

The Bedside Observer: Using patient and family observations to enhance patient safety

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Main Messages

- Soliciting reports of adverse events from families of children admitted to hospital identifies concerns in 30% of hospital episodes.
- The majority of the events are valid safety concerns as judged by safety experts.
- Families of hospitalized children identify safety learning opportunities not reported by healthcare providers.
- Family reporting of adverse events does not alter the rate of healthcare provider reports in pediatric surgical inpatient care.
- Additional research will be required to discover how to optimally use safety reports to engage patients and their families in safety improvement.

Executive Summary

Not all incidents of injury or death in hospital are related to illness. Health problems caused or exacerbated by healthcare delivery (*adverse events*) are a large burden on our healthcare system. Adverse event reporting systems allow hospitals to identify and prevent recurrence of avoidable patient harm. Safety events are under reported in systems that depend solely on healthcare providers to report adverse events and the associated safety learning

opportunities. Patients and their families remain an untapped resource for improved reporting and for the implementation of safety improvements.

This study aimed to design, implement, and evaluate a patient safety reporting system for the parents and guardians of pediatric patients admitted to hospital. The web-based questionnaire was designed for family identification and reporting of adverse events and near misses directly into the hospital electronic incident report system.

The first phase involved a literature review to identify the best method for obtaining safety incident reports from families. Secondly, we designed then validated the usability and reliability of a web-based safety reporting questionnaire. The next step was a 12-month pilot study of the questionnaire undertaken on the Neurosciences & Surgery Unit (3R) at British Columbia Children's Hospital (BCCH) in Vancouver, British Columbia, Canada.

The families of hospitalized children identified many adverse events and safety learning opportunities not reported by healthcare providers. The presence of family reporting did not alter the rate of healthcare provider reporting. Most families were willing to be identified and indicated willingness to participate in safety improvement efforts. Once safety events are reported by families, it is imperative to follow-up with parents and to institute safety improvement solutions so that a tangible change in outcomes can be achieved. Empowering patients and their families to be active partners in their care was the primary impetus behind this project and we hope it will continue to be the focus of future patient safety efforts.

1.0 Context

Health problems caused by healthcare management rather than illness are a large burden on healthcare, both in Canada and worldwide. Recent reports indicate that adverse events during hospital stays result in more deaths per year than deaths from breast cancer, motor vehicle accidents or AIDS.¹ The Canadian Adverse Events study indicated that an adverse event occurs in 7.5% of hospital admissions². Of these adverse events, 37-51% have been judged preventable.² To reduce such numbers, we must first identify and learn from safety incidents (adverse events and near misses) among hospital patients.

Currently, the adverse event reporting systems used in healthcare facilities often rely on healthcare providers to report events. Despite much effort, many barriers still exist for provider-based adverse event reporting, including a perceived lack of protection for revealing incriminating information, a lack of visible feedback, and a perceived lack of value in the process.³ To increase the reporting of adverse events, several institutions have shifted their focus to give adult patients and their families the opportunity to directly report adverse events.^{4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14} These approaches have produced impressive results, identifying more adverse events than traditional techniques with good reliability and validity.^{9, 10, 12}

This study aimed to design and evaluate the implementation of a web-based adverse event reporting system called the *Bedside Observer* (BSO) that allowed parents and guardians of children admitted to hospital to report adverse events that occurred during their hospital stay.

2.0 Implications

The most effective strategies for identifying adverse events are likely to come from partnering with patients. Engaging patients and their families as active partners in their care will allow healthcare providers to use their input to make healthcare systems safer. Furthermore, designing solutions to safety hazards that were identified by families are likely to be well received by healthcare providers.

The questionnaire designed for family identification of adverse events and near misses stands to have several advantages over traditional provider based reporting systems including:

1. Improved detection of adverse events and especially near misses.
2. Increased reporting of adverse events by healthcare providers.
3. Improved adoption of policies and procedures designed to improve patient safety by engendering a culture of safety.

3.0 Methods

3.1 Phase I: Literature Review

A literature review of existing patient safety reporting efforts was performed as the initial step in the development of the *Bedside Observer* (BSO) patient safety reporting system. Two databases, PubMed and MEDLINE, were searched for literature on patient reporting of medical errors and adverse events. Comparisons were performed to identify the optimal method for eliciting patient initiated reports.

