Characterising the nature of clinical incidents reported across a tertiary health service: a retrospective audit

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ABSTRACT

Background: Reducing the number of adverse patient safety incidents (PSIs) requires careful monitoring and active management processes. However, there is limited information about the association between hospital settings and type of PSI.

Objective: Describe the severity, nature and characteristics of PSIs from an analysis of their incidence, and assess the relationships between the type of PSI and its setting.

Design: Retrospective audit of a clinical incident management system database.

Methods: A tertiary health service in Australia, with 620,000 residents. Records of PSIs reported for patients between 01/07/2017 and 30/06/2018 with Safety Assessment Codes (SAC) of PSIs were extracted from the clinical incident management system and analysed using descriptive and inferential statistics. PSIs involving paediatrics, mental health and primary care were excluded.

Results: 4,385 eligible PSIs were analysed: 24 SAC1, 107 SAC2 and 4,254 SAC3 incidents. Across reported PSIs, the most common incidents related to skin injury (28.6%); medication (23.2%); falls (19.9%); and clinical process (8.5%). Falls were reported significantly more often in the medical division whereas skin injury incidents were reported significantly more often in the surgical division ($\chi^2 = 43.85$, $p < .001$ and $\chi^2 = 22.56$, $p < .001$, respectively).

Conclusions: A better understanding of the nature of PSI and where they occur may lead to more targeted quality improvement strategies.

Key questions summary

What is known about this topic?

- Improving patient safety requires effective safety learning systems, which include incident reporting and management processes.
- While incident reporting systems typically underestimate the incidence of iatrogenic harm, they do provide valuable opportunities to improve the future safety of health care.

What does this paper add?

- This study reports the extent and severity of different types of PSIs that typically occur in a large tertiary hospital in Australia.
- The most common types of incidents are skin injury, falls, medication errors, and clinical process.
- There are empirical associations between the type of PSI and clinical division (medical, surgical).

What are the implications for practitioners?

- A greater understanding of the types of PSI and the settings in which they occur may inform development of more targeted quality improvement strategies that potentially reduce their incidence.

Background

Patient safety incidents (PSIs), sometimes referred to as adverse events, incidents, or patient safety events, are defined as an unplanned event or circumstance that may have resulted in unnecessary harm to a patient.[1,2] PSIs are classified according to different characteristics, including severity and degree of preventability[2,3] Across studies of preventable PSIs, estimates of the overall median incidence of PSIs leading to patient harm ranges from 9.2% to 12%.[4-8] According to the Australian Commission on Safety and Quality in Health Care (ACSQHC), some of the most common harmful PSIs relate to surgical procedures (e.g., wrong patient/site, retention of foreign object), haemolytic blood transfusion reactions and medication errors (drug/fluid administration).[9] PSIs are associated with considerable morbidity comparable to cervical cancer or multiple sclerosis.[8]

Harmful PSIs also represent a major financial burden to healthcare systems globally, with estimates between 10% to 15% of healthcare expenditure resulting from healthcare related harm.[8] Consequently, early detection and prevention of PSIs has become an international policy imperative.[10,11] Early detection and prevention requires safety learning systems, inclusive of incident reporting and management processes.[6,12] Effective safety learning systems should include reliable methods for reporting, detecting, monitoring and managing the investigation of PSIs.[13,14] The use of voluntary incident reporting systems (IRS) and processes provide data about the nature of safety problems, allow analyses and learning from PSIs, and facilitate the development and implementation of commensurate improvement strategies to address the contributing factors.[14,15]

However it is important to focus on gaining a better understanding of what types of PSIs are being reported and the context in which they occur rather than merely focussing on raw numbers of events. Further, PSIs occur within complex socio-technical and adaptive

systems.[7,16] A PSI is not necessarily the result of one person making a mistake at the frontline of care—rather a combination of system-related conditions that culminate in such incidents.[7,17] This is why reporting should be viewed as 'a process of social and participative learning, rather than as a mechanism of data collection and analysis'.[18]

Understanding the severity, nature and characteristics of reported PSI in an IRS is therefore the first important step to building strong and mature safety learning systems.[6,12] Such understandings provide a foundation and frame of reference for all subsequent work in this area. The aim of this study was to gain an in depth understanding of the severity, nature and characteristics of PSIs from an analysis of their frequency. In this study, we also wanted to describe the association between clinical division and type of PSI. Nevertheless, these learnings are not necessarily specific to the particular organisation. Trends in PSI and their contexts can inform others of potential threats that may exist in their own organisations.

