IS IMPLEMENTATION OF WHO SURGICAL SAFETY CHECKLIST (2009) WILL REDUCE THE RATE OF MAJOR POST OPERATIVE COMPLICATIONS AT ZAGAZIG UNIVERSITY HOSPITAL? (AN INTERVENTION STUDY)

Amany R. Aboel-Seoud, Fadia E. El-Sabbagh, Yehia M. Zakaria * and Mona H. Ibrahim
*Departments of Public Health and General surgery *, Faculty of Medicine, Zagazig University*

ABSTRACT

Background: Surgical care is associated with a considerable risk of complications and death that represents a substantial burden of disease worthy of attention from the public health community worldwide. A surgical checklist is an inexpensive tool that will facilitate effective communication and teamwork to prevent patient harm. **Aim & Objectives:** This study aims to improve the safety of surgical care to decrease morbidity and mortality associated with surgery at Zagazig University Hospital through the following objectives: 1- To assess the performance of surgical team (surgeons, anesthetists and nurses) about surgical safety before and after intervention. 2- To assess the incidence of major post-operative complications before and after intervention. 3- To assess surgical team attitude about patient safety in operating rooms (OR) before and after intervention. 4-To increase the awareness for all surgical team about surgical safety to decrease post operative complications. **Subjects & Methods:** an interventional study was conducted in general surgery department of Zagazig University Hospital during the Academic year 2012-2014. Comparing 157 patients before and 157 patients after intervention who are 16 years of age or older undergoing inpatient major surgical operation were consecutively enrolled in the study and all surgical teams (surgeons, anesthetists and nurses) of the selected group were included during the period of the study. The study was carried out through 3 phases. **Results:** Results of this study showed that there was a high statistically significant reduction in 30 days major post-operative complications after implementation of WHO surgical safety checklist, the total number of complications decreased from 50.96% to 27.39% ($p = 0.0001$), in-hospital mortality decreased from 3.18% to 0% ($p = 0.02$). There was statistical significant improvement of surgical team attitude about OR surgical safety after intervention ($p<0.05$), there was high statistical significant negative correlation between physician and nurse coordination and occurrence of postoperative complications($r= -0.27$) ($p<0.05$). The checklist was considered easy to use by 94.6% of physicians, 62% of nurses. **Conclusion:** In conclusion, this study revealed that a relatively simple education program for implementation of WHO surgical safety checklist was associated with reduction in major post-operative complications and mortality in a hospital with a high standard of care. It is recommended to use the Surgical Safety Checklist in all operative procedures.

Keywords: patient safety, surgical safety checklist, post operative complications, operation room, safety attitude

INTRODUCTION

Surgical care is an integral part of health care throughout the world, with an estimated 234 million operations performed annually [(1)]. The World Bank reported that an estimated 164 million disability-adjusted life years, representing 11% of the entire disease burden, were attributable to surgically treatable conditions [(2)].

Although surgical care can prevent loss of life or limb, it is also associated with a considerable risk of complications and death. The risk of complications is poorly characterized in many parts of the world, but studies in industrialized countries have shown a perioperative rate of death from inpatient surgery of 0.4 to 0.8% and a rate of major complications of 3 to 17% [(3,4)]. These rates are likely to be much higher in developing countries [(5, 6)].

A systematic review has shown that 1 in every 150 patients admitted to a hospital dies as a result of an adverse event, and almost two-thirds of in-hospital events are related to surgical care [(7)].

Data suggest that at least half of all surgical complications are preventable [(4)]. The majority of these are not caused by technical problems but a failure of teamwork skills, leadership, communication, decision-making and situational awareness [(8, 9)].

Previous efforts to implement practices designed to reduce surgical site infections or anesthesia related mishaps have been shown to reduce complications significantly [(10, 11)].

So World Health Organization (WHO) designed the Surgical Safety Checklist (SSC). This is a 19-item checklist designed to improve communication between the operating team and provide a

minimum standard of care that reduces complications and deaths associated with surgery [12].

The Safe Surgery Saves Lives Study Group at the WHO analyzed the effects of the SSC on a global scale in eight hospitals in both developed and non-developed countries which demonstrated that use of a simple checklist can substantially and significantly reduce risk of morbidity and mortality associated with surgery [13].

Previous studies have shown that use of a comprehensive surgical checklist enhances communication and reduces postoperative complications and death [13, 14].

Aim: to improve the safety of surgical care to decrease morbidity and mortality associated with surgery in Zagazig University Hospital through the following **objectives:** 1- To assess the performance of surgical team (surgeons, anesthetists and nurses) about surgical safety before and after intervention. 2- To assess the incidence of major post-operative complications before and after intervention.3- To assess surgical team attitude about patient safety in operating rooms (OR) before and after intervention. 4- To increase the awareness for all surgical team about surgical safety to decrease post-operative complications.

SUBJECTS AND METHODS

I. Technical design:

Study design: An interventional study was conducted at General Surgery Department, Zagazig University Hospital during the period 2012-2014.

Target groups:

A) Patients who are 16 years of age or older undergoing inpatient major surgical operation at General Surgery Department were included in the study during the period of study (Gasterointestinal, vascular, cancers and etc……..).

B) All surgical teams (surgeons, anesthetists and nurses) of the selected group were included during the period of the study.

