Chapter

Adverse Events Capture Systems, Checklists and Teamwork as Relevant Tools to Reduce Complications and Increase Patients' Safety in Spinal Surgery

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Abstract

Adverse events in Hospitals are often related to surgery and they represent a relevant problem in healthcare. Different approaches have been introduced during the last decade to address the problem of patient safety, especially in the surgical environment. The teamwork is crucial in all these actions which aim to decrease adverse events and improve clinical outcomes. We analyze in particular the use of adverse events capture systems in spinal surgery and the use of checklist systems, starting from the Surgical Safety Checklist introduced by the World Health Organization (WHO) in 2008.

Keywords: adverse events, checklist, outcome, safety, teamwork

1. Introduction

In Hospitals adverse events are not rare. Most of these adverse events are related to surgery. The incidence of surgical complications has remained largely unchanged during the past two decades. Inherent complexity in surgery, new technology possibilities, increasing age and comorbidity in patients may contribute to this. The incidence of surgery-related adverse events combined with the increasing volume of surgery results in a relevant healthcare problem [1].

In a review of adverse events incidence, preventability, and outcome conducted by deVries and co-workers [2], the median incidence rate of adverse events was 9.2% with a probable preventability of 43.5%. Adverse events that led to permanent disabilities were 7%.

The most common surgical complications are related to surgical techniques, infections, and postoperative bleeding [3, 4]. Equipment-related failures contribute to a significant part of errors in the operating room and it has been observed that the use of checklists reduces equipment errors by 48.6 to 60.7% [5].

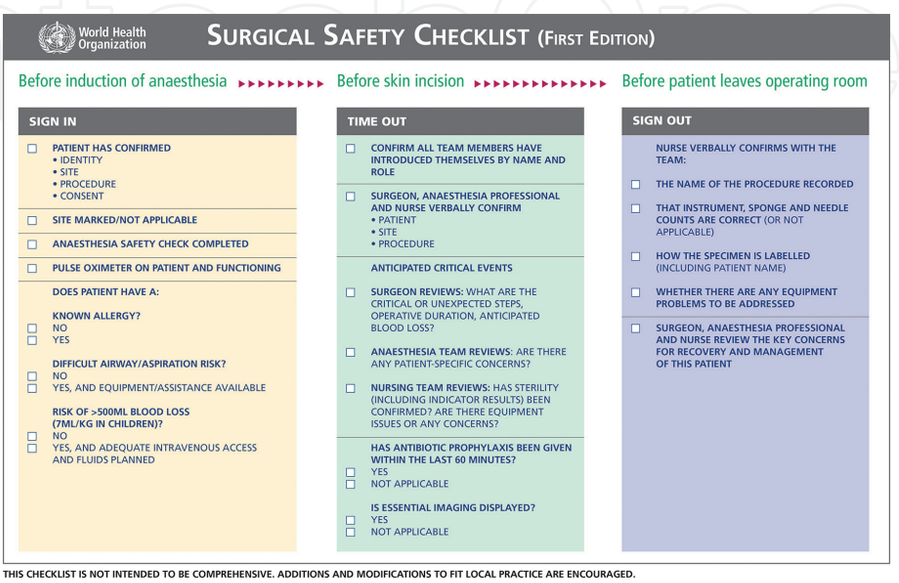
One of the first large- scale studies on checklists use in healthcare (the Keystone study) was carried out in Michigan in 108 intensive care units, where Provonost and co-workers introduced a series of interventions, including a checklist to improve communications [6]. The intervention reduced venous catheter-related blood-stream infections from 2.7 to 0 after 18 months. However, these results could not be replicated in a large-scale United Kingdom program, revealing a particular attention to the context and implementation strategies in improvement programs [7].

2. The use of surgical safety checklist and other checklist systems

To improve care and safety for surgical patients, a checklist, similar to those used in aviation, aeronautics and product manufacturing, was developed by the World Health Organization (WHO). The Surgical Safety Checklist (SSC) consists of 19 items and it is used at three critical perioperative moments: induction, incision and before the patient leaves the operating room (**Figure 1**). The items contain an oral confirmation by the surgical team of the completion of some key steps necessary to ensure safe delivery of anesthesia, antibiotic prophylaxis, effective teamwork and other essential practices in surgery [8, 9].

