Patient Safety in Surgery

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Wrong-site, wrong-procedure, and retained foreign object events in out-of-hospital settings: analysis of closed medico-legal complaints in Canada (2012–2021)

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Abstract

Background Surgical sentinel events (SSEs) are serious safety incidents associated with significant patient harm and medico-legal consequences for healthcare teams and institutions. SSEs include wrong-site surgeries, wrong procedures, and unintentional retention of foreign objects. SSEs occur in hospitals and out-of-hospital operating spaces (physician offices or ambulatory surgical centres). It is unclear how the resource constraints and workflow differences of an out-of-hospital setting contribute to SSEs.

Methods We conducted a retrospective review and descriptive content analysis of all out-of-hospital SSEs reported to the Canadian Medical Protective Association (CMPA) between 2012 and 2021. Medico-legal files, medical records, and peer expert opinions were analyzed to identify the contributing factors to out-of-hospital wrong-site, wrong-procedure, and retained-object SSEs.

Results A total of 276 medico-legal complaints involved a wrong-site, wrong-procedure or retained-object SSE, of which 24 (24/276; 9%) occurred out of hospital. Only twenty of these out-of-hospital complaints were included in the qualitative content analysis. We identified five main contributing factor categories to out-of-hospital SSEs. These categories included (1) incomplete preoperative verification, (2) inadequate intraoperative surgical counts, (3) insufficient review of patient medical records, (4) surgery performed without the necessary resources, and (5) administrative errors or office disorganization. Half of the complaints were assigned more than one contributing factor. The majority of out-of-hospital SSEs (19/20; 95%) resulted in an unfavourable outcome for the operating physician and most (18/20; 90%) required additional healthcare resources to resolve or mitigate the consequences of the SSE.

Conclusions Recognizing the contributing factors to an out-of-hospital SSE enables targeted improvements in facility protocols to support patient safety. Some factors identified in this dataset overlap with hospital-based contributing factors previously identified in literature (incomplete preoperative verification and inadequate surgical counts), whereas other novel factors are associated with the practice environment of an out-of-hospital setting (resource constraints, office disorganization). Addressing the identified contributing factors may mitigate the risk of SSEs in all facilities.

Keywords Office surgery, Never event, Error, Medico-legal, Patient safety, Ambulatory surgery, Sentinel event

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Introduction

Surgical sentinel events (SSEs), sometimes called never events [1–3], are a subset of serious safety incidents that occur within the perioperative window [4]. These safety incidents are not considered an acceptable risk of surgery. The most frequently cited SSEs include wrong-site surgeries, wrong procedures, and unintentional retention of surgical instruments or foreign objects [5, 6]. SSEs are associated with significant physical harm to patients and with psychosocial distress for patients, their caregivers, and the clinical team [7, 8]. SSEs can also have substantial medico-legal implications for healthcare teams and institutions [8, 9].

The preventability of SSEs is contested. Some researchers believe that the risk of an SSE can be eliminated by hospital staff adherence to preestablished perioperative protocols, whereas others suggest only partial preventability of SSEs [6]. Despite considerable efforts from professional societies and governing jurisdictions [10, 11], SSEs still occur [4, 8, 12–15]. To date, most research on SSEs and their contributing factors has focused on hospital-based surgeries [4]. The contributing factors to a hospital-based SSE are well described and include both organization- and human-level factors [4, 13, 16, 17]. Organization-level factors include inadequate policies, deficient perioperative protocols, and staffing shortages. Communication failure is the most cited human-level contributing factor [4].

Communication failure includes miscommunication amongst the surgical team and missing patient or case information [4]. Communication is a recurring theme across SSEs and analyses suggests the need for improved communication to mitigate SSEs [18, 19]. In addition to communication failure as a standalone contributing factor, human-level and organizational-level factors may interact in complex ways to influence SSEs. For example, a machine-learning analysis of SSEs suggests that the number of staff participating in a surgery had a proportional effect on SSE occurrence [20]. Authors hypothesize that this observed effect is related to underlying communication failures.