3.2 Phase II: Questionnaire Development

A list of adverse events obtained from the papers reviewed in Phase I and the current hospital Patient Safety Learning System (PSLS), a critical incident reporting application (DATIX Software, London, UK), produced an initial list of 44 adverse event items. These were subsequently grouped into six main categories of possible incidents (Table 1).

The hospital PSLS currently deployed for provider-based reporting was adapted to provide the web interface for patient reports of adverse events. The web interface used a series of drop-down lists and pop-up boxes. The web page was designed to include introductory information (Figure 1), links to further details (such as the study information and consent form), and instructions for use of the form.

Table 1 - BSO categories and corresponding questions

Category	Question
Medication Problems	Do you think a problem with medication occurred or was stopped before occurring?
Complications of Care	Do you think a complication of care occurred or was stopped before occurring?
Equipment Problems	Do you think an equipment problem occurred or was stopped before occurring?
Miscommunication Between Staff	Do you think miscommunication between staff occurred, or was stopped before occurring?
Miscommunication Between Family and Staff	Do you think miscommunication between your family and staff occurred or was stopped before occurring?
Other Problems	Do you think any other problems occurred or were stopped before occurring?

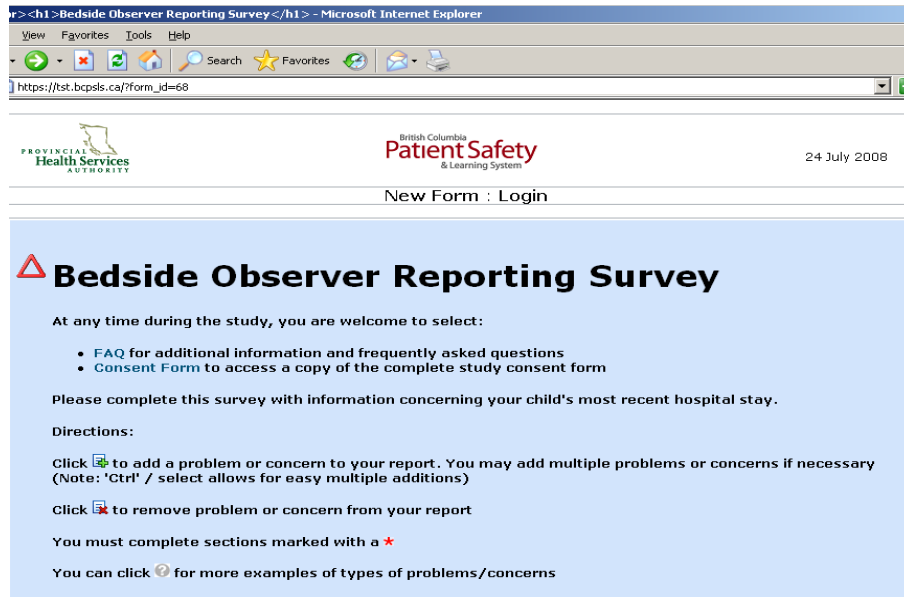


Figure 1 - Introductory screen for family initiated adverse event reporting system

Respondents were recruited and provided informed consent to participate at the time of discharge from the surgical ward. Respondents did not require a login name and received no training prior to using the system. Based on the six categories of errors, specific questions were used to identify the types of adverse events that may have occurred during hospitalization (Figure 2). Each category was explained using a concise definition and clarifying examples. Participants responded to each of the six items by indicating if a safety problem had occurred or if it was stopped before occurring (a *near miss* or *close call*).

Section 1: Medication Problems

When a medication is not given exactly as it was meant to be.

Examples:

- An incorrect time (medication given according to a different schedule than prescribed)
- An incorrect amount (too much or not enough medication was given)
- An incorrect type of medication or intravenous solution was given

* Do you think a medication problem occurred or was stopped before occurring?

Figure 2 - An example category with explanation and examples


Responses to each question were mandatory. Selecting *yes* from the drop-down box provides a list of follow-up questions to provide additional information about the identified problem (Figure 3). Selecting *no* from the drop-down box allows for a quick transition to the next category.


When a medication is not given exactly as it was meant to be.

Examples:

- Medicine given in the incorrect amount
- An allergic reaction to medicine

* Do you think a medication problem occurred or was stopped before occurring?

