

Effect of Adherence to the World Health Organization Surgical Safety Checklist on Morbidity and Mortality in a Defined Surgical Patient Population

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Received: May 2019

Accepted: May 2019

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ABSTRACT

Background: To improve patient safety and prevent complications, WHO introduced surgical safety checklist (WHO SSC). However, the actual effect of WHO SSC on patient morbidity, particularly surgical site infections (SSI), and mortality on post-operative patients is one of the least studied area. Our study was to measure the effects surgical safety checklists have in reducing morbidities and complications, particularly surgical site infections, post-operative length of stay and mortality resulting from the surgical procedures. **Methods:** A prospective observational comparative study was conducted among all patients who underwent elective general surgical procedures from 01st July 2015 to 30th June 2016 in the Main OT Complex (OT1 and OT2), Indoor Surgical Wards and higher dependency units (ITU & CCU) of IPGMER & SSKM Hospital, Kolkata, after applying proper exclusion criteria. Pre-implementation (before implementation of WHO Surgical Safety Checklist) data was collected for first 6 months, then WHO Surgical Safety Checklist was implemented over next 6 months. Pre and post-implementation cohorts were compared and analysed. **Results:** Total 382 patients (187 Control group and 195 implementation group) were included. Both groups matched regarding age, sex, type of surgery, type of anaesthesia, post-operative length of stay. However, incidence of SSI significantly decreased (30.48% to 16.41%, p value 0.002, <0.05, statistically significant). Overall complication rate, unplanned return to operating room (OR) also decreased though the results were statistically not significant. **Conclusion:** Implementation of WHO SSC decreases morbidity related to SSI significantly. Further studies are required to assess the effects on mortality and unplanned return to OR.

Keywords: WHO, Surgical safety checklist.

INTRODUCTION

Surgical service is one of the fundamental health care services given in the healthcare system. Over 234 million surgical operations are performed annually worldwide and complications occur in 3-16% of surgical procedures; and at least half of the surgical complications are preventable.^[1] Surgical complications are a major cause of morbidity and mortality and pose a major financial burden to patients and providers. However, it has been estimated that at least half of the complications that occur are avoidable. The importance of strong safety culture that enhances patient safety initiatives has been reiterated for years in the global healthcare system and the safety of surgical care therefore is a global concern.^[2]

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The image shows the WHO Surgical Safety Checklist form, which is organized into three main sections:

- Before induction of anaesthesia (with at least nurse and anaesthetist):**
 - Has the patient confirmed his/her identity, site, procedure, and consent?
 - Yes
 - No
 - Not applicable
 - Is the site marked?
 - Yes
 - No
 - Not applicable
 - Is the anaesthetic machine and medication check complete?
 - Yes
 - No
 - Not applicable
 - Is the pulse oximeter on the patient and functioning?
 - Yes
 - No
 - Not applicable
 - Does the patient have a:
 - Known allergy?
 - No
 - Yes
 - Not applicable
 - Difficult airway or aspiration risk?
 - No
 - Yes
 - Not applicable
 - Risk of >500ml blood loss (taking in children)?
 - No
 - Yes
 - Not applicable
- Before skin incision (with nurse, anaesthetist and surgeon):**
 - Confirm all team members have introduced themselves by name and role.
 - Confirm the patient's name, procedure, and where the incision will be made.
 - Has antibiotic prophylaxis been given within the last 60 minutes?
 - Yes
 - No
 - Not applicable
 - Anticipated Critical Events
 - To Surgeon:
 - What are the critical or non-routine steps?
 - How long will the case take?
 - What is the anticipated blood loss?
 - To Anaesthetist:
 - Are there any patient-specific concerns?
 - To Nursing Team:
 - Has identity (including indicator results) been confirmed?
 - Are there equipment issues or any concerns?
 - Is essential imaging employed?
 - Yes
 - No
 - Not applicable
- Before patient leaves operating room (with nurse, anaesthetist and surgeon):**
 - Nurse Verbally Confirms:
 - The name of the procedure
 - Completion of instrument, sponge and needle counts
 - Specimen labelling (need specimen labels about, including patient name)
 - Whether there are any equipment problems to be addressed
 - To Surgeon, Anaesthetist and Nurse:
 - What are the key concerns for recovery and management of the patient?

