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*REVIEW ARTICLE*

# Relevance of World Health Organization surgical safety checklist to trauma and orthopaedic surgery

Sudarshan MUNIGANGAIAH, Murali K. SAYANA, Brian LENEHAN

*From Midwestern Regional Hospital Limerick, Ireland*

**Surgery like civil aviation is a risk-prone occupation. Civil Aviation has reported a death rate of less than 1 in a million exposures. On the other hand, surgery has a reported mortality rate of 100 per million surgeries. The National Reporting and Learning System (NRLS) database in England reported 152,017 'incidents' occurred during 4.2 million surgeries in 2008. Trauma and orthopaedic surgery accounted for 32.4 percent of these 'incidents'. Wrong-site surgery occurred in a total of 133 patients, with an incidence of 31.6 per million surgeries. A system to implement and maintain safe surgical practice is mandatory to prevent these 'incidents'. The factors identified in the genesis of these incidents are errors in decision making, lack of communication, leadership and teamwork. These human errors can easily be prevented using a formal structured communication, like the checklists. In 2008, the WHO published a set of guidelines to ensure the safety of surgical patients. In 2009, the checklist was modified with an intention to reduce major surgical complications and was proved to be effective. Wrong level spinal surgery needs special emphasis. There may be an increasing role for checklists in Trauma and Orthopaedic surgical practice to improve its safety profile by being procedure-specific.**

**Keywords** : safety checklist ; WHO checklist ; orthopaedic surgery ; trauma surgery ; surgical complications ; wrong-site surgery.

## INTRODUCTION

Every year appoximately 234 million surgical procedures are performed across the world (*32*). These procedures are carried out in various settings and different socio-economic environment. The delivery of surgical care is complex. Surgery can prevent loss of limb and life but at the cost of significant risk of morbidity and mortality. Few previous studies have suggested at least 40 to 50 percent of these surgical complications are preventable (*9,13*). These complications occur as a result of errors which could be attributed to various human factors, failure of system or a combination of both (*11*). Stratagies to reduce surgical wound infections and anaesthesia related complications have been successful in the past (*5,7,28*). Previous

■ Sudarshan Munigangaiah, MRCSI , Registrar.
■ Murali K. Sayana, FRCSI (T & Ortho), Specialist Registrar.
■ Brian Lenehan, FRCSI (T & Ortho), Consultant Orthopaedic Surgeon.
*Department of Trauma & Orthopaedic Surgery, Midwestern Regional Hospital Limerick, Dooradoyle, Limerick, Ireland.*
Correspondence : Sudarshan Munigangaiah, MRCSI, Department of Trauma & Orthopaedic Surgery, Midwestern Regional Hospital Limerick, Dooradoyle, Limerick, Ireland.
E-mail : drsudarshan79@gmail.com



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studies have shown that teamwork in surgery improved the outcomes and reduced the rate of complications in high functioning teams (*16,17*).

It is estimated that 4.2 million surgical procedures are performed annually in England with serious adverse events in 1 per 10,000 procedures (*19*). In trauma surgery, the incidence of serious complications is substantially higher, approximately 1 per 100 surgical procedures compared to other surgical specialities (*1*). The focus in orthopaedic surgical training has been mainly on technical skills and advances in technology with little importance placed on non-technical skills like human factor. A majority of preventable errors that occur during surgery can be attributed to these human factor situations like error in decision making, communication and lack of leadership and teamwork (*8*).

## Lessons from other fields

The aviation industry has led the way in adressing this human factor errors. ''In 1935, the U.S. Army Air Corps held a flight competition for airplane manufacturers vying to build its next-generation long-range bomber. In early evaluations, the Boeing plane had trounced other designs. The flight "competition," was regarded as a mere formality. With the most technically gifted test pilot in the army on board, the plane roared down the tarmac, lifted off smoothly, and climbed sharply to three hundred feet. Then it stalled, turned on one wing, and crashed in a fiery explosion. Two of the five crew members died, including the pilot. An investigation revealed that nothing mechanical had gone wrong. The pilot had forgotten to release the new locking mechanism on the elevator and rudder controls. A few months later, army pilots were convinced the plane could fly and invented something that would be used on the few planes that had been purchased... A checklist, with step-by-step checks for takeoff, flight, landing, and taxiing. With the checklist in hand, the pilots went on to fly the model (B-17) a total of 1.8 million miles through several conflicts without one accident'' (*24*). This incident led to the development of the concept of checklist to prevent human error, with great success.

