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Surgical safety checklists: do they improve outcomes?

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Editor's key points

- Checklists, notably the WHO Surgical Safety Checklist, have an established place in safe theatre practice.
- There is emerging evidence that checklists may have further applications in acute and emergency situations.
- Effective implementation of checklists requires individual clinicians to adapt to a changing safety culture.

Summary. The concept of using a checklist in surgical and anaesthetic practice was energized by publication of the WHO Surgical Safety Checklist in 2008. It was believed that by routinely checking common safety issues, and by better team communication and dynamics, perioperative morbidity and mortality could be improved. The magnitude of improvement demonstrated by the WHO pilot studies was surprising. These initial results have been confirmed by further detailed work demonstrating that surgical checklists, when properly implemented, can make a substantial difference to patient safety. However, introducing surgical checklists is not as straightforward as it seems, and requires leadership, flexibility, and teamwork in a different way to that which is currently practiced. Future work should be aimed at ensuring effective implementation of the WHO Surgical Safety Checklist, which will benefit our patients on a global scale.

Keywords: adverse events; communication; human factors; teamwork; WHO Surgical Safety Checklist

Complications due to healthcare are well documented and constitute an important public health problem. A number of studies have described an adverse event rate of 3–17% in hospitals in North America, Australia, New Zealand, Denmark, and the UK.[1–12] The human cost to patients, families, and their carers is considerable, as is the cost to healthcare systems. Adverse events in healthcare are estimated to result in more deaths in the USA annually than road traffic accidents, breast cancer, or acquired immune deficiency syndrome,[13] and it has been estimated that adverse events in the NHS cost £1bn and require an additional 3 million bed days annually.[11] Adverse events associated with surgery deserve particular attention—a recent systematic review suggested that the most common location of adverse events in hospital was the operating theatre. Most were associated with a surgical care provider (although few directly related to anaesthesia), and 43% of the incidents were preventable using the current standards of care.[14] If published complication rates from surgery are extrapolated to a global population (estimated 234M operations performed annually), surgery may be responsible for 7 million complications and 1 million deaths every year, twice the number of maternal deaths.[15]

The US Institute of Medicine report 'To err is human' was published more than 10 yr ago and called for efforts to reduce the epidemic of healthcare-related complications.[13] In England and Wales, the Chief Medical Officer's report 'An organisation with a memory' similarly highlighted the need to improve the safety of care in the NHS[16] and the National Patient Safety Agency (NPSA) was established as a consequence. An additional reporting arm of the NPSA was established at the same time (the National Reporting and Learning Service; NRLS), which now contains the largest database of adverse events in healthcare worldwide.

It is interesting to consider the impact of reporting incidents and how effective this is at improving the safety of healthcare. There have been more than 6 million reports to the NPSA to date, most of them minor, but the absolute numbers of those injured are high. Data from the most recent report indicate that 10 875 patients died or came to severe harm from adverse events during 2010–11, with more than 4000 events due to errors in the treatment or procedure, or implementation of care and ongoing monitoring/review.[17] The analytical capacity required to evaluate this information is enormous, but without this, there is very little to be gained from national incident reporting.

How can errors in healthcare be reduced? Training in anaesthesia and surgery has typically focused on technical skills and technological innovation. Improving safety requires an understanding of the science of error and a consideration of human factors and systems failures, recognizing the need to improve the organizational safety culture and to train to avoid and mitigate errors when they occur.[18 19] Quality improvement initiatives that focus on the implementation of simple evidence-based interventions are likely to offer opportunities to improve care for our patients. This was highlighted in the Darzi review 'High quality care for all' linking safe care with effective care; 'getting the basics right, first time, every

time'.[20–22] This approach of doing the right thing, every time, for every patient, is the basis of a number of checklists recently introduced in healthcare and will be described further in this review, along with available evidence to support their use.[22 23]

Checklists

Checklists can be adopted in varied formats. They may constitute a series of 'read and do' checks, for instance for checking a piece of equipment. They may be 'challenge/response' checks to confirm that procedures have been completed, or an 'aide memoire' to provide a series of structured prompts for a team briefing or debriefing. Or they may be a combination of all three.[24] Checklists were first introduced in aviation in the 1930s to address human error, as newer more complex aircraft were introduced, and are now common in high-risk industries.[23 24] Much is known about checklist development from industry—for example, checklists should ideally be one page, use simple familiar language, and each element should contain no more than five to nine items.