Most of our knowledge on SSEs and their contributing factors comes from analyses of hospital-based events. However, surgeries are performed both in hospital and out-of-hospital settings. The out-of-hospital setting includes a physician's office and an ambulatory surgical centre. The number of out-of-hospital surgeries are increasing, and surgeries in this setting may be associated with increased cost savings and reduced operative time [21–25]. An SSE can occur anywhere that a surgery or surgical procedure is performed [13, 18, 25–27], and there are unique challenges in maintaining patient safety during out-of-hospital surgeries [28]. Out-of-hospital settings may not have the same resources as a larger hospital or health authority. Additionally, the responsibilities of establishing and maintaining perioperative policies and protocols, administrative records, and staffing fall on a smaller group of physicians and administrators. Out-of-hospital settings also face less regulatory oversight, and existing standards may be less comprehensive or inconsistent.

To our knowledge, no studies have reported the contributing factors to SSEs during out-of-hospital surgeries. The objective of this study is to describe the types of SSEs that occur in an out-of-hospital setting and identify their contributing factors on the basis of a detailed content analysis of medico-legal data. Understanding the facility and perioperative factors that contribute to SSEs in an out-of-hospital setting may inform more effective educational initiatives, interventions, and practice changes, which can positively impact patient safety. Additionally, we want to describe the claim resolutions and patient outcomes associated with out-of-hospital SSEs to better understand how contributing factors translate into real-world consequences for patients and healthcare providers.

Methods

Study design

We performed a descriptive content analysis of medico-legal complaints supported by the Canadian Medical Protective Association (CMPA) that were closed between 2012 and 2021. The CMPA is a national not-for-profit, mutual defense organization representing more than 95% of physicians practicing in Canada (over 115,000 physicians). The CMPA maintains a repository of medico-legal data about civil legal actions and complaints to medical regulatory authorities (Colleges) and hospitals. Each complaint represents a matter voluntarily brought to the CMPA by a physician seeking medico-legal advice or support.

This study was approved by the Canadian ethics review panel of the Advarra Institutional Review Board (CR00389884) in compliance with Canada's Tri-Council Policy Statement on the Ethical Conduct for Research Involving Humans (TCPS 2). The consolidated criteria for reporting qualitative research (COREQ) checklist was used to report the findings of the qualitative content analysis (Additional File 1) [29].

Case selection

Registered nurse analysts at the CMPA review all closed medico-legal claims, including peer expert opinions and decisions, and characterize clinical details via the enhanced Canadian version of the *International Statistical Classification of Diseases and Related Health*

Problems, 10th revision (ICD-10) and the Canadian Classification of Health Interventions [30]. Analysts used an in-house coding framework to categorize SSEs (wrong-site, wrong-procedure, or retained object) [31].

Complaints were included if an SSE code was associated with the complaint and if the SSE occurred during an out-of-hospital surgery. Wrong-procedure SSEs included surgeries where the wrong implant was inserted. In this study, out-of-hospital surgery was defined as any surgery or surgical procedure that occurred in an ambulatory surgical centre or physician office that was not associated with a hospital. No limits were applied to geographical location or provider specialty.

Data extraction and content analysis

Demographic and surgical details were extracted from case files. Outcomes resulting from SSEs were also extracted. Additionally, we performed a qualitative content analysis to understand the contributing factors to SSEs. All medico-legal files were reviewed for the content analysis. These files included perioperative documentation, medical records, peer-expert reviews, and statements of claim. Additionally, case outcome summaries created by qualified nurse analysts were reviewed. These summaries were created by nurse analysts via a previously published framework to capture contributing factors on the basis of opinions from peer experts [31]. Peer experts are usually physicians with experience comparable to that of the named operating physicians.

A conventional content analysis approach with inductive coding development was employed for this study [32, 33]. One researcher (OIH) conducted a comprehensive review of the medico-legal case files and nurse analyst summaries multiple times to understand the data. A coding template was developed on the basis of this initial review. This initial list of codes was reviewed by the rest of the investigative team, and the codes were consolidated into broader categories on the basis of overlap and relatedness. Two investigators (OIH, JZ) then independently reviewed the medico-legal files and used the consolidated list to assign categories to the medico-legal cases. The investigators reviewed the codes assigned to several cases together to ensure consistency of the coding. When there were discrepancies in the categories assigned for a case, a third independent adjudicator (RES) resolved these discrepancies.