Medication problems that occurred:
(Click the  icon on the right to add.)

Medication problems that were stopped before occurring:
(Click the  icon on the right to add.)

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:

Was staff aware of this problem or concern?

If you discussed this problem or concern with staff, did the discussion meet your needs?

Did you or your family receive an apology from staff?

If you think staff could do anything to prevent this from happening to patients, please select from the list:

Figure 3 - An example of additional questions displayed after a positive response to one of the six initial question items

Following the completion of the six question items, respondents had the option of including identifying information (name, contact information, relationship to the patient, willingness to participate in efforts to prevent similar occurrences). This was used to contact

parents to obtain further information about a reported event and for including parents in efforts to prevent similar harm to future patients.

3.2.1 Relevance

De-identified provider reports of adverse events from the study ward for the one year prior to the study period were obtained from the PSLs. Each report was matched to one of the six initial questions and subsequent question items on the BSO by investigators AK and JMA. In the event of a disagreement, consensus was reached by further discussion. Revisions were made to the design of the classification system to include unsuccessfully mapped adverse events.

3.2.2 Face Validity

Face validity of all question items (89 in total) were evaluated by five patient safety experts. An online survey application (SurveyMonkey.com, Oregon, USA) was used to collect feedback on the validity of each question or statement used. All components rated as inadequate or unsuitable were reviewed by a panel of three of the investigators. Modifications and improvements were made to the questions statements and language used in the BSO to improve validity. This procedure was repeated with 15 members of the hospital Family Advisory Committee, and additional modifications were made to questions, examples, and statements.

3.2.3 Usability

Fifteen parents/guardians of children being discharged from the surgical ward were recruited to report any patient safety problems that occurred during their stay. After they had completed the web-based questionnaire, the Lewis Computer System Usability Questionnaire

was administered. Any aspect of the BSO that scored below a four on the seven point Likert scale and/or had negative comments was reviewed and revised.

3.2.4 Repeatability

Six fictional scenarios based on an in-hospital training manual used to instruct nurses on how to use the PSLS and reviewed by the patient resource language officer was provided to 10 family members. Participants were each asked to classify three of the six scenarios that had been randomly selected into a category.

3.3 Phase III: Questionnaire Evaluation

3.3.1 Recruitment of subjects

With informed consent, parents and guardians of children admitted to the Neurosciences and Surgery unit (3R) were recruited by a research assistant on the morning of their discharge from hospital following at least 24 hours of hospitalization. Those who did not understand, read, and write English were excluded. Those who agreed to participate were given a short tutorial on how to use the system prior to completing the survey.

3.3.2 Survey completion

The web-based questionnaire developed in Phase II was used to illicit reports. Narrative descriptions and details of the reported event were then requested if relevant (Figure 4). If an adverse event was reported, the participant was asked whether or not staff were aware of the problem or concern. They were asked whether or not the problem had been discussed with staff

and, if so, whether the discussion met their needs and if an apology had been offered. Response options included: *none*, *inadequate*, *adequate*, and *very adequate* (Figure 5).

* Do you think a miscommunication between staff occurred or was stopped before occurring? Yes

Miscommunications between staff that occurred:
(Click the icon on the right to add.)

Miscommunications between staff that were stopped before occurring:
(Click the icon on the right to add.)

* Please tell us more about the communication problem.

Was staff aware of this problem or concern?

If you think staff could do anything to prevent this from happening to patients, please select from the list:

Figure 4 - An example of the prompts to provide a narrative description of the safety event