Figure 1: WHO Surgical Safety Checklist

WHO Surgical Safety Checklist:

As a part of improving patient safety, the World Health Organization (WHO) launched 'Safe Surgery Saves Lives' Programme in 2008. The aim was to harness political commitment and clinical will to address important patient safety issues, including adequate anaesthetic safety practice, avoidable surgical infection and poor communication among team members. The WHO set a core of safety

standards by creation and implementation of a 19 item 'WHO Surgical Safety Checklist' [Figure 1].^[4] Since the development of checklists for use in the operating rooms, their use (compliance to all the three time frames) has become greater than ever and associated with a significant reduction in postoperative complications and mortality. Recently, however, questions have arisen about their ease of introduction into workflow patterns and their true impact on safety.

While critics point out that checklists alone are not enough to improve patient safety and must be accompanied by wider strategies for quality improvement, it is hoped that the implementation of the checklist will reduce surgical mortality and morbidity. The benefits of the checklist, however, depend upon the individual hospitals' ability to implement it effectively.

For its implementation, WHO issued an implementation manual, which gives detail on how each step should be conducted. The manual highlights the importance of leadership and institutional buy-in and emphasizes that the department practices using the checklist before introduction and should modify as needed to adapt with the normal operative workflow. Resources to help with the implementation of the checklist are available on the WHO website http://www.who.int/patientsafety/safesurgery/tools_resources/en/. Example videos from around the world can be seen on the SafeSurg website <http://www.safesurg.org/videos.html>.

Surgical Complications:

Post-operative surgical complications has been broadly defined as "an undesirable, unintended event and would not have occurred had the operation gone as could be reasonably hoped".^[5] Post-operative complications are devastating to the patients, costly to healthcare systems, and often preventable, though their prevention typically requires a change in systems and individual behaviour.

Surgical Site Infection:

Surgical Site Infections (SSI) accounts for about 15% of all healthcare associated infections and 37% of the hospital acquired infections of surgical patients.^[6,7] As per NNIS definition, SSI is divided into two main groups - incisional & organ space infections. Incisional infections are subdivided further into superficial (skin & subcutaneous tissue) and deep (deep soft tissue such as fascia and muscle layers). The criteria for different sites of infection are given below.^[8]

Superficial Incisional Surgical Site Infections:

Infections occurring in the incision site within 30 days of surgery and involves only skin or subcutaneous tissue at the incision and at least one of the following:

- Purulent drainage from superficial incision;

- An organism isolated by culturing fluid or tissue from the superficial incision;
- Deliberate opening of the wound by the surgeon because of the presence of at least one sign or symptom of infection (Pain, tenderness, localized swelling, redness or heat), unless the wound culture is negative; or
- Diagnosis of superficial incisional surgical site infection by the surgeon or attending physician.

The following conditions are not generally reported as SSI:

- Stitch abscess with minimal inflammation and discharge confined to the points of suture penetration;
- Infection of an episiotomy site;
- Infection of a neonatal circumcision site; or
- Infected burn wound.

Deep Incisional SSI:

Infection occurs at the site of operation within 30 days of surgery if no implant (non-human derived foreign body permanently placed in the patient during surgery) is left in place and within 1 year of surgery if an implant is left in place. In addition, infection appears to be related to surgery and involves deep soft tissue (muscle and fascial layers) and at least one of the following:

- Purulent drainage from deep incision but not from the organ space component of the surgical site;
- Wound dehiscence or deliberate opening by the surgeon when the patient has fever (>38OC) or localized pain or tenderness, unless the wound culture is negative;
- An abscess or other evidence of infection involving the deep incision seen on direct examination during surgery, by histopathological examination or by radiological examination; or
- Diagnosis of deep incisional SSI by the surgeon or attending physician.