Methods

Design

A descriptive study was undertaken using a retrospective audit and analysis of PSIs drawn from the electronic clinical incident management system used by the health service. The 12-month audit period was from 1 July 2017 to 30 June 2018. This study is part of a larger program of research intended to establish an effective safety learning system in a health service in Queensland, Australia.

Study setting and sample

The study was conducted in a large tertiary health service in Queensland, Australia in a catchment area of over 620,000 residents.[19] The health service included three hospitals: a tertiary-level hospital, a regional health facility, and a six-theatre day-surgery hospital. In all, there were approximately 1,250 beds across these three facilities.[20]

Eligibility criteria

Table 1 lists the eligibility criteria, developed prior to identifying PSIs that occurred during the provision of acute medical and surgical health care. Documented clinical incidents were screened and reviewed systematically by two researchers (IS and RB).

Coding of PSI and health service locale

The health service where this study was undertaken uses the Safety Assessment Code (SAC) classification system[3,21] to code clinical incidents (PSIs) which includes adverse and sentinel events. The coding system used by the health services is based on health department definitions of SAC categories and specific incidents (e.g., falls, pressure injuries, clinical processes, medication, consent etc.). SAC codes are assigned only to incidents that are judged to be related to the care patients received and not their underlying condition. Thus some incidents in the IRS do not have SAC codes, and the SAC we analysed are a subset of the incidents reported. The SAC scoring system is based on the consequence of a PSI (i.e., severity or level of harm) and the likelihood of its reoccurrence.[3,12] **Table 2** provides working definitions for each SAC category.

Not all PSI in the total sample originated from medical and surgical care units. As part of the analyses, we extracted a subsample of incidents based on wards and units within service streams according to whether they were from a medical or surgical location. For

instance, PSI occurring in the service stream 'Cancer and Specialty Services' were coded under 'medical', while PSI occurring in 'General surgery and Gastroenterology Services' were coded under 'surgical' care.

Incident reporting and management

Across the health services, all PSI are reported in accordance with relevant legislation, regulations and best practice guidelines. Following entry of the PSI into the IRS by the person who was involved or witnessed the incident, its management involves staff at different clinical and managerial levels. If the PSI is coded by the reporting staff member as a SAC incident (i.e., related to a process of care rather than related to a patient's medical condition), the Nurse Unit Manager and attending physician are required to review the incident within 24 hours of its occurrence. Based on their initial assessment of the PSI, they may write additional notes in the IRS to supplement what the person involved has reported. Where death or permanent harm has occurred (SAC 1 incident), the physician and treating team engage in the 'Clinician Disclosure' process and document the outcome in the patient's digital record. Then the SAC incident is reviewed by the Patient Safety Coordinator and discussed at the Executive Triage Meeting where it is confirmed as a SAC 1 (completed within 90 days). If confirmed, a decision is made on further analysis methodology (i.e., Root Cause Analysis, Human Error/Patient Safety review, Clinical/Comprehensive review or External review) of investigations to be conducted according to health services policy.

Ethics approval

This study was approval by the hospital (LNR/2019/QGC/46977) and university (NRS/08/19/HREC) human research ethics committees. Following approval, we sought

permission from the Director-General, Queensland Health, as required by the Public Health Act (2005), to obtain de-identified clinical incident data.

