

# Ensuring Surgical Safety: Initial Footstep in a Thousand Mile Journey. An Initial outcome Study from a Developing Country

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## ABSTRACT

**Background:** Surgical adverse events due to negligence are increasingly recognized as an important aspect for preventing morbidity and mortality in healthcare system. WHO Safe Surgical Checklist provides an opportunity for surgical teams to minimize surgical adverse events by following just a simple checklist. The aim of this study is to assess the compliance of different members of the surgical team to this checklist and post operative outcomes before and after an orientation programme regarding the checklist. **Methods:** We observed 100 elective surgeries in the Department of Surgery of our institution and collected the baseline data regarding the use of WHO Safe Surgical Checklist in these surgeries. Following the collection of baseline data we organised an orientation program for the surgical team at our institution and collected the same data after orientation. Data obtained both before and after the data collection were compared. **Results:** This study has shown significant improvement in certain sections of the WHO Safe Surgical Checklist such as conformation, by the patient himself, of his identity (10%) , site of surgery (23%) and procedure to be performed (35%) . A significant increase has also been shown in estimation of the duration of surgery by the surgeons (11%) and specimen labelling (44%). The members of the surgical team introduced themselves more number of times (17%) after the orientation. Number of deaths (50%) and surgical site infections (80% class 1 SSI, 25 % class 2 SSI, 13% class 3 SSI, 52% class 4 SSI) has also been shown to decrease following the checklist implementation. **Conclusion:** Implementation of this WHO Safe Surgical Checklist is beneficial both to the patient and to the surgical team and is not very difficult to comply with, considering the excellent post operative outcomes shown in this study. Compliance with all items on the checklist with active co-operation, co-ordination and participation by all team members are key factors that led to the successful implementation of the checklist.

**Keywords:** WHO, Safe Surgical Checklist, Surgical Safety.

## INTRODUCTION

Surgical adverse events due to negligence are increasingly recognized as an important aspect for preventing morbidity and mortality in healthcare system.<sup>[1]</sup> Surgery has become an integral part of global health care, with an estimated 234 million operations performed yearly. Although surgical care can prevent loss of life or limb, it is also associated with a considerable risk of complications and death.<sup>[2]</sup> Half of all the adverse events in healthcare occur in surgical care and more than half of these are preventable. The number of these adverse events is directly proportional to the complexity of surgery,

length of the hospital stay and patient's poor compliance.<sup>[3]</sup>

Surgical care can be divided into pre-operative, peri-operative and post-operative care. Previous studies have shown that improvement in peri-operative care can prevent postoperative complications.<sup>[4,5]</sup> The risk of complications in surgical care is poorly characterized in many parts of the world; studies in the industrialized world have shown major complications of 3-17% and a mortality rate of 0.4-0.8%.<sup>[6]</sup> Joint Commission on Accreditation of Healthcare Organization (JACHO) implemented universal protocol in 2004 for preventing wrong-site, wrong-procedure and wrong-person surgery.<sup>[7-9]</sup> In recent years, the most notable effort to prevent complications from negligence is by World Health Organisation (WHO) which developed a Surgical Safety Checklist. The checklist outlines essential standards of surgical care and is designed to be simple, widely applicable, and to address common and potentially disastrous consequences. Use of the

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checklist can identify the gaps in perioperative care and can establish or confirm adherence to proven standards of care that can improve surgical results and decrease death and complications.

## MATERIALS AND METHODS

A prospective interventional, non-comparative, non-randomised outcome study was conducted at R.G.Kar Medical College and Hospital, Kolkata over a period of 18 months from March 2017 to September 2018. It is a premiere teaching and tertiary care hospital catering to a large and heterogeneous population. This study was done to assess the use of WHO Safe Surgical Checklist, compliance and its effectiveness in reducing complications and final outcome of the patients after surgery.

This study began on March, 2017 by observing 100 sequential cases of surgery of one particular surgical unit in the elective surgical settings of general surgical operation theatres at R.G Kar Medical College. These 100 cases were observed and Pre designed proformas based on WHO Safe Surgical Checklist were filled using a likert score. This constituted the baseline data of the study.

After collection and computation of the baseline data, the magnitude of the problem was assessed.

Following the baseline data collection, we organised a orientation program on the use and implementation of WHO Safe Surgical checklist for the multidisciplinary surgical unit consisting of Surgeons, anaesthesiologists, O.T technicians and nursing staff.

