

Authors

Arti Saini

Pediatric Surgery Operation Theatre,
Advanced Paediatric Centre, PGIMER,
Chandigarh

Dr. Sukhpal Kaur

National Institute of Nursing Education,
PGIMER, Chandigarh

Prof JK Mahajan

Dept of Paediatric Surgery, Advanced
Paediatric Centre, PGIMER, Chandigarh

Mrs. Prabhjot Kaur

National Institute of Nursing Education,
PGIMER, Chandigarh

Corresponding author

Arti Saini

Pediatric Surgery Operation Theatre,
Advanced Paediatric Centre, PGIMER
artisaini51f@gmail.com

Precision in practice: Developing and validating a protocol and a checklist for standardization of 'surgical counts.'

Abstract

Background: The prevention of unintentional retention of surgical items (RSIs) inside a patient's body is one of the primary responsibilities of operating room nurses. Surgical counting is a simple and efficient method that helps prevent this human error.

Aim: To develop and validate a standard operating protocol (SOP) and a checklist for surgical counts conducted during abdominal surgeries.

Methods and materials: A methodological study, divided into six phases (2021-2023), was conducted in the paediatric surgery operating theatre of a tertiary care centre in northern India. Initial observations (N = 30), focus group discussions (N = 20) and nurses' knowledge assessment (N = 24) were carried out to explore baseline knowledge and practices related to surgical counts. The first draft of the SOP and checklist was prepared. A three-round Delphi process involving nine experts was employed to ensure content validity. The reliability of the protocol was evaluated across 75 surgical procedures using Cronbach's alpha coefficient and nurses' acceptance of the protocol was gauged through a structured questionnaire.

Results: Content validity was high, with a scale-level content validity index based on the average method (S-CVI/Ave) of 0.98 and a scale-level content validity index based on the universal-agreement method (S-CVI/UA) of 0.80. The mean item-level content validity index (I-CVI) was 0.90. The checklist comprised 37 items covering the key phases of surgery. Internal consistency was strong (Cronbach's $\alpha = 0.82$). Following implementation, surgical counting practices improved considerably, and nurses reported greater clarity and confidence.

Conclusion: The SOP and checklist were found to be valid, reliable and well accepted in this single-centre study; further multicentre validation is recommended.

Keywords: checklist, delphi study, delphi technique, institutional policy, foreign body, reliability and validity, retained surgical, surgical sponge, surgical tools.

Introduction

Surgery is a complex and unpredictable process, which that is prone to errors at each step. Nurses play a major role in good surgical outcomes by influencing the pre-, intra- and post-operative phases of the surgery. While the pre- and post-operative role of nurses is well established and appreciated, the intraoperative role remains least recognised. Patient safety during surgery and being a patient's advocate at their most vulnerable time is a major but

less discussed role of an operating room nurse.

One important aspect of patient safety is the prevention of inadvertent retention of surgical items (RSIs) inside the body cavity of the patient, which is achieved through a process commonly called 'surgical counting'^{1,2}.

The risk of unintentional RSIs is covered under the nursing diagnosis 'risk for injury related to incorrect surgical counts'. The expected outcome will be 'the patient is

This article is under a Creative Commons Attribution Licence 4.0 International (CC BY 4.0).

Copyright to this work is retained by the authors.

DOI: 10.26550/2209-1092.1399

free from signs and symptoms of injury due to extraneous objects.' The associated interventions that may lead to the desired outcome are "performed required count"¹.

'Surgical counts' are an integral part of any surgery. Gauze pieces, sponges, needles, instruments and miscellaneous items are an inseparable part of surgery and must be accounted for throughout the surgical procedure. The number of these items may vary with the nature of the procedure. However, in any surgery, counts are essential to prevent unintended retained items in the wound.

The RSIs can pose serious health implications for the patient, tremendous mental agony and humiliation for the surgeon. The surgeon and operating team may be held liable for negligence. This ordeal can be prevented by improving the systems and methods used to track surgical items during surgery².

RSIs are considered a rare, preventable, but dangerous complication of surgery, which can have grave consequences for the patient as well as the operating team. The Association of Perioperative Registered Nurses (AORN) states that many factors, such as situational awareness, good communication and consistent compliance with standardised processes, have been shown to reduce the risk of unintentional RSIs in the patient. Careful documentation can significantly reduce the risk of this unfortunate event¹.

Inadvertently leaving a sponge, needle, or instrument in a patient at the end of an operation is a rare but persistent and dangerous surgical error. The best estimates of the frequency of retained surgical items range from 1 in 5000 to 1 in 19 000 inpatient operations, but the likelihood is estimated to be as high as 1 in 1000. These events are underreported due to fear of litigation, so the actual incidence may be much higher. RSIs tend to result in serious consequences such as infection, re-exploration for removal of the item, bowel perforation, fistula or obstruction and even death².

There are multiple risk factors responsible for inadvertent RSIs in the body, the most common being emergency surgery, high body mass index and an unplanned change in the operation³. Surgical items can be retained in any cavity during any

surgery, irrespective of the magnitude or complexity of the procedure.

The World Health Organization (WHO) recommends that each facility implement a policy for surgical counts, which should delineate the responsible personnel, specify the items to be counted and detail the documentation process². A standardised procedure for conducting counts should be established to ensure uniformity and that all surgical team members are adequately familiar with the protocols. Minimizing practice variation is essential in reducing the risk of counting errors. Given the high frequency and risk associated with counting activities, policies governing this process should be reviewed and validated annually to ensure consistency and the alignment of best practices among all members of the surgical team⁴.