Although several investigators have challenged the efficacy of the SSC, it has shown repeated success in reducing preventable intraoperative and postoperative complications, length of hospital stay and overall mortality [10–12]. In addition, the investigators have concluded that the implementation of the SSC in multiple institutions has improved communication, efficiency, and attention to routine details in the operating room.

In a systematic review published on 2014 Bergs and co-workers [10] analyzed the results reported in six studies to assess the effectiveness of the WHO SSC. The results of this meta-analysis suggest that the WHO SSC reduced postoperative complications, including mortality. Meta-analysis demonstrated a significant effect of the checklist on any complication, mortality and surgical site infection. It also suggested that sites with adequate compliance with aspects of patient's care related to the checklist were more likely to demonstrate a significant reduction in postoperative complications. Haynes and colleagues [13] showed that improvements in postoperative outcomes were associated with improved perception of


World Health Organization

SURGICAL SAFETY CHECKLIST (FIRST EDITION)

Before induction of anaesthesia ▸▸▸▸▸▸▸▸▸ Before skin incision ▸▸▸▸▸▸▸▸▸▸▸▸▸ Before patient leaves operating room

SIGN IN

☐ PATIENT HAS CONFIRMED
- IDENTITY
- SITE
- PROCEDURE
- CONSENT

☐ SITE MARKED/NOT APPLICABLE

☐ ANAESTHESIA SAFETY CHECK COMPLETED

☐ PULSE OXIMETER ON PATIENT AND FUNCTIONING

DOES PATIENT HAVE A:

KNOWN ALLERGY?
☐ NO
☐ YES

DIFFICULT AIRWAY/ASPIRATION RISK?
☐ NO
☐ YES, AND EQUIPMENT/ASSISTANCE AVAILABLE

RISK OF >500ML BLOOD LOSS (7ML/KG IN CHILDREN)?
☐ NO
☐ YES, AND ADEQUATE INTRAVENOUS ACCESS AND FLUIDS PLANNED

TIME OUT

☐ CONFIRM ALL TEAM MEMBERS HAVE INTRODUCED THEMSELVES BY NAME AND ROLE

☐ SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE VERBALLY CONFIRM
- PATIENT
- SITE
- PROCEDURE

ANTICIPATED CRITICAL EVENTS

☐ SURGEON REVIEWS: WHAT ARE THE CRITICAL OR UNEXPECTED STEPS, OPERATIVE DURATION, ANTICIPATED BLOOD LOSS?

☐ ANAESTHESIA TEAM REVIEWS: ARE THERE ANY PATIENT-SPECIFIC CONCERNS?

☐ NURSING TEAM REVIEWS: HAS STERILITY (INCLUDING INDICATOR RESULTS) BEEN CONFIRMED? ARE THERE EQUIPMENT ISSUES OR ANY CONCERNS?

HAS ANTIBIOTIC PROPHYLAXIS BEEN GIVEN WITHIN THE LAST 60 MINUTES?
☐ YES
☐ NOT APPLICABLE

IS ESSENTIAL IMAGING DISPLAYED?
☐ YES
☐ NOT APPLICABLE

SIGN OUT

NURSE VERBALLY CONFIRMS WITH THE TEAM:

☐ THE NAME OF THE PROCEDURE RECORDED

☐ THAT INSTRUMENT, SPONGE AND NEEDLE COUNTS ARE CORRECT (OR NOT APPLICABLE)

☐ HOW THE SPECIMEN IS LABELLED (INCLUDING PATIENT NAME)

☐ WHETHER THERE ARE ANY EQUIPMENT PROBLEMS TO BE ADDRESSED

☐ SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE REVIEW THE KEY CONCERNS FOR RECOVERY AND MANAGEMENT OF THIS PATIENT

THIS CHECKLIST IS NOT INTENDED TO BE COMPREHENSIVE. ADDITIONS AND MODIFICATIONS TO FIT LOCAL PRACTICE ARE ENCOURAGED.

