

# Surgical safety checklists

A REVIEW OF  
MEDICAL-LEGAL DATA



# SURGICAL SAFETY CHECKLISTS: A REVIEW OF MEDICAL-LEGAL DATA

## BACKGROUND

While safety checks had long been used in the surgical setting, the 2007–2008 landmark study by Haynes and colleagues<sup>1</sup> was the first to demonstrate a reduction in complications with the use of a comprehensive checklist designed to improve team communication and consistency of care in operating rooms.

This checklist, now recognized as the World Health Organization (WHO) Surgical Safety Checklist (SSCL), solidified a more comprehensive surgical team approach through greater emphasis on communication to ensure the consistent completion of necessary common tasks. The SSCL reinforced accepted safety practices across three surgical phases: before the induction of anaesthesia (briefing), before the first incision (time out), and before leaving the operating room (debriefing). Many hospitals in Canada and throughout the world have since adopted surgical safety checklists based on the WHO standard.

Subsequent studies have continued to link the SSCL to improved outcomes,<sup>2,3</sup> but recent studies from Ontario failed to show similar improvements.<sup>4,5</sup> This has led to some controversy as to the effectiveness of the SSCL. However, these results may have reflected incomplete or poorly performed SSCLs, as Urbach and colleagues recognized that the mandated implementation of the SSCL in Ontario was not standardized and did not require formal team training.<sup>4</sup>



Experts acknowledge that successful SSCL implementation addresses team training, dynamics, and communication, and involves all members of the surgical team.<sup>6,7</sup> Effective strategies include the engagement of leadership and a local “champion,” thoughtful modification of the checklist to local workplace requirements, respectful inter-disciplinary team training, pilot implementation with feedback prior to large-scale training sessions, and feedback to allow for ongoing evaluation and reinforcement.<sup>8,9</sup> While it is recognized that optimal use of an SSCL will not prevent all surgical patient safety incidents, it is considered a fundamental step toward enhanced surgical safety.

**In support of safe surgical care, this review of medical-legal data from the Canadian Medical Protective Association (CMPA) points to the continued relevance of the clinical issues that the SSCL is intended to address, highlights some of the barriers (human and system factors) to its effective use, and identifies priority areas for system and individual practice improvements.**

## METHODS

SSCL-related issues were defined as clinical care issues the SSCL is intended to address and which contributed to a surgical incident.\* The CMPA reviewed closed medical-legal cases (legal actions, regulatory authority [College] complaints, and hospital complaints) that occurred in hospital surgery between 2011 and 2014 to identify SSCL-related issues. This time period was chosen based on the 2010 adoption of the SSCL as an Accreditation Canada requirement of practice (ROP).

Cases were selected for analysis by identifying surgical incidents related to safety protocols within or associated with the SSCL. These surgical incidents included wrong surgeries, retained surgical foreign bodies, the use of an expired graft, lack of appropriate prophylaxis, equipment failures, and issues with specimen management. Analysis of the expert opinions identified system, physician, and other healthcare provider factors that contributed to the surgical incidents. Incidents were mapped according to the SSCL surgical phase (briefing, time out, debriefing) and the task intended to address the issue. Obstetrical cases were excluded due to the unique issues associated with this area of care.

## LIMITATIONS

- Not all surgical incidents are reported to the CMPA.
- Analysis was limited to the information contained in the CMPA files. It was not always possible to determine, from expert opinion or the medical records, the presence or use of a formally implemented SSCL or the extent of adherence to an SSCL in a given circumstance.
- Based on the data used for this study, cases were reported to the CMPA an average of 1 year after the incident occurred. Therefore, if this study were to be updated in the future using the same time period to identify cases, the number of cases and resulting statistics may change.

\* Surgical incident: A patient safety incident that occurred prior to, during, or after a surgical procedure.

