson coefficient of agreement between multiple users operating under the same conditions was not calculated. These are both useful measures of the reliability of a survey instrument such as the FRS [22]. Percentage agreement was used when measuring utility instead of a Kappa coefficient or intra-class coefficient due to our data collection technique. Classification of real world adverse events into a small number of categories is impossible to perform with a high degree of precision. A classic example is a physician writes an order for a medication given by intravenous pump but the dose is given at ten times the prescribed amount—was this a medication error, an equipment error (infusion pump), or a miscommunication? Because all of these classifications are acceptable, we chose to have one expert classify each event, and then asked a second expert whether they would agree with the first expert's classification. Furthermore, criterion validity was not assessed as this requires comparison to a gold standard, which is currently unavailable. It is hoped that the FRS will provide the standard for such future work.

4.3. *Future work*

Future work involves an ongoing evaluation of the FRS on a pediatric surgical ward over a 6-month period. Families of patients admitted to hospital will be eligible to complete a report using the FRS. These reports will be analyzed to determine how the pattern of submitted reports contrasts with a retrospective pattern of provider-initiated reports, particularly in terms of adverse event and near-miss incidence, severity, and problem type. A prospective study will be performed to determine if a system offering families the opportunity to report patient safety events increases provider reporting. Furthermore, investigation of the effect the FRS on provider workload and provider–patient relationship is planned. Finally, to further investigate the value of this approach, the accuracy of the reports submitted from families will be investigated via corroboration with collateral information obtained from patients' medical records.

Summary points

What is already known on the topic:

- Adult patients can report adverse events that occurred to them using a variety of non-validated tools.
- Adult patient adverse event reports can be judged to be useful to patient safety analysts at healthcare institutions.
- Adverse events in healthcare are common, dangerous, and frequently preventable.

What this study added to our knowledge:

- Parents of pediatric patients will report adverse events to an electronic system.
- Parent adverse event reports can be judged to be useful to patient safety analysts at healthcare institutions.
- The application of human factors techniques such as domain analysis and usability testing aids the design of electronic adverse event reporting systems.
- The application of survey methodology techniques such as face validity testing aids the design of electronic adverse event reporting systems.

5. Conclusion

A combination of survey and human factors methodologies were implemented in the design of a web-based system that allows families to report adverse events occurring in the pediatric inpatient population. The efforts expended during this development will translate into increased effectiveness of a system that gives families a voice in patient safety improvement. While enhanced reporting systems on their own cannot improve patient safety, well designed and executed reporting systems are an essential step towards a world where healthcare does no harm. In order for this to occur, hospitals need to research and invest in better ways to translate reported patient safety problems into measurable improvements.

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