Checklist design requires consideration of content, format, timing, trial, and feedback, followed by formal testing and evaluation. Checklists should be evidence-based and address key safety items that are often overlooked, and which, if omitted, would lead to serious adverse outcomes.[23] By standardizing performance, checklists reduce reliance on memory and thus reduce errors of omission. This is particularly applicable to healthcare as processes become more complex, staff become busier, and handovers and shift working become more common. Checklists contribute to team communication and working and increase situational awareness among team members, but successful adoption requires careful implementation to make sure that the checklist is used effectively.[25]

There are clearly differences between healthcare and ultra safe industries such as commercial aviation, and some of these differences may be a significant barrier to using the same techniques at risk reduction. For instance, clinicians typically value clinical autonomy and view themselves as individual craftsmen rather than members of a team after standard operating procedures.[22] These differences help to explain why the implementation of checklists and routine adoption of safety briefings in healthcare may not be straightforward.

Checklists in healthcare

An example of an effective use of a medical checklist is the checklist developed in the intensive care unit (ICU) at Johns Hopkins University School of Medicine.[26] The aim was to reduce bloodstream infections related to the insertion of central lines. The checklist focused on five evidence-based interventions recommended by the Centre for Disease Control that would have the greatest effect and have the lowest barriers to implementation. These interventions were: hand washing, using full-barrier precautions during the insertion of central lines, cleaning the skin with chlorhexidine, avoiding the femoral site if possible, and removing unnecessary catheters.

These items were not novel approaches in infection control, they did not involve the introduction of new devices or techniques, and they were known to have a strong evidence base. The initial study also included a control ICU, where there was an educational programme on how to reduce infections, but without the implementation of the checklist programme. The quality improvement team introduced the checklist programme in a stepwise manner, but focused on more than just using the checklist. The programme had institutional backing; it included staff education, routine surveillance, reporting and investigation of infections, supply of appropriate equipment (such as a dedicated i.v. access trolley), and a focus on teamwork, with encouragement for the nurses to speak up if the checklist was not followed.

The improved system helped to maintain adherence to the infection control guidelines and showed a sustained reduction in bloodstream infections from a baseline of 11.3 infections per 1000 catheter days to zero (no change in infection rate was noted in the control hospital). Interestingly, the nurses found the checklist useful to refer to if the doctors did not adhere to the required processes, and, far from leading to confrontation, the programme led to improved team working in the ICU.[26] The same process was then adopted by the Michigan Health and Hospital Association (MHA) Keystone Center for Patient Safety and Quality Keystone ICU project as part of a state-wide safety initiative in hospitals in Michigan. The results again showed a sustained reduction in bloodstream infections that was maintained with time.[27 28] The same methodology has been introduced to the UK as the NPSA 'Matching Michigan' campaign (http://www.nrls.npsa.nhs.uk/matchingmichigan/). This study highlights the importance of a checklist to ensure adherence to evidence-based interventions, the value of routine good practice in reducing morbidity and also the powerful gains when local teams work together to improve the care of their patients.

Checklists have been used successfully in other areas of ICU practice, for instance to identify daily goals, reduce ventilator acquired infections,[24] and to structure information handover between teams. A structured checklist used after paediatric cardiac surgery improved the quality and safety of ICU handovers by reducing technical and communication errors while also improving teamwork and efficiency of the handover process.[29] Other ICUs have found similar findings,[30–32] and checklists have also been found to be useful during intra-hospital transfers[33] and transfer from theatre to recovery.[34 35]

Improving surgical outcomes

There have been a number of observational studies in operating theatres that illustrate some specific challenges in this environment. Studies looking at cardiac surgery (high-risk complex surgery) and general and orthopaedic surgery