## WHO surgical checklist

In the year 2008, the World Health Organization published a set of guidelines to ensure the safety of surgical patients. Later in 2009, an updated checklist was published which included 19 items that was intended to reduce major surgical complications (*22*). This 19 items checklist is as shown in Figure 1.

## Published Evidence

Haynes *et al* (*10*) conducted a multicentred, non-randomised, prospective study to investigate whether the implementation of 'Safe Surgery Saves Lives' program would make a difference in the rate of deaths and major complications pre and post implementation of WHO surgical safety checklist across global population, in various settings including rural and urban areas, in different socio-economic backgrounds, in private and public health settings. Their intervention was to implement the 19-item WHO safe surgery checklist in their respective institutions across the globe. The authors calculated the sample size to collect the data in 500 consecutive patients at each participating hospital.

The primary outcome was to detect any major complication, death during the 30 day post-operative period. They defined complication according to the American College of Surgeons' National Surgical Quality Improvement Program (*16*). They used logistic-regression analysis for their statistical analysis and calculated the p-values pre and post intervention. In total, 3733 and 3955 patients were enrolled into the study during the pre intervention period and post intervention period respectively. The rate of complication improved from 11 percent to 7 percent after the implementation of the WHO surgical safety checklist ($p < 0.001$). Post-operative death rate in-hospital during the pre intervention period was 1.5 percent. This was reduced to 0.8 percent following the introduction of WHO surgical safety checklist ($p = 0.003$). Also, surgical site infection and re-operation rate decreased significantly after the implementation of WHO surgical safety checklist, which was statistically significant.