Categories and descriptions were reviewed by an interdisciplinary team including health service researchers, physicians and surgeons, a surgical nurse, and a medical trainee. Key takeaways for each category were generated by the authors based on the analysis. To maintain the anonymity of the cases, no quotations are included in this paper. Instead of direct quotes, the investigators created deidentified case samples on the basis of multiple cases that conveyed the main messages identified in those cases. All available out-of-hospital SSE cases were reviewed, and data saturation did not influence our sampling [34]. The investigators used Microsoft Excel (version 2408, Microsoft, Inc.) to assist in coding and code frequency analysis.

Results

The CMPA closed 67,757 medico-legal cases from 2012 to 2021. Among these cases, 276 involved a wrong-site, wrong-procedure or retained-object SSE (Fig. 1). A total of 252 (252/276; 91%) cases were excluded from the qualitative analysis because they occurred in a hospital-associated facility. Only 24 SSEs (24/276; 9%) met this study's definition of an out-of-hospital surgery and were included in the qualitative analysis.

Table 1 displays an overview of the surgical specialties and SSEs identified in our dataset. Among the cases included in the analysis, almost half were performed by plastic surgeons (11/24; 46%), followed by ophthalmologists (7/24; 29%). The remaining cases (6/24; 25%) involved specialists in family medicine, general surgery, gynecology, orthopedic surgery, and urology. The most common surgery was breast augmentation (5/24; 21%), followed by cataract extraction and intraocular lens insertion (4/24; 17%). Details about the nature of the other surgeries were omitted to prevent patient and physician identification.

There were ten cases where an object was unintentionally retained (10/24; 42%). Among the retained objects, sponges were the most common (4/10; 40%). A wrong-procedure SSE (including wrong implant) was equally common (10/24; 42%). The most frequent types of wrong-procedure SSEs were the insertion of an incorrect intraocular lens (4/10; 40%) or an incorrect breast implant (3/10; 30%). The remaining SSEs involved surgery or surgical procedures at the wrong site (4/24; 17%).

Qualitative analysis

A total of 20 SSEs were included in the qualitative analysis after four (4/24; 17%) were excluded for having insufficient data to review. The initial inductive coding list included 25 unique contributing factor codes. These codes were then consolidated into five broader categories. An overview of the qualitative analysis presented in a coding tree is available in Fig. 1. Half of the cases (10/20; 50%) were assigned two or more contributing factor categories. A summary of the categories, their definitions, common case characteristics, and key takeaways is provided in Table 2.