(high volume, rapid turnover cases) demonstrated that minor problems, distractions, or equipment problems were associated with increased operating time and a reduction in operative performance.[36 37] It appears that it is not only the technical skill, but also the behavioural patterns and non-technical skills of the surgeon (leadership, teamwork, problem-solving, decision-making, and situation awareness), that affect surgical outcomes.[37–39] A multicentre study of all arterial switch operations in cardiac centres in the UK over an 18 month period indicated that outcomes were not only dictated by the technical difficulty of the surgery, but also that there was a strong relationship between the non-technical skills of the surgeon and minor adverse events that disrupted the surgical flow in the operating theatre, and death, near misses, or both.[38 39]

Minor errors are particularly problematic as they may be individually unimportant, but they have a multiplicative effect. The challenge therefore is to change the operating theatre culture to reduce minor problems and interruptions that may impact on surgical performance and also to improve non-technical skills in the operating theatre. Formal training in non-technical skills has been shown to improve patient outcomes, but there is often resistance from operating teams,[40] although this may change as training in non-technical skills is recognized as an important part of the undergraduate medical curriculum.[41]

Communication errors are the most common cause of adverse events in healthcare. For instance, information does not reach the right person, or is inaccurate, or issues remain unresolved until they become critical. In the operating theatre, this leads to mistakes, inefficient use of resources, wasted equipment, frustration, poor morale, delays, and cancelled operations.[42] Patterns of interprofessional communication in theatre follow complex hierarchies, and the communication style of senior members of the team acts as an important role model for trainees. A confrontational style may be mimicked, or it may act as a barrier to a trainee speaking up.[43]

Lingard and colleagues addressed communication difficulties by developing a checklist to facilitate structured interprofessional briefings before general surgical procedures. Data were collected prospectively, pre- and post-implementation of the checklist. The mean number of communication failures per procedure declined from 3.95 before the intervention to 1.31 after the intervention ($P < 0.001$).[44] Thirty-four per cent of briefings demonstrated utility, and the checklist also demonstrated associated improvements in situational awareness, decision-making, team working, and reliability of clinical interventions such as antibiotic administration.[44 45]

The WHO Surgical Safety Checklist

The WHO launched its second Global Patient Safety Challenge: Safe Surgery Saves Lives (SSSL) in 2006 in response to the global need to improve outcomes in surgery. Harvard surgeon, public health physician, and writer, Dr Atul Gawande led a team of experts in surgery, anaesthesia, nursing, infection control, human factors, and quality improvement and considered interventions to improve safety for patients receiving surgical care.

Four challenges were considered—the global need for surgery, the paucity of data from many regions, how to make sure that known evidence-based interventions are completed reliably, and how to address the problem of non-technical skills and human error in the face of increasing complexity in surgical care.

WHO Guidelines for Safe Surgery were published following a systematic review of the evidence available, with formal recommendations linked to the strength of evidence.[46] Ten essential objectives for safe surgery were identified that were applicable in all WHO member states; these related to:

(i) correct site surgery,
(ii) provision of safe anaesthesia,
(iii) management of airway problems,
(iv) management of haemorrhage,
(v) avoiding known allergies,
(vi) minimizing the risk of surgical site infection,
(vii) preventing the retention of swabs and instruments,
(viii) accurate identification of specimens,
(ix) effective communication within the surgical team and
(x) routine surveillance of surgical outcomes.

The WHO Surgical Safety Checklist was formulated in order to disseminate these recommendations. The checklist was devised with advice from experts in checklist development and included some items that were challenge/response, but also included short, structured briefings between members of the team at the time out and sign out.[23 46]

The final stage of any guideline development is to test the guideline in a pilot evaluation. The SSSL group investigated the impact of the WHO checklist in eight hospitals worldwide, four in high-income settings and four in low- and middle-income settings.[47] Data on in-hospital complications occurring within the first 30 days after surgery were collected prospectively from consecutively enrolled adult patients undergoing non-cardiac surgery, 3733 before and 3955 after the implementation of the checklist. The overall death rate was reduced from 1.5% to 0.8% ($P = 0.003$) and in-patient complications from 11.0% to 7% ($P < 0.001$).

