

Clinical Audit of Patient Safety Standards Compliance by the Surgical Team: A Cross-Sectional Study in Northeastern, Iran

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Abstract

Background: Clinical auditing is an important way to assess patient care standards and enhance the quality of clinical services. Adherence to patient safety standards in the operating room plays a crucial role in improving the quality of services and ensuring greater safety for surgical patients.

Aim: The present study was conducted with aim to evaluate the compliance of actions taken by the surgical team with patient safety standards in the operating room based on safe surgery guidelines.

Method: This cross-sectional study was conducted during 2022-2023 in a public hospital in northeastern, Iran. The study population included all surgeries in the operating room selected via a convenience sampling method and assessed through observation using revised form of World Health Organization (WHO) Safe Surgery checklist. Data were analyzed by SPSS (version 16) using descriptive statistical methods.

Results: A total of 161 surgeries were evaluated. Overall, the adherence rate to standards was 70.97%. Specifically, adherence rates were 78.34% in the pre-anesthesia induction (sing-in) phase, 62.58% in the pre-incision (time-out) phase, and 81.71% in the pre-exit (sign-out) phase of the operating room.

Implications for Practice: The findings of the present study can be suggested to plan for improving the compliance with patient safety standards by the surgical team.

Keywords: Clinical audit, Operating room, Patient safety, Safe surgery, Surgical team

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Introduction

The concept of patient safety is an essential component of healthcare systems and a cornerstone of quality in healthcare organizations (1). The World Health Organization (WHO) defines patient safety as avoiding unnecessary or potential harm associated with healthcare services (2). Patient safety in the operating room (OR) is an ongoing concern due to the complexities of the operating room environment, high stress levels, and the vulnerability of surgical patients. These factors can increase the likelihood of errors and harm to patients (3). Surgical complications, which are intrinsic to some of the most complex healthcare interventions, remain a leading cause of mortality and disability worldwide (4). It is estimated that approximately 234 million surgeries are performed annually, with nearly 14% of surgical patients experiencing an adverse event (5). Globally, major post-operative complications occur in 3% to 22% of surgeries, with mortality rates reported between 0.4% and 0.8% (6).

In 2008, the WHO published the recommendations for the safety of patients undergoing surgery, introducing a 19-point Safe Surgery Checklist aimed to strengthen the safety practices, improve communication, and enhance teamwork across clinical disciplines (7, 8). A systematic review found that the WHO Safe Surgery Checklist significantly reduced mortality and length of hospital stay over five years (9). In Iran, Mohebbifar and colleagues showed that using the checklist reduced the overall complication rate from 11% to 3.91%, and mortality from 3.44% to 1.30%. Significant reductions were also observed in surgical site infections and unplanned returns to the operating room (10). Studies show that adherence to the Safe Surgery Checklist varies across studies and largely depends on staff awareness, effective training, and strong leadership (11). A study in Iran identified weak teamwork as the primary barrier for implementing the Safe Surgery Checklist (12). Implementing and maintaining the Safe Surgery Checklist is an ongoing challenge requiring regular evaluations, integration into existing hospital workflows, active leadership, clear explanations of its purpose and use, and organizational support (13).

Clinical auditing is an integral component of clinical governance, serving as a comprehensive strategy for assessing and improving the quality of services and adherence to patient care standards in healthcare systems. Multiple audits can yield a more comprehensive understanding of clinical staff performance and contribute to greater patient safety (14, 15). The present study was conducted with aim to assess the adherence of actions taken by the surgical team to patient safety standards in the operating room. Identifying areas needing improvement will help mitigate and eliminate obstacles to standard implementation and reduce the risk of surgical complications and errors for other patients.

Methods

This descriptive and cross-sectional (clinical audit) study was conducted in a public hospital in northeastern Iran from 2022 to 2023. The study population included all surgical procedures performed in the operating room of the selected hospital, with data collected through structured observations. Sampling was conducted using a convenience sampling method. The sample size was determined to be 157, calculated using sample size formula for estimating a population proportion (16), with a significance level (α) of 0.05, a probability (p) of 0.73 based on Seif Hashemi et al.'s study (17), and a margin of error (d) of 0.073. The inclusion criteria was the need for general or spinal anesthesia to perform surgery. The exclusion criteria were cases in which surgery was canceled and the patients who required cardiopulmonary resuscitation during surgery.