Exclusion criteria:

1) Patients less than 16 years of age.
2) Surgeries done at emergency department or at outpatient clinic.
3) Patients with post operative hospital stay less than 24 hours.
4) Special surgeries as (cardiothoracic, neurosurgeries, orthopedics, or urology surgeries).

Sample size and population:

The sample size was estimated using an incidence rate of surgical site infection in Egypt 28.5% [15] and expected to be decreased by 50% to reach 14.5% at 95% confidence interval, power of 80%, allowing for non response rate of 7.5%, so the sample size was calculated to be **314** patients; (**157)** patients before intervention and **(157)** after intervention. The cases were taken sequentially till the whole number reached.

The general surgery department is divided into 3 groups (A, B and C) one of them was selected randomly which was group (A) as it is a general group has wide diversity of operations, All surgical teams of the selected group A (**36 surgeons, 20 anesthetists;** in different positions like professors, assistant professors, lecturers, assistant lecturers and residents **and 29 nurses)** were included during the period of the study.

II. Operational design:

A. Data collection: 3 phases

1st phase (pre intervention):6 months (from December 2012 to May 2013).

Activities:

** **Structured questionnaire**: was used to collect data from 157 patients fulfilling inclusion criteria who were admitted to hospital at the study period about the following: the demographic characteristics of patients including age and sex; type of surgical procedure, type of anesthetic used, history of chronic diseases and previous surgery; duration of hospital stay and post- operative complications.

** **WHO surgical safety checklist 2009:** After collecting base line data about every patient included in the sample, the 19-item WHO safe surgery checklist 2009 was used by the researcher to assess the operating staff performance ***(appendix I)***

- Group A surgical unit has inpatient surgery list on Monday weekly and Wednesday every other week. So operating rooms were visited in these days by the researchers to assess the operating staff performance.
- The checklist was translated into Arabic language and was adjusted to fit into the flow of care at the institution.
- Each patient was followed up in general surgery department yard after operation until discharge or for 30 days, whichever came first, to record incidence rate of death and/or complications. Outcomes were identified through daily monitoring of patient's chart and communication with surgical staff. Completed data forms were stripped of direct identifiers of patients.

** **Operating-room version Safety Attitudes Questionnaire (SAQ):** it is a validated instrument used to measure attitudes and perceptions in

various safety-related domains in healthcare [16]. A modification has been developed for use in the operating rooms (OR), to assess surgical team attitude about surgical safety in OR with more concentration on the following six statements that are most likely relevant to the checklist intervention [17]. These items were: 'I would feel safe being treated here as a patient', 'Briefing OR personnel before a surgical procedure is important for patient safety,' 'I am encouraged by my colleagues to report any safety concerns I may have', 'In the ORs here, it is difficult to speak up if I perceive a problem with patient care', 'The physicians and nurses here work together as a well-coordinated team', and 'Surgical team frequently disregards rules or guidelines that are established for the OR'.

A panel of experts in surgical patient safety developed six additional items specifically related to the intervention [17]: The checklist was easy to use; the checklist improved OR safety; the checklist took a long time to complete; if i were having an operation, i would want the checklist to be used; communication was improved through use of the checklist; and the checklist helped prevent errors in the OR. Responses to these items were not included in the calculation of the mean Safety Attitude Questionnaire (SAQ) score.

Score calculation of SAQ (OR version) questionnaire:

- ✓ All responses were recorded on a five point Likert scale**:** (1- Disagree strongly= **0%,** 2-disagree = **25%**, 3- neutral= **50%**, 4- agree= **75%** and **5**- agree strongly= **100%**)**.**
- ✓ Two items (negative statements) were **reverse-scored** to calculate summary statistics.
- ✓ Then disagree strongly and disagree collected together which represent negative safety attitude (≤ 25%), agree and agree strongly collected together which represent positive safety attitude (≥ 75%).

2nd (intervention phase):1month

Activities:

Training of surgical team how to implement and use WHO surgical safety checklist 2009 in operating rooms to improve practice within institution by using: **1-** Arabic booklet to all surgical teams in general surgery operating rooms which contain facts about surgery, how to implement WHO surgical safety checklist correctly step by step and the importance of this checklist in complications prevention. **2-** The WHO surgical safety checklist 2009 was printed and disseminated to all operating rooms as Arabic and English posters so that staff members could become familiar with the details also distributed as hand out to all surgical team. **3-** Lectures (power point) presentation 1-2 session weekly, group discussion and training video was produced detailing the correct and incorrect way to perform the checklist. It covered the importance of checklist and how to implement it correctly.

3rd phase (post intervention):6 months (from July 2013 to December 2013)

Activities: the same activities as 1st phase.

- Recollect data from another 157 patients and reassess postoperative complications and/or death after implementation of WHO surgical safety checklist.
- Reassess the performance and level of commitments of surgical team to WHO surgical safety checklist implementation.
- Reassess surgical team attitude about surgical safety in OR

Outcomes:

A) Incidence of any major postoperative complication, including death, the primary end point was the occurrence of any major complication, including death, during the period of postoperative hospitalization, up to 30 day. Complications were defined by the American College of Surgeons' National Surgical Quality Improvement Program [18]. Acute renal failure, bleeding requiring the transfusion of 4 or more units of red cells within the first 72 hours after surgery, cardiac arrest requiring cardiopulmonary resuscitation, coma of 24 hours' duration or more, deep vein thrombosis, myocardial infarction, unplanned intubation, ventilator use for 48 hours or more, pneumonia, pulmonary embolism, stroke, major disruption of wound, infection of surgical site, sepsis, septic shock, the systemic inflammatory response syndrome, unplanned return to the operating room, vascular graft failure, and death.