Organ Space SSI:

Infection occurs within 30 days of surgery if no implant (non-human derived foreign body permanently placed in the patient during surgery) is left in place and within 1 year of surgery if an implant is left in place. In addition, infection appears to be related to surgery and involves any part of the anatomy other than the incision that is opened or manipulated during an operation and at least one of the following:

- Purulent drainage from a drain placed through a stab wound into the organ space;
- An organism isolated from an aseptically obtained culture of fluid or tissue in the organ or space;
- An abscess or other evidence of infection involving an organ or space seen on direct examination during surgery, by histopathological examination or by radiological examination; or

- Diagnosis of organ space SSI by the surgeon or attending physician. Multiple studies showed that routine implementation of WHO Surgical Safety Checklist has effectively decreased different intraoperative and postoperative complications. However, very few studies have been done to assess the correlation between occurrence of surgical site infection and adherence to WHO Surgical Safety Checklist. Our study was to measure the effects surgical safety checklists have in reducing morbidities and complications, particularly surgical site infections, post-operative length of stay and mortality resulting from the surgical procedures.

MATERIALS AND METHODS

We conducted a prospective observational comparative study in the Main OT Complex (OT1 and OT2), Indoor Surgical Wards and higher dependency units (ITU & CCU) of IPGMER & SSKM Hospital, Kolkata. All patients who underwent elective general surgical procedures in the Main OT complex under our unit (Unit-V, Department of General Surgery, IPGMER & SSKM Hospital) from 01st July 2015 to 30th June 2016 were included in the study. Patients undergoing emergency surgical procedures, minor surgeries and patients unwilling to participate were excluded from the study. We used case record data, consent form, pre-designed, pretested semi-structured proforma, The WHO Surgical Safety Checklist (version 2009), analysed and interpreted the results using tables, diagrams, charts and statistical formulae. After approval of institutional ethical committee and obtaining written informed consent, patients were checked against the exclusion criteria of the study.

Pre-implementation (before implementation of WHO Surgical Safety Checklist) data was collected for first 6 months, then WHO Surgical Safety Checklist was implemented over next 6 months. Prospective observational comparative study was performed between pre-implementation cohort and post-implementation cohort. Each patient was followed up until discharge for any complication including mortality. Data was collected in a master chart and statistical analysis was done with standard statistical software.

RESULTS

Total 382 patients (187 Control group and 195 implementation group) were included in our study. Among cases (N=195), 51.28% were males (n=100), 48.72% were females (n=95); whereas among control population, (N=187), 45.45% (n=85) were males and 54.55% (n=102) were females.

The mean ± SD age of control group was 43.39 ± 15.12 years (Range: 13-80 years, Median: 45 years), whereas the mean ± SD age of implementation group was 44.69±14.57 years (Range: 12-85 years, Median: 45 years). Both groups matched regarding age (p value=0.38978, >0.05).

The most common surgical procedure performed was open cholecystectomy which was compared with all other type of procedures. Results was not statistically significant [Table 1].

Average ± SD Post-operative length of stay was 7.3 ± 7.215 days in the control group whereas it was 6.48 ± 6.262 days in implementation group (p value = 0.40654, >0.05, statistically not significant, See [Table 3].

Table 1: Distribution of the subjects according to sex, type of surgery and anaesthesia given (statistically not significant)

	Group	Control (n=187)	Implementation (n=195)	p-value
Sex	Male	85 (45.45%)	100 (51.28%)	0.262
	Female	102 (54.55%)	95 (48.72%)	
Surgical Procedures	Open Cholecystectomy	32	41	0.333
	Row%	17.1%	21.0%	
	Other surgical procedures	155	154	
	Row%	82.9%	79.0%	
Type of Anaesthesia	General Anaesthesia*	147	164	0.167
	Row%	78.6%	84.1%	
	Regional Anaesthesia	40	31	
	Row%	21.4%	15.9%	

* Combination of General & Regional Anaesthesia was classified as General Anaesthesia.