## **FINDINGS**

The analysis identified 43 closed CMPA medical-legal cases that involved SSCL-related issues, including 11 cases related to the surgical count. Although these incidents are infrequent, nearly all were considered indefensible as the care provided could not be supported by peer experts (27/30 legal matters were settled and 12/13 College and hospital complaint cases concluded with concerns about the physician's care). Two of the three cases with a favourable medical-legal outcome for the physicians were settled by the hospital. Eight of the cases resulted in settlements paid on behalf of both the physician and the hospital or health authority due to involvement of nurses or a lack of hospital SSCL protocols.

### **Wrong site, wrong procedure, wrong patient surgery**

The 19 cases involving a wrong side, site or procedure revealed deficiencies with surgical verification tasks either prior to anaesthesia (briefing) or before the first incision (time out). These failures involved the entire surgical team and included: patient informed consent not verified prior to the start of surgery; site marked but patient prepped or positioned on wrong side; and diagnostic images or clinical records not available or not reviewed (see table 1, on the next page, for more clinical detail about these issues). Peer experts reviewing the cases were most often critical of operating room teams not adhering to a surgical safety protocol (14 cases); while in 2 cases the inadequacy of a protocol was identified (i.e. lack of protocol to verify implant, inadequate protocol to verify procedure).

### **Unintentionally retained surgical items**

Analysis of the 11 cases involving a retained surgical foreign body revealed deficiencies in surgical count protocols, including: inadequate documentation of the surgical count, not repeating the surgical count on wound closure, or inaccurate counting. In 3 cases the hospital responded by making changes to their surgical count protocols to ensure larger items (e.g. specimen retrieval bags) were added to the count documentation and counts were done for laparoscopic and pacemaker insertion procedures.

### **Other SSCL-related issues**

The surgical incidents in the remaining 13 cases most often involved the team not adequately reviewing key information: the medical record (including the patient's health status and the results of pre-operative tests) or equipment functionality. Miscommunication between surgical team members (e.g. specimen not processed as directed, patient information not verbally shared) was also noted.

The detailed procedures for common tasks, such as surgical count protocols and specimen management, are not specified in the SSCL. Surgical teams must ensure they continue to perform these common tasks according to the needs of the patient and type of procedure.

## **CONCLUSIONS**

Harmful surgical incidents, including wrong site surgeries and retained surgical items, continue to occur in Canada. The number of CMPA cases underrepresents the frequency of occurrence.

Contributing system factors in the CMPA cases included administrative and scheduling issues during pre-operative assessment, inadequate intra-operative surgical safety protocols, and deficient documentation. Peer expert reviewers recommended improved execution of the surgical safety protocols to include more rigorous completion of common tasks, such as verification procedures, equipment management, and surgical counts, appropriate review of the clinical records, and greater intra-operative communication.

Appropriate standardization of surgical practice, as in many high risk industries, will help reduce surgical safety incidents. Enhanced SSCL implementation promises to improve team communication and support safer surgical systems of care. The SSCL is a team procedure in which every team member has a responsibility to participate and respond. The SSCL's emphasis on team collaboration and communication supports verbal confirmation or discussion of issues involving common and necessary surgical tasks for prevention of surgical safety incidents.

A supportive leadership and administration is essential for effective implementation of the SSCL, including continuous quality improvement on its use. Providers should participate in team training and quality improvement measurement.

Use of an SSCL does not replace surgeons' obligations to be knowledgeable about their patients' clinical history, intended surgical procedure, preoperative preparations, and intraoperative and postoperative course. The appropriate use of an SSCL can support surgeons and team members to complete necessary common tasks, anticipate and prepare for potential problems, and facilitate team communication at all stages of surgical care.



