

Review papers

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Surgical Safety Checklists : an Update

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Abstract. Surgical safety checklists aim to improve patient safety by prompting the attention of the surgical team towards critical steps during the operation. The checklist's items are aimed to improve compliance with proven interventions, and to facilitate multidisciplinary communication and teamwork. Based on the current literature, corroborated by systematic reviews and meta-analysis, surgical safety checklists have a positive impact on communication and reduce postoperative complications including mortality. However, despite their effectiveness, the implementation of these checklists is not straightforward. Several determinants leading to behaviour where checklists are checked but not properly executed have been highlighted. As surgical safety checklists are in essence complex sociological interventions, they must be implemented accordingly. Key factors for the implementation of these checklists have been suggested in the literature, although, the most profound way of implementation remains unclear.

Introduction

Surgery is an important part of modern healthcare. The annual volume of major surgical procedures is estimated around 234.2 million worldwide (1). It is well known that surgical patients are prone to healthcare-related harm. The rate of adverse events for surgical patients has been estimated to range from 12.5% to 20.1%, the rate of potentially preventable adverse events ranges from 4.2% to 7.0% (2). In Europe, mortality rates following surgery have been described as '*higher than anticipated*', with significant variations between countries (1.2% to 21.5%) (3). These numbers demonstrate that patient safety remains a major challenge within the surgical context. With these findings in mind, it has been suggested that there is an increased need for national and international strategies to improve the quality and safety of care for surgical patients (3).

Main adverse events within the surgical context include : wrong site/procedure/patient surgery, unanticipated blood loss, surgical items left inside the patient, anaesthesia equipment problems, lack of availability of necessary equipment and the use of non-sterile equipment. Most errors leading to these adverse events are caused by factors unrelated to surgical techniques, but rather to non-operative management (2). These reasons include, inter alia, inadequate teamwork, poor relationships with patients, poor understanding of human factors and inadequate knowledge of the complexity of health-

care (2,4,5). The latter has been recognised by leading agencies involved in patient safety. The complex mechanisms underlying the formation of undesirable events are not only being recognised within the healthcare context ; other high-risk industries, like aviation, have a long tradition in searching solutions to improve safety. The use of checklists is one of the suggested solutions to improve safety in complex environments, which have been demonstrated to be effective tools in ensuring safe operations (6).

With regard to medicine, there is currently no uniform definition about what a safety checklist should be or look like (7). Checklists can have several objectives, including memory recall, standardization and regulation of processes or methodologies (4). The main objective of their implementation is commonly error reduction and improvement of best practice adherence. A safety checklist consists of a limited list of action items or criteria that are crucial for safety. These items or criteria are arranged in a systematic manner, which allows the users to record their respective presence/absence in order to ensure they are considered or completed. A sound checklist highlights the essential criteria in a particular area.

The aim of this literature review is to provide an up-to-date and critical overview of the growing evidence regarding surgical safety checklists, by addressing checklists effectiveness, together with the insights regarding the implementation of surgical safety checklists.

Surgical safety checklists

One of the first formal safety checklists related to surgery was the **Joint Commission's Universal Protocol for Preventing Wrong Site, Wrong Procedure and Wrong Person Surgery™** (8). It became available July 2004 for all accredited hospitals, ambulatory care and office-based surgery facilities. The Universal Protocol was created to tackle the persistent occurrence of wrong site, wrong procedure and wrong person surgery in Joint Commission accredited organizations. The three principal components of the Universal Protocol include a pre-procedure verification, site marking, and a time out.

In 2008, the World Health Organization (WHO) published the **WHO Surgical Safety Checklist** (9). This 19-item checklist intended to be widely applicable in order to reduce the number of major surgical complications. The WHO checklist is designed around three main phases of an operation, each corresponding to a specific phase of the regular work flow, respectively before the induction of anaesthesia (sign in), before the incision of the skin (time out) and before the patient leaves the operating theatre (sign out). In 2009 the checklist was updated, following the input of its users, resulting in 22 items.