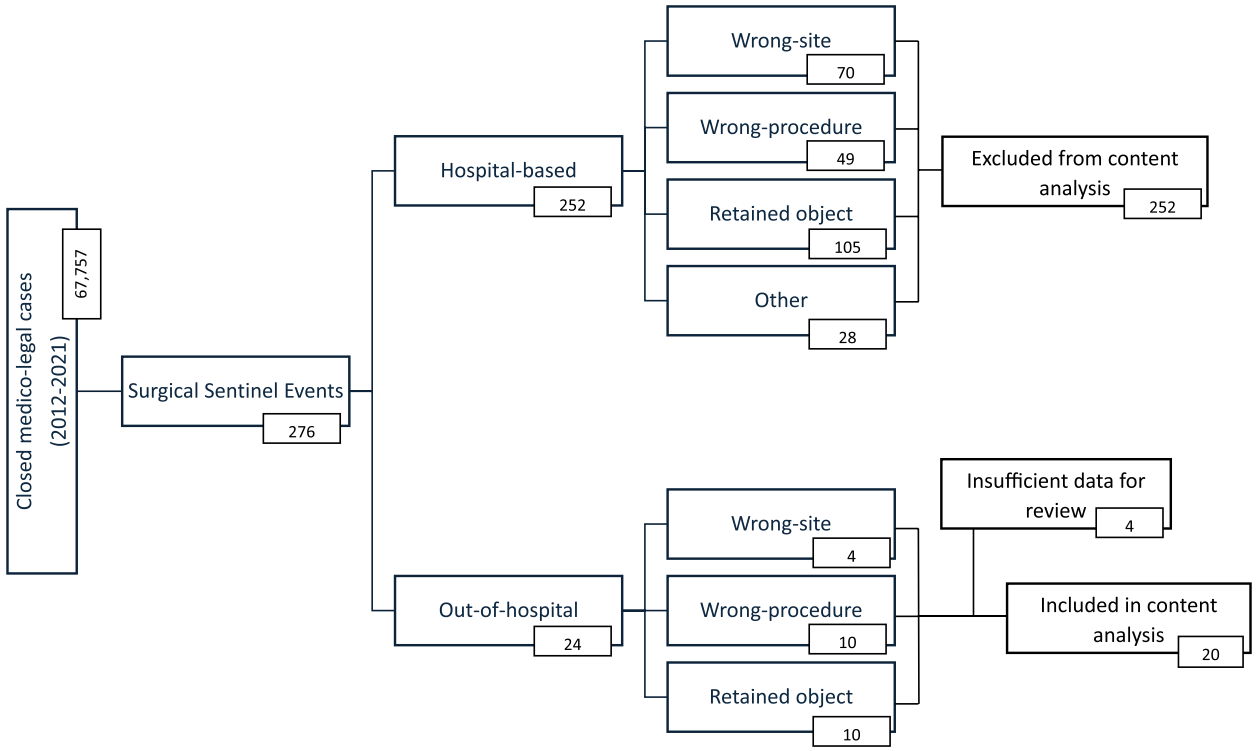

Fig. 1 Overview of surgical sentinel events involving an unintentional retained foreign object or a wrong site procedure (including wrong-procedure and wrong-implant) reported to the Canadian Medical Protective Association (2012–2021)

Table 1 Specialties associated with an out-of-hospital surgical sentinel event and characteristics of events

Specialty, n (%)	***n*** **= 24 (100)**
Plastic surgery	11 (46)
Ophthalmology	7 (25)
General surgery	2 (8)
Gynecology	1 (4)
Family practice	1 (4)
Orthopedics	1 (4)
Urology	1 (4)
Surgical sentinel event	
Retained object	**10 (42)**
Sponge/Gauze	4 (40)
Needle	2 (20)
Other	4 (10)
Wrong procedure	**10 (42)**
Wrong implant – intraocular lens	4 (40)
Wrong implant—breast	3 (30)
Incorrect instrument specifications	2 (20)
Different procedure	1 (10)
Wrong site	**4 (17)**
Wrong skin lesion	2 (50)
Contralateral appendage	1 (25)
Ipsilateral appendage	1 (25)

Category 1: incomplete preoperative verification

Incomplete preoperative verification was identified as a contributing factor in nine SSEs (9/20; 45%). This category was defined as a surgery performed without adherence to components of a preoperative protocol expected for the intended surgery. Most frequently, this category applied to cases in which the surgeon and/or clinical team did not confirm the nature of the surgery prior to the first incision. This category also included cases where the clinical team did not confirm the intended surgical implants with the patient or did not confirm the location of surgery. In other cases, the site of the surgery was confirmed with the patient, but the clinical team did not mark the site or marked the incorrect site.

Some office and surgical facilities do not have a procedure in place to double check the preoperative calculations and measurements input into a medical device used during the surgery. This often presented as the wrong specifications entered into a laser used for refractive eye surgery and a wrong-procedure SSE. Similarly, other facilities did not have a procedure in place to check the specifications of the implant (e.g., its measurement/size or type) prior to bringing the implant into the operating space. Failure to confirm surgical implant specifications also led to multiple wrong-procedure SSEs. Finally, some clinical teams did not perform an adequate informed