Following the orientation program we followed 100 cases of elective surgery of the same surgical unit we observed earlier during the baseline data collection phase who attended the orientation program on the use of WHO Safe Surgical Checklist. Data were collected and analysed using the same format as used during the baseline data collection phase.

Apart from observing the surgeries for data collection all these patients were followed up for post surgical outcomes.

All the 100 cases of surgery observed for data collection (N = 100) were elective surgeries, excluding the emergency surgeries and surgeries where the patient did not give consent. All health care providers of the surgical team were also included in the study after obtaining written consent from them.

The data were coded, cleaned, entered and analysed using the Graphpad Quickcalcs method. Baseline comparisons were performed using Chi Square tests. A two sided 'p value' of 0.05 was considered statistically significant.

Ethical clearance and official permission was secured from the Institutional Ethics Committee of R.G.Kar Medical College and Hospital.

## RESULTS

The total number of surgeries observed were 100, during the period of our study. These are all general surgical cases routinely done in our hospital. The data before the implementation and after the implementation of checklist were observed and outcome in terms of compliance to the items of the checklist and complications before and after the checklist was compared.

100 cases were studied in which it was seen that for 99 cases nurse confirms that the patient confirms his/her identity both before and after the checklist, anaesthetist confirms the same in 95 cases before and in 99 cases after the checklist orientation program. The same data was 77 and 87 when asked by the surgeon. The improvement in outcome was that 0 and 4%. Improvement amongst surgeons were 10% [Table 1]

Before the Checklist was implemented, in only 5 number of cases nurse ensured that the patient confirmed the site, which improved to 21 cases after the Checklist orientation. The same question was asked by anesthetist and the results were 20 and 43 times before and after the checklist orientation the same results were 90 and 96 consequently before and after when the question was asked to surgeons.

97 number of times nurse asked the patient to confirm the operative site after the checklist as compared to 95 number of times before the checklist orientation, anesthetists asked the same 73 and 86 number of times before and after the Checklist, surgeons done the same 42 number of times before and 77 times after the procedure.

Nurses confirmed the patient's consent in all cases both before and after the implementation of the checklist, whereas anesthetist confirmed the consent in 95 number of cases both the time, surgeons done the same in 93 times before the checklist which improved slightly to 95 cases after the checklist.

In our study we found that nurse and anesthetist did not confirm even in a single case that the site is marked or not, before the checklist, which improved a bit. To 5 cases in which nurses confirm the same after the checklist. Surgeons confirmed it 23 number of cases before and 29 number of cases after the checklist.

No significant change found in the item whether anaesthesia machine and medication checked or not as nurses done it 70 number of cases after the checklist as compare to 67 before the checklist, anesthetists done it in 96 and 98 number of cases, and surgeons in 13 and 11 number of cases after and before the checklist.

Anesthetist confirmed in all cases that the pulse oxymeter on the patient and is functioning, both before and after the checklist. Nurses did the same in 85 and 91 number of cases before and after the checklist respectively, surgeons done it in 76 and 79

number of cases before and after the checklist orientation respectively.

Whether the patient have known allergy ,confirmed by nurses in very few cases 3 and 6 number of cases before and after the checklist ,by anaesthetists in 56 and 63 number of cases and by surgeons in 89 and 95 number of cases before and after the checklist orientation respectively

Difficult airway/aspiration risk issue is addressed mostly by anaesthetist in 95 and 96 number of cases pre and post checklist respectively , surgeons done this 66 and 71 number of times , 24 and 19 number of times by the nurses pre and post checklist.

In our study risk of blood loss more than 500ml, issue was addressed mostly by surgeons equally before and after the checklist in 99 cases ,for anaesthetist it was 87 and 91 and for nurse it was 33 and 28 before and after the checklist orientation.

The result of our study regarding introduction of team members only 11 times nurses introduce themselves after the checklist as compared to 7 before the checklist orientation, anaesthetist as well introduce themselves in only 21 cases after the checklist and 4 before the checklist, surgeons done this 16 and 23 number of cases.

100 cases were studied in which it was seen that for 65 cases nurse confirms that the patient name, procedure and where the incision will be made before and 56 cases after the checklist, anaesthetist confirms the same in 57 cases before and in 64 cases after the checklist orientation program, In case of surgeons the values were 34 and 44 before and after orientation.

