

# Operating Room WHO Surgical Safety Checklist Process Completion: An Observational Study

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## ABSTRACT

### BACKGROUND

The World Health Organization (WHO) Surgical Safety Checklist (SSC) is used globally to ensure patient safety during surgery. Two years after its implementation in the Nepal Medcity's operating room (OR), adherence to the protocol was evaluated with mixed-method observational study.

### METHODS

Data collection was on-site non-participant observations of Team WHO checklist completion conduction in the OR. Medical records were also audited. SPSS was used for data analysis.

### RESULTS

The mean number of personnel in the OR was 7. Sign In was not conducted in 3.8% of cases, whereas surgeon unavailability during Sign In was 15%. In 18.2% of cases, antibiotics were administered more than an hour before induction time. In 10.4% of cases, Time Out was not conducted on time prior to surgical incision. Team introduction by name and role was very poor (15.3%). In 26% of cases, sign-out was not conducted. Actual blood loss matched predicted blood loss in 93.6% of cases, whereas the surgeon recorded only 73.4% of matches for actual and predicted surgical duration. On memory assistance, 13.3% of checklist completion was carried out. Factors such as inadequate staff, negative attitude towards the checklist completion and hesitance, and a lack of teamwork hindered its implementation.

### CONCLUSION

The unavailability of key OR team members during sign-in and sign-out time was the most common reason for the omission or partial use of the SSC. The implementation of the surgical safety checklist will upgrade patient safety measures, combine teamwork abilities, and enhance departmental culture locally.

### KEYWORDS

Surgical Checklist; Sign-In; time Out; Sign-Out; WHO

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## INTRODUCTION

In 2008, the World Health Organization (WHO) introduced a surgical safety checklist (SSC), a 19-item tool created in association with the Harvard School of Public Health, applicable to all surgical teams to be used for every patient undergoing a surgical procedure.[1] This 'WHO checklist' aimed to give teams a simple, efficient set of priority checks to improve effective teamwork and communication and encourage active consideration of patient safety for every operation performed.[1]

The WHO has estimated that 234M operations are performed annually around the globe. [2] A systematic review including over 74,000 patient records found a median incidence of in-hospital adverse events of 9.2%, with approximately half of those events being operation or drug-related and 43% deemed preventable.[3] Since a large proportion of the in-hospital events are operation- or drug-related, interventions aimed at preventing these events have the potential to make a substantial difference.

The World Health Organization (WHO) Surgical Safety Checklist (SSC) is used globally to ensure patient safety during surgery. The checklist has three phases: Sign IN, Time Out, and Sign Out.

Sign In is to be performed before the induction of anesthesia, and the Health Quality and Safety Commission recommends that the Anaesthetist sign in, ideally with a surgeon present, but not essential, and verify verbally.

Time Out should be performed before skin incision. It is recommended that the surgeon lead and the anesthetist, nurse, and surgeon all individually confirm the agreement.

Sign Out should be performed immediately after skin closure or before the patient leaves the operating theater, nurse to lead sign out while the surgeon is still present in the Operating Room (OR). [1]

Correct and effective implementation of WHO SSC helps to enhance patient safety and satisfaction, reduce adverse events, and decrease morbidity and mortality. The international multicenter prospective study by Haynes, et al. has shown that implementation of the SSC reduced the incidence of surgical complications by 4% and the total hospital mortality rate by 0.7%, and the incidence of surgical site infections and accidental re-operation rate were also significantly reduced. [4] Implementation of SSC with excellent compliance poses a major challenge to healthcare professionals. To facilitate successful implementation, it is crucial to ascertain the Checklist's appropriateness for your specific setting and encourage adaptation following local consultation.

Two years following the implementation of WHO SSC in the Nepal Medcity's operating room (OR), adherence to the protocol is evaluated with an aim to assess the quality of execution of the time-out in routine clinical practice and to evaluate for any barriers, distractions, and interruptions for proper implementation, deviations from protocol, and the problem-solving strategies used by operating room team members to mitigate the non-routine events.

## METHODS

After the approval from IRB with Ref No. IRC-RP- 201/114g-003e, a prospective Interventional (Clinical Trial Reg no NCT04965285) study, is conducted with Randomized Consecutive Sampling of the participants. It is an open-label health services research study that was started in May 2021 and completed in February 2023.