Table 2 Summary of qualitative contributing factor analysis

Definition	Case characteristics	Takeaways
Incomplete preoperative verification		
Surgery performed without adherence to components of a preoperative protocol expected for the intended surgery	- Did not confirm the nature of surgery with patient - Did not confirm site of surgery with patient - Did not confirm implant with patient - Did not confirm instrument setting, measurement, preoperative calculation - Did not appropriately mark the site of surgery - Did not conduct an adequate informed consent discussion	- Adapt a validated preoperative protocol to fit office practice (e.g. Universal Protocol, WHO Surgical Safety Checklist) - Confirm identity, site, implants & surgery with patient - Review the informed consent form with the patient - Involve operating physician & patient in site marking & draping - Continuously audit preoperative protocol, update as required
Inadequate intraoperative surgical count		
Surgery was completed prior to the completion of a comprehensive instrument, needle, or sponge count Foreign object was retained but there was no instrument, needle, or sponge count included in the patient's files	- Surgical count was not performed - Surgical count was performed incorrectly - Surgical count was incomplete (no preoperative or postoperative count) - Surgical count did not include an instrument or tool utilized during the surgery	- Adapt a validated preoperative protocol to fit office practice (e.g. Universal Protocol, WHO Surgical Safety Checklist) - Ensure that every instrument or tool utilized during the surgery is included in the count - File all surgical documentation in patient medical records - Complete a sufficient intra-operative assessment of the incision prior to closure
Insufficient review of patient medical record before procedure		
Surgery began without the surgeon and/or clinical team reviewing pre-operative documentation pertinent to the current surgery A preoperative consultation note was reviewed but did not contain sufficient information to safely complete the surgery	- Did not review preop consultation note to confirm nature of surgery - Did not review preop consultation note to confirm site of surgery - Did not review preop consultation note to confirm the implants - Did not review preop consultation note to confirm instrument setting, measurement, preop calculation - Preop consultation note was incomplete or lacking the detail necessary for lesion localization - Preop consultation note was not accessible	- Conduct a thorough preoperative consultation and document necessary details. File preoperative note in patient medical record - Confirm the identity, site, implants and surgical procedure by reviewing the patient medical record - Do not perform the surgery without the required medical records
Surgery performed without the necessary resources		
Surgery performed without the necessary surgical instruments, equipment, or staffing	- Trained staff were not available to support surgery - Surgery was performed without any nursing assistance - Medical equipment required for the surgery was not available in the office - Medical equipment required for unexpected complications were not available in the office	- Maintain appropriate staffing levels - If required, operate with nursing assistance - Confirm that the equipment required for the surgery is available in the operating room space - Confirm access to additional equipment that may be required during unexpected complications
Administrative error or office disorganization		
Surgery was performed based on an error in the patient's records or office-booking system Office record keeping and inventory management practices were inadequate compared to industry standards	- Transcription error (typographic error, illegible handwriting) resulting in the wrong measurement or preop calculation being used - Transcription error (typographic error, illegible handwriting) resulting in the wrong implant being used - Preop consultation note was not found in time for procedure - Erroneous appointment booking title - No protocol in place to confirm and manage inventory shipments	- Double check all measurements and implant specifications prior to scheduled surgery - Create detailed and accurate appointment booking titles and confirm booking title prior to scheduled procedure - Implement a policy to confirm and track shipments to ensure correct implant prior to procedure

consent discussion. Most commonly, this presented as an absence of a consent discussion prior to the surgery. In other cases, a consent form for an alternative surgical procedure was mistakenly given, contributing to a wrong-procedure SSE.

Box 1: a case of an incomplete preoperative verification and wrong-site SSE Patient arrives for a left-sided surgery. The location of the surgery was documented in the preoperative consultation notes but was unspecified in the appointment booking. On arrival, the patient was provided with a consent form for the surgery that did not specify the site of the surgery. The patient's right limb was prepped and draped by the operating room team while the patient was under anesthesia. The operating physician operated on the contralateral appendage (left limb). In response to this SSE, the surgical facility adopted a preoperative protocol with a preoperative verification process that included: (1) the clinic clerk confirms the site of the surgery is correct in the operative booking, (2) the operating physician confirms the nature of the surgery with the patient and assists in draping, (3) the patient remains awake during draping.

Category 2: inadequate intraoperative surgical count

Inadequate intraoperative surgical count was the most commonly (12/20; 60%) identified contributing factor to an SSE. This category was assigned to cases in which the surgery was completed prior to the completion of a comprehensive instrument, needle, or sponge count. This category also included cases where a foreign object was retained but there was no documentation that a surgical count occurred.

Most cases associated with a retained object SSE were assigned this category ($n=9$). Typically, a sponge or gauze was retained inside the incision; these cases were associated with a missing or incorrect surgical count. Other times, a surgical count was performed, but the surgical count sheet failed to include an instrument or item used during the surgery. This scenario sometimes arose unexpectedly. For example, if an instrument was needed to manage an unexpected complication during surgery, the instrument was less likely to be included on the count sheet.