In 2009, a research group from the Netherlands introduced the **Surgical Patient Safety System (SURPASS) checklist** (10). This checklist standardizes the operative process of all procedures and appoints responsibilities and specific checks. It includes almost every process from the preadmission phase to the post-discharge phase, aimed to reduce surgical process-related complications and in-hospital mortality.

To meet accreditation requirements, many hospitals expressed the need for a single checklist that includes both the safety checks outlined in the WHO Surgical Safety Checklist and the safety checks of The Joint Commission's Universal Protocol. In response, the Association of periOperative Registered Nurses (AORN) developed the **AORN Comprehensive Surgical Checklist** in 2010 (11).

How surgical safety checklists work

Surgical safety checklists are intended to work as a barrier system against well-known safety threats. By prompting the attention of the surgical team towards critical steps, it aims to improve compliance with proven interventions e.g. prophylactic antibiotic administration and monitoring prior to induction of anaesthesia. Besides its direct function as a barrier, surgical safety checklists also intend to improve the underlying mechanisms of safe environments. These mechanisms are most likely multi-factorial and not well understood. Key factors include the culture of the surgical team, communication, and teamwork (12).

Effects of surgical safety checklists

The implementation of surgical safety checklists has been associated with increased patient safety awareness (13), improved communication (6, 14-19), reduction of surgical claims (20), and a reduction of postoperative complications including mortality (20-28).

Postoperative complications and mortality

The incidence of postoperative complications and mortality are frequently used outcome indicators for patient safety within the surgical context. Five systematic reviews evaluated the available literature related to the impact of surgical safety checklists on these clinical outcomes (6, 14, 29-31). One provides a general overview of safety checklists in medicine (6). Whereas the other four reviews deal specifically about surgical safety checklists (14, 29-31), Three reviews pooled data from the original studies and estimated the effect size by means of meta-analysis. All studies concluded that surgical safety checklists are associated with decreased surgical complications and mortality rates.

The meta-analysis by BORCHARD and colleagues combined the results from three studies (29). They reported on the effectiveness of the WHO surgical safety checklist and SURPASS in reducing in-hospital 30-day postoperative complications and mortality rates. The relative risk (RR) for any postoperative complication was 0.63 (95% confidence interval (CI) : 0.58 to 0.67), the RR for mortality was 0.57 (95% CI : 0.42 to 0.76) (29).

The meta-analysis by LYONS & POPEJOY included the results from five studies (14). They also reported on the effectiveness of the WHO surgical safety checklist and SURPASS in reducing in-hospital 30-day postoperative complications and mortality rates. The standardised mean difference of post-intervention scores for morbidity and mortality was 0.123 ($p = .003$) and 0.088 ($p = .001$), respectively (14).

The meta-analysis by BERGS and colleagues, based on seven studies, pooled data for the effectiveness of the WHO surgical safety checklist in reducing in-hospital 30-day postoperative complications and mortality rates. This study found a decreased probability for postoperative complications (from 16.7% to 7.6% ; RR 0.59, 95% CI : 0.47 to 0.74) and mortality (from 2.9% to 2.4% ; RR 0.77, 95% CI : 0.60 to 0.98). The authors concluded that the totality of evidence is highly suggestive regarding the reduction of postoperative complications and mortality following WHO SSC implementation, but cannot be interpreted as conclusive in the absence of higher quality studies (31).

Wrong site surgery

Currently, there is no literature available confirming the effectiveness of surgical safety checklists in decreasing the rate of wrong site or wrong level surgery (30, 32, 33). As wrong site surgery is rare ; demonstrating a statistical reduction would require an unfeasibly large study (30). Based on clinical expertise some arguments exist regarding the ability of surgical safety checklists to prevent wrong site surgery (30,32).

Safety culture

In addition to increase the compliance with proven interventions, another objective of surgical safety checklists is to ameliorate the safety culture. Improved perception of teamwork and safety culture among team members in the operating theatre has been associated with improvements in postoperative outcomes (34). Suggesting that these changes could be partially responsible for the effect of the checklist. There are indications that exposure to pre-surgery briefings is linked with improved perceptions of safety culture (35). Where we should note that this improvement often only involves specific aspects of a safety culture (e.g. frequency of events reported) (36).