Data collection and extraction

Electronic data were exported from the health service's clinical incident management system by the data custodian, and given to the lead author as an encrypted Excel database. The Excel database included records of only PSIs coded as SAC 1, SAC 2, or SAC 3 and reported between 1 July 2017 and 30 June 2018. Data extraction was undertaken based on date and incident report, using the following data fields: incident ID; incident date, time and date entered; ward/unit; clinical division (e.g., Surgical, Anaesthetic and Procedural Services, Emergency and Assessment Services); facility (hospital within health service); primary incident type; classification (e.g., skin injury, medication, falls, clinical process); details of incident; summary of incident; and, confirmed level of harm (SAC category).

Data analysis

Data were cleaned and analysed using the Statistical Package for Social Sciences (SPSS; V.25, IBM, New York, USA). Descriptive statistics using number and percentage were calculated relative to SAC category, PSI type, and service/stream division. The total number of PSIs with SAC category assigned to them over the 12-month audit period was used as the denominator. The denominator was based on the total number of eligible SAC (across categories 1-3) while the numerators were based on the absolute frequencies of SAC events according to type of PSI (e.g., clinical process, medication incident, skin injury, falls, clinical communication) and clinical division. Raw data (e.g., SAC category, PSI classification, clinical

location) was transferred from SPSS to the program R[22] to generate illustrative circular barplots. Each bar represents a category (e.g., SAC classification, PSI type, clinical department) and bars are displayed along a circle instead of a line that uses an X and Y-axis. The subsample of PSI that occurred in medical and surgical units were subsequently analysed using Chi-square analyses to assess the relationship between location and type of PSI. Statistical significance was set at $p<.05$.

Results

Figure 1 illustrates a flow diagram of numbers of incidents during the extraction and exclusion process. In total, 5,791 PSIs were identified in the database; of these, 4,385 PSIs satisfied our eligibility criteria and were included in the analysis.

Types of PSI across SAC categories and service streams

Figure 2 illustrates the number of all types of PSI within each SAC category. Of the 4,385 events across all SAC categories, 24 (0.5%) were classified as SAC 1. Of the 24 SAC 1 incidents, almost one third (29.2%, 7/24) were clinical process incidents. Nearly one fifth of SAC 2 incidents (temporary harm) involved falls (20/107, 18.7%), while almost one third (1,238/4,254, 29.1%) of SAC 3 incidents (minimal harm/no harm) were related to skin injury (i.e., pressure injuries, skin tears). The most common causes of incidents, representing 80.2% of all PSIs, related to skin injury (n=1,255; 28.6%); medication (n=1,017; 23.2%); falls (n=872, 19.9%); and clinical process (n=373, 8.5%).

Figure 3 depicts absolute frequencies of all PSI across clinical divisions. Almost one third (7/24, 29.2%) of SAC 1 PSI occurred in Emergency and Assessment Services. Nearly one

quarter of SAC 2 incidents occurred in Women's Services (24/107, 22.4%), while almost one third (1,245/4,254, 29.3%) of SAC 3 incidents happened in Speciality and Ambulatory Services.

Association between clinical division and PSI type

To conduct a subgroup analysis of 4,142 /4,385 (94.5 %) events, data were dichotomised into two categories by allocating clinical departments to either medical or surgical divisions. PSI outside acute care (e.g., physiotherapy, speech pathology) were excluded from the analysis (*n* = 243, 5.5%). PSI type was collapsed into five major categories: 1) clinical process; 2) falls; 3) medication; 4) skin injury; (representing 80.2% of data), and 5) other (e.g., deterioration, behaviour, infection).

Table 3 details the individual relationships between PSI types and clinical division. PSI incidents of falls and skin injury were significantly associated with clinical division. The proportion of falls was higher in the medical division compared to surgical division. Conversely, the proportion of skin injury incidents was higher across the surgical division compared to the medical division.