Category 3: insufficient review of patient medical records before surgery

In a quarter of our cases (5/20; 25%), the review of the patient's medical records prior to surgery was inadequate. This category was defined as a surgery commencing without the surgeon and/or clinical team reviewing preoperative documentation pertinent to the surgery. Most frequently, this category was applied to cases in which the operative team did not review the preoperative consultation note to confirm the nature of the surgery or the site of the surgery.

The preoperative consultation note was often not reviewed to confirm the type of implant (e.g., silicone or saline breast implants) or the specifications of the implant (e.g., intraocular lens). Similarly, there were cases where a patient's medical records were reviewed but they did not contain sufficient details to allow the operating physician to identify the correct skin lesion for removal. This category also included cases where the preoperative assessment was missing or inaccessible. Sometimes, the preoperative consultation was performed in a different clinic, and the operating clinic did not have access to those patient records at the time of the surgery.

Box 2: a case of insufficient review of a patient's medical records and wrong-procedure SSE Patient arrives for a surgery with a specialist on a Wednesday. This operating physician specializes in two surgical procedures and performs one on Mondays and the other on Wednesdays. Due to a mix-up with the booking system, they are booked for the surgical procedure commonly performed on Monday on a Wednesday. The patient was given the consent form for a different surgical procedure, the surgical procedure typically performed on Monday. The preoperative consult note, which included the surgical plan, was not reviewed prior to the surgery. The surgery is performed without nursing assistance and is uneventful. After the surgery the patient and surgeon discover the error. The clinic has since implemented a preoperative safety checklist that includes a reminder to confirm the nature and indications for surgery prior upon patient arrival and again prior to surgical preparation.

Category 4: surgery performed without the necessary resources

An out-of-hospital surgery performed without the necessary resources was identified as a contributing factor in six SSEs (6/20; 30%). This category included surgeries performed without the necessary instruments, equipment, or staffing. For example, a surgery typically performed with nursing assistance may have been completed by the operating physician working alone. In other cases, a nurse may not have been available to assist with the surgical count or to preoperatively confirm the nature of the surgery with the patient. In other cases, the clinics did not have the necessary resources to manage unexpected surgical complications. This might include the availability of diagnostic imaging equipment, such as X-ray or ultrasound, to identify if an item has been retained during surgery.

Category 5: administrative error or office disorganization

An administrative error and office disorganization was identified as a contributing factor in six (6/20; 30%) SSEs. This category included surgeries that were performed following an incorrect entry in the patient's medical records or office-booking system. Most frequently, this category was assigned to cases in which a transcription error resulted in a wrong-procedure SSE. In some cases, this presented as a transcription error, resulting in the wrong settings on an ophthalmic device. Other transcription errors resulted in the implantation of the wrong breast implant or intraocular lens. Some cases of a transcription error were the result of illegible handwriting in preoperative consultation notes. Sometimes a wrong-procedure or wrong-site SSE occurred because of an erroneous appointment booking title.

This category was also assigned to cases in which office record keeping and inventory management practices were inadequate compared with industry standards. An example of this category included a missing preoperative consultation note on the day of the surgery. Without the consultation note, the operating physician could not confirm the patient's implant preferences. In other facilities, there were no protocols in place to confirm and manage inventory shipments, resulting in the delivery of the wrong implants and a wrong-procedure SSE.

Box 3: a case of office disorganization and wrong-procedure SSE A patient underwent surgery, which requires an implant. During surgery, it is discovered that the manufacturer had delivered the wrong type of implant, and there were no appropriate substitutions on site. The physician decides to use the incorrect implant as it is the same size specifications as the preferred implant but is made of a different material. They notify the patient that they received an unintended implant after the surgery. This clinic has since updated its office policies to ensure that all shipments are checked by staff upon receiving the package and again prior to bringing the implants into the operating space.

Patient outcomes and medico-legal case resolutions

Of the 20 cases of out-of-hospital SSEs included in the qualitative analysis, 19 (19/20; 95%) resulted in an unfavourable outcome for the operating physician. Four of these cases (4/20; 20%) required action (e.g., office policy change) by the medical regulatory authority (College). Most cases of SSEs required additional healthcare resources to resolve or mitigate the consequences of the SSE (18/20; 90%). This additional expenditure included additional clinic appointments, new referrals, pain medications, hospital admissions and additional surgeries.