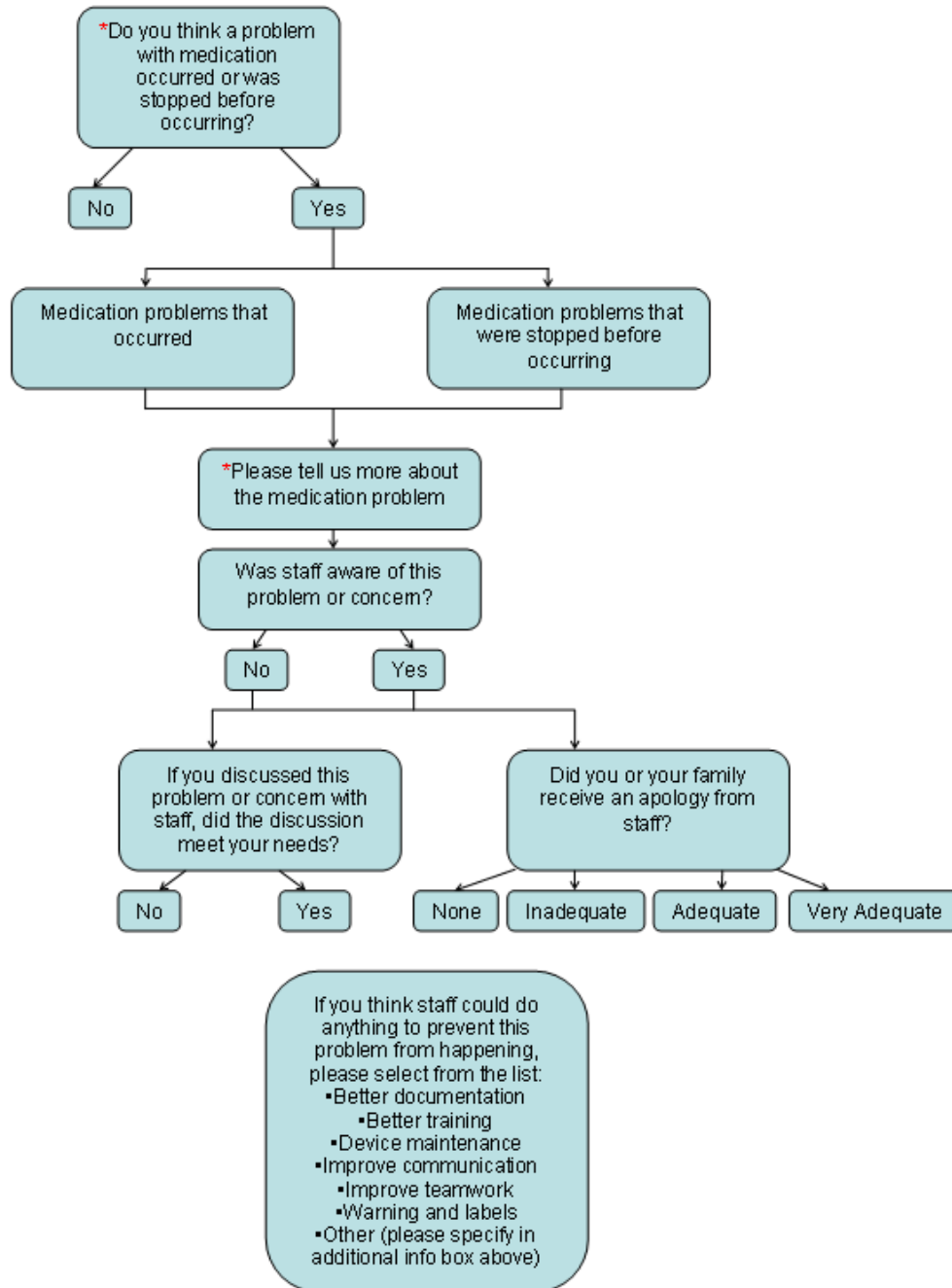


Figure 5 - Flow diagram of an example BSO question

3.3.3 Confidentiality

The survey was anonymous but did allow participants to identify themselves, their relationship to the patient, and to provide their contact information should they wish to participate in future patient safety improvement projects. If personal information was not provided, participants were only identified by unique code number.

3.3.4 Report processing

The web-based nature of the survey allowed all reports to be directly submitted into the electronic PSLs. Reports were reviewed by members of the research team. Any responses that included at least one safety event were immediately referred to the hospital Quality, Safety, and Risk Management (QSRM) department for follow-up.

3.3.5 Evaluation of reports

All reports were evaluated by two independent clinical reviewers. Reports were reviewed and classified by: degree of harm; information quality to judge degree of harm; likelihood of recurrence; information quality to judge likelihood of recurrence; event type; and possible solutions to prevent recurrence of the event. The agreement between the two reviewers was calculated.

3.3.6 Effect of family-initiated reports on provider reporting

Healthcare provider reports submitted by hospital physicians and nurses through the PSLs between November 2007 and November 2009 (12 months prior to and 12 months following the introduction of the BSO system) were retrieved.