Data collection was on-site non-participant observations of Team WHO checklist completion conduction in the OR. Medical records were also audited to determine compliance with checklist use and investigate any discrepancy between practice and documentation.

This study involves elective surgery patients aged 18 and above at Nepal Medcity Hospital, with eligibility extended to all genders. Exclusions pertain to individuals under 18, emergency cases, and those unable to participate verbally. These criteria are established to maintain the study's focus and integrity in data collection while ensuring relevance to the target population.

## RESULT

The mean age of the patients was 44 years, with the majority being females (53.8%). Gastroenterological surgical procedures followed by Obstetrics and gynecological surgeries and uro-surgery were the most common operative procedures carried out. On average, seven people are present inside Operation Theater.

Table 1: Demographic variables showing age and sex of patients along with operative procedural department

Variables		Frequency(n)	Percentage(%)
Age (years)		44.18(mean)	14.966(S.D)
Sex	Male	160	46.2
	Female	186	53.8
Number of personnel in the Operating room		7.36(mean)	2.584(S.D)

Figure1: Departmental distribution of surgical cases

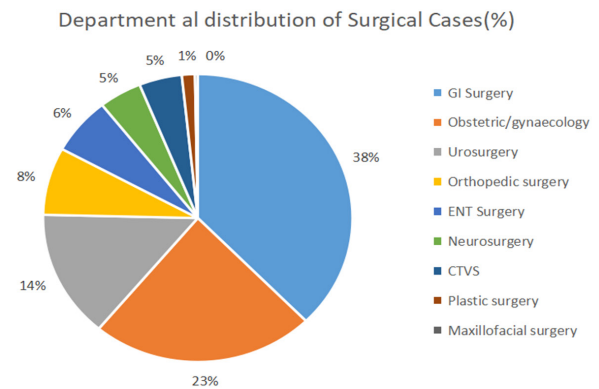


Table 2: Demonstration of Sign In, Time out, and the WHO checklist completion variables

Variables	Yes(n)	NO (n)	( %)	Not applicable
Sign IN conducted	333	13	(3.8)	-
Surgeon Present during Sign In	294	52	(15)	-
Patient Identified himself/herself	338	8	(2.3)	-
Patient confirmed site of operation	317	8	(2.3)	-
Site Mark Done	112	0		234(67.6)
Person marking the site present during sign in	101	15	(4.3)	230
Image displayed	44	43	(12.4)	259
Antibiotics administration		64	(18.4)	1
Within 60 min	261(75.4)	-		-
More than 60 min	21(6.06)	-		-
Time OUT conduction before surgical incision	310	36	(10.4)	-
Any interruption due to equipment malfunction/issues	33(9.5)	313	(90.4)	-
Team introduce him/herself with name and roles	53	293	(84.7)	-
Surgeon reviewing key concerns	331	15	(4.3)	-
Anesthesiologist reviewing key concerns	317	29	(8.4)	-
Music playing during checklist conduction	50(14.5)	296	(85.5)	-

**Table 3: Demonstration of variables conducted during Sign Out and matches of surgical duration and Blood loss**

Variables	YES	NO (%)
Any interruption while conducting checklist	37(10.7)	309 (89.3)
Did the team stop during Sign IN	279	67 (19.4)
Was Sign OUT conducted	256	90 (26)
Did the team stop during Sign OUT	241	105 (30.3%)
Checklist conduction without memory assistance	300	46 (13.3)
Blood Loss matched as mentioned in the checklist	324	22 (6.4)
Total surgical duration matched as mentioned	254	92 (26.6)
Any non-routine steps conduction	23 (6.6)	323 (93.3)

## DISCUSSION

Implementing the WHO surgical safety checklist enhances patient safety, promotes teamwork, improves communication, and fosters a positive departmental culture. By integrating this tool, healthcare facilities can elevate safety standards, encourage collaboration among surgical teams, and facilitate the clear exchange of critical information. A checklist aids in the early identification of potential hazards, enabling proactive measures to prevent complications. Adopting this approach represents a proactive stance toward ensuring exceptional patient care and safety during surgical procedures. To enhance safety, it is crucial to comprehend the principles of error science, consider human factors and systemic breakdowns, and recognize the imperative of improving organizational safety culture through targeted training to prevent and mitigate errors.

