

The impact of surgical safety checklists on theatre departments : a critical review of the literature

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The impact of surgical safety checklists on theatre departments: a critical review of the literature.

Abstract

The World Health Organisation's Safer Surgery Checklist has become an integral part of standard practice in operating theatres in the United Kingdom and other countries. However, there still exist some doubts and questions over how much of an effect the checklist actually has with some staff feeling some resentment towards it. This review explores the impact of the checklist on theatre departments and how this literature can be utilised to inform practice. The evidence found supports use of the checklist showing that it reduces patient morbidity and mortality, improves communication and teamwork, reduces operating time and can reduce theatre costs. Negative perceptions surround the checklist arising from misconceptions and lack of understanding resulting in varied but generally poor compliance. Further research is required across all areas of use but with a focus on education and implementation strategies that address existing barriers.

Keywords WHO checklist, impact, theatre

Introduction

Following the work by Haynes et al (2009) as part of the Safe Surgery Saves Lives study group, the implementation of briefing checklists in theatre departments has become increasingly popular by health organisations as a mode of improving patient safety. The most popular model of these, though others do exist, is that developed and piloted by the Safe Surgery Saves Lives study group (Haynes et al 2009, Weiser et al 2010a) leading to the WHO Safer Surgery Checklist. Since its introduction in 2009, it has been adopted by hospitals in 122 countries and as a national strategy in 25 countries (Conley et al 2011), including the United Kingdom where it was introduced and made a mandatory requirement of operating theatres in the National Health Service (NHS) in 2010 (Panesar et al 2011, Alnaib et al 2012, Fudickar et al 2012). The NHS version of the checklist was modified by the National Patient Safety Agency (NPSA) and can be adapted further for local use to allow for differing surgical procedures (NPSA 2009a), an aspect encouraged by the group that designed it (Weiser et al 2010a).

However, despite increasing use of the checklist, the issue of it being used as a tick box exercise has been raised (Wilson & Walker 2009, Fudickar et al 2012, Levy et al 2012, Coates 2014), along with how sustainable it is over time (Weiser & Berry 2012). Additionally, despite the success of the study by Haynes et al (2009) a number of studies are beginning to challenge the link between checklist use and improved outcomes (Yuan et al 2012, Urbach et al 2014), not just in surgery but also in other clinical areas (Ko et al 2011). One example given by Yuan et al (2012) citing Allen (2010), was that on closer examination of the reported data the improvements observed by Haynes et al (2009) were only statistically significant in three of the eight hospitals, all of which were in developing countries. The variability in effect

sizes between study sites was also noted by Bergs et al (2014). Further examination also shows that while statistically significant improvement for 'any complication' was reported, when looking at individual complications improvement is statistically significant for just three: surgical site infection, unplanned return to theatre, and death. Whilst it cannot be denied that this is still a vital improvement in surgical safety, its applicability to developed countries, many of which already had systems and processes in place that were duplicated by the checklist has been an issue raised by health care staff (Fourcade et al 2012, Fudickar et al 2012, Aveling et al 2013).

The need for improvements in patient safety is paramount in current healthcare management (Alnaib et al 2012) and forms a key component of the NHS Mandate (DH 2014). Successful implementation and utilisation of surgical checklists can potentially contribute significantly towards meeting this and other policies. Correct use of the current checklist prevents many adverse incidents, some defined by the Department of Health (DH) as 'never events' (DH 2012, NHS England 2013). In their taskforce report in addressing the number of surgical never events, NHS England reported that 255 of the 329 never events reported to Strategic Health Authorities in 2012/2013 were surgical never events. These surgical never events with their respective number of incidents were: wrong site surgery (83), wrong implant/prosthesis (42), and retained foreign object post-operation (130). Whilst there is no item on the checklist for checking implants and prosthesis, items exist for correct site marking, and instrument and swab counts, implying that had the checklist been used correctly in each of these cases, the never event would have been prevented. This alone highlights that it is therefore essential that the checklist is used

as a measure to prevent incidents arising (NPSA 2009b, DH 2012, NHS England 2013). Other items on the checklist help meet guidelines and policies for other aspects of patient safety and care such as the National Institute for Health and Clinical Excellence (NICE) guidelines for the prevention of surgical site infection (2008).

Suggestions for if and how the surgical checklist can be developed and enhanced to lead to further improvements in patient safety and operating theatre efficiency is a current topic of interest in healthcare. Some institutes are addressing this by introducing the use of briefings and debriefings before and after surgical lists, other institutes are choosing to develop and utilise more extensive multidisciplinary checklist pathways such as SURPASS (SURgical PATient Safety System) (de Vries et al 2009). Improving compliance, implementation strategies and continuing education of staff are further factors, all of which need to be addressed within development of the checklist design and process.