100 cases were studied in which it was seen that for 34 cases nurse confirms that the patient has been given antibiotic before and 48 cases after the checklist orientation, anaesthetist confirms the same

in 75 cases before and in 80 cases after the checklist orientation program . The same data was 90 and 96 when asked by the surgeon.

75 number of cases surgeon anticipated critical events before and in 83 number of cases after the checklist orientation.

In 100 cases studied 77 number of cases surgeon anticipated duration before and in 83 number of cases after the checklist orientation.

89 number of cases surgeon anticipated blood loss before and in 95 number of cases after the checklist orientation.

88 number of cases anaesthetist anticipated patient specific concern before and in 93 number of cases after the checklist orientation.

95 number of cases Nurse raise equipment issues before and in 92 number of cases after the checklist orientation.

75 number of cases surgeon ensure that essential imaging are displayed before and in 85 number of cases after the checklist orientation.

50 number of cases nurses done the same before and in 60 number of cases after the checklist orientation.

In 10 cases anaesthetist ensure that essential imaging are displayed before and in 30 number of cases after the checklist orientation.

There were 4 cases having class 1 surgical site infections (SSI) after the orientation of the checklist as compared to 5 cases before the orientation of checklist, 6 and 8 cases of class 2 SSI before and after the orientation, 15 and 13 cases of class 3 SSI, and 32 and 67 cases of class 4 SSI respectively before and after the checklist was implemented. [Table 2]

In our study there were 2 deaths observed after the orientation as compared to 4 before the checklist implementation. [Table 3]

**Table 1: Summary of the Use of WHO Safe Surgical Checklist as Observed During the Study**

Checkbox to be ticked off / discussions to be had according to WHO Safe Surgical Checklist	Confirmed by Nurse		Confirmed by Anaesthetist		Confirmed by Surgeons	
	Pre Orientation	Post Orientation	Pre Orientation	Post Orientation	Pre Orientation	Post Orientation
1. Has the patient confirmed his/her IDENTITY (To Nurse , Anaesthetist and Surgeon) ?	99	99	95	99	77	87
2. Has the patient confirmed the site?	5	21	20	43	90	96
3. Has the patient confirmed the procedure?	95	97	73	86	42	77
4. Has the patient confirmed his /her consent for the procedure?	100	100	95	95	93	95
5. Is the site marked ?	0	5	0	0	23	29
6. Is the anaesthesia machine and medication check complete?	67	70	98	96	11	13
7. Is the pulse oxymeter on the patient and functioning?	85	91	100	100	76	79
8. Does the patient have known allergy?	3	6	56	63	89	95
9. Does the patient have a difficult airway and aspiration risk?	24	19	95	96	66	71
10. Does the patient have risk of blood loss >500ml?	33	28	87	91	99	99
11. Have all team members introduced themselves by name and role ?	7	11	4	21	16	21
12. Confirm the patient's name, procedure and site of the incision	65	56	57	64	34	44
13. Has antibiotic prophylaxis been given within the last 60 min ?	34	48	75	80	90	96

14. Anticipated critical steps(To surgeon only)	NA	NA	NA	NA	75	83
15. Duration estimated(To Surgeon only)	NA	NA	NA	NA	77	88
16. Anticipated blood loss(To surgeon only)	NA	NA	NA	NA	89	95
17. Any patient specific concern?(To anesthetist)	NA	NA	88	93	NA	NA
18. Are there equipment issues or any concern (To nursing team)	95	92	NA	NA	NA	NA
19. Is essential imaging displayed?	50	60	10	30	75	85
20. Nurse confirms the name of the procedure(before patient leaving OT)	22	43	NA	NA	NA	NA
21. Nurses confirms count	100	100	NA	NA	NA	NA
22. Specimen Labelling	0	0	NA	NA	30	74
23. What are the key concerns for recovery and management of this patient ?	76	76	76	76	76	76

**Table 2: Evidence of SSI in Pre and Post Orientation Phases**

CLASS	Pre Intervention (Before checklist orientation)	Post Intervention (After checklist orientation)
CLASS I SSI	5	4
CLASS II SSI	8	6
CLASS III SSI	13	15
CLASS IV SSI	67	32

**Table 3: Evidence of DEATHS before and after the implementation of checklist**

	Number of deaths
Before checklist	4
After checklist	2

## DISCUSSION

Surgical care has been an essential component of health care over the world for over a century. As the frequency of traumatic injuries, cancers and cardiovascular disease are continuously rising, the impact of surgical intervention on public health systems is continuously growing. Every year, millions of people undergo surgical interventions that account for an estimated 13% of the world's total disability-adjusted life years (DALYs). While surgical procedures are intended to save lives, unsafe surgical care can cause significant harm.