A regression switch analysis was used to identify trends in the monthly provider report counts. To determine the proportion of patients who experienced an adverse event that was not reported through the traditional method of provider reporting, we compared all BSO and provider reports to identify potential matched events. Reports were compared by date (< 5 days apart, > 5 days apart, exact date) and description (unlikely match, likely, definite match). When evaluating descriptions for degree of similarity, we considered the type of events, type of staff involved, setting or location (inpatient unit, operating room, surgical daycare), and the time frames described.

3.3.7 Sample size

Based on an estimated consenting rate of 30% of discharged patients during a one year period, and a historical discharge rate of 151 patients (post-surgical and non-surgical) per month, we planned to enroll 544 families in the study. Historically, averages of 12 incidents a month are generated from the PSLS, corresponding to a crude rate of 27.9 reports per 1000 patient days. We anticipated that our interventions would double that rate. Calculations based on a Poisson model with an over-dispersion factor of 1.2 (corresponding to an Intra-Class Correlation Coefficient of 0.17) revealed that we would have 88% power in comparing observed rates in the one year intervention period and the one year period prior to the intervention. This corresponded to a standard error for the rate difference of approximately 8.0, yielding a confidence interval around the point estimate of +/- 16.

4.0 Results

4.1 Phase I: Literature Review

Ninety combination keyword database searches identified 11 relevant publications, two of which used the same data set. Two additional publications were located from reference lists. Three publications were focused on the patient's perception of medical errors, two were detailed quality of care issues, and one pertained to error prevention involving patients. Four additional papers were suggested by colleagues, bringing the total to 17.

4.1.1 Healthcare setting

Five papers asked patients about mistakes encountered involving any aspect of healthcare, including emergency and ambulatory care, and six papers asked about errors during hospitalisation. Four papers focused on errors in primary health care, and one included both primary and specialty care. The remaining study surveyed oncology patients in a teaching hospital.

4.1.2 Solicitation and study duration

Study participants were either involved via self-initiated interest or were actively solicited. Eleven papers (65%) elicited patient reports while the remaining five employed self-initiated reporting surveys.^{4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20} On average, more reports were collected from soliciting reports than self-initiated reporting. The shortest time period of study was five days while the longest was two years.^{9, 13} Approximately one third (35%) of the studies collected reports over periods ranging from two to four months.^{4, 7, 8, 11, 15}

4.1.3 Incentives

Two studies used incentives to encourage reporting.^{6, 13} A recruitment technique involving random telephone number dialling and offering a \$50 payment for an in-person interview yielded one study participant per 10-20 calls. Thirty-eight usable interviews resulted from this recruitment method.⁶ The study with the largest number of patient responses used an online survey with customised health and self-management resources as an incentive for participation.¹³

4.1.4 Reporting methods and response rate

The methods used for collecting patient reports varied along with response rates. Recruitment by random digit dialling was not used in any of the hospital patient studies. However, this method achieved the highest response rate of the five studies focused on broad healthcare experiences.¹⁵ Primary care patient reporting studies used a combination of methods: one used telephone recruitment with a follow up in-person interview, another allowed patients to choose written, online, or telephone reporting, and a third used telephone survey.^{6, 9, 20} Interviewing patients in-person was effective in obtaining high response rates from hospital patients (average 87%), compared to telephone reports from non-hospital settings (average 44%). The highest response rate overall was 96%, achieved by in-person patient advocate interviews for a specific hospital unit.¹² The study with the highest number of responses, over a two year period, was a reporting system for various healthcare setting experiences with 44,860 responses.¹³

4.1.5 Corroboration

Patient reports of adverse events were corroborated in three (18%) publications. One study reviewed medical records, while the other two compared patient reported incidents to hospital incident reports and/or incidence rates reported in the literature. All studies that performed corroboration targeted hospitalised patients.^{4, 5, 8} Cross-referencing medical charts, physician notes and orders, and nurse notes proved to be an effective method for inpatients.⁴ The incidence of nosocomial infection, pressure ulcers, and drug related events reported by patients was shown to be comparable to rates documented by healthcare providers in hospital and to the rates reported in the patient safety literature.⁵

4.1.6 Report characteristics

The incidence rate for adverse events across settings and populations varied considerably, ranging from less than 0.1 to 5.8 per patient.^{6, 13, 19} Incident rates in the target populations and healthcare settings varied widely and, thus, were not statistically compared. More than half (55%) of studies targeting hospitals or primary care settings reported a rate of one incident or more per person, while surveys covering a broad range of healthcare environments reported a rate of 0.6 incidents or fewer per person. Disregarding any other differences in reporting method, five studies used only open-ended questions, averaging 1.9 reported incidents per person, whereas strictly closed-ended questions or a combination of both types achieved averages of 0.7 and 0.4 per person, respectively. Incident rates from reports of personal experiences averaged 1.3 per person, while rates from reporters including family or household members' experiences averaged 0.3 incidents per person.

