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Impact of the World Health Organization Surgical Safety Checklist on Patient Safety

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ABSTRACT

The incidence of surgical complications has remained largely unchanged over the past two decades. Inherent complexity in surgery, new technology possibilities, increasing age and comorbidity in patients may contribute to this. Surgical safety checklists may be used as some of the tools to prevent such complications. Use of checklists may reduce critical workload by eliminating issues that are already controlled for. The global introduction of the World Health Organization Surgical Safety Checklist aimed to improve safety in both anesthesia and surgery and to reduce complications and mortality by better teamwork, communication, and consistency of care. This review describes a literature synthesis on advantages and disadvantages in use of surgical safety checklists emphasizing checklist development, implementation, and possible clinical effects and using a theoretical framework for quality of provided healthcare (structure—process—outcome) to understand the checklists' possible impact on patient safety.

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The incidence of surgical complications has remained largely unchanged over the past two decades.[1–3] The most common surgical complications are related to surgical techniques, infections, and postoperative bleeding.[4,5] Healthcare is an inherently complex industry, regularly dealing with high levels of risk and invasive treatments. Population trends mean that aging patients with more numerous comorbidities receive treatments (*e.g.*, surgery) that used to be offered to younger and overall fitter patients in the past—through innovative technologies, medications, and treatment that expand treatment possibilities. In surgery, equipment-related failures contribute to a substantial part of errors in the operating room. Preoperative use of checklists was found to reduce equipment errors by 48.6 to 60.7%.[6] One of the first large-scale studies on checklists in healthcare (the Keystone project) was carried out in predominantly 108 Michigan intensive care units, where Pronovost *et al.*[7] introduced a bundle of interventions, including a checklist to improve communications. The intervention reduced venous catheter-related bloodstream infections after 18 months from 2.7 (95% CI, 0.6 to 4.8) to 0. These Michigan results could not be replicated in a large-scale United Kingdom intervention program (Matching Michigan), revealing a need for careful attention to contexts and implementation strategies in improvement programs.[8]

In a review of adverse event incidence, preventability, and outcome in record review studies, median incident rate was 9.2%, with a probable preventability of 43.5%. Adverse events that led to permanent disabilities were identified in 7%.[9] To improve care for surgical patients, organizational and clinical challenges are targeted. Use of surgical safety checklists may be one element here.[10,11] One problem, however, of using checklists in healthcare is that they are a deceptively simple intervention. A decade's worth of evidence on checklists is now rife with implementation barriers and inconsistencies in clinical effectiveness results.[12,13] Within our team, we have long-term experience and dedication to implementation of anesthesia and surgical safety checklists,[14–19] and we have faced these barriers and inconsistencies.[20–23] Experiences from the aviation industry were drawn upon as the World Health Organization Patient Safety Program team developed the World Health Organization Surgical Safety Checklist. This was then developed with an aim to support clinical practice without disrupting clinical judgments.[24] The World Health Organization checklist was created as a simple sample of checks and not as an algorithm, focusing on items that were agreed upon by clinicians to be of high risk or deadly if omitted or overlooked.[25] At the outset, the World Health Organization stated very clearly that the checklist should not be comprehensive, encouraging modifications and additions to make it fit into local practice. Further development included tailoring the Surgical Safety Checklist to specific surgical procedures, especially those with a high degree of complexity, as in robotic surgical technology.[26] In this article, we offer a synthesis of the World Health Organization Surgical Safety Checklist origin, implementation, and possible clinical effects using a theoretical framework for quality improvement in healthcare (structure—process—outcome)[27] and with a focus on

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the quality of checklist implementation as a decisive factor for effectiveness.

Do Checklists Work and What Can We Expect to Achieve through Their Use?

