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A decade-long overview of adverse events in a tertiary surgical service in South Africa

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Background. Adverse events are common, and impact patients and healthcare systems negatively. Large international systems investigate adverse events at length, but South African data are lacking.
Objectives. To classify all adverse events that have occurred in our department over the last decade.
Methods. Ten years of data from a prospectively collated electronic medical record system were analysed for adverse events. All admitted patients were included. Duplicate entries and those that did not describe adverse events were excluded.
Results. The study period was from December 2012 to January 2023. There were 52 835 distinct admissions covering 321 385 inpatient days. After categorisation, a total of 14 537 adverse events were captured, giving an adverse event rate of 22%. Adverse events were categorised into four groups. Of the total, 8 027 events were clinical care related, 3 106 were pathology related, 2 662 were system related and 442 miscellaneous. A total of 300 were excluded. Clinical care-related adverse events comprised 57.3% of the total number. Of those, adverse events related to indwelling devices (32.4%), iatrogenic injuries (12.5%) and intravenous therapy administration (12.5%) contributed most. Pathology-related adverse events contributed 21.4% of the total, of which wound sepsis (29.5%), anastomotic leak (15.1%) and nosocomial pneumonia (14.4%) were the most common. There was a general downward trend in reported adverse events from 2016 to 2022.
Conclusion. Adverse events are common, and their aetiology is multifactorial. A sustained and multi-faceted approach is needed to address the challenge they pose.

Keywords: adverse event, patient safety, surgical sepsis, complication

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An adverse event refers to any unintended harmful or negative outcome suffered by a patient while receiving care. The event may be related to the care provided or to the underlying pathology, and may or may not require corrective action. Adverse events in healthcare have garnered much interest over the last three decades, particularly since a significant number of these events may be avoidable. There has been increased awareness about the impact that adverse events have on both individual patient outcomes and on overall costs.[1,2] Surgical disciplines are more prone to adverse events than other disciplines.[3] A 2015 systematic review found that a median of 58% of patients were under the care of a surgical discipline at the time of an adverse event, compared with a median of 24% for non-surgical disciplines.[3] Quoted figures regarding the proportion of admissions that experience an adverse event vary between 3% and 48%.[3-7] The reported total cost associated with adverse events in the USA is in the order of USD29 billion annually.[6] Longer hospital stays secondary to adverse events reportedly cost the UK government GBP2billion annually.[3]

The patient safety movement has pointed to fields outside of healthcare, where the introduction of error-reduction strategies has dramatically improved safety. The most famous example is the aviation industry, which has an enviable safety record. The same is true for the nuclear power industry. It was the accrual of routine data on adverse events in these industries that served as a basis off which planners and safety engineers could develop effective error-reducing safety strategies. Ongoing monitoring permitted assessment of the impact post implementation. Modern healthcare needs to develop and implement similar strategies to reduce the impact of adverse events on patient outcome and healthcare expenditure. To facilitate the design of such policies, it is essential that routine data on the spectrum and impact of adverse events be collected and collated. The development of electronic patient record systems has allowed for the accrual of large data sets recording patient healthcare experiences. One such system internationally is the National Surgical Quality Improvement Program (NSQIP) in the USA, which uses a risk-adjusted database to quality benchmark surgical patients.[8] It has evolved into a widely implemented, national quality improvement programme with a measurable impact. It focuses on postoperative complications, and reports on observed v. expected outcomes.[8] The literature suggests that the introduction of NSQIP has impacted positively on patient outcomes.

Adverse events in South Africa

Most published studies on adverse events in surgical patients emanate from high-income countries (HICs). South Africa (SA) is a middle-income country with huge discrepancies in wealth and access to resources, and with a disease and demographic profile different to those of HICs. Although there are several SA studies on adverse events, most are small, short-term studies with a narrow focus.[9-14]

The Department of Surgery at Grey's Hospital in Pietermaritzburg implemented a hybrid electronic medical registry (HEMR) over a decade ago. The HEMR captures basic demographics, admission and discharge information and operative records on all inpatients. In addition, HEMR includes a dedicated module that captures all surgical adverse events.