The WHO also recommends that the counts be recorded on a count sheet or a nursing record, which should specify the names and positions of personnel performing the counts. The results of the counts should be documented as correct or incorrect and instruments and sponges (packings) intentionally left in a patient should also be recorded. There is enough evidence in the literature that states that a standard operating protocol (SOP) or policy for surgical counts can help reduce, if not eliminate, the risk of RSIs².

The Joint Commission (the United States' largest accrediting agency in the healthcare sector) considers RSIs in a patient after surgery as a reviewable sentinel event. According to the sentinel event data, the absence of policies and procedures is one of the root causes of RSIs⁴.

The statement by the American College of Surgeons on the prevention of retained foreign objects recommends the use of standardised counting procedures and documentation of counts, as well as any intentionally retained items⁵.

An (SOP) can be defined as 'a set of written or detailed instructions that document a routine or repetitive activity followed by an organization to achieve uniformity of the performance of a specific function'⁶.

In other words, an SOP is a document that explains the when, what, where how and why of a procedure⁷. SOPs are

essentially helpful for newly recruited staff to provide services according to the standards of their facility. They increase the predictability of work and increase the confidence of staff in that all critical elements of a crucial process are covered. As SOPs are unique for each facility, as every institution has different human and material resources, different consumers and different philosophies.

Credible international agencies, such as AORN and WHO, recommend the use of surgical count sheets or checklists for documenting counts to enhance patient safety. Documentation is performed in various ways across different facilities, with the most common methods being the use of a whiteboard and/or count sheets¹².

Whiteboards can be helpful in easy visualization of counts, both for scrub nurses and operating surgeons. They can help both scrub and circulatory nurses tally the work of each other and give a live report of counts during surgery. However, it does not supplement a count sheet as a means of communication and documentation, as it is erasable and temporary.

Checklists are routinely utilised by high-reliability organizations such as the aviation industry and the nuclear power industry. Use of checklists helps to avoid human error of omission, which is likely because of information overload, complex and multiple steps of procedure, interruptions or distractions and departure from routine procedures. Arriaga et al.⁸ found that checklists may decrease errors for numerous reasons, such as ensuring that all critical tasks are carried out, improving communication, early catching of near misses and anticipation of potential complications.

Documentation and accurate record-keeping are integral to providing high-quality care to patients. The WHO recommends that the information be documented by the nursing team to include (but not limited to) counts of sponges, sharps, instruments and miscellaneous items, names of personnel performing the counts, intentionally packed instruments/sponges and the reason for not conducting a count, if any. The records must be clear, complete, signed, objective, contemporary, tamper-proof and original².

The WHO, in their catalogue 'Safe Surgery Saves Lives (2009)', recommended the standardization of surgical count procedures and the use of count sheets for the documentation and communication of counts². The literature has abundant evidence supporting the standardization of the surgical count procedure.

For decades, surgical counts were considered as a task of judgment and common sense, but human error is always a possibility that can be reduced by standardization and avoidance of deviation from set standards. Surgical count policy development should be undertaken as a collaborative task by surgical team members. Nurses should take initiative in developing an SOP for surgical counts to improve the quality of care and promote documentation of critical processes and events².

All institutions and healthcare facilities that prioritize patient safety should adopt standardised procedures and checklists in their practices.

Although surgical counts are routinely performed at recommended time points in the study setting (before incision, during critical stages, before cavity closure and before skin closure), the absence of a formal SOP has resulted in practice variation. Counting methods are based on individual practice rather than a standardised process, with inconsistent use of counting boards, inadequate documentation and unclear role allocation among team members. These gaps increase the risk of discrepancies. Therefore, a standardised protocol is essential to ensure consistency, clear accountability, effective communication and enhanced patient safety.

Materials and methods

The aim of the study is to develop and validate an SOP and a checklist for surgical counts during abdominal operations in a paediatric operating theatre (OT) of a tertiary care hospital in northern India.

Study setting

The study setting provides paediatric surgical services for the entire population of northern India. The operating theatre has four functional operating tables:

two are allocated to elective surgery, one to emergency surgery and one to day surgery. The work environment is complex, with procedures from several specialties performed in the theatre, including paediatric renal and urological surgery, gastroenterology, orthopaedics, otolaryngology, gynaecology and paediatric oncology. The department provides care for children from birth to 14 years of age.

The main procedures performed in the study setting include repairs of congenital anomalies, surgery for trauma and assault, emergency procedures such as repair of intestinal perforations, paediatric tumour resections, and reconstructive and palliative surgery.

Ethical considerations

Permission was obtained from the Head, the Department of Paediatric Surgery (vide letter no. PGI/NINE/2022/FTS:0399, dated 29 March 2022), and ethical approval to conduct the study was obtained from the institute ethics committee (vide letter no. INT/IEC/2022/SPL-156, dated 4 March 2022). Informed consent was obtained from all study participants, and each participant was provided with a participant information sheet containing comprehensive information about the study.

Methodology

The current study was carried out in the following order, namely, the preparatory phase (Phase 1), the validation phase (Phase 2), the first pilot study (Phase 3), the training phase (Phase 4), the implementation study (Phase 5) and the evaluation phase (Phase 6). The conceptual framework of this study is based on the waterfall model of software development. The major findings of these steps were incorporated with the literature review to generate a draft of the standard operating procedure for surgical accounts and a surgical count checklist for submission.