In the OR, the challenge lies in minimizing the minor problems and interruptions that may impact surgical performance, as minor errors, though individually unimportant, possess a multiplicative effect. Communication errors account for the most common cause of adverse events in healthcare, and to mitigate this Checklist helps us communicate with the team effectively.

There are currently more than 4000 hospitals in 122 countries that have registered as users of the WHO checklist, representing more than 90% of the world's population, with 1790 hospitals actively using the checklist.[5]

Zhu, et al. reported in their study that the implementation rates of "sign in", "time-out", and "sign out" were 93.35, 78.22, and 64.26%, respectively, after 10 years of implementation of the SSC in China, data obtained from the 2019 annual meeting of the Chinese Association of Anesthesiologists.[6] Our study findings of 96.24%, 89.59%, and 73.98% respective implementation rates surpass that of the above study and also a study by Sibhatu MK et al in Ethiopia where an aggregate SSC completeness rate was 60.8% (659 of 1083) while the remaining (39.2%) were neither complete nor filled correctly and 58.9% surgeries were non-compliant to SSC in retrospective audit study.[7] A clinical audit by Gul F et al in Pakistan had even poor compliance where Sign-In was performed and read aloud in 65.2% and 13% of cases, respectively; Time out performed and read aloud in 60.9% and 4.3%, respectively, and Sign-out performed and read aloud in 34.8% and 0%, respectively.[8]

The tasks that were consistently accomplished were those that necessitated the involvement of team members in communication, patient identification, consent, site mark, anesthesia and surgical equipment verification, allergy history, estimation of blood loss, and case duration.

Sign-in process was completed at a higher rate than the time-out and sign-out in our study. Only in 3.8% of cases was Sign In not conducted compared to 10.4% incidence of Time Out and 26% of Sign Out completion. This finding is similar to a study by Mengesha Dessie Allene.[9] Site mark was done in all applicable cases, findings similar to the above study along with items of aspiration risk, anticipation of a difficult airway, allergic history, and estimated blood loss.

During Time out period, surgical teams needed to introduce themselves by name and role, which was missing in 84.7% of cases, which is a very high number compared to only 7.06% missing cases of introduction in a study by Mengesha.[9] Our study finding is supported by Nilsson et al.'s results, showing that only 14% perceived the introductions as very important. [10] A similar study in Sweden inferred the same result: those items of the checklist that promote communication among surgical staff were poorly applied, especially when introducing team members during the time-out stage, due to the lack of awareness regarding safety associated with checklist implementation.[11] Having introductions of the team is crucial as it ensures that all involved personnel are acquainted, feel included, and are comfortable discussing any issues during the time-out and subsequent surgical procedure, fostering trust, team building, and open communication of concerns.

In 3.14% of cases of the above study, antibiotic prophylaxis was not administered within the last 60 min before skin incision, a finding which is double in our study with 6.06%. [9] Of the 402 "clean" surgical cases observed in a study in Cambodia, appropriate timing of prophylactic antibiotic

administration within 60 min of skin incision was achieved in 67.4% of operations, which was lower in comparison to 75.4% in our study.[12] The surgeon missing the announcement of critical/unanticipated steps to the team in 5.94% of cases, a finding similar to our study of 4.3% incidence, and patient-specific concern missed by an anesthetist was 3.92%, which was slightly higher than our study with an incidence of 8.4%.

Essential image display was not found in 12.4% of cases, and checklist items were given less attention than other items, a finding similar to the study by Rydenfält C et al.[11]

In a study by Mengesha, during the Sign Out process completion, equipment problems needed to be addressed in 5.1 % of cases, finding lower than our study with 9.5% occurrence.[9]

The WHO recommends that the SSC should be completed jointly by surgeons, anesthesiologists, and OR-RNs. The Canadian Association of Obstetricians and Gynecologists recommends that surgeons understand and be familiar with all three parts of the SSC and fully support its implementation in clinical practice.[13] The availability of surgeons during the sign-in step was only in 84.97% of cases, which highlights the need for improvement in ensuring consistent presence during this crucial phase.