Discussion

In this study, clinicians of a single tertiary health care service reported 4,385 incidents assigned to a SAC category over the course of a calendar year. Our analysis showed that the proportion of incidents leading to severe harm or death (SAC 1 incidents) was 0.5% and to moderate harm (SAC 2), was 2.4%. In Australia, the national incidence of reported SAC1 incidents (i.e. severe harm or death) ranges from 0.35 to 12.3 per 10,000 hospital admissions.[9] However, international data indicate that the actual incidence of

iatrogenic harm is significantly higher than these estimates. In a recent scoping review of patient safety in 27 countries across six continents, Schwendimann *et al* [7] found a median of 10% of all hospitalised patients were affected by at least one adverse event, of which 7.3% (range 0.6 to 30%) were fatal.

Knowing the most common setting for specific incident types can assist health systems to create targeted quality improvement strategies. Our results suggest the relationship between setting and frequency (or number) of skin injury PSIs is statistically significant; proportionally 8% higher in surgical division units compared with medical units. The higher proportions of skin injuries across the surgical division may be linked to longer surgeries and the increased use of medical devices causing device-related injuries. These injuries may also include hospital-acquired pressure injuries (HAPI). The 2019 international clinical practice guidelines on pressure injury prevention (PI) recommends risk assessment be completed as soon as possible after hospital admission/transfer.[23] However patients may develop PI in an hour or two after hospital admission, depending on their physical condition.[23] Moreover, skin injury PSIs that result in Stage 3 and Stage 4 HAPI can attract financial penalties. As such, the accurate reporting of these injuries is paramount. Findings from a recent national report by the ACQSHC suggest nearly a two-fold increase in the numbers of HAPI reported in IRS over the past five years: In 2014-15 across Australian health services, 2,831 HAPI were reported, and during 2017-18, HAPI numbers increased to 4,369.[9] In practice, clinicians and patient safety professionals can use this finding to prioritise their improvement interventions accordingly.

Results of our analysis indicate that proportionally nearly double the number of falls occurred in medical units as compared with units in the surgical division (23% vs 13%

respectively). Results of other studies support this finding.[24-26] The results of an earlier population based study[26] found that a higher proportion of patients in geriatric and internal medicine units fell compared with patients in surgical units (33% combined vs 2% respectively). The relatively lower number of falls among surgical patients may be due to greater emphasis on bed rest, with mobilisation only under nursing supervision, or these patients may simply have fewer falls risk factors. Notably in our study, three (0.5%) falls reported resulted in permanent injury (SAC 1). Other studies report that up to 42% of inpatient falls result in injury, with around 8% of these resulting in permanent injury or death.[25] Most falls are related to either intrinsic factors (i.e., patient-related: age, weight, prior fall and gender), or extrinsic factors (i.e., physical environment, medications, staffing ratios, delayed or missed care).[27] Clearly, there is rarely a single cause for a fall.[25,26] Though, many of the falls reports we reviewed contained insufficient information relative to patient location and activities at the time of fall, and particular characteristics of the environment (e.g., lighting, noise, layout). Therefore, a more nuanced analysis was not possible. Although intrinsic and extrinsic factors cannot always be controlled, they can be managed, and strategies implemented to mitigate patients' falls risk.

Organisational Implications

Characterising the types of PSIs and describing their frequencies relative to their clinical division is helpful but provides only a superficial understanding of their aetiologies. PSIs are the product of complex adaptive systems in which the prevailing culture, the quality and timeliness of communication and the degree of teamwork can (and usually does), contribute.[28] Understanding error is important, but it is equally important to value how clinicians manage complex, dynamic situations throughout the day, constantly modifying

their responses to get so much right.[16] Therefore, identifying factors and conditions that reinforce success is integral to building these understandings. Reporting rates reflect the safety culture of an institution.[6,29] Transitioning from a blame culture that may incentivise people to cover up, to an ethos of safety management underpinned by a just culture may improve reporting of PSI.[13]

Voluntary IRS are not intended to be an accurate picture of the incidence or severity of PSIs that occur across a health services district. Rather, they serve as a valuable resource to understand and act on latent and contributing factors of a representative sample of PSIs.[29] The ACQSHC recommend that health care services ensure their incident management and investigation systems provide adequate surveillance so that major safety lapses and risks are reliably detected; and that appropriate and timely corrective actions are implemented in response.[9] This needs mature Safety Learning Systems that enable and encourage incident reporting from all the health care settings in which patients present. Additionally, the role of patients as health consumers in patient safety efforts have been recognised for over a decade. Patients and carers are important partners in health improvement and are able to provide valuable insights[30] but their input needs to be valued.