This review explores the impacts that briefing checklists are having on theatres both in terms of practice and staff behaviours. These are also discussed in terms of how they have resulted in any improvements in patient safety, along with how information from the literature can be used to inform checklist development and implementation strategies.

Methods

A search strategy was constructed using synonyms and Boolean operators so that it would encompass a broad range of studies to allow assessment of the many ways in which checklists potentially affect the way a theatre department works. Search terms used were checklist, briefing, debriefing (background reading suggested the checklist was sometimes referred to as a briefing/debriefing); surgery, surgical, operative, perioperative, preoperative, intraoperative; influence, outcome, advantage, disadvantage, consequence, improvement, result, utilise, utilisation, implementation. Databases utilised were CINAHL Complete, MEDLINE and Scopus. Following searches on CINAHL Complete and MEDLINE, CINAHL headings and MeSH terms respectively were identified and also searched. Final searches took place to include all papers up until the end of January 2015. Papers not in English were excluded. Screening of papers for relevance was carried out based on title, abstract and then the full paper itself. At this stage it was decided to exclude those that implemented briefing checklists as part of a wider initiative and focus on those implementing only the checklist at that point in time. This excluded those utilising extended pathways such as SURPASS (de Vries et al 2010, Tang et al 2014, Treadwell et al 2014), and those introducing other methods such as list briefings and debriefings at the same time (Bliss et al 2012, van Klei et al 2012). This was because it would be difficult to attribute any impacts solely to the implementation and use of the checklist. They could have been a result of either part of the additional components introduced, or the cumulative effect of successful introduction of all parts. Publications from the original WHO Safe Surgery Saves Lives project that developed the WHO checklist were excluded. This was because this work was the initiator of the implementation project and subsequent policies. Whilst still important, we know that the impacts from this work were largely positive otherwise it would not have led to global

implementation. It was therefore important to look at how further studies replicated or contradicted these findings when applying the checklist outside of the institutions included in the WHO project.

Critical appraisal of selected papers was undertaken utilising a critical appraisal tool available from BestBETs, an online resource largely based on the works by Crombie, Sackett and Greenhalgh (BestBETS, no date). Thematic analysis of the content of papers was carried out to identify broad themes and subthemes allowing the identification of different impacts of checklist use on theatre departments. Two of these themes were pre-determined as patient safety and teamwork as it was expected that the majority of papers would relate to these.

Results

Initial database searches returned 888 results leading to 533 papers once duplicates had been removed. After the initial screening process based on relevance of title and abstract, 82 full text papers were read applying the further exclusion criteria resulting in 19 papers being identified for inclusion in the review. No further papers were identified for inclusion through citation chaining. The further database searches for papers published up until the end of January 2015 yielded 3 further papers for inclusion leading to 22 in total. Summaries of the findings from each study are shown in Table 1.

Overall, the methodological quality of included studies was high, with the vast majority employing methods that were appropriate to address their research question. They included designs that could achieve the study aims in an appropriate manner which could be repeated, measures to eliminate bias where possible, and samples that represented the population group that their aims and subsequent conclusions applied to. These collectively ensure the reliability of the results and conclusions drawn in the studies. This in turn means that a suitable body of literature was obtained to address this review questions and allow identification and evaluation of the impacts of surgical safety checklists on theatre departments.

Thematic analysis of studies identified two further themes from the included papers in addition to the two that were predetermined. Each theme contained within it further sub themes. These were: Safety (morbidity and mortality, perceptions of safety), Team (communication, perceptions of teamwork, hierarchy and resistance, accountability), Administration (education/training, workload, checklist design, checklist timing, resources), and Efficiency (perceived delays, financial costs). As well as these themes, issues relating to compliance and how these may affect interpretation of results were also identified across studies.

Discussion

Compliance

The papers included in this review, indicated that compliance of checklist use is both varied and inconsistent across studies and therefore likely to be the case in practice.

This is a similar finding to that made in other studies (Levy et al 2012, Hannam et al 2013, Michael et al 2013, Rydenfält et al 2013, Sparks et al 2013, Tang et al 2014, Russ et al 2015b). Only eight of the original studies included in this review reported data relating to the compliance, completeness, or quality of compliance, of the checklist utilised.

Data regarding compliance is essential when interpreting any impacts observed, as those with a higher compliance are more likely to be demonstrating a true impact as the checklist is properly implemented, whereas impacts observed in studies with low compliance could actually be the result of other factors. Compliance rates between studies showed extreme variation, 0-100% in one study alone (Fourcade et al 2012). This was largely due to the varying definitions of what was deemed compliance. Interestingly, Pickering et al (2013) reported that whilst their compliance data showed one level of compliance, administrative audits carried out at the same institutes while their study was ongoing reported much higher levels of compliance of more than 95% in all cases, compared to their findings of 38.5% which is similar to the findings made by Levy et al (2012). This once again demonstrates varying levels but also highlights the differing ways in which compliance is being defined and measured, even within the same institute. It also illustrates the growing concern that the checklist is becoming a 'tick box' exercise rather than fulfilling its purpose. This could actually endanger patient safety by introducing complacency and a false sense of security (Whyte et al 2008, Levy et al 2012, Sparks et al 2013, Russ et al 2015a, Russ et al 2015b).

