

The Effect of a Modified World Health Organization Surgical Safety Checklist on Postoperative Complications in a Tertiary Hospital in Iran, 2012

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ABSTRACT

Objective: The aim of this study is to modify the World Health Organization (WHO) Surgical Safety Checklist in order to be compatible to a hospital in Iran and measure effect of implementing this checklist on postoperative complications. **Methods:** In a cross-sectional study the views of surgeons and anesthesiologists of the main teaching hospital in Tabriz -Imam Reza Hospital- were taken by a form attached to the main checklist. The participants in this study asked to write their opinions on each item of checklist based on the environment of the hospital. Then, we performed before-after study to determine effect of a modified checklist implementing on postoperative complications. **Results:** Surgeons and anesthesiologists had consensus on 15 of 19 items of checklist to remain the same and just 4 items recommended to be changed. In pre intervention period of study, 100 patients (51 males and 49 females) were enrolled with the mean age of 48.5±13.5 years. The number of patients in the post intervention period was the same, but 49 males and 51 females, the mean age was 47.5 ±14.6 years. The incidence of any complications in pre intervention period was 30%, but this rate in post intervention period was 12% and the difference between 2 periods of study was statistically significant (p=0.002). **Conclusion:** World Health Organization Surgical Safety Checklist is better to modify based on the local needs and facilities in each hospital. After implementing of a modified surgical safety checklist, complications decreased by 58%.

Key words: Patient safety, surgical checklist, surgical complications, WHO

Modifiye Dünya Sağlık Örgütü Cerrahi Güvenlik Kontrol Listesinin İran Üçüncü Basamak Bir Hastanede Postoperatif Komplikasyonlar Üzerine Etkisi, 2012

ÖZET

Amaç: Bu çalışmanın amacı Dünya Sağlık Örgütü (WHO) Cerrahi Güvenlik Kontrol Listesinin İran'da bir hastaneye uyumlu hale getirelmesi ve postoperatif komplikasyonlarda bu kontrol listesinin uygulama etkisini ölçmektir. **Yöntem:** Tebriz -Emam Reza Eğitim Hastanesinde cerrah ve anesteziist görüşlerinin kesitsel bir çalışmada ana kontrol listesine bağlı bir form tarafından alınmıştır. Bu çalışmada katılımcıların hastanenin ortama göre kontrol listesinin her bir öge üzerinde görüşlerini yazmaları istendi. Daha sonra biz postoperatif komplikasyonlar üzerinde modifiye kontrol listesi uygulamasının etkisini belirlemek için cerrahi önce ve sonrası uyguladık. **Bulgular:** Cerrahlar ve anesteziistler kontrol listesinin 19 maddesinin 15'inde görüş birliğine sahipti ve sadece 4 ünün değiştirilmesi tavsiye edildi. Çalışmanın müdahale öncesi döneminde yaş ortalaması 48.5±13.5 yıl olan 100 hasta (51 erkek ve 49 kadın) alındı. Müdahale sonrası dönemde hasta sayısı aynıydı. Bunların yaş ortalaması (49 erkek ve 51 kadın) 47.5±14.6 yıl idi. Müdahale öncesi dönemde herhangi bir komplikasyon oranı %30 idi, fakat müdahale sonrası dönemde bu oran %12 idi ve çalışmanın 2 dönem arasındaki fark istatistiksel olarak anlamlı idi (p= 0.002). **Sonuç:** Dünya Sağlık Örgütü Cerrahi Güvenlik Kontrol Listesi her hastanede yerel ihtiyaçlara ve tesislerin imkanlarına göre değiştirmek daha iyidir. Modifiye cerrahi güvenlik kontrol listesinin uygulanması sonrasında komplikasyonlar% 58 oranında azalmıştır.

Anahtar kelimeler: Hasta güvenliği, cerrahi kontrol listesi, cerrahi komplikasyonları, WHO