Strengths and limitations

The results of this study are subject to several well-recognised limitations of IRS including: selective disclosure of incidents resulting in underreporting of PSIs; variable clinician engagement, and the estimated harm rates lack reliability and validity. Our findings provide a solid rationale for developing robust safety learning systems, as PSIs occurred commonly in acute care settings and a small but significant minority are associated with moderate or severe patient harm. Another study limitation is that the mean number of

incidents per admission/bed day/procedure/patient could not be calculated. Conceivably, Specialty and Ambulatory Services and Emergency and Assessment Services have higher workloads; therefore, the mean number of reported incidents may actually be lower than in other areas. We were unable to describe temporal trends in PSIs, thus unable to speculate on their aetiologies. The IRS where the reported PSIs were drawn operates as a 'stand-alone' repository of incidents and is not linked to other health services databases. To enable identification of temporal trends, linkage of the data is essential (Gallego et al, 2015). Finally, analysis of PSI focuses on 'what went wrong' whereas contemporary wisdom has advocated for also focusing on event when 'things go right'.[16]

Conclusions

Our results suggest that preventable patient harm, particularly falls, skin injury and medication events remain a serious problem across all health services contexts. The numbers of PSI involving skin injury and falls appears to be associated with clinical division. Nonetheless, a deeper understanding of the nature and location of preventable patient harm may lead to more targeted quality improvement strategies with greater acceptability to clinicians and increase the likelihood of their normalisation. The lack of detailed information in most incident reports preclude in-depth analysis and generation of more nuanced insights.

Competing interests

The authors declare no conflicts of interest.

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Figure 1: Flow diagram of incident case numbers that satisfied the eligibility criteria

Figure 2: Types of PSI across SAC categories

Figure 3: PSI across clinical divisions within SAC categories

Table 1: Eligibility criteria

Inclusion criteria:
• Individual affected is either surgical, medical or maternity patients
• PSIs reported from 1 July 2017 to 30 June 2018
• Confirmed (verified) PSIs
• SAC 1, SAC 2 and SAC 3 categories
Exclusion criteria:
• PSIs involving neonatal, paediatric, and mental health patients
• PSIs awaiting confirmation
• Non-clinical incidents
• Community-based care incidents

Table 2: Safety Assessment Code (SAC) definitions

Safety Assessment Code (SAC) categories[11,23]
I. SAC 1 includes all clinical incidents/near misses where serious harm or death is/could be specifically caused by health care rather than the patient's underlying condition or illness.
II. SAC 2 includes all clinical incidents/near misses where moderate harm is/could be specifically caused by health care rather than the patient's underlying condition or illness.
III. SAC 3 includes all clinical incidents/near misses where minimal or no harm is/could be specifically caused by health care rather than the patient's underlying condition or illness.

Table 3. Sub-analysis of relationship between PSI type and Medical and Surgical clinical divisions

	Medical		Surgical				
PSI type	*n*	%	*n*	%	*df*	χ^2	*p-value*[a]
Falls	725	23.2	138	13.5	1	43.85	< .001
Skin injury	881	28.2	370	36.2	1	22.56	< .001
Clinical process	227	7.3	90	8.8	1	2.31	.119
Medication	744	23.9	223	21.8	1	1.70	.187
Other[b]	542	17.4	202	19.7	1	2.77	.091
Total	3,119	100%	1023	100%			

[a]Chi-square test for independence with Yates Continuity Correction; [b]PSI types: behaviour, biomedical equipment/consumable, blood products, clinical communication, consent, deterioration, food/diet, infection, maternal complication, medical imaging, medication, pathology, patient flow, patient identification, psychosocial, surgical/procedure complication, vascular access devices, venous thromboembolism.

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