Communication and teamwork

Communication and teamwork are two specific aspects of a safety climate which have been extensively investigated within the surgical context. Two systematic reviews addressed the impact of surgical safety checklists on teamwork and communication in the operating theatre (14, 15).

The review by LYONS and POPEJOY (14) included ten studies. The effect size was estimated by using the standardised mean difference of post-intervention scores. Given the considerable methodological differences between the included studies (e.g. surveys, observations) one might argue that pooling of the results was methodologically inappropriate. Results obtained from surveys, based on the safety attitude questionnaire, are difficult to compare with survey results obtained from locally self-developed questionnaires, or observational data. Therefore, it is difficult to draw stringent conclusions based on this meta-analysis.

The review by RUSS and colleagues (15) included twenty studies assessing the impact of safety checklists on communication and teamwork. The original studies did not always assess team skills as the primary outcome and varied widely on the methodologies including : surveys, observations, interviews, and 360° assessments. Seven of the twenty articles focused on the effect of the WHO surgical safety checklist. The remaining 13 articles reported on perioperative briefings (e.g. Joint Commission's Universal Protocol) or locally developed check-

lists. Russ and colleagues reported the following findings (15) :

- Self-perceptions of teamwork and communication improved following the implementation of safety checklists.
- Visible consequences of poor communication and near-misses associated with communication errors reduced after the checklist implementation.
- The observed mechanisms through which checklists improved teamwork centred around establishing an open dialogue at the start of the case, promoting provision of case-related information, revealing knowledge gaps, encouraging articulation of concerns, provoking a change in the care plan, supporting interdisciplinary decision making and coordination, and enhancing team "feeling."
- The effect of the checklist on teamwork differed between disciplines. Nursing personnel perceive the most positive impact, while surgeons perceive the least positive impact, anaesthesiologists fall somewhere in between.

These reported improvements were, as previously mentioned, measured by a wide variety of methods and relatively soon after the introduction of a checklist. Despite these short-term improvements, evidence regarding long-term effects are scarce and could not demonstrate long-term improvements (37). Other studies reported only little or no change for the entrenched hierarchy and relationship dynamics of the operation theatre staff after implementing the WHO checklist (28, 38, 39).

The totality of evidence regarding communication and teamwork is divided between suggestions of positive effects and the lack of beneficial effects. It has to be noted that surgical staff members rated teamwork with members of their own profession higher than teamwork with those of other professions ; surgeons rated overall teamwork higher than perioperative nurses (40). These results are not surprising ; as communication and teamwork takes place in a complex environment it is influenced by various factors. Assuming that simple interventions, like checklists, could mitigate complex social interventions (communication and teamwork) seems unrealistic. Qualitative research demonstrates that the relation between communication, teamwork, culture, and checklist usage is not static. These studies suggest that team involvement is adjusted to obtain professional and social acceptance within the team (41). To date, the exact underlying principles and possible covariates remain unclear. It is by example plausible that communication and teamwork are, at least partially, influenced by the climate established in the operating theatre. If this climate relies heavily on hierarchical differences among team members, the implementation of a checklist will probably not lead to

sustainable improvements in communication and teamwork.

In conclusion, the implementation process of surgical safety checklists has an effect on team dynamics and safety culture. The underlying paradigms and their methodological implications complicate the pragmatic interpretation and comparison of published studies. The complex reality requires methods with sufficient depth ; however, the current evidence is largely based on (not validated) questionnaires. Therefore, it is premature to assume communication would not improve as a result of implementing surgical safety checklists. Further research, using more specific methods, is needed to fully understand the complex relations between culture, communication, teamwork, and checklist implementation. Surgical safety checklists, by themselves, do not improve safety culture. Instead, a good safety culture prior to the introduction of the checklist is likely to enhance successful implementation, and could therefore positively influence the impact of the checklist on safety outcomes.