Classification of reports was inconsistent among publications. Eight studies (47%) used reporter self-assessment, five had clinicians review reports, three authorized researchers to classify categories, and one had lawyers evaluate possible compensation.^{4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19} Severity of health consequences was used to classify events in five studies.^{4, 8, 12, 13, 15}

4.2 Phase II: Questionnaire Development

4.2.1 Relevance

Two hundred and eighty-five paper-based reports were completed (between 1 November 2008 – 31 January 2009). Two hundred and five (72%) of the reports mapped to only one BSO 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.

4.2.2 Expert face validity review

Experts ranked 52 items as in need of review (58% of total). Of these items 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. Additionally, all of the experts' comments were reviewed, and an additional 17 changes were made to the BSO (19% of total items).

4.2.3 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 reviewers, 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/or the investigators could not determine the reason. In the case where the investigators did not know the problem with the item, and it was of acceptable reading level, it was not changed. Additionally, all of the family members' comments were reviewed and 9 additional changes were made to the BSO (38% of total items).

4.2.4 Usability

Twelve percent of the questionnaire items were considered for further review, which resulted in a total of 9 minor corrective changes to the usability of the BSO.

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.

4.2.5 Repeatability

Repeatability of the BSO was 67% for the *Complications of Care*, *Miscommunications Between Staff* and *Miscommunications Between Family and Staff*, and *Other* sections; and 100% for *Medication Problems*, and *Equipment Problems* domains.

4.3 Phase III: Questionnaire Evaluation

4.3.1 Family initiated reports

Five hundred and forty-four families submitted reports through the BSO system. Three hundred and thirty-six (62%) respondents chose to provide some form of identifying information (name, relationship to patient, email address). Two hundred and sixty-two (78%) participants were mothers, 60 (18%) were fathers, five were relatives, two were grandparents, and seven (2%) chose not to disclose their relationship to the patient.

Of the 544 reports submitted, 201 (37%) included at least one response to the six BSO categories. There were 321 events from these 201 reports. Miscommunication between staff or between family and staff made up the largest group of reports (Figure 6). Thirty-nine percent of reported events were judged as near misses or causing harm (Table 2).

The typology of the reported events is shown in Figure 6. The degree of harm and likelihood of recurrence of the reports is given in Tables 2 and 3.