The mechanism by which the checklist resulted in such impressive outcomes was not clear, but is likely to have been multifactorial. In some cases, the checks required the surgical system to be addressed—for instance, to establish a policy for antibiotic administration. Improvements may also have been due to changes in team dynamics and safety climate at the pilot hospitals. The SSSL study group subsequently found that there was an improvement in safety attitudes as measured by a modified Safety Attitudes Questionnaire that correlated with the reduction in postoperative complication rate. Of those questioned, 93.4% said that they would want the checklist used if they were having an operation.[48]

Recent publications from other centres have confirmed that the sustained use of the WHO checklist improves

communication and ensures the reliability of routine interventions such as antibiotic prophylaxis and thromboembolic prophylaxis.[49–53] In Sweden, increasing numbers of primary knee arthroplasties were associated with increasing infection rate—a national quality improvement project addressing this issue coincided with the adoption of the WHO checklist and the appropriate timing of antibiotic prophylaxis improved from 57% of the patients in 2007 to 79% of the patients in 2010, when 73 of the 75 hospitals had introduced the checklist.[49]

A criticism of the SSSL pilot study was the absence of a control group and that the effects may have been strengthened by an observer bias (the Hawthorne effect).[47] A recent cohort study of 25 513 patients from a single institution analysed patients retrospectively after the introduction of the WHO checklist, thus removing the effect of an observer bias; a significant reduction in mortality was seen after adjustment for baseline differences. The effect was smaller than seen in the SSSL pilot study and was critically dependent on effective checklist completion.[54]

Using the WHO checklist to perform safety checks on patients who are awake, for example, in obstetric surgery, has led to the question of whether this would cause additional anxiety for the patient. Reassuringly, a study in an obstetric unit has found the reverse to be true; that obstetric patients having surgery using the WHO checklist have lower levels of anxiety and feel comforted by the safety checks performed.[55] Concerns are often voiced that the checklist may be difficult to use in urgent or emergency situations, but the SSSL team found that the checklist was equally applicable to those undergoing urgent surgery, and improved compliance with standard safety measures in a timely manner.[56] The checklist may act as a valuable prompt to focus the team, even in an extreme emergency.[57]

Other surgical checklists

Two recent publications describing surgical checklists provide proof of concept and move surgical checklists from 'a good idea' to 'standard of care'.[58] A study from the Netherlands described the use of a series of checklists for the patient journey from admission to discharge (the Surgical Patient Safety System, SURPASS).[59] This was a before and after study in six participating hospitals, and the results were strikingly similar to the SSSL pilot study; the proportion of patients with one or more complications decreased from 15.4% to 10.6% ($P < 0.001$), and in-hospital mortality decreased from 1.5% [95% confidence interval (CI), 1.2–2.0] to 0.8% (95% CI, 0.6–1.1). Importantly, there were five control hospitals, and outcomes did not change in the control hospitals over the same time period.

Neily and colleagues[60 61] described the teamwork training and introduction of briefings and de-briefings in the operating theatre and the use of a surgical checklist in 108 Veteran Health Administration Hospitals in the USA. This quality improvement programme included 2 months of preparation, 1 day training for theatre teams, and 3 monthly coaching interviews for the implementation team over the following year. More than 180 000 procedures were analysed—there was an 18% reduction in annual mortality and 15% reduction in morbidity, significantly greater than in hospitals where training had not yet been delivered.[60 61] A 'dose–response' relationship was noted for the training programme—for every 3 months of the training programme, a reduction of 0.5 deaths per 1000 procedures occurred (95% CI, 0.2–1.0; $P = 0.001$).[60]

Challenges in implementing the WHO Surgical Safety Checklist

The SSSL pilot study was a landmark publication in surgical safety and provided evidence to support the introduction of the WHO Surgical Safety Checklist into surgical practice worldwide. In England and Wales, the NPSA issued a patient safety alert in January 2009 requiring all NHS organizations to implement the WHO Surgical Safety Checklist for every patient undergoing a surgical procedure,[62] with similar requirements in NHS hospitals in Scotland and Northern Ireland. A review of 161 acute hospital trusts in England in 2010 showed that all trusts had started to implement the checklist, the majority starting in one or two theatres and then rolling out the checklist using 'plan-do-study-act' cycles to adapt the checklist to their local situation.[63]