Introduction of the World Health Organization Surgical Safety Checklist reduced complications from 11.0 to 7.0% ($P < 0.001$), with a mortality drop from 1.5 to 0.8% ($P = 0.003$), in a global setting of eight hospitals in eight countries.[10] Haynes *et al.*[10] also investigated and observed that the checklist had impact on selected safety process measures directly related to items on the checklist such as: objective airway evaluation performed before anesthesia; use of pulse oximeter; prophylactic antibiotics given appropriately; oral confirmation of patient's identity; and sponge counts completed. Essential objectives of the World Health Organization Surgical Safety Checklist were to improve teamwork, communication, and consistency of care.[10] However, the study was not designed to provide a "dose–response" relationship. The most rigorous Surgical Safety Checklist study as described by Atul Gawande *et al.*[28] is our stepped wedge cluster randomized controlled trial performed in two Norwegian hospitals. Implementation of the Norwegian version of the World Health Organization Surgical Safety Checklist resulted in reduction of surgical complications from 19.9 to 12.4% ($P < 0.001$) in the intervention group, and the concurrent length of stay was reduced by 0.8 days ($P = 0.022$).

The mechanisms behind the checklist effects on patient outcome have not been very clear. The World Health Organization implementation guide introduced the Donabedian framework for quality improvement,[29] in which structures (checklists) improve care processes (timing of antibiotics and protection of hypothermia) and both, in turn, improve patient outcomes.[24] Hence, using Donabedian's approach, we identified significant associations between process measure improvements and actual use of the three parts of the Surgical Safety Checklist and accordingly concluded that use of the checklist resulted in improved patient outcomes such as reduced infections, wound rupture, respiratory complications, bleeding, blood transfusions, and cardiac complications through better care processes in the operating room.[17] Use of the checklist specifically resulted in improved care processes to protect patients' core body temperature, such as forced air warming blankets, which increased from 35.3 to 42.4% ($P < 0.001$) and more frequent and more timely use of prophylactic antibiotics before incision in 54.5 to 68.5% ($P < 0.001$) of procedures.[17] Keeping the patient warm is recognized as essential to reduce bleedings and blood transfusions, while use of the correct antibiotic at the right time is recognized to mitigate infections.[30–33] Clearly, it is not possible to expect any effects from a checklist unless it has been used correctly, as with any clinical intervention. Such use needs to be at a certain agility level to ensure the operating team performs critical important tasks and care processes for every patient.[34]

Beyond the Surgical Safety Checklist, effects on morbidity and mortality after introduction of safety checklists have been investigated in several studies.[35–39] Systematic reviews find evidence in favor of checklist use having effects on patient outcomes such as reduced complications,[36–38] wound infections,[38] blood loss,[38] and mortality rates.[37,38] Checklist use suggested improved outcomes in high-risk pediatric surgery in developing countries.[39] Their use also contributes to improved information transfer and communication in different phases in of surgery.[40] Very few studies report any negative patient outcome effects when using checklists,[41] but implementation requires time and effort.[9] The comprehensive Surgical Patient Safety System checklists needed input from care providers across multiple disciplines, and its implementers' emphasized that a "culture of safety" was required. Still, some studies report no reduction of complications or mortality.[42,43] A more recent publication reported a lowered mortality rate (odds ratio, 0.49; 95% CI, 0.32 to 0.77) but no changes in complication rates (odds ratio, 1.02; 95% CI, 0.88 to 1.19).[44] Russ *et al.*[20] found that teamwork could be negatively impacted from a suboptimal implementation process. However, the quality of operating room teamwork and communication was perceived as improved due to more sharing of case critical information, better decision-making and team coordination, openness about knowledge gaps, and improved team cohesion. Barriers to effective use of the surgical safety checklists may be reasoned to have a negative impact on operating room efficiency. In a study of efficiency, use of the Surgical Safety Checklist in itself did not increase operation time, first starts on time, or same-day cancellations. A reduction of mean operating room disposable cost ($70/operation) was observed in the postchecklist group ($P < 0.01$).[45] Using the checklist should, as we previously have shown, influence the operating room work processes so as to have an impact on patient outcome. Work processes are not included as outcome in most of the above-referred studies, and we should not expect to achieve any improvements in patient outcomes or operating room efficiency, unless the intervention has impact on the work processes and improves care.