To address surgical safety WHO has undertaken many global and regional initiatives. Much of this work has been taken from the WHO Second Global Patient Safety Challenge - "Safe Surgery, Saves Lives". "Safe Surgery ,Saves Lives" targeted to improve the safety of surgical care around the world by defining a core set of safety standards that could be applied in all WHO Member States . The WHO Surgical Safety Checklist is a tool designed to improve the safety of surgical procedures by the help of surgeons, anaesthetists and nurses to perform key safety checks during vital phases of perioperative care before the induction of anaesthesia, prior to skin incision and before the team leaves the operating room.<sup>[10]</sup>

The total number of surgeries observed were 100, during the period of our study.

These are all general surgical cases routinely done in our hospital. The data before and after the orientation of checklist were observed and outcome in terms of compliance to the items of the checklist

and complications before and after the checklist orientation were compared.

If we summarise the results according to the members of the surgical team concerned, there were 21 cases where the nurse asked the patient to confirm the site of operation after the orientation of the checklist, the same data were 5 before the checklist implementation. In 5 cases nurses checked whether the site is marked or not as compared to 0 before the orientation, in 43 cases nurses asked the patient to confirm the procedure. No difference was found in some questions (patient identity, checking consent, sterility, instrument count) where nurses were checking these in almost 100 per cent of cases before and after the orientation of the checklist.

When it comes to anaesthetists, there were 43 cases where anaesthetists asked the patient to confirm the site of operation as compared to 22 before the checklist orientation .In 86 cases, the anaesthetist ensured that the patient confirmed the procedure after the orientation as compared to 73 cases earlier.

In the question of team members introducing themselves, anaesthetist introduce themselves 21 times after the checklist orientation as compared to 4 times before the orientation. Moreover there were 30 cases where anaesthetist ensured that essential imaging was displayed after the orientation as compared to 10 cases before the orientation.

No difference was found in some questions (consent, pulse oximeter checking, difficult airway and aspiration risk), as they were almost 100% before and after the orientation.

Where surgeons are concerned, there were 77 cases where surgeons confirmed that the patient knew about the procedure after the implementation of the checklist as compared to 42 cases before the orientation, moreover there were 74 cases where the surgeon ensured that the specimens are labelled after the surgery as compared to 30 cases before the orientation.

No differences were found in some items as risk of blood loss (>500ml) was addressed by the surgeons which was 99 % both before and after the checklist. Also there was no difference in all the cases regarding the questions - 'discuss patient recovery' for nurse anaesthetists and surgeons. There were 4 cases having class 1 surgical site infections (SSI) after the checklist as compared to 5 cases before the orientation, 8 and 6 number of class 2 SSI before and after the checklist orientation consequently, 13 and 15 number of class 3 SSI, and 67 and 32 number of class 4 SSI before and after the checklist was implemented. In our study there were 2 deaths was observed as compared to 4 before the checklist implementation. Overall compliance improved from 50 to 58% by nurses, 64 to 71% by anaesthetist and from 64 to 74 % by surgeons.

Our study like other studies done in the same subject shows that after orientation the checklist there was a significant increase in compliance to the questions related to safe surgery and reduction in post surgical complications and death.

Our initial concern was successful implementation of the checklist, but the teams were able to implement the same with minimal difficulty after the trial period. The checklist was neither costly nor lengthy, which helped us to successfully implement the same.

[As in our study a less number of cases have been studied, some data despite being improved after the intervention were statistically insignificant. Further studies on mortality and morbidity needs to be done to improve the outcome.]

## CONCLUSION

In our study we saw that the quality of implementation of the Safe surgical checklist was suboptimal, with a definite scope for improvement. Compliance with all items on the checklist and active participation by all team members are extremely important for successful implementation of the checklist.

Although our study population is small still it has shown to reduce the postoperative mortality and morbidity. Senior surgical leadership for the implementation of the checklist was associated with significantly better compliance and checklist utilization. Surgeons should take up the challenge of leading checklists implementation in the Operating room and be the champions of safety within their hospitals.

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