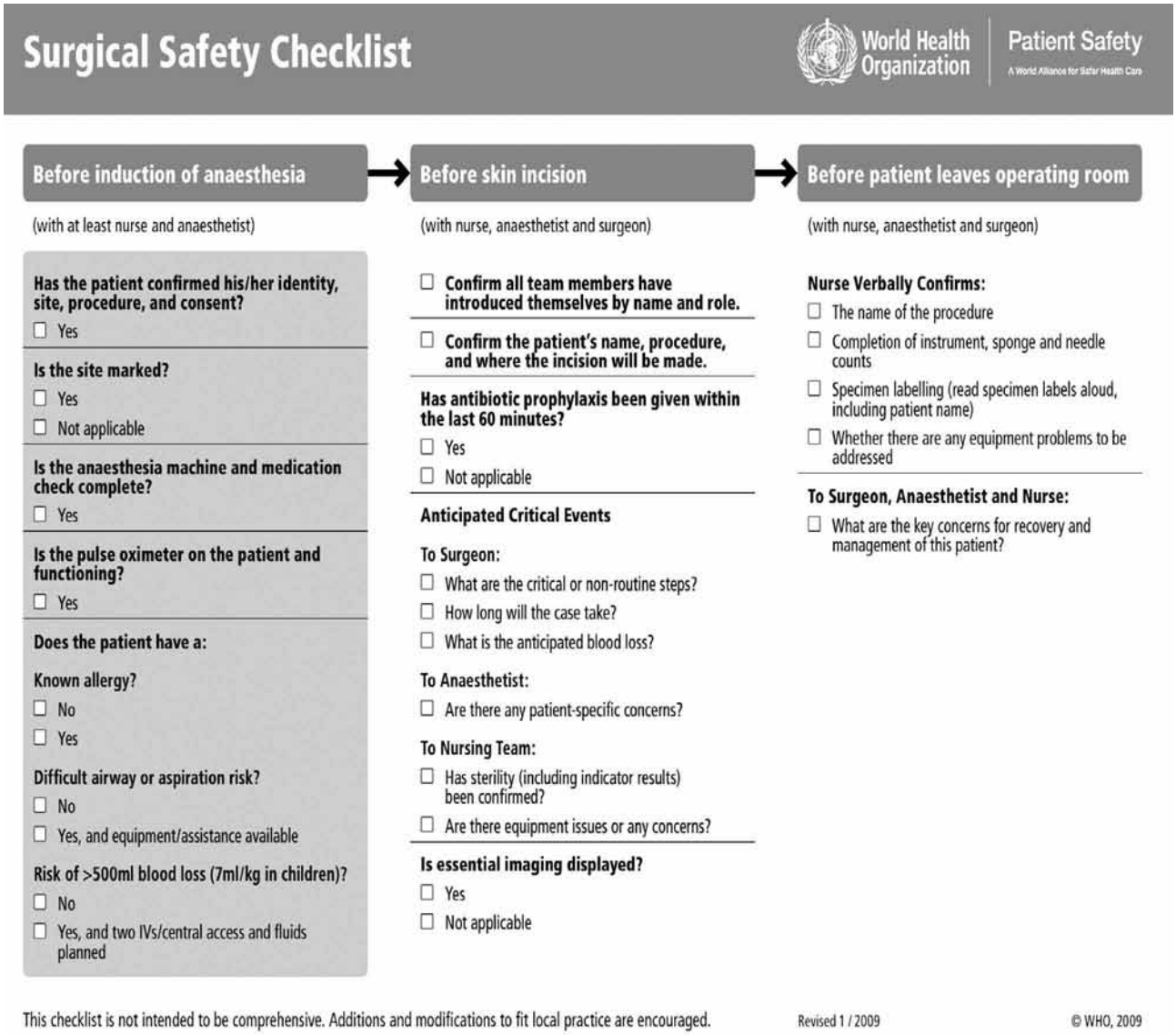


***Fig. 1.*** — WHO Surgical Safety Checklist (reproduced with kind permission of WHO)

They concluded that the 19-item WHO surgical safety checklist introduction in 8 different hospitals across the globe significantly reduced the postoperative morbidity and mortality in spite of their difference in socio-economic status, geographical difference, in public and private settings and rural and urban environments. While the overriding strength of this study was its sample size, other strengths include a validated tool for postoperative surgical complications (*14*) and the eight different participating hospitals in varied global setting. The limitations of this study were that it is a non-randomised study, the data being collected at two different time intervals, namely pre and post introduction of WHO surgical safety checklist which could increase the chances of confounding factors. However, this study failed to explain the reason for the significant difference in the postoperative surgical morbidity and mortality following the introduction of WHO surgical safety checklist. The authors attributed this difference as multifactorial. The complications were recorded only during the postoperative in-

Table I. — Shows initiatives taken by various surgical bodies

| INITIATIVE | ORGANISATION |
|---|---|
| "Sign your Site" | AAOS (American Academy of Orthopaedic Surgeons) |
| "Operate through your Initials" | Canadian Orthopaedic Association |
| "SMaX" | Royal College of Surgeons' and NPSA |

hospital stay but failed to record the complications after discharge, which was another of the limitation of this study.

## Orthopaedic literature

A human error like wrong-site surgery is devastating not only for the patient but also the surgeon. To prevent wrong-site surgery various Orthopaedic Associations across the world have taken initiatives (*18,20,33*), which is shown in Table I.

Panesar *et al* (*24*) conducted a retrospective review of the National Reporting and Learning Service (NRLS) database from January 2008 to December 2008. The aim of the study was to estimate the number of wrong-site surgery incidents that could have been prevented by implementation of the WHO surgical safety checklist in orthopaedic surgery. The authors collected all the incidents of wrong-site surgery in orthopaedic surgery from the National Reporting and Learning Service (NRLS) database. These incidents were considered as wrong-site surgery if they belonged to any of the following groups : wrong site marked on the consent form, wrong side marked on the theatre list, wrong side marked on the patient, wrong patient, wrong side block, wrong side surgery, wrong prosthesis. They were again classified according to the incidents resulting in near misses and actual harm. Two reviewers were involved in classifying and assessing the incidents.