Objectives

This study aims to classify all adverse events that have occurred in a single metropolitan surgical department over the last decade. The results will feed into a larger project to understand the contribution

of human error to adverse events and to develop strategies to limit them. In addition, we seek to validate our data collection methodologies.

Methods

We defined an adverse event as any unintended negative or harmful incident that occurred to a patient while in hospital. All patients entered onto HEMR were included in the study, including patients of all ages, sexes and admission type (emergency or elective). All adverse events captured were extracted for analysis. The three exclusion criteria were duplicate entries, insufficient information, and where the captured event was deemed to not be an adverse event. The HEMR facilitates data capture for all patients admitted to Grey's hospital. Outpatient interactions are not captured. Data are entered by clinical staff on admission, and include demographics, admission type (emergency or planned), details of current problems, relevant history, allergies, investigation results, admission diagnosis and initial management plan. Additional entries are made as required by the operating surgeon. On discharge, a summary of care is generated.

Adverse event recognition

The HEMR has a specific module for the recording of adverse events. We combine multiple modalities to recognise an adverse event. These include daily patient interactions, and data gathered during procedures, on grand/academic rounds, on chart review, during mortality conferences and at other meetings where patients are discussed. Ordinarily, the staff member who recognises the event is responsible for capturing it. However, this is occasionally delegated to a junior team member. The staff member tasked with capturing the adverse event is encouraged to provide as much detail as possible.

Results

All morbidity entries captured on the HEMR between 1 December 2012 and 5 January 2023 were analysed. During the study period there were 52 835 distinct admissions, accounting for 321 385 inpatient days. In total, there were 11 947 distinct data entries describing 14 537 adverse events, with several entries describing multiple adverse events. This computes to a 22% incidence of adverse events in admitted patients. There were 7 525 male patients and 4 413 female patients. The mean (standard deviation (SD)) age was 40 (20.2) years. Adverse events were categorised into four domains: clinical care related, pathology related, system related and miscellaneous. Of the 14 537 events, 300 (2.1%) were excluded owing to not being considered adverse events (280), or as duplications (20). Of the remainder, 8 027 (55.2%) were clinical care related, 3 106 (21.4%) pathology or patient related, 2 662 (18.3%) system related and 442 (3.0%) miscellaneous. Fig. 1 breaks down the adverse events according to domain. The most common domain was clinical care, contributing 8 027 (55.2%) of all adverse events. Of these, adverse events related to indwelling devices (2 597; 32.4%), medication errors (1 665; 20.8%) and iatrogenic injuries (1 004; 12.5%) contributed most (Table 1). Pathology-related adverse events contributed 21.4% of the total, of which wound sepsis (27.6%), anastomotic leak (14.1%) and nosocomial pneumonia (13.4%) were most common (Table 2). System-related adverse events contributed 18.3% of the total. Delays in transport (62.3%) and cancelled or delayed operations (29.1%) formed the bulk (Table 3). Three percent of all adverse events could not be classified and were labelled as miscellaneous. These included transfer delays, bed shortages, or delays in obtaining consent. Fig. 2 depicts adverse event entries per year and shows an overall decrease in absolute numbers, from a peak in 2016 to the end of the study period. Fig. 3 shows adverse event entries expressed per 1 000 admissions, and accounts for variations in patient encounters per year over the study period. A similar pattern is noted to the total adverse events. Fig. 4 demonstrates the total adverse events, as well as selected more common individual adverse events, expressed by year. This shows that the most common adverse event types follow a similar trend to the overall numbers.

Table 1. Clinical care-related adverse events

Event	*n* (%)
Indwelling device-related	2 597 (32.4)
Iatrogenic injury	1 004 (12.5)
Intravenous therapy administration	1 000 (12.5)
Intravenous therapy prescribing	665 (8.3)
Assessment failure	585 (7.3)
Stoma-related	397 (4.9)
Documentation	331 (4.1)
Protocol violation	232 (2.9)
Not seen daily by surgery	224 (2.8)
Missed injury	193 (2.4)
Pressure sore	167 (2.1)
Wrong or inadequate surgery	160 (2.0)
Wound not dressed	88 (1.1)
Not seen by other department	82 (1.0)
Blood results not traced	64 (0.8)
Wrong patient	59 (0.7)
Anaesthesia-related	50 (0.6)
Fall	42 (0.5)
Radiology reporting error	24 (0.3)
Incorrect investigation ordered or performed	20 (0.2)
Anastomotic stricture	14 (0.2)
Burn or fire	13 (0.2)
Retained foreign body	10 (0.1)
Wrong side	6 (0.1)
Total	8 027 (100)