Phase 1: preparatory phase

Phase 1 of the study involved preparing a preliminary draft of the standard operating procedure (SOP) and checklist for surgical counts. In this phase, the observation of current practices of surgical counts, assessment of the knowledge of nurses related to surgical

counts and focus group discussions with surgeons and nurses were used to identify various problems related to surgical counts. The draft was developed through a literature review, an assessment of current practices, focus group discussions (FGDs) with nursing officers and surgeons, an assessment of nursing officers' knowledge of surgical counts, and generation of an item pool.

Literature review

A comprehensive literature review was undertaken to identify guidelines and recommendations related to surgical counts, as well as information about the incidence, prevalence and causes of count errors and retained surgical items. Relevant quality-improvement projects were also identified through manual and electronic searches. Guidelines published by the Association of periOperative Registered Nurses (AORN), the International Federation of Perioperative Nurses (IFPN) and the World Health Organization (WHO) were reviewed to generate an item pool for the preliminary draft. PubMed, CINAHL and Google Scholar were searched to identify and retrieve relevant articles. The guidelines, along with the various findings of the preparatory phase, were used as a framework to formulate the standard operating protocol suitable for the Indian setting.

Assessment of current practices

Current surgical-counting practices in the paediatric surgery operating theatre were assessed using an observation checklist based on the 2009 WHO's *Safe Surgery Saves Lives*. The checklist was reviewed by ten experts for content validity and pilot tested during five abdominal surgical procedures. Following the experts' recommendations and the pilot testing, the checklist was revised, and the researcher conducted 30 observations during morning and evening shifts.

The checklist included variables such as the patient's age and sex, the type and duration of surgery, and whether the WHO Surgical Safety Checklist was used. It also included response options of 'yes' and 'no' to indicate whether the recommended practice was followed, as well as a comments field for recording additional observations or incidents. The content validity index for each item was

1, indicating acceptable content validity. Reliability was assessed through five pilot observations using the checklist. The researcher also recorded field notes to document significant observations outside the scope of the checklist. Consecutive sampling was used, and observations were conducted from 23 June to 15 July 2022.

Focused group discussions (FGDs)

Three FGDs were conducted with nine nursing officers from the paediatric surgery operating theatre, and one FGD was conducted with four surgeons. The FGDs were held during both morning and evening shifts and aimed to identify the main problems encountered by nurses and surgeons during surgical counts, as well as their views and recommendations regarding standardisation of the procedure. Consecutive sampling was used to recruit nurses and surgeons according to their availability.

An FGD guide containing 13 open-ended questions was developed and validated by nine experts before data collection. Following written informed consent, the discussions were audio-recorded and supplemented by handwritten notes. The recordings were transcribed, and thematic analysis was undertaken to identify the major themes. These themes were incorporated into the preliminary draft.

Assessment of knowledge

A structured questionnaire was developed and administered to assess nursing officers' knowledge of surgical counts.

Generation of the item pool and preliminary draft

An item pool was generated from the literature review, observations of current practices and the main themes identified through the FGDs. The items were then developed into a preliminary draft of the SOP and checklist, which was submitted for Delphi review in the subsequent phase.

The terminology and recommendations relating to surgical counts align with the WHO guidance, which recommends counting instruments, sponges, needles and other relevant items and documenting whether the final count is correct.

Phase 2: Validation phase

The second phase of the study marked the validation of the preliminary draft of the SOP and checklist. This was accomplished by the Delphi method that consists of three rounds. For each round, the item-content validity index (I-CVI) and scale-content validity index (S-CVI) were calculated. The scale validity index (SVI) was calculated using both the universal agreement method and the average method.

The content validity and the reliability of the developed protocol and checklist are important psychometric properties that determine the quality of the developed content. Content validity is defined as 'the degree to which an instrument has an appropriate sample of items for the construct being measured'¹².

In other words, content validity means the degree to which a group of items represents an appropriate operational definition of a construct. The content validity establishment involves two distinct phases: a priori efforts exerted by the scale developer to improve the content validity by analysis of various domains and careful conceptualization before the generation of an item pool. After developing the content, its relevance is evaluated through expert judgment.

Several methods are available to measure how much experts agree on the relevance of the content. These methods include calculating the average rating given by experts for each item using coefficient alpha when content is reviewed by a small number of experts and applying the multi-rater kappa coefficient. Another commonly used method is the average congruency percentage (ACP)¹³. In this method, experts judge whether each item is relevant to the concept being measured. The percentage of relevant items identified by each expert is calculated and the average of these percentages is obtained. An ACP value greater than 90% is considered acceptable. In this study, the content validity index (CVI) was used to assess the content validity of the developed protocol and checklist. The CVI has two components, I-CVI and SCVI. The I-CVI represents the proportion of experts who rated an individual item as relevant. The SCVI reflects the overall content validity of the entire scale and can be calculated

in two ways: S-CVI/UA, which indicates the proportion of items rated as relevant by all experts and SCVI/Ave, which is the average of the I-CVI values for all items¹⁰.

To calculate the content validity in this study, the Delphi technique was employed. The Delphi method refers to a systematic forecasting process, where a collective opinion of panel members is obtained. The Delphi method can be defined as 'a structured technique to modulate a group communication process effectively in allowing a group of individuals, as a whole, to deal with a complex problem'¹⁴.

The vital elements of a Delphi study are the anonymity of panel members, controlled feedback, iteration, consensus, closing criteria and statistical stability of the expert consensus. The Delphi method has gained acceptance as a method to develop best practice guidelines using collective intelligence in areas where there is limited research evidence, the available evidence is conflicting, or when studies can be ethically or logically difficult to conduct¹⁴.