B) Percentage of adherence to six safety measures as an indicator of good performance: The six measures are the objective evaluation and documentation of:

1. The status of the patient's airway before administration of the anesthetic;
2. The use of pulse oximetry at the time of initiation of anesthesia;
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 preexisting 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 is made.

III. Administrative design and Ethical issues:

An official permission from Zagazig University, Faculty of medicine, General Surgery Department was taken. The title and objectives of this study was explained to them to insure their cooperation. The local authority and manager of General Surgery Department, Zagazig University Hospital was informed about the nature and steps of the study and written consent was taken. The study group was informed about the nature and the purpose of the study and verbal consent was taken before interview. The study group was not exposed to any harm or risk. Patient's data was confidential.

IV. Data management:

The collected data were computerized and statistically analyzed using SPSS program (Statistical Package for Social Science) version 16 [19] and **Epi-info** (Epidemiological Information Package) soft ware version 6.04 [20]. For the statistical calculations data coding was done, qualitative data were represented as frequencies and percentages, Chi-square test (χ^2) and Z-test of proportion was carried out for testing the association between the qualitative data whenever possible. Quantitative data were compared using student's t-test and Mann-Whitney test and paired t test. The Spearman correlation coefficients (r) were used to estimate association between changes in mean safety attitude score versus relative reduction in complications. The test results were considered significant when p-value **<0.05** and all p values were two-tailed.

RESULTS

- **Characteristics, preoperative risk factors and operative details of the studied patients:**

Results of this study showed that there were 157 patients during the pre-intervention period; (47.8%) males and (52.2%) females were enrolled respectively. The mean age of studied patients was (46.5±15.18) years old. There were 157 patients during the post-intervention period; (49%) males and (51%) females were enrolled respectively. The mean age of studied patients was (43.84±14.1) years old respectively with no statistical significant difference between them**.** Also there were no statistical significant differences between patients before and after intervention as regard co-morbid risk factors (diabetes mellitus, hypertension and cardiac problems) (p>0.05).

Regarding the mean length of hospital stay and mean length of post-operative hospital stay (days); the pre-intervention group was (10.76±9.94 and 6.53±5.9) days respectively; and that of the post-intervention group was (10.29±9.85 and 6.03±4.96) days respectively with no statistical significant difference between them. Regarding type of anesthesia used; it was found that general anesthesia most commonly used in both groups (82.17% and 84.71%) respectively with no statistical significant difference (p>0.05).

Concerning type of surgical procedures performed; it was found that the most common procedures done were gastrointestinal and vascular procedures during pre intervention group (47.13% and 24.20%) and also during post-intervention one (36.94% and 22.93%) respectively with no statistical significant difference between them.

- **Post-operative morbidity and mortality of studied patients before and after SSC implementation:** The present study reported that surgical site infection (SSI) (p=0.001), pneumonia (p=0.002), bleeding need more than 4 units of blood (p<0.0001) and unplanned return to OR (p=0.006) were significantly lower among post-intervention group than pre-intervention group**.** The proportion of patients who had ≥ 2 complications were significantly declined post-intervention (from 29.30 % to 18.47 %) respectively (p=0.024) and the overall complications decreased from 50.96% in the pre-intervention group to 27.39% in the post intervention group (p<0.0001). Meanwhile there were no significant differences between the two groups regarding DVT/pulmonary embolism and ICU/ventilator use ≥48 hours **(table 1).** Concerning post-operative mortality; it was found that there was statistical significant reduction in death rate from 3.18% pre-intervention to 0% post-intervention (P=0.02) **(table 1).**

- **Assessment of surgical team performance (surgeons, anesthetists and nurses) before and after surgical safety checklist implementation:**

This study showed that most items of "**sign-in"** (before induction of anesthesia by nurse and anesthetist) increased after intervention specially oral confirmation of: site of surgery (60.51%), type of procedure (96.18%), consent (82.80%),

anesthesia safety check (98.73%) and estimation of risk of blood loss >500 ml (100%) which were significantly higher among post-intervention group **(p<0.01)**; meanwhile there was no statistical significant differences between them as regard patient identity (99.36%; 100%), pulse oximeter functioning (99.36%; 100%) and airway assessment (98.73; 100%) which were high in both groups and site of surgery marking was low in both groups (8.92%; 14.01%) at pre-intervention and pos-intervention estimation respectively (p>0.05) **(Table 2).**

Concerning completion of **"time-out"** items (immediately before skin incision by surgeon, anesthetist and nurse): It was found that the majority of items increased after intervention specially confirmation of patient identity (8.28%; 19.11%), site of surgery (19.11; 59.24), type of procedure (57.32; 92.36), timely administration of prophylactic antibiotic (13.38%; 56.69), surgeon reviewing operative duration (0%; 12.74%), anticipated blood loss (3.82%; 40.76%), anesthesia team reviewing patient specific concern (3.18%; 10.19%) and nurse reviewing any equipment issues (1.27%; 22.93%) which were significantly higher among post-intervention group (p<0.0001) **(table 3).**