Discussion

Since the seminal work by Leape *et al.*[15] in 1991, there have been several studies documenting surgical adverse events in institutions across the world.[15-18] Most of these studies have been conducted in HICs, and have used a variety of methodologies to determine if an adverse event has occurred, and to assess its impact. These collection methods include chart review, self-reporting and trained third-party observation. The reported rate of adverse events in general surgery ranges between 3% and 48%. This wide variation is difficult to interpret, owing to differing data collection methodologies between studies, and variations in what defines an adverse event. Studies form Spain have shown a rate of adverse events impacting 17.8% of surgical patients.[16,17] Studies from the USA quote an incidence of 3.7%, and from Australia an incidence of 21.9%.[15,19] A small prospective Canadian study in a paediatric surgery unit found an adverse event rate of 48%, while another larger prospective observational study from the USA reported a rate of 17%.[7,20] A 2013 meta-analysis drawn from 14 studies in 9 countries calculated that a median (interquartile range (IQR)) of 14.4% (12.5% - 20.1%) of surgical patients experienced at least one adverse event.[21]

Our rate of adverse events is 22%, which is in keeping with these international reports. There are studies from SA that have assessed adverse events in surgical units.[9-14] They all differ from the results

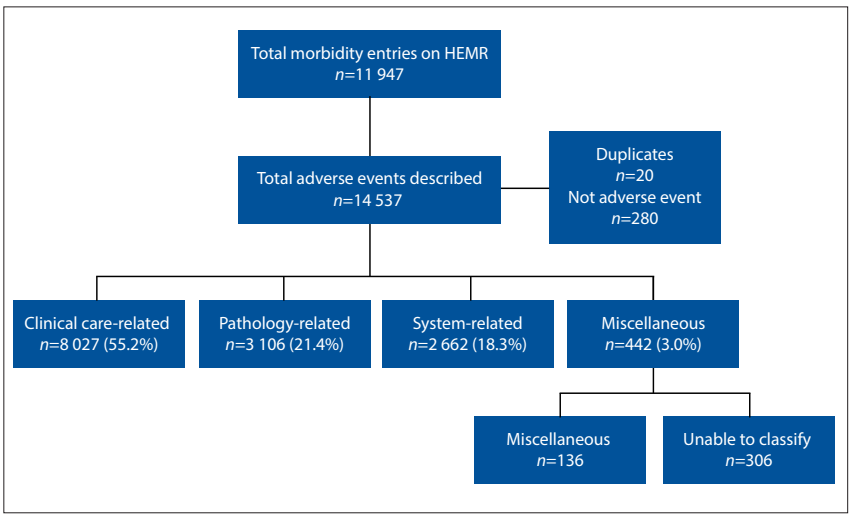

Fig. 1. Consort diagram depicting the overall classification of all captured adverse events. (HEMR = hybrid electronic medical registry.)

Table 2. Pathology- or patient-related adverse events

Event	*n* (%)
Wound sepsis	915 (29.5)
Anastomotic leak	469 (15.1)
Pneumonia	446 (14.4)
Organ space collection	276 (8.9)
Acute kidney injury	163 (5.2)
Fistula	152 (4.9)
Postoperative bleed	137 (4.4)
Cardiac event	98 (3.2)
Electrolyte	74 (2.4)
Adhesive bowel complication	59 (1.9)
Adverse drug reaction	51 (1.6)
Venous thrombo-embolism	42 (1.4)
Abdominal compartment syndrome	42 (1.4)
Mesh or graft related	37 (1.2)
Urinary tract infection	36 (1.2)
Systemic sepsis (source unknown)	25 (0.8)
Cerebrovascular accident	24 (0.8)
Ileus	23 (0.7)
Seizure	23 (0.7)
Multiorgan failure	14 (0.5)
Total	3 106 (100)

Table 3. System-related adverse events

Event	*n* (%)
Transport delay	1 524 (62.3)
Operation cancelled or delayed	712 (29.1)
Logistics error	99 (4.0)
Drug stock issues	69 (2.8)
COVID-19 logistics	25 (1.0)
Absconded	18 (0.7)
Total	2 447 (100)

of the present study. Most have assessed patients post surgery, and none provide a generalised overview of adverse events in all surgical patients, both operative and non-operative. All have been carried out over shorter periods than this current study, and most are focused on a specific adverse event or events. None of these studies compare with the longevity or size of this current data set.