The WHO published a comprehensive implementation manual to accompany the introduction of the WHO checklist that encouraged modification to fit with local practice, cautioning against making the checklist overly complex.[64] In the UK, where most surgery is arranged on a sessional basis, the major modification has been 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'),[62] and preoperative team briefs are now used by 66% of trusts in England.[63] Modifications of the checklist have also occurred to fit different procedures such as cataract surgery, radiology, Caesarean section, and endoscopy.[62] The impact of the WHO checklist in five UK sites is to be presented in the near future (K. Moorthy, personal communication 2012).

There are currently more than 4000 hospitals in 122 countries that have registered as users of the WHO checklist, representing more than 90% of the world's population, with 1790 hospitals actively using the checklist.[65] The WHO checklist has been heralded as a major innovation in medicine,[66] but unlike a new piece of technology, the challenges to introducing changes in the safety culture in the operating theatre are significant. The retrospective review by van Klei and colleagues noted that the overall decrease in mortality was less than had been noted previously, and crucially was only seen in those theatres showing full checklist completion. It is not clear whether the effect is due to association or causation, as safety conscious teams may be more likely to adopt innovations that improve safety.[54] The real challenge is how to encourage all theatre teams to adapt to the checklist culture.

Translation of any new idea into practice typically follows Everett Rogers' theory of diffusion of innovation;[67] individuals acquire knowledge about the innovation, are persuaded of utility, make a decision to adopt, determine the usefulness of the innovation, and then decide to continue using the innovation to full effect. Education and local champions are key to success. Champions are typically leaders who are easily accessible and who have good skills of persuasion and negotiation, and who are not necessarily part of the senior management team. Experience in our own institutions has identified typical behaviours—innovators and early adopters who were quick to start using the WHO checklist, an early majority who contributed to a critical mass of users, and 'laggards' who resisted change. One of the tensions with the WHO checklist has been that the NHS made the decision to adopt the checklist from the centre, but the responsibility to implement change fell to local leaders (consultant surgeons and anaesthetists). Local training and data management systems, for instance routine reporting of incidents, surgical site infections, and the safety climate in theatre, may not always have been in place to support them.

Leadership is a critical factor in motivating operating teams to adopt new ideas.[68] A recent report from the Theatre Team Resource Management Project (TTRM) showed that individuals who gave a positive response to the statement 'briefings are common in the operating theatre' also reported a better safety climate in theatre measured by the Safety Attitudes Questionnaire. The decision to implement safety briefings (or not) was crucially left to the individual surgeon in the theatre. Some surgeons were enthusiasts for the project and contributed in a positive way, but some did not, which resulted in a negative effect on safety attitudes in their theatre.[69] The 2010 report by Patient Safety First showed that while most trusts reported that the checklist led to improved safety and teamwork, the most common challenges were negative clinician attitudes and lack of clinician buy-in or engagement (77% of trusts).[63]

Implementation of the WHO checklist was studied in five hospitals in Washington State through structured interviews with implementation leaders and surgeons. The importance of local champions was highlighted and effective implementation was seen when senior clinicians showed good leadership skills, demonstrated how to use the checklist, and explained why it was necessary. Coaching in theatre, encouragement to read the checklist rather than relying on memory, and regular audit also contributed to success.[70] Conversely, examples of badly used checklists will be familiar to many—the WHO checklist may be seen as a 'tick box' exercise, checks are omitted (commonly sign out), surgeons and anaesthetists indicate that the checks are causing delay, senior clinicians give dismissive responses, or checks are done when key people are not present. Used in this way, the checklist will not benefit patients and may cause harm.[71]