Data collection was performed the revised form of WHO Safe Surgery Checklist (18). A version of this checklist has been translated and validated in Iran (7). Given that the original WHO checklist only requires the marking of item completion, and that multiple standards are assessed within certain items, based on the translated WHO checklist and utilizing the same standards, the researchers developed a research tool by separating the standards, assigning a single standard to each item, and defining response options for the checklist. The checklist used in the present study is divided into three main sections: pre-anesthesia induction (Sign-in), pre-incision (Time-out), and pre-patient exit from the OR (Sign-out). The checklist items were scored on a three-point scale: correctly performed (2 points), incorrectly performed (1 point), and not performed (0 point). To minimize the bias, all non-applicable items were counted as correctly performed. The checklist included 15 items in the first section (30 points), 23 items in the second section (26 points), and 8 items in the third section (16 points), totaling 92 points. Higher scores indicated greater adherence to standards. To simplify interpretation, the mean

scores for each section and the entire checklist were converted to a percentage score, ranging from 0 to 100. The qualitative content validity of the checklist was assessed by a panel of 10 experts, including faculty members specializing in nursing, anesthesiology, and surgical operation room management. The panel reviewed the checklist for clarity, word choice, item placement, and scoring appropriateness, and feedback was incorporated. The reliability of the checklist was determined using inter-rater reliability. Two observers with equivalent levels of precision, skill, knowledge, and awareness simultaneously completed the checklist for 10 patients, calculating the Intra-class Correlation Coefficient (ICC) as follows:

ICC for the Sign-in subscale: 0.83, ICC for the Time-out subscale: 0.81, ICC for the Sign-out subscale: 0.79

Data collection was conducted by a single fixed researcher who visited the selected operating room across various shifts and performed the structured observations of the surgical team's actions from the patient's arrival in the OR until the end of surgery and the patient's transfer to recovery. Observations were recorded on the checklist. As it was not feasible to assess multiple surgeries simultaneously, each surgical procedure was evaluated sequentially within a shift. Data collection spanned approximately six months, from late autumn 2022 to spring 2023. After data collection and coding, analysis was performed using SPSS (version 16) and descriptive statistical methods (frequency, percentage, mean, and standard deviation).

Ethical Consideration

The present study is derived from a research project approved by North Khorasan University of Medical Sciences (ethical code: IR.NKUMS.REC.1400.136). It is important to note that the primary objective of the study was explained solely to the head nurse. Given the educational setting of the healthcare facility where the research was conducted, the presence of students and instructors was a natural occurrence. As a result, the presence of the data collector did not significantly influence the behavior of the staff. In adherence to ethical guidelines, the staffs were informed that data collection was being carried out for a research project, though no additional details were disclosed.

Table 1: Frequency distribution of checklist items (Sign-in phase)