A panel of nine experts was selected for three Delphi rounds to establish the CVI of the developed SOP and checklist. The panel consisted of senior nursing officers with more than 15 years of experience in OT, surgeons, including senior nursing teachers as well as associate professors and senior residents from the Department of Paediatric Surgery. The modifications/recommendations suggested by the expert panellists were incorporated into the preliminary draft.

Multiple Delphi rounds with nine experts (surgeons, nursing education faculty and senior nursing officers with >15 years of experience in OT) were conducted

After the Delphi rounds, the pilot testing of the developed SOP and checklist was performed by training five nursing officers of APC-OT and then using the SOP guidelines and surgical count checklist in five abdominal surgeries they scrubbed for. Feedback was taken from the nurses, and the suggested modifications were incorporated into the SOP (including the surgical count sheet for abdominal surgeries) and the surgical count checklist.

Delphi round one

A preliminary draft of the SOP and checklist for surgical counts conducted during abdominal surgeries was circulated among nine experts. Three options were given to the panellists to respond to any item, i.e., 'yes' if the item was relevant, 'no' if the item was irrelevant or needed rephrasing/modification and 'comment' if any recommendations were to be given.

Delphi round two

The modified draft of the SOP and the developed checklist were recirculated among the nine panellists for Delphi round 2. The surgical-count checklist was divided into four sections. The first three sections corresponded to the phases 'before incision', 'during the procedure' and 'after skin closure'. The fourth section addressed the special conditions that may arise during surgery.

The checklist consisted of 37 items representing the steps of the surgical count procedure. Panellists used a 4-point ordinal scale to rate each checklist statement as very relevant (4), relevant (3), somewhat relevant (2) or irrelevant (1).

The statements that were marked as very relevant and relevant were kept in the checklist, the statements that were marked as a little relevant were modified and the statements that were marked irrelevant were eliminated from the subsequent versions of the checklist.

As per the suggestions of the panellists, the checklist and SOP were modified and recirculated for the third and final round.

Delphi round three

The modified draft was recirculated among the panellists. The suggested modifications were incorporated into the draft and finalised and were subsequently used for the pilot study.

Phase 3: Pilot study

Phase 3 included the pilot testing of the SOP and checklist. The pilot study was conducted on the 7th and 8th of September 2022. Five nurses were selected by a non-probability purposive sampling technique and trained in the SOP related to surgical counts. They also demonstrated the use of a surgical count sheet for abdominal cases.

All five nurses were instructed to implement the SOP and the surgical count

sheet in the cases where they scrubbed or circulated in the following days. A total of five cases were observed where these nurses used the SOP and checklist.

This was followed by a focus group discussion (FGD) to identify the problems they faced in the implementation of the SOP and surgical count sheet and any modifications. Suggested changes were incorporated into the SOP, checklist and surgical count sheet.

After establishing the validity of the SOP (including the surgical count sheet for abdominal surgeries) and the surgical count checklist, training was provided to all the nursing officers of the study setting using PowerPoint presentations and demonstrations, which marked the training phase.

Phase 4: Training phase

Phase 4 marked the training of all the nurses of the paediatric OT in the use of SOP for surgical counts, checklists and surgical count sheets for abdominal cases. It was carried out from 9 to 12 September in all shifts. The sample size was 25 nurses, selected using a total enumeration technique.

A PowerPoint presentation was used to educate the scrub nurses regarding the use of the SOP. The use of a surgical count sheet for abdominal cases was demonstrated to the nurses. They received instructions to apply the SOP guidelines and the surgical count sheet to all the abdominal surgeries they participated in.

Phase 5: Implementation phase

The developed checklist was applied in 75 abdominal surgeries operated on in the OT from 8 September to 7 November 2022 to assess the reliability of the SOP. A surgical count checklist was used to evaluate the change in practice related to surgical counts after the training of staff in the use of the developed SOP.

Reliability was calculated using Cronbach's alpha. Lee Cronbach developed alpha in 1951 as a measure of the internal consistency of a scale/test and its value lies between 0 and 1. It describes the interrelatedness of the various items of the test, i.e., the degree to which the items of the scale measure the same construct¹³.

Inter-rater reliability is considered an appropriate method for assessing agreement in observational tools such as surgical count protocols. Due to the nature of this study being conducted as a part of an individual postgraduate thesis, all observations and data collection were performed by a single investigator, limiting the feasibility of involving multiple raters. In this context, the internal consistency of the developed SOP was assessed using Cronbach's alpha to evaluate the coherence and uniformity of its components. While this does not substitute for the inter-rater agreement, it provides an initial measure of reliability.

Phase 6: Evaluation phase

In this phase, acceptance of SOP among nurses was also assessed using a structured questionnaire. Data analysis and interpretation were completed and the final validated and reliable SOP in the form of a booklet and checklist was submitted to the Head, the Department of Paediatric Surgery for use in their surgical procedures.

Results

Phase 1: Baseline findings

Thirty abdominal surgeries were observed. Most observations were conducted in emergency cases (63.3%). More than half of the surgeries involved male paediatric patients (63.3%), less than 1 year of age (76.7%), with a history of gastrointestinal disorders and underwent gastrointestinal surgeries (70%). More than half of the surgeries had a duration of 1 to 1.5 hours (63.3%).