Regarding completion of **"sign-out"** items (before patient leaving operating room by surgeon, anesthetist and nurse); this study found that there was high statistical significant difference between the two groups as regarding addressing any equipment problems (38.22%; 89.81%) and reviewing key concerns of patient recovery and management (5.73%; 14.01%) respectively which were significantly higher among post-intervention group (p<0.01); meanwhile there were no statistical significant difference between them as regarding recording the name of procedure and the specimen labeled which were low in both groups; correct count of instrument, sponge and needles which were high in both groups **(Table 4).**

Regarding the selected 6 safety process measures before and after implementation: this study showed that proper administration of the prophylactic antibiotic; oral confirmation of patient's identity and operative site were significantly higher among post-intervention group compared to pre-intervention one (p=0.0001); however there were no statistical significant difference between them as regard objective airway evaluation performed, pulse oximeter used, two peripheral or one central IV catheter present at incision when EBL ≥ 500ml and sponge count completed **(Table 5).**

- **Demographic characteristics of the surgical team:**

The studied surgical team consisted of 56 physicians and 29 nurses; 47.06% males and 52.94% females; their mean ages were 35.15±7.8 years old with range from (26-63) years old. Regarding to their specialty; there were 34.12% surgical staff, 23.53% anesthetists, 8.24% surgical residents and 34.12% nurses. Their median years of work in hospital were 12 (1-35) years and 10 (1-35) years of work experience in the current specialties.

- **Modified surgical safety attitude questionnaire (SAQ) in OR:**

This study showed changes of surgical teams' attitude about operating room safety pre- and post-intervention. There was statistical significant improvement of surgical team attitude after intervention as shown in **(Table 6).**

- **Surgical team opinion about the checklist use post-intervention**:

When comparing opinion about checklist use between physicians and nurses; it was found that they shared the same positive attitude about the utilization of the checklist; nurses had statistically significant positive attitude about surgical safety checklist use in comparison to physicians. They agreed with the statements of "communication was improved through use of the checklist "and" The checklist helped prevent errors in the operating room" (82.76%) respectively, meanwhile physicians had statistically significant positive attitude about easy use of the checklist (94.64%) and not take long time to complete (60.72%) (p<0.001). All physicians (100%) agreed on the statement of "if I were having an operation, I would want the checklist to be used".

Regarding relationship between change in safety attitude of surgical team and 30-day post-operative complications: This study showed that there were high statistical significant negative correlation between physician and nurse coordination and occurrence of postoperative complications (r= - 0.27) (p<0.01**),** however there were no statistical significant correlation between other safety attitude items of surgical team and postoperative complications .

Table (1): 30 days post-operative complications before and after checklist implementation.

Complications	Pre-intervention (N.=157)		Post-intervention (N.=157)		Z- test of proportion	p value
	N.	%	N.	%		
• **Surgical site infection (SSI)**	39	24.84	16	10.19	3.41	**0.0006***
• **Respiratory (**Pneumonia)	14	8.92	2	1.27	3.08	**0.002***
• **DVT**/Pulmonary embolism**	3	1.91	2	1.27	0.45	0.65
• **ICU**&Ventilator use ≥48 hours**	18	11.46	14	8.92	0.75	0.45
• **Bleeding need > 4 blood units**	47	29.94	20	12.74	3.71	**0.0002***
• **Unplanned return to the OR****	12	7.64	2	1.27	2.73	**0.006***
• **Death**	5	3.18	0	0.0	2.25	**0.02***
• **Others**	20	12.74	10	6.37	1.92	0.055
• **≥ 2 complications**	46	29.30	29	18.47	2.25	**0.024***
• **Total complications**	80	50.96	43	27.39	4.28	**0.0001***

***Statistically significant**

NB: *DVT*: deep venous thrombosis, ***ICU: intensive care unit, ***OR:*** operating room.

Table (2): Items of checklist about "sign in" completion before and after intervention.

"Sign in" items	Pre-intervention (N.=157)		Post-intervention (N.=157)		Z- test of proportion	p value
	N.	%	N.	%		
• **Patient has confirmed:**	156	99.36	157	100.00	1.0	0.32
-Identity	16	10.19	95	60.51	9.32	**0.0001***
- Site	30	19.11	151	96.18	13.82	**0.0001***
- Procedure	92	58.60	130	82.80	4.71	**0.0001***
- Consent						
• **Site marked**	14	8.92	22	14.01	1.42	0.16
• **Anesthesia safety check completed**	143	91.08	155	98.73	3.08	**0.002***
• **Pulse oximeter on patient and functioning**	156	99.36	157	100.00	1.0	0.32
• **Patient has a known allergy?**	145	92.36	151	96.18	1.46	0.14
• **Difficult airway/aspiration risk?**	155	98.73	157	100.00	1.42	0.16
• **Risk of > 500ml blood loss?**	150	95.54	157	100.00	2.68	**0.007***

***Statistically significant**

Table (3): Items of checklist about "time out" completion before and after intervention.