Of all of the studies included in this review, not one reported 100% compliance with checklist use overall. This was even the case in the UK studies where the checklist is mandatory (NPSA 2009b) and should therefore have shown full compliance. This in turn raises questions about policy making, and professional standards of theatre personnel, as a strategy is in place which is required by both local and national policy, yet staff fail to carry out their duty in meeting this (HCPC 2012, NMC 2015). Such non-compliance has been investigated in other studies and arises from a variety of reasons such as lack of leadership, poor implementation strategies, and normalisation of deviance (Carthey et al 2011).

In the context of this literature review, the reported variance in compliance, and potential false compliance thus poses problems for assessing the scale or reliability of any of the impacts observed in any study. This was a problem also encountered in the review study by Tang et al (2014). Many studies do not provide any information on compliance rates at all and so given the variance observed in other studies it is wise to assume the same potential variance and inconsistency when interpreting findings from other studies unless they state high levels of compliance themselves.

Patient Safety

From papers included in this review it can be concluded that use of the checklist leads to a statistically significant reduction in morbidity and mortality (Askarian et al 2011, Yuan et al 2012, Bergs et al 2013, Lepänluoma et al 2013, Gillespie et al 2014, Lyons & Popejoy 2014, Patel et al 2014). Other studies that did not meet the criteria

for this review also draw this conclusion (Haynes et al 2009, Weiser et al. 2010b, Bliss et al 2012, van Klei et al 2012, Treadwell et al 2014). There were however two studies (Sewell 2011, Urbach et al. 2014) that showed no significant reduction in morbidity and mortality. Given the quality studies included, and the fact that it is repeatedly found in other studies it is highly probable that this reduction is an actual effect due to checklist use, despite potential differing compliance rates. A much larger variance is seen in the data for morbidity when compared to mortality. Lyons and Popejoy (2014) offer an explanation for this; mortality being a single event, whereas a single patient can suffer from multiple morbidities.

Observed reductions in complications generally appear to be in events where there is a specific item on the checklist that addresses their prevention such as surgical site infection. These items have been shown by other work to often have higher compliance than other items on the checklist (Rydenfält et al 2013). This better compliance demonstrates recognition by staff that the item is beneficial, and this improved compliance may also be partly responsible for the size of the observed reductions. This however, could also question the relevance of some of the other clinical items if they are not having a demonstrable effect on any patient outcomes. It is these items that appear to be responsible for generating the negative perceptions that staff members hold with regard to the checklist, resulting in lower compliance which may be the cause of smaller effect sizes.

The area of staff perceptions of safety is complex and is closely linked to communication and team work. Overall an improvement in staffs' perceptions of patient safety through use of the checklist was reported in the majority of studies (Sewell et al 2011, Yuan et al 2012, Haugen et al 2013, Papaconstantinou et al 2013a, Lyons & Popejoy 2014, Patel et al 2014) and reflects the observed improvements in patient morbidity and mortality. However, there still remains a dismissive attitude by some staff members towards the checklist regarding its influence on safety and its applicability towards every theatre (Aveling et al 2013, Russ et al 2015a). Some staff appear to view critical events as something that would never happen to them and therefore have no need for the checklist. This indicates an underlying problem within safety culture and a failure to recognise that without effective mechanisms in place, adverse incidents can, and will happen. Unfortunately this negative attitude towards safety was often linked to surgeons' behaviour in the included studies. This in turn has detrimental effects on the theatre team and is discussed later.

Teamwork

Teamwork is a complex area relating to communication, team dynamics, work culture, attitudes of staff, and staffs' perceptions of these. Examining this theme was complicated as a result of this and also because not only does the checklist have an impact upon aspects of teamwork, but it itself impacts on use of the checklist, and the extent at which other impacts are observed. However, overall, the evidence from the literature indicates that there is both an observed, and a perceived improvement in communication and teamwork (Sewell et al 2011, Takala et al 2011, Böhmer et al

2012, Lepänluoma et al 2013, O'Connor et al 2013, Papaconstantinou et al 2013a, Russ et al 2013, Lyons & Popejoy 2014). This is through the checklist working as a prompt for key communication events to take place and subsequently enhances teamwork through a shared awareness of the patient and their treatment demonstrating the positive impact that the checklist aimed to achieve (Nilsson et al 2010, Rydenfält et al 2013).