Initial and final complete counts of all surgical items, including gauze pieces, sponges, sharps, etc., were performed in all the observed cases and two personnel were involved in performing the counts. Each item was separated and counted individually in 63.3% of cases.

In all cases, adequate handover was given to the reliever at the time of shift change, although the handover was verbal due to the unavailability of documentation sheets for counts. Whenever a count was interrupted, it was restarted. It was noted that a recount was conducted whenever new items were added to the sterile field. In almost all (96.7%) cases, the nurses audibly declared the count results after

the final count and an acknowledgement of the result was provided by the surgeon. In all the observed cases, surgeons documented the count results in the patient's surgical record.

The maximum obtainable score of the observation checklist was 25. The mean score observed was 18.97 (SD1.27).

Surgical counts were conducted thoroughly, but only 13.3% of surgeries documented counts using whiteboards. No formal use of checklists was noted (Table 1).

For the assessment of knowledge, half of the nurses who participated in the study were between 23 and 30 years old with the median age of 29 years old. Majority were female (83.3%), designated as nursing officers (87.5%) and had a bachelor's degree in nursing (87.5%). The median duration of total work experience was 6.5 years, and the median OT experience was 3.5 years.

A structured questionnaire was used to assess nurses' knowledge regarding the surgical counts, which included different types of questions divided into four parts. Nurses' knowledge of surgical counts was assessed, yielding a mean score of 74.25 (SD 9.9) with a minimum of 56 and a maximum score of 89. The full score is 100. Around half of the nurses possessed very good knowledge of surgical counts (knowledge score above 75). Approximately 30% had good knowledge scoring between 66 and 75). The identified areas of weak knowledge were 'safe technology for counts', the incidence of various RSIs and standardised terminologies related to surgical counts.

To further explore the surgical count practices, FGDs were carried out with the surgeons and nurses working in the study setting. Nine nurses and five surgeons participated in the focus groups. Thematic analysis was performed to analyse the data from focus group discussions. The main themes that were generated from the FGDs with nurses were 'shortage of staff', 'shortage of time', 'unavailability of written protocol', 'no briefing sessions for ancillary and new staff', 'no written documentation', 'unavailability of radiopaque packing material' and 'poor communication' between the team members.

Phase 2: Validation phase

To determine the content validity of the checklist, three Delphi rounds were carried out. The content validity was assessed by a panel of nine experts using Lynn's criteria (Table 2). The I-CVI for each item was 1.00, exceeding the minimum acceptable value of 0.78 for a panel of 6–10 experts. After three subsequent Delphi rounds, the content validity of the SOP and checklist was established. The SCVI/UA was 0.94 and SCVI/Ave was 0.99.

Both were acceptable value according to Lynn's criteria)).

The final checklist included 37 items across 4 surgical phases. The SCVI/UA was 0.80, and SCVI/Ave was 0.98, Mean I-CVI was 0.90, indicating excellent agreement (Table 3)

Phase 5: Implementation phase

Cronbach's alpha was calculated for 33 of the 37 checklist items (Tables 4a–d). The remaining four items had no variance.

Table 1: Observation of current practices (as per structured observation checklist based on WHO recommended practices for surgical counts) at baseline (N=30)

S. no.	Recommended practices	Yes (%)
1	Initial count of sponges done	30 (100)
2	Initial count of gauze pieces done	30 (100)
3	Initial count of instruments done	30 (100)
4	Initial counts for sharps done	30 (100)
5	Initial count of miscellaneous items done	30 (100)
6	Counts documented using white boards	04 (13.3)
7	Counts documented using count sheets	0
8	All items separated and counted individually	19 (63.3)
9	Count started again, if interrupted in between	30 (100)
10	Same two personnel doing counts during entire procedure	24 (80)
11	Adequate hand over to reliever at shift change	30 (100)
12	All counts done by scrub nurse and circulator	30 (100)
13	All items viewed and audibly counted concurrently by both personnel	11 (36.7)
14	Consistent sequence used to perform counts	0
15	Recount done on addition of new items to sterile field	30 (100)
16	Full count done at closure for sponges	30 (100)
17	Full count done at closure for gauze pieces	30 (100)
18	Full count done at closure for instruments	30 (100)
19	Full count done at closure for sharps	30 (100)
20	Full count done at closure for miscellaneous items	30 (100)
21	Result of count declared audibly by scrub nurse	29 (96.7)
22	Acknowledgement of count result obtained from surgeon	29 (96.7)
23	Methodical wound exploration by surgeon before closure	03 (10.0)
24	Documentation of count result in nursing record	0
25	Documentation of count result in surgical record of patient	30 (100)

They were retained in the final checklist as they were crucial steps of the surgical count procedure.

All the items had a Cronbach alpha value (if item deleted) of less than 0.80, which is an acceptable value. The corrected item-total correlation value was less than 0.50 in some items due to low variance, but these items were retained in the final checklist after discussion with panellists, as these items represent mandatory steps of the surgical count procedure. Two items were removed from the final checklist, i.e., 'The circulatory nurse records the type and number of the item packed in the cavity, as announced by the surgeon, on the whiteboard' and 'The circulatory nurse removes the entry of the item from the whiteboard once it is removed from the cavity', because of low feasibility.

The scale had a mean (SD) score of 45.8 (6.29). The Cronbach's alpha for the checklist was 0.82 while the Cronbach's alpha for standardised items were 0.80. Both are acceptable values, indicating that the checklist is reliable.

Multiple observers were not available, so interrater reliability and Cohen's kappa could not be calculated.