N	Before patient anesthesia (by nurse and anesthesiologist)	Yes, N (%)		No, N (%)	Not necessary N (%)
		Done correctly	Not done correctly		
1	The patient confirms his/her identity.	149 (92.5)	0	2 (1.2)	10 (6.2)
2	Type of surgery is confirmed by the patient.	117 (72.7)	1 (0.6)	33 (20.5)	10 (6.2)
3	Surgical site is confirmed by the patient.	127 (78.9)	0	22 (13.7)	12 (7.5)
4	The patient confirms consent for the surgery.	161 (100)	0	0	0
5	The patient is asked about any underlying medical conditions.	142 (88.2)	1 (0.6)	8 (5)	10 (6.2)
6	Required imaging and paraclinical findings have been displayed in the room.	128 (79.5)	0	23 (14.3)	10 (6.2)
7	Pre-surgery medical consultations are completed.	58 (36)	0	71 (44.1)	32 (19.1)
8	The patient's medications taken over the past 72 hours are checked.	55 (34.2)	5 (3.1)	85 (52.8)	16 (9.9)
9	It is checked whether the patient has received preoperative prophylactic medications.	91 (56.5)	3 (1.9)	61 (37.9)	6 (3.7)
10	It is checked whether the patient has any known allergies.	148 (91.9)	0	6 (3.7)	7 (4.3)
11	It is checked whether the patient has respiratory issues or is at risk for aspiration.	152 (94.4)	1 (0.6)	3 (1.9)	5 (3.1)
12	The anesthesia safety checklist is completed.	1 (0.6)	153 (98.8)	0	1 (0.6)
13	Blood products are reserved for the patient.	12 (7.5)	1 (0.6)	14 (8.7)	134 (83.2)
14	The patient is placed under vital sign monitoring.	154 (95.7)	0	2 (1.2)	5 (3.1)
15	The surgical site has been marked.	17 (10.6)	1 (0.6)	107 (66.5)	36 (22.4)

Results

Adherence to patient safety standards was evaluated in 161 surgeries that 88 surgeries (54.7%) were orthopedic, 51 (31.7%) were general surgeries, 16 (9.9%) were neurosurgeries and 6 (3.7%) were other surgical fields. The findings indicated that in the pre-anesthesia induction phase (Sign-in), the most consistently followed standard was obtaining surgical consent, which was correctly performed in all cases (100%). However, marking the surgical site was the most frequently missed standard that 107 surgeries (66.5%) lacking this step. In addition, the anesthesia checklist was not properly completed in the majority of cases (98.8%) (Table 1).

Table 2: Frequency distribution of checklist items (Time-out phase)

N	Before skin incision (by surgeon, anesthesiologist, and nurse)	Yes, N (%)		No, N (%)	Not necessary N (%)
		Done correctly	Not done correctly		
1	The names and roles of all team members are confirmed.	160 (99.4)	1 (0.6)	0	0
2	The patient's name is confirmed by the surgeon.	71 (44.1)	2 (1.2)	87 (54)	1 (0.6)
3	The patient's name is confirmed by the anesthesiologist.	34 (21.1)	0	121 (75.2)	6 (3.7)
4	The patient's name is confirmed by the nurse.	155 (96.3)	0	2 (1.2)	4 (2.5)
5	The surgical site is confirmed by the surgeon.	133 (82.6)	0	27 (16.8)	1 (0.6)
6	The surgical site is confirmed by the anesthesiologist.	42 (26.1)	1 (0.6)	112 (69.6)	6 (3.7)
7	The surgical site is confirmed by the nurse.	157 (97.5)	0	3 (1.9)	1 (0.6)
8	The surgical procedure is confirmed by the surgeon.	11 (68.9)	1 (0.6)	48 (29.8)	1 (0.6)
9	The surgical procedure is confirmed by the anesthesiologist.	30 (18.6)	1 (0.6)	124 (77)	6 (3.7)
10	The surgical procedure is confirmed by the nurse.	134 (83.2)	0	26 (16.1)	1 (0.6)
11	The correct positioning of the patient is checked by the surgeon.	157 (97.5)	0	4 (2.5)	0
12	The correct positioning of the patient is checked by the anesthesiologist.	46 (28.6)	0	110 (68.3)	5 (3.1)
13	The correct positioning of the patient is checked by the nurse.	161 (100)	0	0	0
14	The estimated duration of the surgery is announced by the surgeon.	35 (21.7)	4 (2.5)	119 (73.9)	3 (1.9)
15	The potential amount of bleeding during surgery is estimated by the surgeon.	3 (1.9)	3 (1.9)	111 (68.9)	44 (27.3)
16	The need for special equipment or support (such as blood reservation) suitable for the surgery is anticipated by the surgeon.	137 (85.1)	2 (1.2)	2 (1.2)	20 (12.4)
17	The possibility of deviation from the normal course of surgery is anticipated by the surgeon.	4 (2.5)	2 (1.2)	115 (71.4)	40 (24.8)
18	Any specific concerns related to the patient's anesthesia are assessed by the anesthesiologist.	37 (23)	0	101 (62.7)	23 (14.3)
19	The ASA grade is determined by the anesthesiologist.	24 (14.9)	127 (78.9)	0	10 (6.2)
20	The sterility of surgical instruments is confirmed by the nursing team.	117 (72.7)	15 (9.3)	28 (17.4)	1 (0.6)
21	The surgical site has been shaved.	16 (9.9)	2 (1.2)	5 (3.1)	138 (85.7)
22	Blood sugar control has been conducted to prevent surgical site infection.	63 (39.1)	1 (0.6)	96 (59.6)	1 (0.6)
23	Disinfection of the surgical site is completed	159 (98.8)	0	0	2 (1.2)