Although collecting data on adverse events is essential, it remains challenging. A number of methodologies can be employed. These include retrospective chart review, third-party observation, voluntary self-reporting, supervisor reporting and routine electronic reporting systems. In addition to morbidity and mortality conferences, adverse events are discussed during clinical rounds. This serves to enhance the ability of staff to recognise and record an adverse event. The use of multiple methodologies of reporting enhances data collection.[22] The method used in our institution relies chiefly on prospective self-reporting facilitated by an electronic medical record system. This is occasionally bolstered by supervisor-based reports after retrospective chart review. Fears that voluntary self-reporting may lead to under-reporting are well founded; however, based on the adverse event rate we have shown, we consider that our data collection methodology is contextually appropriate to inform further research.

Adverse events related to provision of care accounted for the largest category in this study. Given the inherently invasive nature of surgical care, this stands to reason. Medication errors also contribute significantly. These include incorrect drug, incorrect dose, incorrect route, prescription in allergic patients, prescription when contraindicated, as well as errors in medication administration. The impact of most medication errors is negligible; however, they can be dangerous. Heightened vigilance around prescribing habits, frequent medication chart reviews and training regarding medication administration practices is required at all levels to impact this number. Adverse events relating to indwelling devices and iatrogenic injuries have been explored in other work by the authors.[14]

Pathology-related adverse events are not universally included in discussions around morbidity, as some definitions of adverse event specifically exclude pathology-related morbidity, and hence select in favour of error. The HEMR regards any unintended negative event as an adverse event. Analysis of the pathology-related events highlights the fact that just over half of these events comprised surgical site sepsis. Nosocomial pneumonia accounted for 13% of all pathology-related adverse events. Postoperative haemorrhage, cardiac events, venous thrombo-embolism (VTE) and cerebrovascular accidents (CVA) accounted for only 9.7% of pathology- or patient-related adverse events. Appropriate

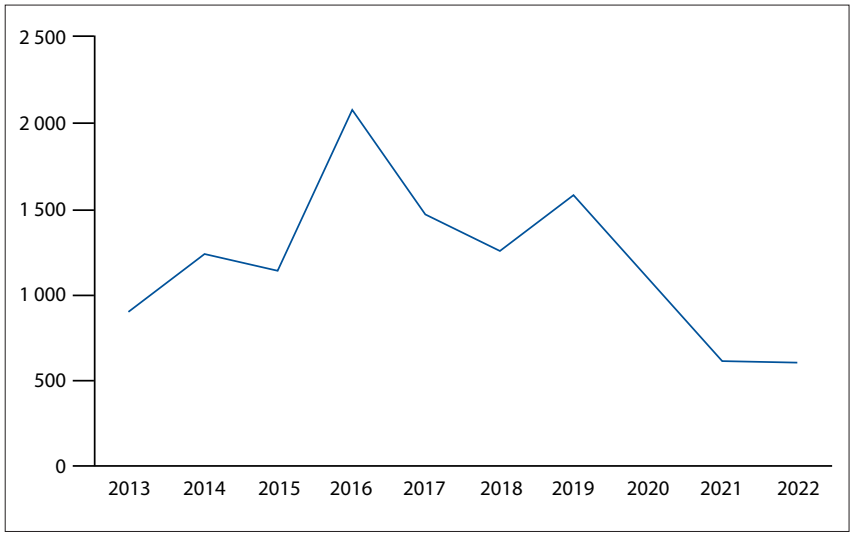

Fig. 2. Total adverse event entries per year.