Change in knowledge and practice

The surgical count checklist demonstrated acceptable internal consistency (Cronbach's $\alpha = 0.82$). There was an improvement in the surgical count procedure. Documentation completeness rose to 95% (Table 5).

One of the nurses was on maternity leave during baseline assessment and later participated in the post-implementation assessment. Post-test nurses' scores increased significantly ($p < 0.01$). (Table 6).

Phase 6: Evaluation phase

Nurses rated the protocol in terms of clarity ($M=4.6$), perceived safety benefit ($M=4.7$) and ease of use ($M=4.5$) on a 5-point scale ($M=Mean$).

Discussion

The Agency for Healthcare Research and Quality (AHRQ) also identifies RSIs as a preventable patient safety event and emphasizes the importance of standardised surgical count processes in preventing RSIs. The AHRQ notes that practice variation, unclear role allocation

Table 2: Lynn's criteria

Number of experts	Number giving rating of 3 or 4	I-CVI	Evaluation
9	9	1.00	Excellent
9	8	0.89	Excellent
9	7	0.78	Excellent

and inconsistent documentation increase the risk of count discrepancies. These recommendations support the development of context-specific SOPs to reduce variation and improve surgical safety¹⁰.

With a similar objective, the present study was designed with a methodological approach to develop and validate SOPs for surgical counts, a surgical count checklist and a surgical count sheet for documenting surgical counts performed during abdominal surgeries, aiming to reduce practice variation.

The procedures and protocols currently used for various perioperative nursing interventions in the study setting are not standardised. Since most perioperative procedures are high-risk and error-prone, it is highly recommended that standardised, institution-specific guidelines for these procedures be developed.

While most of the recommended practices were followed, our study identified some areas with potential for improvement. In most of the surgeries observed in this study, the counts were communicated verbally, and written documentation was not provided.

Table 3: Content validity index of the developed standard operating protocol for surgical counts at the end of Delphi round 3 (N=9)

Sr. no.	Component of the Standard Operating Protocol	I-CVI
1	Introduction to surgical counts and the SOP	1
2	Purposes of the SOP	1
3	Intended users and abbreviations used	1
4	Definitions	1
5	Responsibilities of Circulatory nurse	1
6	Responsibilities of Scrub nurse	1
7	Responsibilities of the surgeon	1
8	Responsibilities of OT in charge	0.9
9	Frequency of counts	1
10	Common guidelines for all team members	1
11	Characteristics of surgical counts procedure	1
12	Indications of surgical counts	1
13	Items for be accounted for	1
14	Methodical wound exploration	0.9
15	Safe technology for counts	0.9
16	Algorithm for discrepancy management	1
17	Documentation of counts	1

Table 4a: Reliability statistics for individual items in Phase 1 of the developed checklist after the second trial (N = 75 observations; n = 11 items in the scale)

Item	Scale mean (if item is deleted)	Corrected item- total correlation	Cronbach's alpha if item deleted
Phase 1- Before the incision			
Survey of OT by circulatory nurse to remove any stray, accountable item from previous case.	44.53	0.04	0.83
Circulatory nurse updates whiteboard with data of current case including name, age, CR no., diagnosis, surgery and names of surgical and anaesthesia team members, when patient enters OT.	44.32	0.47	0.81
Scrub nurse keeps all items on the designated area of surgical trolley.	44.72	0.14	0.82
Scrub nurse keeps items for skin preparation (counted number of gauze pieces, sponge holder and bowl) separately, not included in initial count.	44.72	0.06	0.82
Scrub nurse and circulatory nurse count each item taken for surgery audibly and concurrently in a consistent sequence *	44.39	0.38	0.86
Simultaneously, circulatory nurse records all items taken for surgery on surgical count sheet for abdominal cases.	44.33	0.67	0.81
Circulatory nurse records initial count of gauze pieces, sponges, sharps, miscellaneous items and small instruments on whiteboard, legibly.	44.37	0.46	0.81
Scrub nurse provides skin preparation items to surgeon and asks circulatory nurse to remove them from OT after skin preparation is done.	44.71	0.19	0.82
The circulatory nurse ensures that no gauze piece/sponge is around the patient or the OT table before draping.	44.68	0.29	0.82
The circulatory nurse and scrub nurse recheck the initial count, just before the incision.	44.69	0.02	0.82
The first pack of gauze pieces is counted twice, concurrently by the scrub nurse and circulatory nurse.	44.63	0.01	0.83
The operating surgeon takes verbal confirmation of the correct initial count from the scrub nurse and proceeds with the incision.	44.67	0.24	0.82

The initial and final counts were adequately performed by nurses, but they were not performed in a consistent sequence as recommended. Documentation of surgical counts in the nursing record was not completed. The recommended practice of methodical wound exploration was not routinely completed for each case but was carried out in high-risk surgeries or when a discrepancy was suspected.

These findings can be attributable to the fact that modern safe technologies related to surgical counts are not very popular in India, except for the use of radiopaque markers and intraoperative radiographs in case of discrepancy. These

findings emphasised the development of SOP. A similar descriptive cross-sectional study of four referral teaching hospitals assessed the knowledge and practices related to surgical counts among 160 randomly selected nurses and midwives. Despite the differences between the educational level and length of clinical experience in both studies, both reported poor practices ¹¹.

The surgical count practices after the training of nurses in the use of the developed SOP were assessed using the surgical count checklist during the post-assessment phase in 75 abdominal surgeries. Post-implementation, some practices, although improved

from the pre-implementation phase, were still followed less, for example, following a consistent sequence while counting (76.3%).