The outcome measure in this study was the number of incidents of wrong-site surgery in orthopaedic surgery. The authors found that there were 316 incidents, which were classified as wrong-site surgery in orthopaedic surgery from the National Reporting and Learning Service (NRLS) database. On further analysis of the database, it was revealed that the actual wrong-site surgery occurred in 133 patients out of 316 reported events. The authors reported a small proportion of near misses, which could have been prevented by a checklist, which was 18 out of 121 incidents against the incidents that caused actual harm which was 10 out of 12 incidents.

In summary, the WHO surgical safety checklist could have prevented 28 incidents including the near misses and actual harm. Strength of this study, though retrospective it is one of the first reports of the extent of wrong site surgery in orthopaedic surgery. The limitations of this study relates to the interpretation and analysis of the data from the National Reporting and Learning Service (NRLS) database which was challenging as there was lack of details in some incidents reported. Furthermore, it is believed that the databases are always under reported compared to the actual incidents which might be misleading.

Sewell *et al* (*29*) conducted a prospective audit in the Department of Trauma and Orthopaedic Surgery, The King George's Hospital, London. The aim of this study was to prospectively audit the use of WHO surgical safety checklist in the orthopaedic patients before and after an educational program to facilitate the accurate use of surgical safety checklist in order to compare the early complications and mortalities between the two groups. It also aimed at collecting the staff perception of surgical safety checklist. Four hundred eighty patients undergoing emergency and elective orthopaedic procedures at The King George's Hospital, London, were prospectively reviewed between February and May 2009. Four authors were involved in data collection from the hospital notes and clinical reviews. The accurate use of 19-item WHO surgical safety checklist was audited. The complication rates and mortality rates during the first 30 days or until hospital discharge were recorded based on the American College of Surgeons' National Surgical Quality Improvement Program (*14*). After the first audit, a compulsory educational video program was arranged for all the team members responsible for the surgical safety checklist. Following the compul-

sory training program, another audit was conducted between June and October 2009 using the same methodology ; 485 patients were included in this study and data was collected prospectively. The accuracy of the use of WHO surgical safety checklist, early complications and mortality rates were recorded. Statistical analysis was conducted to assess the relative risk with 95 percent confidence interval.

In the pre-training audit group, the accurate use of WHO surgical safety checklist was seen in 7.9 percent of the patients, mortality was observed in 1.9 percent of the patients and 8.5 percent of patients developed early major complications. During the post-training audit, the authors found the accurate use of WHO surgical safety checklist in 96.9 percent of the patients, mortality was observed in 1.6 percent of the patients and 7.6 percent of patients developed early major complications. There was no statistically significant difference in mortality and early major complications between the two audit groups.

In conclusion, the more accurate usage of WHO surgical safety checklist was statistically significant, it was increased from 7.9 to 96.9 percent of the patients after staff training, but there was no statistically significant reduction in the rates of mortality and early major complications between the pre and post-training audit groups. This study noted a modest non-significant reduction in the early major complication after the correct use of the WHO surgical safety checklist. No patients were anaesthetised without the availability of correct orthopaedic instrumentation in the operating theatre. This may be attributed to the improved communication between the team members. Checklist also instills consciousness to start pre and postoperative antibiotic therapy as well as antithromboembolic prophylaxis, which reduce the risks associated with surgery (*2,25,26,27,30,31*). The limitation of this study was that it is a prospective study designed without randomization in a single hospital setting. The authors have not calculated the sample size ; lack of statistical power estimation might have failed to demonstrate significant difference between the two groups, which introduces type II error into the study. Only complications defined by the American College of Surgeons' National Surgical Quality Improvement Program have been considered which includes complications until 30 days or until hospital discharge, which is an underestimation of the overall complications.