The most common patient health outcome attributed to an SSE was postoperative infection due to a retained object (10/20; 50%). In some of these cases, the operating physician was aware of the SSE or had a suspicion but failed to monitor the patient postoperatively and did not order the appropriate follow-up investigations.

These out-of-hospital SSEs were also associated with physical and mental health complications. Some patients reported postoperative anxiety, depression or posttraumatic stress disorder. Other patients had postoperative cosmetic complications, such as scarring, from the SSE or the required revision surgery. Finally, patients also reported physical impairment resulting from surgery, including chronic pain, vision loss, and impaired mobility.

Discussion

In this descriptive and qualitative analysis, SSEs occurring during out-of-hospital surgeries were reviewed, and cases were assigned one of five contributory factor categories. The five contributory factor categories include (1) incomplete preoperative verification, (2) inadequate intraoperative surgical counts, (3) insufficient review of patient medical records, (4) surgery performed without necessary resources, and (5) administrative error and office disorganization.

There are unique challenges to an out-of-hospital surgical practice. Out-of-hospital settings often operate with fewer resources than larger hospitals or health authorities. The responsibility for establishing and maintaining perioperative policies, managing administrative records, and ensuring adequate staffing falls on a smaller group of physicians and administrators. Out-of-hospital settings may face less regulatory oversight, and existing standards may be less comprehensive or inconsistently enforced compared to hospital environments. Although ambulatory surgical centres and physician offices may have less safety infrastructure and fewer resources, the changes in facility policies that would support patient safety, such as completing a surgical count and standards for preoperative verifications, are often simple and inexpensive to implement. These safety measures have been validated extensively in the hospital setting and will address some of the contributing factor categories identified in this study. Additionally, the smaller scale of out-of-hospital office practices may allow for more rapid and efficient implementation of such policies and protocols that support patient safety.

Incomplete preoperative verification was a common contributory factor to an SSE. This frequently presented as a failure to confirm the nature of the surgery prior to incision. In 2004, the Joint Commission Universal

Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery was released [35]. The protocol outlined practice recommendations, including preoperative verification, marking of the operative site, and a "time out" prior to surgery. The limited available evidence suggests that adherence to components of the universal protocol is effective in curtailing the incidence of wrong-site, wrong-procedure, and wrong-person SSE [4, 36, 37].

In our study, clinics adapted their preoperative protocol after a wrong-site or wrong-procedure SSE to include components of the Universal Protocol. Improvements implemented or suggested by the medical regulatory authority (College) included a patient verification process conducted by more than one member of the clinical team. This could also include an additional verification process for all measurements and instrument settings. Additionally, some opted to include the operating physician in the surgical preparation and draping processes. If possible, involving the patient in the site marking and preparation process may also help avoid wrong-site or wrong-procedure SSEs [35].

Changes in facility operating procedures and policies to protect against SSEs should be tailored to the specialty and nature of the surgeries performed. In plastic surgery and dermatology, biopsy healing and infection can be risk factors, but if associated with a wrong-site SSE, it may increase the possibility of a patient filing a complaint [38, 39]. When identifying the site of the surgery, some suggest against overreliance on the sole assertation of the patient or provider. Instead, the use of objective photographs, measurements and landmarks saved in the patient's medical record should be referenced [38, 39]. Out-of-hospital surgeries dependent on preoperative calculations and/or intraocular lens insertion, as in ophthalmology, are a particular area of concern [40–42]. Practice guidelines and tailored checklists exist to support the prevention of these SSEs [41, 42]. Specific recommendations from the available literature include double checking all intraocular lens powers and clear documentation of preoperative measurements and calculations. Additionally, the "time-out" immediately preceding the operation should include a confirmation that the correct implant is present and that the correct surgery is to be performed on the correct eye [41, 42].

Inadequate surgical count or missing surgical documentation was the contributing factor category assigned to the majority of cases and was frequently associated with a retained-object SSE. The World Health Organization Surgical Safety Checklist (SSC) was released in 2008 to combat these SSEs [43, 44]. This SSC includes an instrument, sponge and needle count. Most Canadian hospitals have adopted the SSC, but real-world Ontario-based studies have failed to demonstrate improved outcomes [45, 46]. The lack of improved outcomes may be related to variable engagement with the SSC [44, 45]. Additionally, concerns were raised that individual hospitals were responsible for implementation of the checklist without any administrative support. There are no data on the uptake of checklist(s) in out-of-hospital settings.