Similarly, the use of count sheets and whiteboards for the documentation of counts was 56% and 54.7%, respectively. This can be attributed to the high case turnover in the study setting and the shortage of staff, especially in evening shifts, when most cases were observed in the 2nd try-out. The practice of methodical wound exploration was improved, but it was used in only 57.3% of cases.

Table 4b: Reliability statistics for individual items in Phase 2 of the developed checklist after the second trial (N = 75 observations; n = 8 items in the scale).

Item	Scale mean (if item is deleted)	Corrected item- total correlation	Cronbach's alpha if item deleted
Phase 2- During the surgery			
Scrub nurse audibly announces while passing sharps to the surgeon (knife, suture with needle) and surgeon announces 'needle back' or 'knife back' while passing sharps back	44.63	0.07	0.82
On packing an item in the cavity, the surgeon audibly announces the type and number of items packed.	44.72	0.24	0.82
The circulatory nurse records the type and number of items packed in the cavity, as announced by the surgeon, on the whiteboard.	44.13	0.47	0.81
On removing an item from the cavity, the surgeon announces the number and type of item and hands it over to the scrub nurse	44.67	0.13	0.82
The circulatory nurse removes the entry of the item from the whiteboard once it is removed from the cavity.	44.13	0.47	0.81
Before closing the main cavity, the surgeon performs methodical wound exploration.	44.35	0.02	0.83
Simultaneously, the scrub nurse and circulatory nurse perform a thorough count of all items and record it on the surgical count sheet for abdominal cases.	44.33	0.67	0.81
The scrub nurse declares the count result audibly to the surgeon and takes verbal acknowledgement and the surgeon proceeds with wound closure.	44.75	0.14	0.82

Table 4c: Reliability statistics for individual items in Phase 3 of the developed checklist after the second trial (N = 75 observations; n = 6 items in the scale).

Item	Scale mean (if item is deleted)	Corrected item- total correlation	Cronbach's alpha if item deleted
Phase 3- After skin closure			
The circulatory nurse makes sure that no discarded items are removed from OT till the patient is on the table	44.69	0.19	0.82
The circulatory nurse documents the count result in the surgical count sheet for abdominal cases.	44.33	0.67	0.81
The scrub nurse discards the disposable items according to biomedical waste management guidelines.	44.67	0.29	0.82
The circulatory nurse checks that all items used in the surgery are removed from the OT after the patient is transferred out.	44.68	0.11	0.82
The circulatory nurse checks that all garbage bins have been emptied by the sanitation attendant and that no item is left behind.	44.63	0.04	0.82
The circulatory nurse checks that the scrub nurse and circulatory nurse have signed the duly filled surgical count sheet for abdominal cases.	44.33	0.69	0.80

Table 4d: Reliability statistics for individual items in Phase 4 of the developed checklist after the second trial (N = 75 observations; n = 7 items in the scale).

Item	Scale Mean if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
Phase 4- Special conditions during the surgery			
The surgeon announces before closing a cavity within a cavity (e.g.- before closing the bladder) and prompts the scrub nurse to perform a count.*	43.44	0.63	0.80
The Scrub nurse and circulatory nurse perform a thorough count concurrently and audibly before the closure of the cavity within a cavity.	43.44	0.63	0.80
The scrub nurse announces the count result to the surgeon and takes verbal acknowledgement after the closure of cavity within a cavity, before main cavity closure.	43.44	0.63	0.80
The Scrub nurse keeps all soaked gauze in a container till the count reaches 10 and then puts them in the unsterile field for the circulatory nurse to cross-check the count	44.73	0.05	0.82
If any item is dropped from the sterile field, it is announced loudly by the surgeon/scrub nurse.	43.24	0.14	0.83
On adding new items to the sterile field, the circulatory nurse immediately updates the count sheet and board legibly.	44.03	0.40	0.81
The scrub nurse keeps used needles in the designated area throughout the surgery	44.63	0.12	0.82

*Items, including gauze pieces, sponges, sharps, instruments and miscellaneous items, must be removed in a consistent sequence.

The surgeons could not participate in the training phase of the SOP and checklist because of time constraints, which may be responsible for less improvement in methodical wound exploration practice. However, the nurses were asked to request that surgeons perform methodical wound exploration before each cavity closure, which improved the practice to some extent compared to the pre-implementation phase.

The completion of various components of the surgical count sheet for abdominal surgeries was also analysed. The last phase was the evaluation phase, which involved a post-test of knowledge related to surgical counts, a comparison of surgical count practices, pre- and post-implementation of SOP and an assessment of the acceptability of SOP among nurses.

Table 5: Comparison of scores of the checklist for assessment of surgical count practices in abdominal surgeries at baseline and endline

Assessment time	Mean $\pm$ SD (Range)	N	Paired t test (t, p value)
Baseline	18.97 $\pm$ 1.27(16-22)	30	
Endline	22.27 $\pm$ 1.89 (19-25)	30	8.05 <0.001*

*p<0.05, statistically significant

Table 6: Comparison of scores of the knowledge related to surgical counts among nurses at baseline and endline

Assessment time	Mean $\pm$ SD (Range)	N	Paired t test (t, p value)
Baseline	74.25 $\pm$ 9.90 (56-89)	24	
Endline	89.33 $\pm$ 2.39 (85-93)	25	8.45 <0.001*

*p<0.05, statistically significant

In the knowledge assessment, significant improvement was noted in some components of the questionnaire as well as the overall score, at the endline. In the comparison of surgical count practices, pre- and post-SOP implementation, significant improvement was seen in the overall observation checklist score at endline, and in some individual components of the checklist. The SOP was accepted by the nurses as a helpful and welcome initiative.