In the pre-incision phase (Time-out), the correct positioning of the patient by the nurse was consistently followed in all cases (100%). The most neglected standard in this phase was the verbal confirmation of the surgical procedure by the anesthesiologist, which was not performed in

124 cases (77%). Additionally, determining the ASA (American Society of Anesthesiologists) classification was performed by the anesthesiologist in 127 cases (87.9%), but the method was not fully accurate (Table 2).

Table 3: Frequency distribution of checklist items (Sign-out phase)

N	Before leaving the operating room (verbal confirmation by the surgeon, anesthesiologist, and nursing team)	Yes, N (%)		No, N (%)	Not necessary N (%)
		Correctly	Not correctly		
1	The surgery procedure has been documented.	161 (100)	0	0	0
2	Surgical instruments, gauze, and needles have been correctly counted.	43 (26.7)	34 (21.1)	80 (49.7)	4 (2.5)
3	Labeling of surgical specimens has been completed.	45 (28)	1 (0.6)	2 (1.2)	113 (70.2)
4	Any equipment malfunctions needed to be addressed for the next surgery are reported.	7 (4.3)	5 (3.1)	7 (4.3)	142 (88.2)
5	The surgeon has outlined key points for recovery and post-surgical management.	141 (87.6)	0	8 (5)	12 (7.5)
6	The anesthesiologist has outlined key points for recovery and post-surgical management.	25 (15.5)	0	123 (76.4)	13 (8.1)
7	The nursing team has outlined key points for recovery and post-surgical management.	157 (97.5)	0	1 (0.6)	3 (1.9)
8	The required post-operative care has been recorded in the patient's file.	161 (100)	0	0	0

In the phase prior to leaving the operating room (Sign-out), all surgeries adhered to the proper documentation of the surgical procedure and post-operative care. The most frequently missed standard in this phase was the communication of important points for recovery and post-operative management by the anesthesiologist (76.4%) (Table 3).

The mean scores for adherence to standards were as follows: Pre-anesthesia induction phase: 23.50 ± 2.61 ; Pre-incision phase: 28.78 ± 5.56 ; Pre-exit phase: 13.00 ± 1.39 (Table 4). Overall, 70.97% of the safe surgery standards were adhered to in the operating room of the selected hospital. Specifically, 78.34% of the standards were met during the pre-anesthesia phase, 62.58% during the pre-incision phase, and 81.71% during the pre-departure from the operating room phase (Table 4).

Table 4: Scores of the checklist dimensions

Fields	Mean \pm SD of obtained score	Percentage of score obtained	Maximum standard score
Before induction of anesthesia (Sign-in)	23.50 \pm 2.61	78.34	30
Before skin incision (Time-out)	29.57 \pm 5.46	62.58	46
Before leaving the operating room (Sign-out)	13.00 \pm 1.39	81.71	16
Total	66.08 \pm 6.87	70.97	92

Discussion

Patient safety is a significant concern in healthcare in order to prevent and reduce the risks, errors, and harm that may occur during the provision of health services. The Safe Surgery Checklist serving as an effective guideline is designed to reduce errors and adverse events while improving teamwork and communication during surgery. The performance of the surgical team and current conditions can be assessed through auditing safe surgical standards, and by comparing with established standards, barriers and challenges to safe surgery in the operating room can be identified and resolved.