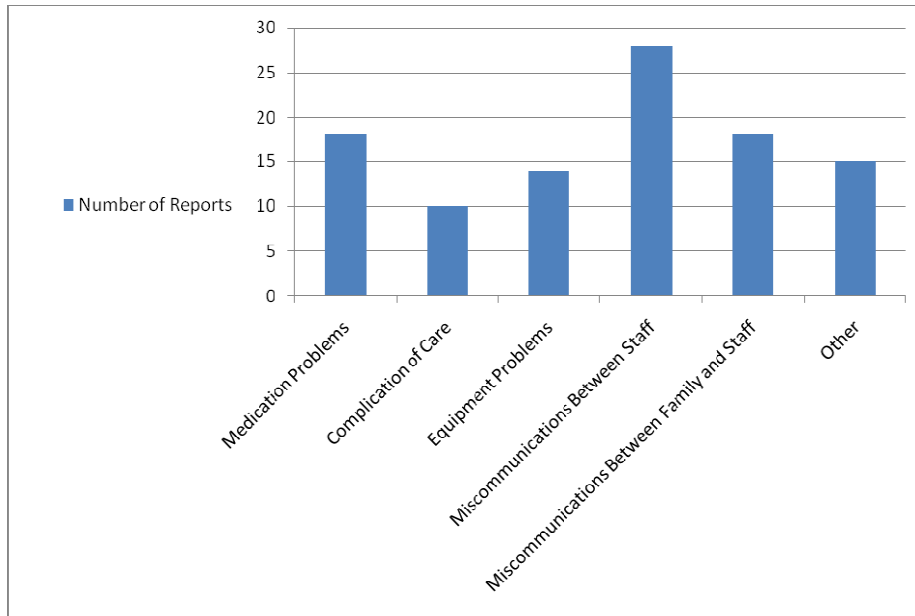


Figure 6 - Number of reported events

Table 2 - Degree of harm of family reports

Degree of Harm Classification	Frequency
Near Miss	26%
Minor Harm	11%
Moderate Harm	0%
Severe Harm	2%
Death	0%
Cannot Evaluate	27%
Not a Patient Safety Issue	34%

Table 3 - Likelihood of recurrence of family reports

Likelihood of Recurrence Classification	Frequency
>90%	55%
51-90%	12%
11-50%	3%
1-10%	7%
<1%	5%
Cannot Evaluate	18%

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The quality of information in the reports was deemed to be adequate or excellent in 73% of the reports for judging degree of harm. Report information quality was estimated to be adequate or excellent 80% of the time for judging likelihood of recurrence.

4.3.2 Healthcare provider reports

There were 4864 direct admissions or transfers to the Neurosciences and Surgery Unit (3R) and 351 provider reports filed between November 2007 and November 2009.

4.3.3 Effect and comparison of BSO reports on healthcare provider reporting

No statistically significant trends were found between the number of healthcare provider reported events before and after the initiation of the BSO system (Figure 7).

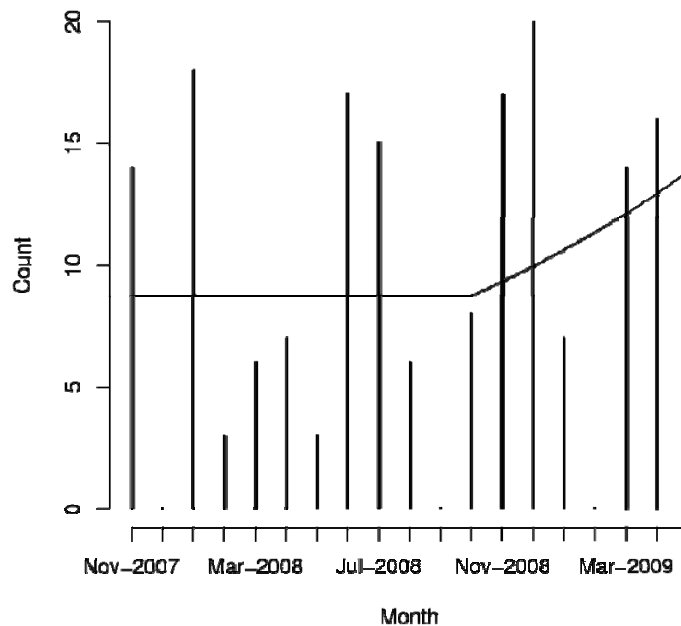


Figure 7 - Regression switch analysis (using Poisson regression with an over-dispersion parameter) of provider reported events before and after the initiation of the BSO system

The BSO and provider reports employed different degree of harm classification systems, preventing direct comparison. Forty-eight percent of BSO reports were classified as patient safety issues (events that caused either minor or moderate harm), while 37% of provider reported events caused harm. Twenty-eight percent of BSO reports were considered not patient safety issues (events that did not cause harm), with another 24% failing to provide sufficient information for reviewers to judge harm. Sixty-three percent of provider reports fell into the no harm category.

In total, eight likely or definite matches were identified between BSO and provider reports based on date and description. Seven events were identified as *likely* descriptive matches. Of these, three were more than five days apart in date, three were reported less than five days apart, and one was an exact date match. One report was a *definite* descriptive match and was less than five days apart by date.

5.0 Key Findings and Recommendations

- Patients and families should be recruited to report safety learning opportunities.
- Soliciting reports from each family at the time of hospital discharge has a high degree of acceptance as evidenced by the high response rate.
- A simple web interface provides a rapid and reliable method for families to report safety events.
- All reporting for safety events, regardless of the source of the report, should be consolidated in a centralized reporting system.
- Engaging patients and families in reporting of safety events provides a platform for participation in patient initiated safety improvements.

- Dependable reporting of safety events requires a robust system for addressing and implementing safety improvements.

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