"Time out" items	Pre-intervention (N.=157)		Post-intervention (N.=157)		Z- test of proportion	p value
	N.	%	N.	%		
• **Confirm all team members have introduced themselves by name and role**	0	0.00	10	6.37	3.21	**0.001***
• **Surgeon, anesthesia professional and nurse verbally confirm:**	13	8.28	30	19.11	2.79	**0.0001***
- Patient	30	19.11	93	59.24	7.28	**0.0001***
- Site	90	57.32	145	92.36	7.15	**0.0001***
- Procedure						
• **Antibiotic prophylaxis been given within the last 60 minutes before incision**	21	13.38	89	56.69	8.04	**0.0001***
• **Essential radiological imaging displayed?**	151	96.18	155	98.73	1.43	0.15
Anticipated critical events						
❖ **Surgeon reviews:**	3	1.91	6	3.82	1.01	0.31
- The critical or unexpected steps.	0	0.00	20	12.74	4.62	**0.0001***
- Operative duration.	6	3.82	64	40.76	7.86	**0.0001***
- Anticipated blood loss.						
❖ **Anesthesia team reviews:**	5	3.18	16	10.19	2.48	**0.013***
- Are there any patient-specific concerns?						
❖ **Nursing team reviews:**	157	100.00	157	100.00	0	1
- Has sterilization been confirmed?	2	1.27	36	22.93	5.88	**0.0001***
- Are there equipment issues or any concerns?						

***Statistically significant**

Table (4): Items of checklist about "sign out" completion before and after intervention.

"Sign out" items	Pre-intervention (N.=157)		Post-intervention (N.=157)		Z- test of proportion	p value
	N.	%	N.	%		
❖ The name of the procedure recorded	26	16.56	38	24.20	1.68	0.09
❖ The instrument, sponge and needle counts are correct.	154	98.09	157	100.00	1.74	0.08
❖ The specimen is labeled	46	29.30	60	38.22	1.67	0.09
❖ There are any equipment problems to be addressed	60	38.22	141	89.81	9.52	**0.0001***
❖ Surgeon, anesthesia professional and nurse review the key concerns for recovery and management of this patient	9	5.73	22	14.01	2.46	**0.014***

***Statistically significant**

Table (5): Selected process measures before and after implementation of surgical safety checklist.

Process measures	Pre-intervention (N.=157)		Post-intervention (N.=157)		Z- test of proportion	p value
	N.	%	N.	%		
1- Objective airway evaluation performed	155	98.73	157	100.00	1.42	0.16
2- Pulse oximeter used	156	99.36	157	100.00	1.0	0.32
3- Two peripheral or one central IV catheter present at incision when EBL ≥ 500ml.	157	100.00	157	100.00	0	1
4- prophylactic antibiotics given appropriately	21	13.38	89	56.69	8.04	**0.0001***
5- Oral confirmation of patient's identity and operative site	86	54.78	126	80.25	4.82	**0.0001***
6- Sponge count completed	154	98.09	157	100.00	1.74	0.08
• All six safety indicators performed	122	77.71	141	89.81	2.91	**0.003***

NB: **EBL**: estimated blood loss **IV**: intravenous. ***Statistically significant**

Table (6): Comparison of surgical teams' attitude changes about operating room safety pre- and post-intervention.

Attitude items of operating room safety	Pre-intervention (N.=85)	Post-intervention (N.=85)	Paired t test	P value
	Mean score±SD	Mean score±SD		
• I would feel safe being treated here as a patient	30.3±27.3	31.5±25.3	0.29	0.77
• Briefing OR personnel before a surgical procedure is important for patient safety	79.12±22.8	83.8±15.3	1.6	0.12
• I am encouraged by my colleagues to report any safety concerns I may have	63.5±25.5	76.8±14.3	4.2	**0.0001***
• In the ORs here, it is difficult to speak up if I perceive a problem with patient care**	60.6±24.8	66.2±27.7	1.3	0.18
• The physicians and nurses here work together as a well coordinated team	42.9±24.6	58.2±23.3	4.2	**0.0001***
• Personnel frequently disregard rules or guidelines that are established for the OR**	46.5±28.9	56.2±27.5	2.3	**0.024***

***Statistically significant** ** **these statements reverse-scored.**

DISCUSSION

Patient safety is the absolute priority in every surgical procedure. Despite expertise, knowledge and skills, complications and errors nonetheless occur [21, 22]. An estimated 234 million major surgical operations are performed annually worldwide [1]. Nearly one in 10 in-hospital patients experience iatrogenic events and more than half of them occur within perioperative care [7].

As led by the airline industry, peri-operative services demand high organizational reliability and commitment for reduction of safety compromising events. The airline industry has a long history of checklist implementation to reduce risk and avoid catastrophic outcomes [23]. The purpose of the checklist is to prompt the operation room (OR) team to ensure that critical items in patient safety are not ignored or forgotten [24].

Results of this study showed that the pre-intervention group consisted of 157 patients, of whom 52.23% were females and 47.77% were males. Their mean age was 46.52±15.18 years old. The post-intervention group consisted of 157 patients, of whom 50.96% were females and 49.04% were males. Their mean age was 43.84±14.1 years old showed no statistical significant difference between the two groups (p>0.05). This was in agreement with **Haynes et al. (2009) [13]; De Vries et al. (2010-a) [25]; and Bliss et al. (2012) [23]** who found similar results. But this was in disagreement with **Askarian et al., (2011) [26]** who found that female patients significantly higher in post-intervention period. Preoperative co-morbidities of the studied patients showing no statistical significant difference between the two groups, these results were similar to **Askarian et al., (2011) [26]**and **Bliss et al., (2012) [23];** This showed that the two groups were matched so any difference between them in results will be due to the intervention done.

Regarding the mean length of hospital stay and mean Length of post-operative hospital stay (days); There were no statistical significant difference between the two groups**.** This was in agreement with **De Vries et al. (2010-a) [25]** and **Khorshidifar et al. (2012) [27].** The present study revealed that general anesthesia most commonly used in both groups (82.17% and 84.71%) respectively but with no statistical significant difference**; Haynes et al. (2009) [13]** found similar results.