Table 2: Comparison of Age between two groups (statistically not significant)

Group	N	Mean Age (Years)	SD	Standard Error	Median	Min/Max (Years)	Lower/Upper Quartile	t-value	p-value
Control	187	43.39	15.12	1.106	45.00	13/80	30/55	-0.860494 (df380)	0.38978
Implementation	195	44.69	14.57	1.044	45.00	12/85	35/55		

Table 3: Comparison of post-operative length of stay (days) (statistically not significant)

Group	Number	Mean	Median	Minimum	Maximum	Lower Quartile	Upper Quartile	SD	Standard Error	Z value	P value
Control	187	7.3	4.00	1	37	2	11	7.215	0.528	0.8333	0.4065
Implementation	195	6.48	4.00	1	32	2	9	6.262	0.448	2	4

Table 4: Comparison between incidence of SSI, over complications, mortality and unplanned return to OR among different groups

Group		Control (N=187)	Implementation (N=195)	P value (significant if <0.05)
SSI	Yes	57 (30.48%)	32 (16.41%)	0.002
	No	130 (69.52%)	163 (83.59%)	
Overall Complications	Yes	70 (37.43%)	48 (24.62%)	0.0078
	No	117 (62.57%)	147 (75.38%)	
Mortality	Yes	5 (2.67%)	1 (0.51%)	0.115
Unplanned return to OR	Yes	4 (2.14%)	3 (1.54%)	0.719

Fifty-seven (30.48%) patients out of total 187 patients had SSI in control group whereas 32 patients (16.41%) out of 195 patients had SSI (p value 0.002, <0.05, statistically significant). Results are depicted in [Table 4]. Overall complication rate was 37.43% (n=70) in control group whereas 24.62% (n=48) in implementation group. The control group had 2.67% (5 out of 187) mortality and the implementation group had 0.51% (1 out of 195), though the result was statistically not significant. Results of unplanned return to operating room (OR) was also statistically not significant. Results are presented in [Table 4].

DISCUSSION

Our study reveals the relationship between adherence with the WHO SSC and reduction in postoperative complications.

Adequate adherence was defined as adherence to the provided measures for at least 90% of all patients⁹. We assessed to a subgroup of six safety measures as an indicator of process adherence. The six measures were

1. the objective evaluations and documentation of the status of the patient's airway before administration of the anaesthetic;
2. the use of pulse oximetry at the time of initiation of anaesthesia;
3. the presence of at least two peripheral intravenous catheters or a central venous catheter before incision in cases involving an estimated blood loss of 500 ml or more;
4. the administration of prophylactic antibiotics within 60 minutes before incision except in the case of pre-existing infection, a procedure not involving incision, or a contaminated operative field;
5. oral confirmation, immediately before incision, of the identity of the patient the operative site, and the procedure to be performed; and
6. completion of a sponge count at the end of the procedure, if an incision was made.

We found six studies which measured adherence with SSC. Five of them reported adherence to a subgroup of six safety measures as an indicator of checklist adherence.^[10-14] One study used a subset of five safety measures as an indicator of checklist adherence.^[15]

In our study period, 382 patients underwent major elective surgical procedures, with 187 patients in the Control Patients (Without Checklist) and 195 in the Implementation Group (With Checklist). As evident from our results, both controls and Implementation groups matched in socio-demographic characteristics (Age, Sex) and Operative Data (Surgical Procedures and Type of Anaesthesia).