Checklist Implementation: A Thorny and Understudied Issue

A perioperative checklist, as with any clinical intervention, will only ever be as effective as its implementation. This in turn may be further impacted by the implementation strategies that a country, region, or healthcare organization use to bring a checklist into their operations.[46,47] In the case

of surgical checklists, we believe a rather naive approach to implementation has been taken in many studies: a checklist is introduced to improve care processes and patient outcomes with no regard to or an analysis of how precisely it is being introduced within the surgical or anesthesia service or how it is applied at the frontline. Strategies to support implementation remain unknown and the fidelity of checklist use in the operating room remain understudied. This naivety has contributed to an almost "mythologic" narrative found in some literature around checklists, because they have extended beyond perioperative care to other areas of medicine as a simple and effective solution. However, checklists will always depend on high-quality implementation to be effective, both strategically and at the frontline. In cases where healthcare providers have significant safety culture or organizational problems, checklists will not offer a solution.

Implementation of surgical safety checklists takes time and requires persistency and a long-term commitment. Leaders need to persuasively explain its rationale and picture for the staff how to use the checklist.[48] If staff members were not adequately prepared, they became frustrated, disinterested, and eventually abandoned use despite hospital-wide mandate.[48] When there is lack of buy-in to the implementation process or use is suboptimal, the checklist may have a negative impact on teamwork.[20] In an English multicenter observational study, large variations were observed as to how the "Time Out" and "Sign In" parts of the World Health Organization checklist were performed across operating teams. When surgeons were engaged or all team members participated and paused during checklist performance, checklist implementation was at its best.[21] In the national United Kingdom evaluation of the World Health Organization checklist implementation, Russ *et al.*[22] reported numerous cases where the checklist "just appeared" in the operating rooms one day. Lack of an implementation strategy reduces the chances of high-fidelity implementation, which in turn reduces the room for a checklist to achieve its intended improvement.[28]

We implemented the World Health Organization checklist in our hospitals with a comprehensive strategy including presentations to the different surgical teams on its use. Members of the implementation team were present in the operating rooms during start-up and during follow-up evaluation meetings and provided feedback on compliance.[15,16] After our study was completed in 2010, the World Health Organization checklist was further rolled out across all surgical specialties within our hospital. Roll-out was supported by the Norwegian national patient safety campaign (2011–2013) and program (2014–2018),[49] with use of the checklist being monitored through mandatory registrations and reports on compliance rates nationwide across various electronic or manual record systems. Here we have applied implementation strategies already known to positively impact healthcare interventions.[47,50]

Analyses of compliance rates are useful to understand whether parts of the checklist are being omitted. This provides possibilities for more targeted quality improvement interventions on checklist use. Importantly, compliance rates do not offer any information on how well a checklist is actually being performed, *i.e.*, compliance is very different from fidelity. We take the view that assessing fidelity (*e.g.*, through snapshot rapid ethnography in the operating room) is essential if we are to thoroughly understand barriers to checklist use and effectiveness. In both aviation and medicine, high workloads, production demands, and time pressure are elements that may contribute to substandard checklist performance.[51,52] Use of aviation-like "read–do" checklists needs careful thought and tailoring if introduced in surgery. Doing a checklist as a "checkbox" exercise, omitting items when going through the checklist, and having difficulties in gathering team members' attention are real problems to be understood and addressed.[20–22,52] Growing recognition among clinicians and professional bodies like the anesthesiologists' and nurse anesthetists' associations to support use of checklists as best practice and high standards of care is a positive contribution.[53,54]

Conclusion

Actual use of surgical safety checklists needs to be at a certain agility level to ensure that operating teams perform critical important tasks and care processes for every patient. The theoretical framework as outlined by Donabedian (structure—process—outcome) provides some insight to why and how the Surgical Safety Checklist works. To have any impact on patient safety, use of checklists in anesthesia and surgery need to improve our work processes in the operating room.

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Competing Interests

Dr. Sevdalis is the Director of London Safety and Training Solutions Ltd., London, United Kingdom, which provides quality and safety training and advisory services on a consultancy basis to healthcare organizations globally. The other authors declare no competing interests.

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