Clinicians want to do what is best for their patients—it is important therefore to understand why they are often seen to resist change and why interventions supported by good evidence, such as checklists, are difficult to introduce into routine clinical practice. There are cultural and professional hierarchies, embarrassment about introductions, and often an implicit denial that routine tasks may be forgotten. Surgeons are the natural leaders in the theatre setting; yet, in a pressurized working environment, they may report that they feel powerless to change environmental, organizational, and systemic problems.[72] From personal experience (I.A.W.), implementation of the checklist depended on a team of committed individuals from anaesthesia, surgery, nursing, and clinical audit who met on a monthly basis, delivered numerous teaching sessions, addressed barriers to success, offered coaching, and suffered set backs, but never gave up.[73] The evidence from the Keystone project[27 28] and the Veterans Affairs project[60] is that checklist implementation is not a quick fix, and requires significant commitment at the grassroots level if a sustained change in the safety climate in theatre is to be achieved.[25]

Lifebox

The WHO checklist was designed for a global population and is as equally applicable in middle- and low-income countries as it is in high-income countries, with the gains likely to be significantly higher. Patient outcomes in the low- and middle-income settings, particularly from anaesthesia, are orders of magnitude worse than in high-income settings.[74] The anaesthesia team that worked with the SSSL project considered the interventions required to improve anaesthesia safety in all settings, and on the basis of evidence concluded that safe anaesthesia was not feasible without basic monitoring in the form of a pulse oximeter.[46] There are an estimated 77 700 operating theatres worldwide that do not have access to pulse oximeters, despite this being a minimum requirement in 58 countries with national anaesthesia monitoring standards[75] and a requirement of international standards for a safe practice of anaesthesia.[76] A quality improvement study indicated that it was feasible to introduce pulse oximeters into low-income settings with appropriate educational support and that this was associated with a change in practice.[77]

The introduction of the WHO checklist with pulse oximetry is the focus of the WHO Global Pulse Oximetry Project and a new charity called Lifebox has been formed by the Association of Anaesthetists of Great Britain and Ireland, the World Federation of Societies of Anaesthesiologists, and the Harvard School of Public Health specifically for this purpose (www.lifebox.org). Pilot studies are underway to assess the impact of this initiative, and as of April 2012, over 1700 low-cost pulse oximeters have been supplied through this project.

The future

The WHO Surgical Safety Checklist has been designed for routine use in operating theatres as a 'standard operating procedure'. This begs the question of what should be done

in a crisis situation? The Harvard group has recently developed a number of checklists to be used during commonly encountered emergencies in theatre. Twelve 'crisis checklists' were developed after an appraisal of evidence and according to best practice.[23,78] Teams were tested in the simulator and were randomly assigned to use the crisis checklist or to deal with simulated emergencies (such as hypotension or bronchospasm) according to memory. The use of the crisis checklist was associated with a six-fold reduction in failure to adhere to critical steps in the management of the emergency, providing a suggestion that just as in the airline industry, checklists may help avoid missing crucial steps in highly pressurized situations.[77]

Anaesthetists are used to checklists in theatre, the best known being the anaesthetic machine checklist. Safety checklists are now available for multiple situations, on the ward, in the ICU, and in the operating theatre. While seemingly simplistic, the evidence supports the fact that our patients benefit from well-designed checklists when they are used effectively. Effective implementation requires training, coaching, and a change in safety culture, with routine measurement and regular feedback of outcomes. The NPSA vision of implementing the WHO checklist on a national scale was bold, but it is a goal worth achieving. For those who find the culture of using checklists difficult, the barriers are not the time taken, or that the checks are unnecessary, but lie within ourselves and our ability as clinicians to adapt our safety culture to perform checks in a prescribed manner. When we catch a plane, none of us object to our passport being checked and we expect that routine safety procedures will always be followed. Our patients should be guaranteed the same.

Declaration of interest

I.A.W. is a Lifebox trustee, Council member of the Association of Anaesthetists of Great Britain and Ireland, Chair of the Publications Committee of the WFSA, and is on the Editorial Advisory Board of *Pediatric Anesthesia*. S.R. is employed as implementation manager by the Lifebox Foundation. I.H.W. is a Lifebox trustee, President of the Association of Anaesthetists of Great Britain and Ireland, and WFSA Executive.

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