Our study suggested that implementation of WHO SSC was associated with significant reduction of SSI rates until hospital discharge (from 30.48% to 16.41%). SSIs were reported in six studies. Three of them reported a significant decrease in SSI rates following SSC Implementation: from 6.2% to 3.4% (p < 0.001)¹⁰, 11.2% to 6.6% (p<0.001)¹⁶, and 14.9% to 4.7% (p<0.001%).^[15] Other studies did not demonstrate a significant change in SSI rate after implementation of the WHO SSC: 4.4 versus 3.5%¹², 10.4 versus 5.3% (p=0.1)¹³ and 6.2 versus 5% (p=0.845).^[14]

Data from our study suggested that the implementation of the WHO SSC was associated with reduced post-operative complications (37.43% in Control Group to 24.62% in Implementation Group) until discharge from hospital. We found six studies reporting data on any complications within 30 days following surgery or until discharge from hospital. Five studies supported our result of decreasing overall complication rates: 11.0 vs 7.0% (p<0.001)¹⁰, 18.4 vs 11.7% (p=0.001)¹⁶, 22.9 vs 10.0% (p=0.03)¹³, 23.6 vs 8.0% (p<0.001)¹⁴ and 21.5 vs 8.8% (p<0.001)¹⁵. One study did not demonstrate a significant difference between evaluation intervals (8.5 vs 7.6%, RR 0.89, 95% C.I. 0.58 to 1.37).^[12]

In our study, in-hospital mortality decreased from 2.67% (n=5) to 0.51% (n=1) but the result was not statistically significant. We found two studies which showed significant decrease in mortality following implementation of WHO SSC: 1.5 vs 0.8% (p=0.003)¹⁰ and 3.7 vs 1.4% (p=0.007).^[11] Van Klei et al reported a decrease in crude mortality rates from 3.1 to 2.9% but the result was statistically insignificant (p=0.19)¹⁷. After adjustment for baseline differences, mortality decreased significantly after checklist implementation (OR 0.85, 95% C.I. 0.73 to 0.98). This effect was strongly related to checklist compliance or if the checklist was completed fully, compared to non-compliance or partial compliance respectively.^[17] Few studies

did not demonstrate a significant reduction in mortality.^[12,15]

Our study showed decreased rate of unplanned return to OR (2.14% to 1.54%, $p=0.719$). We found three studies reporting details of unplanned return to OR. Haynes et al,^[10] showed a decreased rate of unplanned return to OR from 2.4% to 1.8% ($p=0.047$). Sewell et al,^[12] reported unplanned return to OR after 1% of procedures in both audits. Kwok et al reported that the unplanned return rate decreased from 1.9% to 1.5% ($p=0.151$).

The mean post-operative length of stay (LOS) reduced from 7.3 days to 6.48 days in our study following introduction of checklist, with a mean difference of -0.82 days, though the data was statistically not significant. In a cluster randomised control trial from Norway by Haugen et al. patients' LOS was compared at control and SSC intervention stages of the study. The total in-hospital LOS for both study hospitals reduced significantly from 7.8 days to 7.0 days ($p=0.022$) after introduction of the checklist, with a mean difference of -0.8 days, $t=2.30$ (95% CI, 0.11-1.43).^[18]

Our study was conducted in only one setting, and in brief period, comprised a relatively small sample; therefore, the results might not be applicable in general throughout the country. The survey included only elective surgeries, but not emergency surgeries; thus, the effect of including both elective and emergency surgeries are not known. The documentation of complications was limited to the period of admission only. Data on complications and death occurring after death was not collected. Finally, interpretation of compliance with the SSC was based on the adherence to a subgroup of safety measures. This is an important distinction as these reported measures represent adherence to the specific aspects of care embedded in the WHO SSC. The full checklist probably functions in a different way to the individual items singled out for measurement. Compliance with the subgroup of safety measures does not necessarily imply appropriate use of the checklist. In addition, there is a need to identify the key barriers to improve adherence to SSC.^[18]

CONCLUSION

We conclude that the use of WHO Checklist prevents overall complications, surgical site infections. Reduction in-hospital length of stay and mortality may potentially occur but cannot be confirmed in absence of higher quality studies.

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How to cite this article: Kabra S, Sinha S, Das S, Mondal RR. Effect of Adherence to the World Health Organization Surgical Safety Checklist on Morbidity and Mortality in a Defined Surgical Patient Population. Ann. Int. Med. Den. Res. 2019; 5(4):SG24-SG29.

Source of Support: Nil, **Conflict of Interest:** None declared