Figure 1.
World Health Organization- Surgical Safety Checklist (2008).

teamwork and safety climate, suggesting that changes in this attitude may be partially responsible for the effect of the checklist. Also the team's compliance with the checklist is as important as evaluating outcomes.

During the last decades we analyzed the complications occurring in our Spine Surgery Department and reported an overall incidence of complications of 17.3% during three years [14]. Indeed, spinal surgery complications are a relevant and unsolved problem. The incidence of complications in spinal surgery literature ranges between 7% and 20% [15–22].

Nasser et al. [17] performed a systematic evidence-based review of 105 published studies (84 retrospective, 21 prospective) and found a higher incidence of complications (19.9%) in prospective studies compared with retrospective studies (16.1%). The incidence of complications varied widely in spinal surgery literature, even in prospective studies. Rampersaud et al. [23] reported an overall incidence of intraoperative adverse events of 14% (98 adverse events in 700 patients), but only 23 adverse events led to postoperative clinical sequelae. Yadla et al. [16] reported a very high rate of early complications, occurring within 30 days of surgery: global incidence of 53.2%, with a minor complication incidence of 46.4% and a major complication incidence of 21.3%.

It has been also observed that there is no standard definition of complications in spinal surgery literature [23], so it is difficult to compare studies. The Clavien-Dindo and SAVES capture and grading systems [24–26] divide the surgical complications into levels of severity based on the grade of treatment required to face the complication. Glassman et al. classified complications as major or minor: significant complications requiring reoperation or leading to permanent deficit were considered major complications. Other perioperative adverse events with time-limited effect were considered minor complications [27].

To date, few studies have evaluated the effect of complications on clinical outcomes [27–29]. Glassman et al. analyzed a prospective multicenter database for adult spinal deformity to investigate the effects of major and minor complications on disability, pain, postoperative quality of life at 1 year follow up and found that major complications negatively affected the quality of life [27]. However, Fritzell et al. found no significant differences of effects of major and minor complications on 2-years outcomes in three different types of fusion surgery [28]. Grainger et al. examined the relationship between severity of complications and outcomes following Clavien-Dindo classification of complications, and found that the severity of perioperative surgical complications does not appear to influence 1- or 2-years pain and disability outcomes [29]. Lambat et al. performed a large retrospective study and observed that ODI (Oswestry Disability Index) at 2- years follow up was not statistically different between patients having no complications, minor complications or major complications. However, the minimum clinically important difference (MCID) for ODI resulted significantly smaller in the major complication group (31%) than in the minor complication (51%) and no complication groups (65%), demonstrating an impact of complications on the functional outcome [20].

Chen et al. [30] recently performed a 10-week prospective study where SAVES V2 and OrthoSAVES capture systems were used by six orthopedic surgeons and two independent, non-MD clinical reviewers to record adverse events after all elective procedures. They compared the complications rate among groups of patients undergoing spine, hip, knee and shoulder surgery. The first relevant result of this study was the highest rate of complications in spinal surgery compared to the other surgeries; but the most important observation of this study was that overall 99 adverse events were captured by the reviewers, compared with 14 events captured by the surgeons. Surgeons adequately captured major adverse events, but failed to record minor events that were captured by the reviewers; in the spinal surgery group, reviewers captured 45 adverse events versus 8 events captured by surgeons [30].

Considering the high incidence of complications in spinal surgery and their relevant impact for the patients and the health system, during the last years several authors focused their attention on the risk factors related to the onset of complications and on predictive models of complications after spinal surgery [31–35].

Moreover, several preventive measures have been studied and recently described in order to reduce complications in spinal surgery, concerning intraoperative neuromonitoring, blood loss reduction, infections and thrombosis prophylaxis [36–40]. Sethi and co-workers [41] described the application of Lean methodology in spinal surgery. Lean methodology was developed in the manufacturing industry to increase output and decrease costs and then applied in many areas of health care. The authors illustrated a step-by-step process designed specifically to optimize and standardize preoperative, intraoperative and postoperative care for patients undergoing complex spine surgery and they reported a significant reduction of overall complication rate [41].