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INTRODUCTION

Complications of surgical care have become a major cause of death and disability worldwide, Data from 56 countries showed that in 2004 the annual volume of major surgery was an estimated nearly one operation annually for every 25 human beings alive(1,2). This is a large volume with significant implications for public health(3). In industrialized countries the rate of major complications has been documented to occur in 3-22% of inpatient surgical procedures, and the death rate 0.4-0.8% (4,5). Nearly half the adverse events in these studies were determined to be preventable. Studies in developing countries suggest a death rate of 5-10% associated with major surgery (6,7). Despite dramatic improvements in surgical safety knowledge, at least half of the events occur during surgical care (4,5). In May 2004, the world health organization (WHO) approved the creation of an alliance to improve patient safety globally; WHO Patient Safety was launched the following October. For the first time, heads of agencies, policy-makers and patient groups from around the world came together to advance accomplishment of the goal of "First, do no harm" and to reduce the adverse events of unsafe health care. The goal of WHO Patient Safety is to help patient safety policy and practice. Designing tools for improvement of patient safety including surgical safety checklist was one of their actions. Together these efforts could save millions of lives by improving basic health care. Surgical care is complex and involves dozens of steps which must be optimized for individual patients. In order to minimize unnecessary loss of life and serious complications, operating teams have 10 basic, essential objectives in any surgical case, which the WHO safe surgery guidelines support. Ten essential objectives included: Objective 1: The team will operate on the correct patient at the correct site, Objective 2: The team will use methods known to prevent harm from administration of anaesthetics, while protecting the patient from pain, Objective 3: The team will recognize and effectively prepare for life-threatening loss of airway or respiratory functions, Objective 4: The team will recognize and effectively prepare for risk of high blood loss, Objective 5: The team will avoid inducing an allergic or adverse drug reaction for which the patient is known to be at significant risk, Objective 6: The team will consistently use methods known to minimize the risk for surgical site infection, Objective 7: The team will prevent inadvertent retention of instruments and sponges in surgical wounds, Objective 8: The team will secure and

accurately identify all surgical specimens, Objective 9: The team will effectively communicate and exchange critical information for the safe conduct of the operation, Objective 10: Hospitals and public health systems will establish routine surveillance of surgical capacity, volume and results. Regarding these 10 objectives, WHO surgical safety checklist covered 3 surgical stages -before anesthesia, immediately before an incision, and before moving the patient to a recovery room respectively SINE IN, TIME OUT and SIGN OUT parts (1). Between October 2007 and September 2008, eight hospitals in eight cities (Toronto, Canada; New Delhi, India; Amman, Jordan; Auckland, New Zealand; Manila: Philippines; Ifakara, Tanzania; London, England; and Seattle, WA) participated in the World Health Organization's Safe Surgery Saves Lives program. Implementation of the checklist was associated with reductions in the rates of complications among patients at least 16 years of age who were undergoing noncardiac surgery (8). In 2011, application of surgical safety checklist in Shiraz, Faghihy hospital decreased complications after Implementation of the checklist (9).

The Checklist should be modified to account for differences among hospitals according to their processes and the culture of their operating rooms. Modification of the Checklist should be done critically. Surgeons and anesthesiologists should be involved in the modification process(1). Tabriz Imam Reza hospital is a referral and the largest specialty and subspecialty hospital in Northwest of Iran. Considering benefits of WHO surgical safety checklist and importance of clinical governance which patients safety is one of its key components, we decided to modify WHO surgical safety checklist to fit with Tabriz Imam Reza hospital conditions for application in this hospital and determine the efficacy of this modified checklist in patient care.

MATERIAL AND METHODS

The First stage of this investigation was cross-sectional study which carried out in June 2012, in Tabriz Imam Reza hospital, tertiary teaching and referral and the largest hospital in Northwest of Iran. This hospital has three main general surgery operation units and almost all kinds of general surgery operations have been done in this hospital. Eight anesthesiologists and eleven surgeons are the main directors of operating rooms in different shifts in a year. These 19 academic members took part in this study. The first edition of WHO surgical safety checklist