Some limiting factors included the failure to involve surgeons in the training phase due to time constraints, which could have otherwise improved certain practices. Only abdominal surgeries were included, and the observations were performed mainly on emergency surgeries. Inter-rater reliability could not be established.

It is recommended that the study be replicated in multiple settings with larger sample sizes and longer durations to support the findings. Future studies involving multiple observers are recommended to establish inter-rater reliability and further strengthen the robustness of the SOP.

A quality improvement initiative can be planned to improve the surgical count practices in the OTs and enhance the implementation of the protocol. Similar studies with more involvement of surgeons and anaesthetists can be planned to increase the strength of findings. Similar studies can be planned for surgeries other than abdominal procedures, for minimally invasive procedures and for endovascular procedures, such as central line insertion.

The study can be helpful for nurse managers and policymakers. The nurse manager can utilize the developed SOP and checklist to orient new nursing staff and other perioperative team members to the count practices of the unit. The nurse manager can use the SOP and checklist for surgical count audits periodically to scrutinize the practices in the unit. Perioperative nurses can use the SOP and checklist to increase the uniformity of surgical count practices in OT, thereby reducing errors and conflicts.

Conclusion

Surgical counts are an indispensable part of any surgery and provide a threefold benefit to prevent RSIs, to enhance patient safety and to prevent litigation against health care providers. All agencies recommend that healthcare institutions develop SOPs for surgical counts, as per their local requirements.

The study resulted in the development of a reliable and valid protocol using the Delphi method, which was found to be effective in improving the knowledge and practices of nurses related to surgical counts. To conclude, the SOP and checklist were found to be valid, reliable and well accepted in this single-centre study; further multicentre validation is recommended.

Conflict of interest and funding statement

The authors have declared no competing interests with respect to the research, authorship and publication of this article.

This research did not receive any specific grant from funding agencies in the public, commercial or not-for-profit sectors.

References

- Putnam K. Guideline for prevention of retained surgical items. *AORN J*. 2015[cited 2022 Jan 24];102(6):P11-P13. doi:10.1016/s0001-2092(15)01014-5.
- World Health Organization. *WHO guidelines for safe surgery 2009: safe surgery saves lives* [Internet]. Geneva: World Health Organization; 2009 [cited 2022 Jan 24]. Available from: <https://iris.who.int/handle/10665/44185>
- Gawande AA, Studdert DM, Orav EJ, Brennan TA, Zinner MJ. Risk factors for retained instruments and sponges after surgery. *N Engl J Med*. 2003;348(3):229-235. doi:10.1056/NEJMsa021721.
- The Joint Commission. Sentinel event alert 51: preventing unintended retained foreign objects [Internet]. Oakbrook Terrace (IL): The Joint Commission; 2013 Oct 17 [cited 2022 Jan 24]. Available from: www.jointcommission.org/resources/patient-safety-topics/sentinel-event/sentinel-event-alert-newsletter
- American College of Surgeons. Prevention of unintentionally retained surgical items after surgery [Internet]. Chicago (IL): American College of Surgeons; 2016 Oct 1 [cited 2022 Jan 26]. Available from: www.facs.org/about-acsc/statements/92-retained-items
- Amare G. Reviewing the values of a standard operating procedure. *Ethiop J Health Sci*. 2012[cited 2022 Jan 24];22(3):205-208.
- United States Environmental Protection Agency. *Guidance for preparing standard operating procedures (SOPs)* [Internet]. Washington (DC): United States Environmental Protection Agency; 2007 [cited 2022 Oct 23]. Report No.: EPA/600/B-07/001. Available from: www.epa.gov/sites/default/files/2015-06/documents/g6-final.pdf
- Arriaga AF, Bader AM, Wong JM, Lipsitz SR, Berry WR, Ziewacz JE, et al. Simulation-based trial of surgical-crisis checklists. *N Engl J Med*. 2013[cited 2022 Jan 24];368(3):246-253. doi:10.1056/NEJMsa1204720.
- Lynn MR. Determination and quantification of content validity. *Nurs Res*. 1986[cited 2022 Jan 24];35(6):382-385. doi:10.1097/00006199-198611000-00017.
- Agency for Healthcare Research and Quality. Retained surgical items: causation and prevention [Internet]. Rockville (MD): Agency for Healthcare Research and Quality; 2023 [cited 2025 Dec 17]. Available from: <https://psnet.ahrq.gov/primer/retained-surgical-items-causation-and-prevention>
- Mukantwari J, Omondi L, Ntakirutimana C, Nyirasafari E. A description of surgical counting safety practices among operating room nurses and midwives in Rwanda. *J Surg Nurs*. 2019[cited 2022 Jan 24];1(1):e17422. doi:10.21203/rs.2.17422/v1.
- Polit DF, Beck CT. *Nursing research: principles and methods*. 7th ed. Philadelphia (PA): Lippincott Williams & Wilkins; 2004. p. 423.
- Popham WJ. Criterion-referenced measurement: the state of the art. *Educational Measurement*. 1978;3:19-25.
- Linstone HA, Turoff M, editors. *The Delphi method: techniques and applications* [Internet]. Reading (MA): Addison-Wesley; 1975 [cited 2022 Jan 24]. Available from: <https://web.njit.edu/~turoff/pubs/delphi/ch1.html>