<b>Table 1. Analysis of SSCL-related issues, CMPA closed cases, date of occurrence 2011–2014 (n =43)</b>	
<b>Task</b>	<b>Surgical safety incident</b>
<b>Briefing (before anaesthesia induction) (23 cases)</b>	
Confirm patient information: identity, informed consent, surgical site, procedure	<ul style="list-style-type: none"> <li>▪ Inconsistency between operating room schedule and consent form not noted</li> <li>▪ Wrong patient's documentation used following reordering of operating room schedule which resulted in patient receiving wrong implant</li> <li>▪ Team proceeded with wrong procedure listed on hospital registration sheet despite patient's name not being listed on operating room schedule; absence of any documentation from the surgeon's office; no access to electronic medical records</li> <li>▪ Team members who performed briefing were not present for surgery and surgical team proceeded with wrong side surgery</li> <li>▪ Surgical checklist in place but nurse referred to computer screen for verification of procedure and mistakenly read the wrong line which resulted in wrong surgery</li> </ul>
Review clinical documentation and confirm essential diagnostic imaging is displayed or final diagnostic tests available	<ul style="list-style-type: none"> <li>▪ Surgeon did not note inconsistency in radiologist report and did not review available CT images; right nephrectomy performed on patient with left kidney tumour</li> <li>▪ Absence of a review of patient's clinical records resulted in missing significant comorbidities or not recognizing that consent did not correspond with clinical record</li> <li>▪ Patient signed consent for wrong procedure on day of surgery because verification consisted of a leading question (i.e. "You are having a ....") rather than a direct question (i.e. "What surgery are you having?"), and the clinical record was not reviewed</li> <li>▪ Essential testing or imaging not completed or results not available (e.g. blood glucose testing, chest X-ray)</li> <li>▪ Surgery performed before receiving final pathology result which would have pre-empted the procedure</li> </ul>
Assess patient risk, including allergy status, prophylactic requirements	<ul style="list-style-type: none"> <li>▪ Antibiotic given despite documented allergy</li> <li>▪ Pre-operative antibiotic not administered</li> </ul>
Review airway status and specific patient risks	<ul style="list-style-type: none"> <li>▪ Airway not assessed prior to general anaesthesia</li> <li>▪ Patency of intravenous access or patient's anaesthesia preference not assessed</li> <li>▪ Blood sugar not assessed pre- or post-operatively in poorly controlled diabetic patient</li> </ul>
Confirm sterility and equipment issues or concerns	<ul style="list-style-type: none"> <li>▪ Expired orthopaedic graft inserted</li> <li>▪ Non-functioning fluoroscopy arm and operating room bed used</li> </ul>
<b>Time out (before first incision) (7 cases)</b>	
Confirm patient information: identity, surgical site, procedure Determine optimal positioning of patient	<ul style="list-style-type: none"> <li>▪ Surgical site correctly marked, but team members set up on opposite side; a late surgical time out was called after scope insertion</li> <li>▪ Drapes covered marked surgical site and team did not verify site</li> <li>▪ Patient positioned on wrong side and despite a time out the physician did not verify surgical side before proceeding</li> <li>▪ Site correctly marked and formal time out called, but team members prepped and placed tourniquet on wrong side</li> <li>▪ Site correctly marked but after induction patient was turned over and surgery initiated on wrong side; diagnostic images not done in prone position and not flipped as per usual practice</li> </ul>

<b>Table 1. Analysis of SSCL-related issues, CMPA closed cases, date of occurrence 2011–2014 (n =43)</b>	
<b>Task</b>	<b>Surgical safety incident</b>
<b>Debriefing (before patient leaves the operating room) (13 cases)</b>	
Surgical count	Retained surgical foreign body due to: <ul style="list-style-type: none"> <li>▪ Surgical count not documented</li> <li>▪ Team did not perform a second count prior to wound closure</li> <li>▪ Error in surgical count compounded by inadequate check of cavity prior to closure</li> <li>▪ Hospital did not require surgical count for laparoscopic procedures or minor procedures</li> <li>▪ Surgical count did not include specimen retrieval bags</li> <li>▪ X-ray not ordered despite incorrect count or lengthy complicated surgery</li> </ul>
Label and manage specimens	<ul style="list-style-type: none"> <li>▪ Retrieved specimen not sent to microbiology as requested, and culture could not be done as specimen was stored in formalin</li> <li>▪ Bone flap not stored as per protocol and could not be used</li> </ul>
<b>Note:</b> Medical-legal cases usually involve multiple contributing factors.	

**References**

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