James *et al* (*12*) carried out a retrospective review of the database of the American Board of Orthopaedic Surgeons from 1999 to 2010. The aim of their study was to estimate the incidence of wrong site surgery by orthopaedic surgeons applying for The American Board of Orthopaedic Surgeons Certification between 1999 and 2010. The study also aimed to assess whether implementation of universal protocol of The Joint Commission (TJC) has made difference to the incidence of wrong site surgery. The American Board of Orthopaedic Surgeons database was searched for number of people who applied for certification via Part II oral exam before 2008 and certification via written or the oral exams after 2010. The outcome measures used in this study were total number of cases reported, number of wrong site surgery and incidence of wrong site surgery. The authors defined the wrong site surgery precisely as follows. Wrong site local or regional anaesthesia, wrong site skin incision, wrong site surgical procedure, incomplete operation on the wrong site, wrong procedure, wrong side, wrong digit, wrong level of the spine.

Forty-four wrong site surgical procedures occurred out of 609,715 surgical procedures from 1999 to 2005 before the introduction of TJC universal mandate, with an incidence of 0.0072 percent of wrong site surgery. After the implementation of TJC universal mandate there were 435,382 cases reported from 2006 to 2010, out of which 27 were labeled as wrong site surgery with an incidence of 0.0062 percent. This difference in the incidence of wrong site surgery before and after the implementation of TJC universal mandate was not statistically significant. Twenty-four wrong site surgeries occurred out of 568,438 non-spine cases from 1999 to 2005, with an incidence of 0.0042 percent. Of 398,873 non-spine surgeries carried out from 2006 to 2010, 11 were labeled as wrong site surgery with an incidence of 0.028 percent. This difference in the incidence of wrong site surgery in non-spine cases before and after the implementation of TJC univer-

sal mandate was not statistically significant. Sixty-six out of 8206 orthopaedic surgeons undergoing Part II board certification process from 1999 to 2010 admitted performing 71 wrong site surgeries. Sixty-one of these 71 were considered wrong site surgeries according to the wrong site surgery definition criteria by the authors. Four common mistakes among 61 wrong site surgeries were identified. Firstly, 26 wrong level of spinal surgery ; secondly, 9 wrong site skin incision ; followed by 7 wrong procedures and 7 wrong site surgeries.

Atleast 26 of the wrong level spinal surgery and 10 non-spine procedures may have caused permanent irreversible harm to the patient. Implementation of TJC universal protocol and mandate reporting did not appear to decrease the wrong site surgery. The authors were not able to extract whether any additional layer of precaution such as more detailed time out procedures and checklists would make a difference in eliminating wrong site surgery. Wrong level spine surgery needs special emphasis. Majority of wrong level spinal surgery occurred mainly because of misinterpretation of the intraoperative images. Good points about this study were that 9255 orthopaedic surgeons reported performing 1,291,396 surgical procedures, which is one of the largest databases in orthopaedic surgery. Explicit information was collected on wrong site surgery by interviewing the operating surgeons. The authors gave a well-described definition of wrong site surgery. Also, the authors carried out appropriate statistical tests. The limitations of this study are as follows. This study is only a review of the American Board of Orthopaedic Surgeons database of all the surgeons who applied for Part II board certification but there must be a good number of surgeons who were not board certified but still practicing in the United States and hence this study represents an under estimation of the incidence of wrong site surgery. Some of the surgeons who performed wrong site surgery during case collection period might have postponed their certification to avoid being examined regarding wrong site surgery.

Authors concluded in their study that additional layer of precautions may yield diminishing returns. Attention should be focused on preventing wrong level spinal surgery. Increasing communication between the healthcare team workers and shared responsibilities may improve the incidence of wrong site surgery.