A common theme of communication failure emerged across multiple contributing factor categories. For Category 1 (incomplete preoperative verification), failure to effectively communicate with the patient and confirm surgical details contributed wrong-site SSEs. For Category 2 (inadequate intraoperative surgical counts) failures in communication between operative staff, particularly in relation to surgical checklists, often resulted in retained-object SSEs. For Category 5 (administrative errors and office disorganization) poor communication between the physician and office staff contributed to transcription errors and wrong-procedure SSEs. These findings align with literature emphasizing communication failure a key contributing factor and reaffirms the need for efficient communication in out-of-hospital settings [4].

Like previously published research, our dataset shows that retained-object SSEs are not limited to hospital-based surgeries on large body cavities [13, 18, 25–27, 47, 48]. In an out-of-hospital setting, the administrative burden of developing, implementing and adhering to the SSC falls on the operating physician and office administration. Encouraging the motivated use [49, 50] and shared stewardship [51] of an SSC for all out-of-hospital surgeries should be considered. In our study, most facilities implemented or revised their intraoperative instrument, sponge and needle count procedures following a retained-object SSE. Continuous quality improvement and modifications of a facility's SSC may protect against repeated occurrences of an SSE [52]. Facility leadership and administration might consider improvements to the implemented SSC to support improvements in patient safety and mitigate medico-legal risk. Additionally, ongoing evaluation to determine the impact of the change (using safety metrics other than the occurrence of an SSE) could be valuable.

The out-of-hospital facilities in our study adapted their practices following an SSE to improve clinic staffing, workflow, and organization. The out-of-hospital physician should consider confirming that they have the required equipment and staffing levels for surgery before beginning. If indicated, the out-of-hospital physician could consider performing the surgery with assistance from nurses and other trained staff [53]. Additionally, policies, roles and responsibilities concerning good record-keeping practices should be shared among the entire facility. This could include strategies to ensure that

consultation notes are legible and accessible and support the use of booking information that is sufficiently detailed to avoid confusion [54].

This study is subject to the limitations inherent to qualitative analysis and secondary uses of data. Additionally, only cases of out-of-hospital SSEs in which physicians self-reported to the CMPA were included, and likely is an under representation of such cases. The nature of this self-reported data repository also prevents direct comparisons of SSE incidence rates between hospital and out-of-hospital settings. On the other hand, the contributing factor analysis is strengthened by its detailed and comprehensive review of medico-legal files that included expert physician, nursing and medical regulatory authority (College) assessments. These medico-legal files also included physician and patient statements of claim/defense that supported the contributing factor and patient outcome analysis.

Conclusion

Wrong-site, wrong-procedure, and retained-object SSEs can occur in all healthcare settings, including an out-of-hospital operating space. We identified five main contributing factor categories to an out-of-hospital SSE. These categories included (1) incomplete preoperative verification, (2) inadequate intraoperative surgical counts, (3) insufficient review of patient medical records, (4) surgery performed without the necessary resources, and (5) administrative error or office disorganization. Some of these contributing factors overlap with those identified in hospital-based literature, whereas other factors are novel and associated with the resource constraints and workflow differences of an out-of-hospital setting. These SSEs resulted in harm to patients' physical and mental health and required additional healthcare-related resources, such as repeat surgeries. Given the consequences of SSEs, regulatory bodies may have a role in in establishing clearer safety protocols and oversight mechanisms tailored to out-of-hospital surgical settings. Continuous quality improvement and good office practices are essential in reducing the risk of SSEs during out-of-hospital surgeries.

Abbreviations

CMPA	Canadian Medical Protective Association
SSC	Surgical Safety Checklist
SSE	Surgical Sentinel Event

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13037-025-00432-4.

Supplementary Material 1.

Authors' contributions

All authors contributed to the study conception, data collection, data analysis, manuscript preparation, and manuscript review.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

This study was approved by the Canadian ethics review panel of the Advarra Institutional Review Board (CR00389884) in compliance with Canada's Tri-Council Policy Statement on the Ethical Conduct for Research Involving Humans (TCPS 2).

Human ethics and consent to participate declarations

Not applicable.

Competing interests

The authors declare no competing interests.

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