We proposed to analyze the impact of the introduction of the WHO Surgical Safety Checklist in our Spine Surgery Department, as preventive measure to reduce complications [14].

We retrospectively evaluated the clinical and radiological charts prospectively collected from 917 patients who underwent a spinal surgery procedure from January 2010 to December 2012. The aim of this study was to compare the incidence of complications between two periods, from January to December 2010 (without checklist) and from January 2011 and December 2012 (with checklist) in order to assess the checklist's effectiveness.

We found no correlation between diagnosis and overall complications' incidence. We found a rate of early complications (arising within 1 month after surgery) of 43.3%, a rate of complications requiring surgical revision of 7.6% and a rate of neurological sequelae causing permanent damage of 2.4%. These types of complications have a relevant impact on the health system and, especially the last two categories, on the patients' quality of life and clinical outcomes.

We observed a reduction of the overall incidence of complications following the introduction of the WHO Safety Surgical Checklist: in 2010 without the use of the checklist, the incidence of complications was 24.2%, while in 2011 and 2012 following the checklist introduction, the incidence of complications was 16.7% and 11.7%, respectively (mean 14.2%).

Despite some limitations of our study, the WHO Surgical Safety Checklist resulted to be effective in reducing complications in our Centre.

We recent analyzed also the rate of re-admission and re-operation following spinal surgery. A systematic review [42] of the data concerning the "thirty-day readmission" in spinal surgery indicated percentages between 4.2% and 7.5%, with a variability associated to the presence of one or more centers in which the study takes place and to the type of vertebral pathologies treated. This high frequency is associated with a significant impact from a social and economic point of view, which primarily affects the patient and the National Health System. The most common cause of re-admission was wound complication (39.3%), even if a pooled analysis of risk factors and causes of re-admission was limited by the lack of reporting in spine literature.

Re-admission is very often associated with a re-intervention, or a re-intervention can also occur within the same hospitalization. Our Center treats a wide variety of spinal diseases of oncological, degenerative, traumatic and infectious origin. Therefore we proposed to analyze the rate of re-intervention and surgical revision in the treatment of these pathologies and the causes of these re-operations.

From January 2017 to December 2019, 1260 surgeries were performed at our Spine Surgery Department. Among these, two patients underwent 5 operations,

four patients underwent 4 operations, twenty patients underwent 3 operations, 124 patients underwent 2 operations, for a total of 150 patients who underwent more than one spine surgery in a period of three years in the same center (10.7%).

We are now analyzing the causes of these re-operations, which can be a relapse of the disease in the case of oncological pathologies or, for all diagnosis, they can be complications occurring during the follow up period.

A surgical revision is a particularly relevant aspect in assessing the degree of severity of a complication, due to the impact on patient's recovery, and it is relevant also for the economic impact on the National Health System.

We think that a checklist system should be introduced also during the pre-operative and post-operative phases, in order to highlight all the key steps where complications can arise, not only during surgery. The introduction and validation of these checklists, implemented for pre-operative, intra-operative and post-operative phases, should be followed by the identification of targeted actions to prevent complications, improve patients' safety and reduce the economic impact.

Following the WHO Surgical Safety Checklist, a checklist for the complex process of ward round (WR) was developed by Caldwell et al. in 2011 [43] and it has been recently implemented and evaluated through different studies. The prime objective of ward round is to assess the clinical state of the inpatient and plan further management. For WR assessment it is fundamental the gathering of new information and reviewing of information already available. Additional information are provided by verbal communication with the patient and the family, nursing staff, medical colleagues, patient examination, clinical charts, pathology and radiological investigations. Such assessment allows a rational approach to further management including the alteration of therapy, arranging further investigations or surgery, referral to other specialists, planning the discharge. In a busy surgical ward round there is the potential to overlook important aspects of care, their documentation and communication. So the use of a checklist during medical ward round has been described by Caldwell [43] with consideration of key aspects of care being bedside consultation, patient safety, chart review, planning and appropriate documentation. Pitcher et al. [44] implemented and evaluated the WR checklist: they identified the deficiencies in general surgical WRs and the benefits of a checklist approach in overcoming this. Initially, members of the surgical team were unaware of the checklist and some deficiencies were detected. Subsequently, the team was prompted against the checklist and during the ward rounds a designated member of the team acted as 'prompter' if aspects of care were not considered according to the checklist. A structured ward round progress form was developed and it was assessed before and after specific education in its use. This form was based on the original checklist and became an integral part of the medical record. Following the use of the checklist and prompting during ward rounds, a significant improvement occurred for the majority of criteria included in the checklist, all of which reached statistical significance. The introduction of the structured progress form, even with prompting, did not initially improve documentation but this was substantially improved with specific education. The authors concluded that the use of a checklist during surgical ward rounds improved consideration of most key aspects of care and education in the completion of a structured progress form substantially improved documentation. A randomized controlled trial of the impact of surgical WR checklist conducted in a simulated environment showed improved standardization, evidence-based management of post-operative complications and quality of ward round [45].