## DISCUSSION

Surgery has been considered high-risk prone occupation with an adverse mortality rate of 1 per 10,000 surgeries (*1*). In trauma surgery, the rate of major complication is 1 percent (*1*). A system to implement and maintain safe surgical practice is a must (*1,32*). Gawande *et al* (*9*) and Kable *et al* (*13*) in their retrospective reviews have suggested that at least 50 percent of all surgical complications are preventable. Majority of these are from failure of teamwork skills, communication, leadership, decision-making and awareness of the situation (*3,15*). This led the World Health Organisation to start a programme, which was aimed at improving the safety of surgical care worldwide. This initiative was called as "Safe Surgery Saves Life" (*21*).

Trauma and orthopaedic surgery is a very high volume specialty with a vast range of technical complexities in terms of demand for the equipment, familiarity of instruments and staff training (*24*). Good communication and better team work in the theatre environment improves the outcomes and also decreases the risk of surgical error. Teamwork is measurable and also definable, which in turn could be improved with formal structured communication, like the checklists (*24*). It is not just the few specific points on the checklist that help in making healthcare safer but it is the spirit in which it is used and also the team building that goes along with it, which are the important factors (*8*). In the current situation, with the European Working Time regulation in hospitals, continuity of patient care may be compromised because of the number of healthcare professionals involved in providing care as well as multiple patient handovers. In such a scenario, the use of WHO surgical safety checklist can act as a means to improve the patient care and also to prevent the surgical errors by better teamwork and good communication. As with many things in life 'it's not what you do but the way that you do it'.

The National Health Service (NHS) in the United Kingdom in February 2009 and the National Patient

Safety Agency (NPSA) alerted all hospitals in England and Wales to implement the WHO surgical safety checklist by February 2010. The National Patient Safety Agency (NPSA) has National Reporting and Learning System (NRLS), which is one of the largest databases available on patient safety incidence (*23*) and reports from surgery (*4*). The National Health Service Litigation Authority (NHSLA) in 2007 revealed that the orthopaedic and trauma surgery has the highest number of wrong-site surgery claims with 29.8 percent of total claims (*24*). In 2008, the National Reporting and Learning System (NRLS) database revealed that, 152,017 incidents were related to surgery and among them 32.4 percent were related to trauma and orthopaedics (*4*). The Task Force appointed by the American Academy of Orthopaedic Surgeons showed that 225 claims out of 331 during 1985 to 1995 were related to orthopaedic procedures (*6*)

Sewell *et al* (*29*) concluded in their study that the WHO surgical safety checklist did not improve the early complication and mortality rates in trauma and orthopaedic surgery, whereas it did improve the team communication after a compulsory educational training programme regarding the WHO surgical safety checklist in a single center study in the United Kingdom. This study also showed that the changes in infrastructure and education increases the accuracy of the use of WHO surgical safety checklist and also improves its perception among the staff members. Panesar *et al* (*24*) in their retrospective database review concluded that the WHO surgical safety checklist and associated briefings and debriefings are the way ahead to deliver safe and reliable surgical care. James *et al* (*12*) concluded in their study that additional layer of precautions may yield diminishing returns. Attention should be focused on preventing wrong level spinal surgery. Increasing communication between the healthcare team workers and shared responsibilities may improve the incidence of wrong site surgery.

There is an abundant literature available on the effectiveness of the WHO surgical safety checklist in various surgical specialties. However, there is only limited evidence in trauma and orthopaedic surgery. Further studies are needed to investigate whether the WHO surgical safety checklist has been effective in decreasing the incidence of wrong site surgery, postoperative morbidity and mortality in trauma and orthopaedic surgery. These studies should also focus on how the safety checklists lower the postoperative morbidity and mortality. Wrong level spinal surgery needs special emphasis in particular. Using the WHO checklist is mandatory in all hospitals in Europe since 2009 ; this could arise ethical issue to carry out randomised controlled trials comparing surgeries performed with WHO checklist versus no WHO checklist. The only way of addressing this issue is to carry out retrospective studies comparing the postoperative morbidities, mortalities, near misses and wrong side surgery pre and post introduction of WHO surgical safety checklist period. The role of procedure-specific checklists in trauma and orthopaedic surgery should be investigated to check their reliability, reproducibility and validity.

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