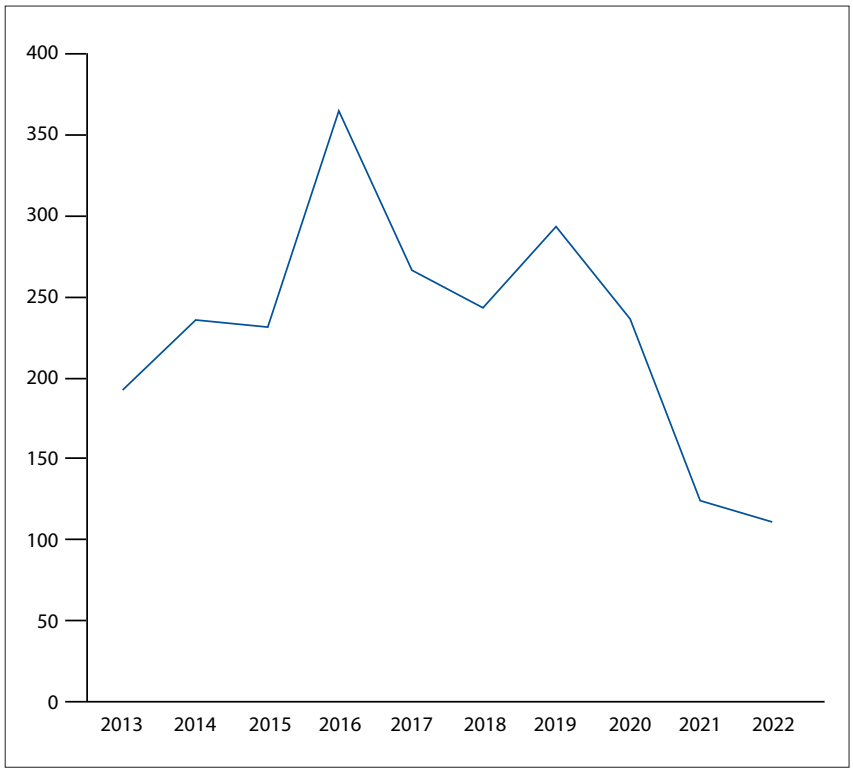

Fig. 3. Adverse event entries per 1 000 admissions, by year.

management of surgical sepsis is central to therapeutic efforts.

System-related adverse events are outside the control of clinicians, and are often ignored. Very few discussions on adverse events mention system-related issues. In our environment, they account for approximately one-fifth of all adverse events, and therefore cannot be overlooked. The majority were related to transport delays due to lack of ambulances, qualified staff and other logistical challenges. Each additional day a patient spends in our hospital has financial and workload implications for the hospital. Input and intervention from hospital management, the ambulance services and government will be necessary to decrease the burden that transport delays impose.

When assessed by year, a clear pattern is demonstrated. An increasing trend from 2013 to 2016 is noted, and this likely represents increasing departmental awareness and reporting of adverse events. From the peak in 2016, a general decrease in adverse events is noted. This applies to both the total number, as well as the most common individual types (Fig. 4). This suggests that all adverse event types followed a similar pattern, and that there is a general decrease in these adverse events. The number of adverse events per 1 000 admission follows a similar pattern (Fig. 3) and demonstrates a true decrease in adverse events when factoring for varying admissions per year over the study period. The years 2022 and 2021 were significantly impacted by the COVID-19 pandemic, in which admission and operative procedure numbers decreased. The rate per 1 000 admissions shows that the decrease in adverse events is not due to a decrease in the number of admissions.

The general decrease in adverse events reported between 2016 and 2022 is considered to be multifactorial. Several interventions have been undertaken within the department. HEMR was introduced in 2012, and became fully operational at the beginning of 2013. Handbooks for general surgery and trauma surgery were introduced in 2013 and 2019, respectively. They served to outline departmental policies on common conditions and standardise diagnostic and interventional approaches in select circumstances. From 2014, a revised format morbidity and mortality conference was introduced, with dedicated deliberation on reported adverse events playing a central role. Importantly, these discussions are typically non-punitive and anonymous, which serves to engender an ethos of voluntary self-reporting. Weekend handover forms were introduced in 2016, and bolstered the personal handovers already in place between the outgoing and on-duty teams over weekends and public holidays. In addition to the above, although implemented prior to this study, the World Health Organization surgical safety checklist and Advanced Trauma Life Support course has been implemented and taught locally throughout the last decade. It is our opinion that these multiple safety improvement measures have had an impact on adverse event numbers, rather than one single intervention. In short, an improved awareness of risk has generated a culture of safety.