Surgical Safety Checklist



Patient Safety
A World Alliance for Safer Health Care

Before induction of anaesthesia	Before skin incision	Before patient leaves operating room
(with at least nurse and anaesthetist)	(with nurse, anaesthetist and surgeon)	(with nurse, anaesthetist and surgeon)
<p>Has the patient confirmed his/her identity, site, procedure, and consent?</p> <input type="checkbox"/> Yes	<input type="checkbox"/> Confirm all team members have introduced themselves by name and role.	<p>Nurse Verbally Confirms:</p> <input type="checkbox"/> The name of the procedure
<p>Is the site marked?</p> <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable	<input type="checkbox"/> Confirm the patient's name, procedure, and where the incision will be made.	<input type="checkbox"/> Completion of instrument, sponge and needle counts
<p>Is the anaesthesia machine and medication check complete?</p> <input type="checkbox"/> Yes	<p>Has antibiotic prophylaxis been given within the last 60 minutes?</p> <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable	<input type="checkbox"/> Specimen labelling (read specimen labels aloud, including patient name)
<p>Is the pulse oximeter on the patient and functioning?</p> <input type="checkbox"/> Yes	<p>Anticipated Critical Events</p> <p>To Surgeon:</p> <input type="checkbox"/> What are the critical or non-routine steps? <input type="checkbox"/> How long will the case take? <input type="checkbox"/> What is the anticipated blood loss?	<input type="checkbox"/> Whether there are any equipment problems to be addressed
<p>Does the patient have a:</p> <p>Known allergy?</p> <input type="checkbox"/> No <input type="checkbox"/> Yes	<p>To Anaesthetist:</p> <input type="checkbox"/> Are there any patient-specific concerns?	<p>To Surgeon, Anaesthetist and Nurse:</p> <input type="checkbox"/> What are the key concerns for recovery and management of this patient?
<p>Difficult airway or aspiration risk?</p> <input type="checkbox"/> No <input type="checkbox"/> Yes, and equipment/assistance available	<p>To Nursing Team:</p> <input type="checkbox"/> Has sterility (including indicator results) been confirmed? <input type="checkbox"/> Are there equipment issues or any concerns?	
<p>Risk of >500ml blood loss (7ml/kg in children)?</p> <input type="checkbox"/> No <input type="checkbox"/> Yes, and two IVs/central access and fluids planned	<p>Is essential imaging displayed?</p> <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable	

This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged. Revised 1 / 2009

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which is available in English and Farsi versions (free to download) (1) was used in this study. WHO surgical safety checklist have been shown in Figure 1. The surgeons and anesthesiologists were asked to read the Farsi checklist and suggest any change considering the environment of Imam Reza hospital in order to make the checklist compatible to the local needs. A sheet including an explanation about WHO surgical safety checklist along with all checklist items with options, remain the same and have changed, and a blank space after each item was given to the surgeons and anesthesiologists, for choosing and writing their recommendations about each item. Items could be changed if more than half of all responders choose "have changed" option, then we made changes to items according to recommendations if were written by responders. Participants names was never revealed. The proposal of this study was approved in research deputy and ethical committee of medicine faculty, Tabriz university of medical science.

After modifying checklist, we performed before-after

study to determine effect of a modified checklist implementation on postoperative complications. We used convenient sampling method to select patients in both periods of study. the inclusion criteria included: 1) patients who undergone elective surgery, 2) patients older than 16 years, and 3) general surgical patients. Exclusion criteria included: end-stage and immunocompromised patients. In the both periods, we recorded demographic characteristics of all eligible patients entering the study included: age, gender and comorbidity factors; procedural information and complications included: surgical site infection, pneumonia, unplanned return to operating room until patients discharge. In the second period, operating room team members such as surgeons, anesthesiologists and general surgery assistants undergone training with WHO surgical safety checklist film which shown implementation of checklist in operating room and WHO guidelines for safe surgery in order to implement modified checklist effectively. General surgery assistants are one of main members of operating room in this hospital and they al-

ways presented in operating room, so they helped us in implementing checklist. We collect data by visiting patients and completing designed specific forms.

Statistical Analysis

We did analysis of data using SPSS for windows ,version 16 and chi-square (x2) analysis, Independent Samples t-test for comparing proportions and means. Statistically significant was set at a p-value of less than 0.05

RESULTS

The main directors of operating rooms in Imam Reza hospital are eight anesthesiologists and eleven surgeons who are academic members of Tabriz university of medical science with an average of 12 years experience in their jobs. they all participated in study. All of participants were male with mean age of 46 years as well. The opinions of the general surgeons and anesthesiologists on 19 items of the World Health Organization (WHO) surgical safety checklist were analyzed by the researcher .Seven anesthesiologists and two surgeons recommended to change the forth item of "before induction of anesthesia" part, overall as follow: "changing pulse oximeter to vital

sign and base monitoring". Just one of the anesthesiologists and two surgeons recommended to change the third and fourth items of "before skin incision" part by adding these two statement:" Is there any internal medicine and anesthesiologist's consultation in the records?" and" Is there urine output monitoring?". Six anesthesiologists recommended to change the fifth item of "before patient leaves operating room" part by adding the following items to it: hemorrhage, nausea ,vomiting and hemodynamic disorders. None of the anesthesiologists and surgeons agreed to change the other items of this checklist. The recommendations have been shown in Table1.