The findings of the present study indicated that compliance with standards in the OR of a public hospital in northeastern Iran was below three-quarters of the standards. Since these standards are considered minimum acceptable conditions, the performance of the surgical team was not optimal. In Iran, Seif Hashemi et al. reported that the overall compliance with safe surgery standards in the

operating rooms of the selected hospital of Shahid Beheshti University of Medical Sciences was 60.73%, also noting that adherence to safe surgery standards was below the announced standards (17). Similarly, in a study by Zadi Akhule et al., the performance level of operating room staff at Mazandaran University of Medical Sciences hospitals in all three areas of the Safe Surgery Checklist was reported as moderate that was not considered satisfactory (19). In Kermanshah, compliance with patient safety standards was reported at 77.1%, which was low (4). High workload, insufficient time between surgeries, improper use of the Safe Surgery Checklist, and a lack of attention to its importance are among the reasons for this low rate of compliance. Although clinical guidelines emphasize the checklist's positive impact on reducing mortality, complications, and errors, as well as improving patient safety quality, unfortunately, surgical team members often simply check off the items on the list routinely without focusing on the objectives, leading to poor adherence to standards. In a survey conducted by Tan et al. among surgeons and operating room staff in China, overall compliance was reported at 79.8%, with over 85% of OR staff recognizing the checklist's value for patient safety and communication improvement (20). In Pakistan, Azhar et al. found the highest compliance was during the sign-in phase and the lowest during time-out, with no successful completion of the sign-out phase questionnaires (5). Kisacik's study showed that although all operating room nurses recognized the importance of the checklist, most participants stated it was not effectively implemented in the OR. They emphasized that successful implementation depends on team awareness about patient safety and the checklist's importance (21).

In the present study, the highest standard followed in the pre-anesthesia phase was obtaining surgical consent, while marking the surgical site was the most neglected. Surgeons in our hospital seldom marked the surgical site routinely. In the pre-incision phase, the highest standard was patient positioning by nurses, whereas the surgical procedure check by the anesthesiologist was the most neglected. Sterility control of surgical instruments was often carried out improperly due to a lack of attention to indicators in the set by circulators, limited scrubbing, and improper discarding of class 4 indicators in packs. Before leaving the OR, recording the surgical procedure and post-op care was completed accurately due to the routine monitoring by station nurses. However, the least followed standard was noting key post-op care by the anesthesiologist, often absent at the end of the surgery. Typically, the anesthesia technician took over patient transfer to recovery.

Although the primary goal of the Safe Surgery Checklist is to highlight the importance of communication and teamwork as integral parts of care, studies show that coordinating nurses, anesthesiologists, and surgeons remains challenging, sometimes leading to frustration for checklist leaders. A lack of responsibility and cooperation among team members results in the checklist becoming an added task rather than a valuable tool. Each team member's accountability during checklist execution is crucial (13).

The present study provided foundational information for further research and continuous quality improvement in team-based surgery; however, this study has limitations. We only examined general team performance compliance with patient safety standards without deep analysis of challenges or causes for unsuccessful checklist implementation. Future studies should consider factors such as surgical case diversity, surgeon variations, team demographics, and shift-specific workloads. Additionally, the educational nature of the hospital setting and student presence may influence team performance, warranting further examination.

Implications for practice

As the findings of the present study showed, compliance with essential safe surgery standards in the selected hospital was not optimal. It is recommended that training sessions focused on safe surgery principles, the checklist's goals, and teamwork requirements be held for all surgical team members by the management.

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Conflicts of interest

The authors declare that there is no conflict of interest.

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Authors' Contributions

Sima Sadat Hejazi, Nasrin Kamali and Sanaz Keyvanlu performed study conception and design. Amir Hossein Vatandust and Nasrin Kamali performed data collection. Sima Sadat Hejazi contributed in analysis and interpretation of the data. Nasrin Kamali and Iman Vasifeparast drafted the initial manuscript. All authors reviewed the results and approved the final version of the manuscript.

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