The US National Surgical Quality Improvement Program (NSQIP) is a powerful tool with demonstrable benefits to patients.[8,23-25] There are a number of factors that make it difficult to replicate such a system in a middle-income country such as SA. The logistical structures required for a project such as the NSQIP are prohibitive. The lack of information technology infrastructure, in terms of both hardware and reliable internet connection, as well as lack of institutional buy-in and perceived costs, may also be barriers to implementation. Data collection will not in itself translate into improved outcomes, and proponents of

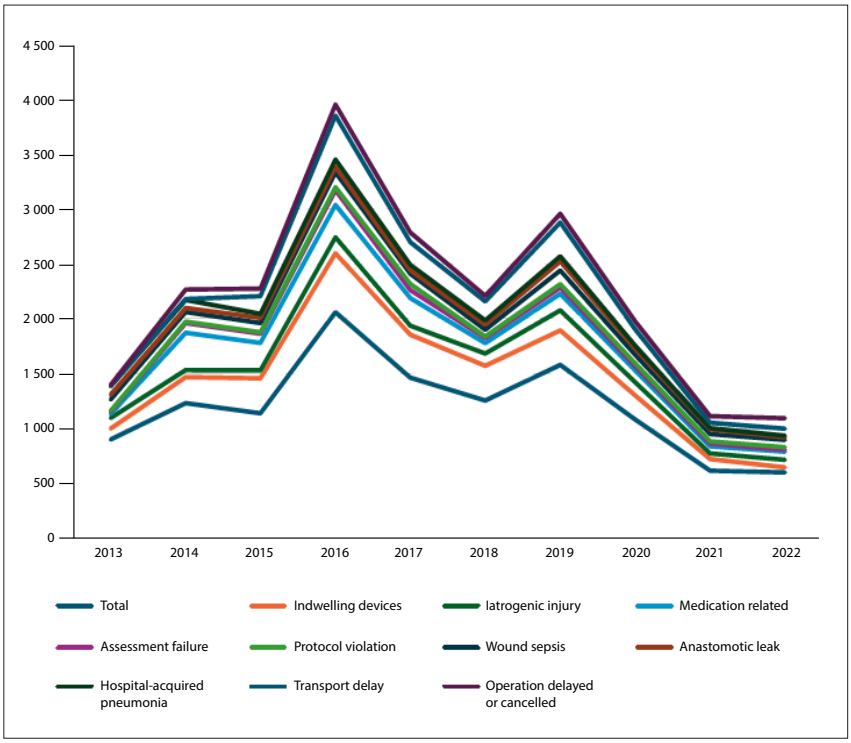

Fig. 4. Stacked line graph depicting total and selected individual adverse event types, per year.

the NSQIP point out that '[data collection in the NSQIP] is an important catalyst to trigger productive conversations to improve the overall quality and safety of surgical care'.[23] Beesoon *et al*.[23] note that the key point about data collection on adverse events is the recognition of shortcomings, and stimulation of productive discussion. Our system is certainly not as expansive as the NSQIP. However, we maintain that it facilitates data collection and allows easy retrieval of data, and thereby promotes further discussion.

Limitations

Although this article is a retrospective review, the data were captured in real time in a dedicated module on HEMR. This provides for a degree of reliability. The data are only captured for inpatients, thus excluding all adverse events that become manifest outside the hospital.

Conclusion

This extensive single-centre review of adverse events shows that adverse events are common and multifactorial in aetiology. Efforts to limit their incidence must first enhance surveillance, while addressing clinician factors. Surgical sepsis is common in our patients, mandating aggressive management at patient deterioration. No single intervention will significantly reduce adverse events; rather, there needs to be a multifaceted system-wide approach to address patient safety.

Data availability. Data are not publically available. Requests can be directed to the corresponding author.

Declaration. This publication forms part of the fulfilment of HW's PhD degree.

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Author contributions. HW: concept, data curation and analysis, manuscript. DC: concept, manuscript, supervisor. SW: data analysis, manuscript, co-supervisor.

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