Regarding type of surgical procedures performed; some differences between the pre-intervention and post-intervention groups were observed. It was found that the most common procedures done were gastrointestinal and vascular procedures during pre intervention and post-intervention groups with no statistical significant difference between them. There were similar results reported by **Askarian et al., (2011) [26] and De Vries et al., (2010-b) [28]** who found that there were no statistical significant differences between the two groups as regarding the surgical procedures. This was in contrast to results reported by **De Vries et al., (2010-a) [25]** who found that patients in the post-intervention group were more likely to undergo surgery for a gastrointestinal condition or for trauma and less likely to undergo surgery for a vascular condition (P<0.001). The patients were randomly enrolled in the study according to surgical list not due to specific research plan of the department or specific selection of the diseases.

Concerning 30 days post-operative complications before and after checklist implementation; the present study reported that SSI, pneumonia, bleeding need more than 4 units of blood and unplanned return to OR were significantly lower among post-intervention group than pre-intervention group**.** The overall complications decreased from 50.96% in the pre-intervention group to 27.39% in the post intervention group (p<0.0001). Meanwhile there were no significant differences between the two groups regarding DVT/pulmonary embolism and ICU/ventilator use ≥48 hours **(Table 1).**

These improvements may be due to the checklist use as it had items to prevent these complications however there were no improvement in other complications like DVT for example as WHO surgical safety checklist (2009) not comprehensive and can be modified to increase items as prophylactic anticoagulants to prevent these complications as in some checklists used in different studied [23, 25].

These results were in agreement with a multicentre study done by **Haynes et al., (2009) [13]** who found that overall complications declined from 11% to 7% after checklist (p<0.001), also SSI and unplanned return to OR were significantly lower among post-intervention group than pre-intervention group (p<0.001); **De Vries et al., (2010-a) [25]** found that the total number of complications decreased from 27.3% to 16.7% (P<0.001), SSI (p=0.006), pneumonia (p=0.004) and bleeding (p=0.001) were significantly decreased after checklist implementation; and

Weiser et al., (2010-a) [14] found that overall complications declined from 18.4% to 11.7% after checklist.

The proportion of patients who had ≥ 2 complications were significantly declined post-intervention (29.30 %; 18.47 %) (p=0.024) **(Table 1);** this was in agreement with **De Vries et al., (2010-a)** [25] who found that it was 15.4% in the pre-implementation period versus 10.6% in the post-implementation period (p<0.001); Similar results reported by **Rosenberg et al., (2012)** [29] who found that the total number of complications decreased from 15.1 to 2.72 after checklist implementation (p <0.0001); The proportion of patients with one or more complications decreased from 11.9% to 2.72% (p =0 .0006).

On the other hand, this was in disagreement with the study done by **Askarian et al., (2011)** [26] who found that although the overall complications declined from 22.9% to 10% after checklist (p<0.03) but on the other hand they found that SSI and pneumonia decreased by half but proved to be non statistically significant; **Bliss et al., (2012)** [23]**;** found reduction in overall adverse events from 23.6% for historical control cases and 15.9% in cases with only team training, to 8.2% in cases with checklist use (p=0.000) but on the other hand they found that SSI, bleeding requiring transfusion and pneumonia decreased but proved to be non statistically significant.

Regarding post-operative mortality; the present study reported that there was statistical significant reduction in death rate (P=0.02) **(Table 1)**. This was in agreement with **Haynes et al., (2009)** [13] and **De Vries et al., (2010-a)** [25] who found that the death rate declined from 1.5% to 0.8% (P = 0.003) with a relative improvement by 47%; it was reported by **Weiser et al. (2010-a)** [14] reduction of mortality from 3.7% to 1.4% with a relative improvement by 62%; **Neily et al.,(2010)** [30]**,** found that there was 18% reduction in annual mortality among the 74 facilities had the training program included checklists (p=0.01) compared with a 7% decrease among the 34 facilities that had not yet undergone training (p=0.59), and **Van Klei et al. (2012)** [31] reported that crude mortality decreased from 3.13% to 2.85% (P = 0.19), but after adjustment for baseline differences, mortality was significantly decreased after checklist implementation (odds ratio [OR] 0.85; 95% CI, 0.73–0.98).

Concerning compliance with the different components of the WHO surgical safety checklist which reflects the performance of the surgical staff: the present study reported that most items of **"sign-in"** increased after intervention specially oral confirmation of: site of surgery, type of procedure, consent, anesthesia safety check and estimation of risk of blood loss >500 ml which were significantly higher among post-intervention group **(p<0.01)**; meanwhile there were no statistical significant differences between them as regard patient identity, pulse oximeter functioning and airway assessment which were high in both groups and site of surgery marking was low in both groups at pre-intervention and pos-intervention estimation respectively **(Table 2).** These results similar to that of **Askarian et al. (2011)** [26] who found that pulse oximeter functioning and risk of blood loss >500 ml were in total compliance for the surgeries performed (100%) after intervention; **Bliss et al. (2012)** [23] found that most individual checklist components were completed by >90%, and also **Rosenberg et al. (2012)** [29] reported that site and side marking increased from 69.9% prechecklist to 97.8% (p<0.0001) and anticipation of estimated blood loss increased from 0% to 82.1% (p<0 .0001); also **Khorshidifar et al., (2012)** [27] **and Toor et al., (2013)** [32] reported similar results. In a study carried out by **Sayed et al. (2013)** [33]**;** reported that only 3% of all the patients had the operation site marked for surgery and an incident of a single wrong side surgery was recorded.