The compliance rate for the assessment of bleeding risk in the "sign-in" phase was notably low, 15.1% in the first phase to 34.0% in the second phase, as it was frequently deemed unimportant by the surgeon, particularly in the case of apparently healthy individuals undergoing elective surgery. [14] Although compliance for assessment of bleeding risk prediction was present in all cases where Sign In was conducted, actual blood loss during surgery matched only in 93.64% of cases.

A study by Gong J et al, where attitudes and barriers among gynecological surgery teams were evaluated with a survey regarding SSC implementation, showed the results as "Too many operations to check" and "Hard to ensure the three groups implement the checklist properly" ranked first among the reasons for gynecologists not to assign a full score regarding satisfaction; "Hard to ensure the three groups implement the checklist properly" and "Surgeon" is eager to start for surgery" ranked first among the reason for anesthesiologists and OR-RNs, respectively.[15]

The major factors negatively influencing the OR-RNs' satisfaction were "Surgeon is not present for 'sign out'" and "No one initiates," also was a core issue.[15]

The educational intervention, aiming to foster a culture of collaboration and effective communication in task accomplishment, demonstrated a significant positive impact by markedly improving compliance rates in the "time-out" and "sign-out" sections of the checklist, achieving over 85% overall compliance, while also highlighting challenges such

as structural impediments and hierarchical issues within the surgical department, notably evident during the "time-out" phase where the break taken by the checklist coordinator, often a nurse or junior trainee, was not well-received by the consultant surgeon.[14] A similar increment in compliance was observed during Audit cycle two after the educational intervention in the form of a departmental presentation.[8] Addressing challenges such as hesitation to speak up among junior staff, fostering teamwork, and mitigating negative attitudes from surgeons is imperative to ensure overall patient safety.

## FACTORS:

Various factors influenced the effectiveness and adherence of the WHO Surgical safety checklist. Inadequate staffing during early morning and late evening cases posed challenges, potentially leading to rushed or incomplete checklist completion. Negative attitudes towards safety protocols and hesitancy to speak up about concerns hindered effective checklist implementation. "Checklist Fatigue" due to overuse could diminish staff engagement and attention to detail for checklists. Lack of awareness and training regarding the checklist's importance and in coordinated teamwork contributed to suboptimal utilization. The same surgeon or anesthetist's simultaneous conduction of the checklist may have also compromised its thoroughness. Staff members who were preoccupied with other tasks or no longer present in the operating room could have further detracted from the checklist's efficacy. These factors collectively could have impacted our study results, underscoring the need for targeted interventions and ongoing education to improve checklist compliance and enhance patient safety.

The purpose of the checklist is not to simply complete it for the sake of ticking boxes. This measure is designed to ensure that the team collaboratively performs crucial safety checks, eliminating the need to rely on memory. It also encourages verbal communication within the operating room and fosters a shared sense of accountability for the procedure's success.

## LIMITATIONS OF STUDY:

Emergent cases were excluded, which limited the generalizability of findings. Lack of control over movement in and out of the operating theater during the time-out procedure could introduce bias over the number of people during the checklist completion and interference during the checklist conduction that could have led to repetition. Oversight of laparoscopic surgery site marking could have different results for surgical site mark findings. Addressing these limitations in future research is crucial for improving the effectiveness and validity of surgical safety protocols.

## CONCLUSIONS:

The most common reason for omitting or partially using the WHO SSC was the unavailability of key OR team members during sign-in and sign-out time.

Lack of compliance and an excessively casual approach to checklist completion result in the necessity to repeat questions while doing the checklist, conduct the checklist from memory and experience more interruptions.

## RECOMMENDATION:

In order to promote a culture of consistent adherence to the checklist and to foster effective teamwork, it is essential to motivate personnel to integrate it into their daily routines seamlessly. Special attention should be given to raising awareness, particularly among new nursing and anesthetic staff. Regular audits serve to monitor adherence, while periodic refresher courses and multidisciplinary training sessions improve communication and compliance. Providing supplementary training that concentrates on checklist utilization reinforces its significance and facilitates its effective integration into surgical environments, fostering a culture of patient safety and teamwork.

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