Implementation

Notwithstanding the previously described positive effects associated with the implementation of surgical safety checklists, the actual impact of using surgical safety checklists on patient outcomes varied consistently with the effectiveness of the hospital's implementation process. The implementation of surgical safety checklists is complicated by several factors (19, 42-54). As these checklists rely heavily on communication between team members, it should be of no surprise that the previously mentioned issues regarding communication and safety culture are reflected in the literature.

Dissemination

Since the publication of the landmark study by Haynes *et al.* (2009), a widespread interest in the WHO surgical safety checklist occurred. Today, 1970 hospitals worldwide have indicated to use the WHO checklist in at least one operating theatre (<http://maps.cga.harvard.edu:8080/Hospital/>).

The Joint Commission's Universal Protocol has been implemented in every institution certified by the Joint Commission ; which is active in more than 90 countries. (<http://www.jointcommissioninternational.org/About-JCI/>) Apparently, the SURPASS has not been widely used outside the Netherlands. Although, locally adapted versions of this checklist probably exist. Due to its simplicity and its affiliation with the WHO's 'Safe surgery, safe lives' programme the WHO surgical safety checklist is the most widely accepted checklist overall. In accordance with the literature, the WHO checklist has become the golden standard.

Compliance

Full compliance to checklists is often difficult to achieve. As a result, the potential clinical benefit is hard to detect. Compliance rates differ among hospitals, surgical staff members, and for specific items and parts of the checklists (10, 29, 30, 55). BORCHARD *et al.* summarised 15 studies evaluating the compliance with surgical safety checklists. The overall compliance rate ranged from 12% to 100% (mean : 75%) and for the Time Out from 70% to 100% (mean = 91%) (29). Other studies, based on administrative data, showed that even if checklists seem to be used almost routinely during surgery, compliance with the underlying actions could not be consistently observed. This implies that items could be marked, without actually performing the tasks (43, 47, 50, 56, 57). This behaviour leads to a 'false sense of safety' (12).

Barriers to implementation

Several studies provide insights into potential barriers when implementing surgical safety checklists (30). These barriers generally can be distinguished into four categories : i.e. confusion regarding how to properly use the checklist, pragmatic challenges to efficient workflow, lack of access to resources, and individual beliefs and attitudes (30). However, one single theory with relevant hypothesis to evaluate is still lacking.

Facilitators for implementation

The current literature provides different methodologies for effective implementation of surgical safety checklists. Three main steps are highlighted. First, checklist items should be perceived as relevant and effective by clinical staff. Checklists are only effective if the items it contains match real safety risk events and if these are evidence-based without any redundant items (29). Second, the checklist should fit the process flow in the operating theatre. Third, the checklist should be implemented according to its intentions. As checklists aim to improve communication and teamwork in the operating theatre, the implementation process should be aligned with these objectives. This requires a different approach compared to implementing a list of items to be checked (17).

Conclusions

Surgical safety checklists are promising tools to improve surgical safety. Implementation of the WHO surgical safety checklist and the SURPASS have been associated with a reduction of postoperative complications and mortality rates. The clinical effectiveness of these checklists has been related with improvements in team communication and safety culture following implementation. Hence,

the precise way these underlying mechanisms affect safety outcomes remain unclear. Surgical safety checklists by themselves do not improve safety culture nor team communication. Instead, a good safety culture prior to introduction of a checklist enhances implementation.

The actual impact of these checklists on patient outcomes varies with the effectiveness of the hospital's implementation process. It has become clear that implementation of surgical safety checklists is difficult to achieve. Even if all items are marked, it cannot be assumed that the underlying tasks have been correctly executed. If compliance to the checklists is measured by assessing the number of checked boxes, a false sense of safety is created. More precise indicators describing the actual use of these checklists by operating theatre personnel need to be considered.

As surgical safety checklists aim to improve communication between surgical team members, the implementation of surgical safety checklists is in essence a complex sociological intervention. This implies that these checklists should be implemented differently than e.g. technical applications. The correct way to do so remains unclear. The use of leading clinicians as role models, accompanied with effective leadership seems most crucial and promising among implementation facilitators. In order to maximise the full potential and clinical benefit of these surgical safety checklists further research, focusing on the implementation and the achievement of sustained compliance, is necessary.

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