Site marking was still low after intervention may be due to limited resources as marking pens not available, may be reluctance from the surgeons or their assistances or had no time to do that due to work pressure.

Regarding completion of **"time-out"** items; it was found that the majority of items increased after intervention specially confirmation of patient identity, site of surgery, type of procedure, timely administration of prophylactic antibiotic, surgeon reviewing operative duration, anticipated blood loss, anesthesia team reviewing patient specific concern and nurse reviewing any equipment issues which were significantly higher among post-intervention group (p<0.0001) **(Table 3).** These results were in agreement with **Askarian et al., (2011)** [26] who found increase in all items of time-out (p=0.001); **Takala et al., (2011)** [34] reported that patient's identity was more often confirmed and also anesthetists and surgeons discussed critical events preoperatively more frequently done after the checklist (p <0.001); **Helmio et al.,**

(2011) [35] also reported that the knowledge of the names and roles among the team members improved. The anesthetists discussed possible critical events more often (P< 0.001); **Bliss et al., (2012)** [23] also found that site was marked and visible; relevant images properly labeled and displayed; any equipment concerns (100%); antibiotic prophylaxis within one hour before incision and sterilization indicators have been confirmed (95.9%) respectively after checklist implementation and also **Toor et al., (2013)** [32] reported that (11.7%) of team members introduced themselves by name and role; surgeons discussed critical steps in (58.3%) cases; anaesthetist reviewed specific patient concerns in (59.2%); nursing team reviewed sterilization in (71.8%) cases; and prophylaxis antibiotic was administered in (61.3%) cases within the final 60 minutes.

Although there were improvements in most items after checklist implementation, there some items percentages still low. This may be due to the permanent change need longer time, as change behavior needs several stages (perceive the importance of different checklist items are factors that influence checklist usage, knowledge and positive attitude about importance of change) specially hospital managers and administration to improve the safety culture.

Communication failure is one of the leading factors contributing to surgical errors and medical adverse events, including the wrong side / wrong site, wrong procedure and wrong patient [36, 37]**.** Use of standardized communication improves the information transfer process, with an effect on clinical and patient outcomes [38]**.** Although team introduction was significantly higher among post-intervention group (p=0.03) but still low in general **(Table 3)**, this may be due to it was viewed as redundant by staff in an environment in which everyone present was already known to others as they always work in definite groups.

Concerning completion of **"sign-out"** items; this study found that there was high statistical significant difference between the two groups as regarding addressing any equipment problems and reviewing key concerns of patient recovery and management which were significantly higher among post-intervention group (p<0.01); meanwhile there were no statistical significant difference between them as regard recording the name of procedure and the specimen labeled which were low in both groups and correct count of instrument, sponge and needles which were high in both groups (p>0.05) **(Table 4).** These results was similar to **Askarian et al., (2011)**[26] and **Toor et al., (2013)** [32]**.**

Regarding the selected 6 safety process measures before and after implementation: this study showed that proper administration of the prophylactic antibiotic; oral confirmation of patient's identity and operative site were significantly higher among post-intervention group compared to pre-intervention one (p=0.0001) **(Table 5).** This was in agreement with **Haynes et al., (2009)** [13] and **Askarian et al., (2011)** [26]; however there were no statistical significant difference between them as regard objective airway evaluation performed, pulse oximeter used, two peripheral or one central IV catheter present at incision when EBL ≥ 500ml and sponge count completed **(Table 5).** This was in contrast to results found by **Haynes et al., (2009)** [13] who reported that all items were significantly increased after checklist implementation (p<0.001)

The present study showed that the studied surgical team consisted of 47.06% males and 52.94% females; their mean ages were 35.15±7.8 years old with range from (26-63) years old. Regarding to their specialty; there were 34.12% surgical staff, 23.53% anesthetists, 8.24% surgical residents and 34.12% nurses. Their median years of work in hospital were 12 (1-35) years and 10 (1-35) years of work experience in the current specialties. These results were in agreement with **Eshun et al., (2013)** [39]**;** who found that the mean age of surgical team was 43.7±9.9 years old with range (24-64) years old; their mean years of work in medical field were 18.4±9.9 years and their mean years of work in the current specialties were 13.8±9.8 years.

Regarding surgical teams' attitude changes about operating room safety pre- and post-intervention; this study revealed that there was statistical significant improvement of surgical team attitude after intervention about the statements of "I am encouraged by my colleagues to report any safety concerns I may have", The physicians and nurses here work together as a well coordinated team" and "personnel frequently disregard rules or guidelines that are established for the OR" (p<0.05); while the improvement in the other three items did not reach statistical significance (p>0.05) **(Table 6).** These results were in agreement with **Haynes et al., (2011)** [17]**.**

Comparing opinion about checklist use between physicians and nurses; this study clarified that they

shared the same positive attitude about the utilization of the checklist; nurses had statistically significant positive attitude about surgical safety checklist use in comparison to physicians. They agreed with the statements of "communication was improved through use of the checklist "and" The checklist helped prevent errors in the operating room" (82.76%) respectively, meanwhile physicians had statistically significant positive attitude about easy use of the checklist (94.64%) and not take long time to complete (60.72%) ($p<0.001$). All physicians (100%) agreed on the statement of "if I were having an operation, I would want the checklist to be used" ($p<0.05$). These results were consistent with **Eshun et al., (2013) [39];** who reported that majority of nurses (>93%) viewed use of SSC positively. Similarly, in a study done by **Papaconstantinou et al., (2013) [40] and Helmio et al., (2012) [41]** it was found that checklist-related attitudes were mostly positive