In pre intervention period of study,100 patients (51 males and 49 females) were enrolled with the mean age of 48.5 and a standard deviation of 13.5 years.the number of patients in the post intervention period was the same, but 49 males and 51 females, the mean age was 47.5 with a standard deviation of 14.6 years. Patients demographic characteristics and comorbidities in 2 periods of study listed in Table2. Hypertension, diabetes mellitus, hyperlipidemia and coronary heart disease are comorbities were asked patients in our study. There were no statistically significant difference among patients demographic characteristics and comorbidities in 2 periods of study.

Table 1. Recommendations about items of World Health Organization (WHO) surgical safety

<i>Items recommended to change</i>	<i>Content of items</i>	<i>recommendations</i>
<i>forth item of "before induction of anesthesia" part</i>	<i>-Is the pulse oximeter on the patient and functioning?</i>	<i>Instead of pulse oximeter</i> ✓ <i>vital sign monitoring</i> ✓ <i>base monitoring</i>
<i>third item of "before skin incision" part</i>	<i>-Has antibiotic prophylaxis been given within the last 60 minutes?</i>	<i>This item is better to remove because of anaphylactic shock and sensitivity to antibiotics</i>
<i>forth item of "before skin incision" part</i>	<i>Anticipated Critical Events (To Surgeon):</i> ▪ <i>What are the critical or non-routine steps?</i> ▪ <i>How long will the case take?</i> ▪ <i>What is the anticipated blood loss?</i>	<i>It is better to add these options to this item:</i> ✓ <i>Is there internal medicine and anesthesiology consultations?</i> ✓ <i>Is there urine output monitoring?(in particular operations)</i>
<i>fifth item of "before patient leaves operating room" part</i>	<i>-What are the key concerns for recovery and management of this patient?</i>	<i>It is better to add these options to this item:</i> ✓ <i>Hemorrhage</i> ✓ <i>Vomiting and nausea</i> ✓ <i>Hemodynamic disorders</i>
<i>Other items</i>		<i>Same</i>

Table 2. Patients characteristics in 2 periods of study

	Before	After	p-value
Age	48.5	47.5	0.599
Sex(female %)	49%	51%	0.777
Comorbidity	41%	43%	0.774

The incidence of any complications in pre intervention period was 30%,but this rate in post intervention period was 12% and this difference between 2 periods of study was statistically significant ($p=0.002$). the difference in complication rates was 18% (95% confidence interval [CI], 17.4 to18.6) and Number Needed to Treat (NNT) was 5.5. Rate of complications included pneumonia, surgical site infection, unplanned return to operating room in 2 periods of study is shown in Table 3.difference in pneumonia and surgical site infection rates between 2 periods of study are not statistically significant, but difference about unplanned return to surgical room rates between 2 periods of study was statistically significant($p=0.03$).

DISCUSSION

The WHO surgical safety checklist identified important safety steps divided in to 3 phases, each related to specific period during normal practice workflow: before the induction of anesthesia (Sing in),before skin incision (Time out), and before the patient leaves the operating room (Sine out). In each phase, the checklist helps confirm that the surgical team has done its important safety tasks before proceeding. This checklist is clear, user friendly and promotes an ongoing dialogue among surgeons ,anesthesiologists and nurses. Although, first edition of WHO surgical safety checklist is not intended to be comprehensive, so, additions and modification to fit local practice are encouraged (10). In the first phase of implementing the WHO surgical safety checklist in Tabriz Imam Reza hospital and before implementation there was a need to modify the checklist based on the opinions of main service providers in operational rooms. Surgeons and anesthesiologists had consensus on 15 of 19 items of checklist to remain the same and just 4 items recommended to be changed. Three participants recommended

Table 3. Complications in 2 Periods of Study

	Before	After	p-value
Surgical site infection	13%	7%	0.157
Pneumonia	8%	3%	0.121
Un planned return to operation room	9%	2%	0.030

the change of 3rd and 4th items of time out section ,so we left them without change. six anesthesiologists and two surgeons recommended the change of 4th item of sign in part, regarding that it was not basic change and the concept of the item remained the same, so we performed it on checklist. Six anesthesiologists recommended adding some options to fifth item of Sign Out part , because these options made this item more simple and explicit, adding them seemed useful.