A WR checklist was introduced also on orthopedic ward round and evaluated by a prospective cohort study [46]. The authors observed that after introduction of the checklist, daily documentation of surgical details improved from 38.6% to 85.3%

of patient encounters. Fasting status documentation improved from 9.1% to 70.6% of patient encounters. Venous thromboembolism prophylaxis documentation increased from 6.8% to 92.6%. Documentation of weight-bearing status improved from 11.4% to 83.8%. Thus, the use of a structured checklist during orthopedic ward rounds led to significant improvement in both the consideration and the documentation of key aspects of surgical care.

These findings were recently confirmed by Krishnamohan and co-workers [47] who implemented and assessed a surgical WR checklist for daily surgical ward rounds. The authors observed that the overall documentation of the six parameters analyzed improved following implementation of the WR checklist (from 26% pre-checklist to 79% post-checklist). In particular, documentation of assessment of fluid balance improved from 8–76%. The key parameters analyzed were: VTE prescribed, Antibiotics reviewed, Fluid balance reviewed, Blood tests reviewed, Patient observations, Drug chart. These selected parameters were identified as often overlooked or inadequately reviewed during surgical WR. The checklist helped bring focus to these aspects of care and the number of adverse events reported decreased following WR checklist implementation. Subsequent audit at 3 months post-checklist implementation maintained improvement with documentation at 72%. The authors concluded that the WR checklist benefits patient safety. It improves communication, documentation and ensure that key issues are not missed at patient assessment on WRs.

3. Conclusions

The data reported underline the relevance of checklist systems to improve patients' safety and clinical outcomes. Effects on morbidity and mortality after introduction of safety checklists have been investigated in several studies [10, 48–51]. Systematic reviews find evidence in favor of checklist use having effects on patient outcomes such as reduced complications [10, 49, 50], wound infections [50] blood loss [50] and mortality rates [49, 50]. Checklist use suggested improved outcomes in high-risk pediatric surgery in developing countries [51].

Their use also contributes to improved information transfer and communication in different phases of surgery [52]. Very few studies report any negative patient outcome effects when using checklists [53], but implementation requires time and effort [2] because a "culture of safety" is required. Still, some studies report no reduction of complications or mortality [54, 55]. A more recent publication reported a lowered mortality rate but no changes in complication rates [56]. Russ et al. [57] observed that the quality of operating room teamwork and communication was improved due to more sharing of case critical information, better decision-making and team coordination, openness about knowledge gaps, and improved team cohesion. In a climate of greater safety for the patient and improved outcome, the use of checklists should influence the operating room (or ward round) work processes so as to have an impact on patient outcome and in this context the teamwork is crucial.

During the last decade, teamwork has been addressed as interprofessional practice or collaboration and described by attributes of this practice such as: interdependence of professional actions, focus on user needs, negotiation between professionals, shared decision making, mutual respect and trust among professionals, and acknowledgment of the role and work of the different professional groups. Teamwork and interprofessional collaboration are considered as a strategy for effective organization of health care services because the complexity of healthcare requires integration of knowledge and practices from different professional groups.

Health organizations in western countries are committed to improving patient safety through education of staff and teamwork education programs, including the use of checklists and other tools dedicated to improving clinical outcomes.

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Conflict of interest

The authors declare no conflict of interest.

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