The present study revealed that there were high statistical significant negative correlation between physician and nurse coordination and occurrence of postoperative complications ($r= - 0.27$) ($p<0.01$**),** however there were no statistical significant correlation between other safety attitude items of surgical team and postoperative complications ($p>0.05$)**.** These results were in agreement with **Haynes et al., (2011) [17];** who reported that there was relative reduction in complications in relation to change in mean safety attitude score at the studied sites after intervention.

CONCLUSION

In conclusion, this study revealed that a relatively simple education and training program for implementation of WHO surgical safety checklist was associated with reduction in major post-operative complications and mortality in a hospital with a high standard of care.

RECOMMENDATIONS

To reach an optimal level of patient safety in the OR, it is recommended that the checklist should be implemented as part of the daily surgical routine and encourages its use in all surgical operations and in other hospitals; provide surgical safety checklist posters and brochures, which include measures on patient safety, especially in the operating rooms; rules and guidelines for the operating rooms safety should be strictly implemented, the importance of positive safety culture without blame, encouraging better communication and teamwork between members of surgical teams; on-going training and education of all surgical staff about safety measures, increasing commitment of the theatre team in the checklist process and demonstrating support for checklist adherence from senior personnel; increasing number of nursing staff with adequate education and training to cope with the work load in Zagazig University Hospitals; continuous managerial monitoring and evaluation of surgical team performance; encouraging notification of unsafe maneuvers in OR; it is recommended to modify the WHO checklist to cope with the hospital; like removing the questions about pulse oximeter as it is used routinely in all operations and availability of radiological images as it present nearly in all cases; also adding items to prevent complications such as DVT/pulmonary embolism like giving pre-operative anti-coagulants or mechanical maneuvers; further studies are needed to cover all surgical departments in the different hospitals in Egypt. Further studies including control groups.

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Appendix I

قائمة التحقق من السلامة فى العمليات الجراحية لمنظمة الصحة العالمية 2009

اسم المريض : السن: اسم العملية:

قبل البدء بتخدير المريض **(بواسطة ممرض واحد واخصائى تخدير)**	**قبل اجراء الفتح (الشق) الجراحى** **(بواسطة ممرض واخصائى تخدير وجراح)**	**قبل مغادرة المريض غرفة العمليات** **(بواسطة ممرض واخصائى تخدير وجراح)**
هل اكد المريض : ☐ اسمه ☐ نوع الجراحة (العملية) ☐ مكان العملية ☐ موافقته على العملية	☐ **تأكيد ان جميع اعضاء الفريق قد قدموا أنفسهم وذكروا أسماءهم وأدوارهم** ☐ **تأكيد اسم المريض ونوع العملية وموضع العملية**	**يؤكد الممرض ما يلى شفهيا:** ○ **اسم العملية الجراحية.** ○ **اكتمال عدد الأدوات والشاش والابر.** ○ **كتابة بيانات العينات** (يجب قراءة محتوى بطاقة بيانات العينات بصوت مسموع بما فى ذلك اسم المريض). ○ **وجود اى مشاكل فى المعدات يتعين حلها.**
هل وضعت علامة على مكان الجراحة؟ ☐ نعم ☐ لا ينطبق	**هل أعطى المريض المضاد الحيوى الوقائى خلال 60 دقيقة السابقة؟** ☐ نعم ☐ لا ينطبق	
هل تم التحقق من اجهزة وادوية التخدير؟ ☐ نعم	**استباق الأحداث الحرجة** **اسئلة تطرح على الجراح:** ☐ **ما الخطوات الحرجة او الغير روتينية؟** ☐ **ما المدة التى ستستغرقها العملية** ☐ **ما كمية الدم المتوقع فقدانها؟**	**سؤال يطرح على الجراح واخصائى التخدير والممرض:** ☐ **ماهى الاعتبارات الأساسية المتعلقة بافاقة المريض والتدبير العلاجى لحالته؟**
هل تم توصيل جهاز قياس التأكسج النبضى (pulse oxymeter) بجسم المريض والتأكد من انه يعمل؟ ☐ نعم	**سؤال يطرح على أخصائى التخدير:** ☐ هل هناك اى محاذير محددة بخصوص المريض؟ **اسئلة تطرح على فريق التمريض:** ☐ **هل تم التأكد من التعقيم (بما فى ذلك نتائج مؤشر جهاز التعقيم).** ☐ **هل هناك مشاكل فى المعدات او اية محاذير اخرى؟**	
هل يعانى المريض مما يلى: • **حساسية معروفة** ☐ نعم ☐ لا • **صعوبة فى الطرق التنفسية او خطر حدوث استنشاق** ☐ لا ☐ نعم، ومعدات المساعدة متاحة • **خطر فقدان كمية من الدم اكبر من 500 ملليليتر** ☐ لا ☐ نعم، وتم تركيب قسطرتين وريديتن / او واحدة مركزية لاعطاء السوائل	**هل صور الأشعة الضرورية معروضة؟** ☐ نعم ☐ لا ينطبق	