OR surgical safety checklist which is modified form of Johns Hopkins and WHO surgical safety checklist, developed by OR Team Communication Project. In this checklist, some items for example "patient positioning and support, warmers" added to sign in part and "glycemic control\beta blockers" and "DVT prophylaxis (heparin\boots and stockings)" added to time out part of checklist. Overall, it has 25 items and three parts as well as WHO surgical safety checklist (11). In UK, modification of the checklist has been done by the addition of a team brief at the start of surgery ,ideally with a debrief at the end of the session (NPSA ; five steps to safer surgery),and pre-operative team briefs are now used by 66% of trusts in England (12). In our study, modification of checklist has been done by using the opinions of anesthesiologists and surgeons of Tabriz Imam Reza hospital to adapt with general surgery operations.

After implementing of the modified surgical safety checklist, we found out complications decreased by 58%, this decline was similar to the study conducted in Shiraz, Faghigi hospital in which complications decreased 57% after implementing of WHO surgical safety checklist and also our results was similar to the study by Haynes in which Inpatient complications occurred in 11.0% of patients at baseline and in 7.0% after introduction of the checklist ($p<0.001$) (8,9). A study in Dutch in 2011

conducted in order to assess what proportion of surgical malpractice claims might be prevented by the use of a surgical safety checklist, concluded the checklist might have prevented 40% of deaths and 29% of incidents leading to permanent damage (13). The other study in Netherland examined the effects on patient outcomes of a comprehensive, multidisciplinary surgical safety checklist, including items such as medication, marking of the operative side, and use of postoperative instructions. In a comparison of 3760 patients observed before implementation of the checklist with 3820 patients observed after implementation, the total number of complications per 100 patients decreased from 27.3 (95% confidence interval [CI], 25.9 to 28.7) to 16.7 (95% CI, 15.6 to 17.9), for an absolute risk reduction of 10.6 (14).

The most common complication was surgical site infection (SSI) in our study. Although, SSIs constitute the second largest category of adverse events in the United States, similar to our study, in the study performed in Shiraz, Faghighi hospital SSI was the most common (8,9). SSIs result in increased morbidity, prolonged hospital stays, and increased direct costs. Rates of infection after surgery vary widely by surgical procedure, and feedback of infection rates is helpful in preventing infections. Most SSIs become evident after discharge, therefore post discharge surveillance should be considered in institutions. Pneumonia was the second common complication in our study. But pneumonia and lower respiratory tract infections is third common complication in the United States and associated with significant morbidity, mortality, and costs (15). A study conducted in Canada in 2000, to determine the incidence and nature of complications on a general surgery service, concluded that complications are common and are underreported by traditional methods. Since hospital funding and quality improvement efforts depend on accurate identification and recording of adverse events. Incidence of pneumonia and SSI was respectively 16% and 11.8% (16).

The other study conducted in Canada in 2005, to determine the risk factors for pulmonary complications after elective nonthoracic surgery. Of 1,055 consecutive patients attending the Pre-Admission Clinic of a university hospital, 28 (2.7%) suffered a postoperative pulmonary complication within 7 days of surgery. Mean lengths of stay were substantially prolonged for those patients who developed pulmonary complications within 7 days of surgery (17).

Some risk factors resulting from lack of communication between staff members of operation room and the experience of checklist seems to have improved communication between all clinical disciplines involved in patient care in operating room (10).

Our study had limitations. First, we used convenient sampling method it might lead to selection bias. Second, the before-after study failed to control for confounding factors, including the concurrent implementation of outcome measurement and feedback. The surgical Hawthorne effect which has it that outcomes tend to improve rapidly when surgeons know they are being evaluated- is widely recognized (18). Third, we did follow up until patients discharge, although Most SSIs become evident after discharge (15). Fourth, the study's checklist consisted primarily of common-sense items and it was implausible to some people that improved compliance with these practices could lead to such drastic reductions in postoperative complications. Finally, our study included patients who undergone selective surgery and we excluded Urgent operations but the study of Weiser, concluded Implementation of the checklist was associated with a greater than one-third reduction in complications among adult patients undergoing urgent noncardiac surgery (19).

In conclusion, implementing a modified WHO surgical safety checklist which was based on general surgeons and anaesthesiologist's opinion and adapted to the hospitals conditions led to decreasing postoperative surgical complications. WHO surgical safety checklist is a simple and useful tool for surgical care quality improvement and implementation this check list help to improve patients safety, one of the key components of clinical governance.

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