However, some interesting negative impacts also arose from these studies. Firstly the use of the checklist appears to have generated some confusion over who in the team is ultimately accountable for items on the checklist, the person who is responsible for answering the question, or the person who signs to say that the check took place. This is a particular problem when scepticism and resistance exist between staff members who then do not participate fully in the checklist, leading to mistakes (Fourcade et al 2012).

This leads onto the second negative impact found, the effect of hierarchy, discussed in several of the studies (Fourcade et al 2012, Aveling et al 2013, O'Connor et al 2013, Russ et al 2013, Gagliardi et al 2014). The checklist aims to foster teamwork and lead to a shared ownership of patient care. This was demonstrated in the study by Avansino et al (2011) where participants felt more encouraged to speak up about any concerns they had through the use of the checklist. Yet it cannot do this whilst hierarchy persists. Whilst the checklist can help in diminishing hierarchy through providing a mechanism for team discussion thus improving teamwork, both Russ et al (2013) and Gagliardi et al (2014) reported that it can also worsen this. This

occurred if there was a strong resistance from a senior member, as this led to tension and the differing opinions of the value of checklist antagonised team dynamics. As mentioned previously, such resistance and resulting tensions, in the majority of studies appears to be caused by surgeons. This negative impact on teamwork needs addressing, initially through education both with regards to patient safety data and to communication and teamwork skills. This would help eliminate the common misconceptions that this reluctant group have, and help to break down existing hierarchy. If such measures are unsuccessful then management need to implement disciplinary measures, applicable to all resistant staff members. Non-adherence to other hospital policies is not tolerated and results in disciplinary action, therefore why should non-adherence to the checklist be treated differently and persist without consequences? This in itself could be leading to low compliance as resistant individuals are not being reprimanded, whereas if there was a demonstrable consequence it would provide another incentive to carry out the checklist properly and meet standards of care. Such individuals currently not acting in patients' best interests through proper use of the checklist are not upholding patient safety and are therefore contravening their professional codes of conduct (HCPC 2012, NMC 2015).

Administration

Several aspects regarding the administration of the checklist were found to impact on the department. Negative issues surrounding management involvement of the checklist can be seen to have led to demoralisation of staff and low compliance. Pickering et al (2013) comments on the implementation of mandatory reporting of

compliance of the checklist with a 100% target that led to it becoming a tick box exercise, a concern shared in other work (Levy et al 2012).

The design and timing of the checklist generate particularly negative impacts on staff through causing confusion both in terms of what was meant, and its timing. Staff members regard some items of the checklist to be ambiguous, and the duplication with other processes often leads to frustration over increased workload and repetition. This could be addressed by rephrasing items and by looking at integration with, or omission of other existing processes along with increased education. From the literature it appears that many institutes complete a paper copy of the checklist for each patient (sometimes integrated into the peri-operative care plan), often documenting responses to items, to be filed in the patients' notes. This does indeed duplicate existing processes but is this separate paper copy necessary? Could the checklist be performed just as effectively, if the checklist was carried out using for example a poster copy in theatre to prompt the discussion? Existing care plans could be modified to include a single line for each of the three parts of the checklist for practitioners to sign to acknowledge that the checklist was performed and so still meet policy requirements rather than including a copy of the checklist in its entirety. This measure would omit the barrier of perceived duplication and increased workload which could subsequently lead to a more positive attitude towards the checklist.

The sign out stage of the checklist seems to be an area of concern, with the impact of timing resulting in an impact on compliance. This conclusion has been noted by others (Vats et al 2010, Hannam et al 2013) and is also demonstrated by a recent

observational study by Russ et al (2015b). This can be explained by it occurring at a critical time of high workload for anaesthetists and circulating staff making it difficult to pause at this point to complete the checklist. This negative impact indicates an incompatibility with standard theatre practices (Pickering et al 2013, Russ et al 2015b) and so therefore needs reviewing in terms of when exactly it is best to complete this stage of the checklist. Current recommendations are that sign out takes place before the surgeon leaves and can coincide with wound closure (WHO 2009) yet answers to some items are not known at this stage (Russ et al 2015b), for example, final swab and instrument counts, and concerns for recovery which from an anaesthetic viewpoint may not arise until extubation. However, if left until after closing, the surgeon is often no longer present as demonstrated by Russ et al (2015b) and circulating staff may also be absent clearing away equipment or setting up for the following case. These design and timing issues demonstrate the need to periodically review and evaluate the checklist and its use (Putnam et al 2014) as well as the need to educate and instil the value of the checklist as a safety tool amongst staff.

From this review it is clear that the checklist impacts on the educational needs of staff and vice versa. A lack of knowledge and awareness of all aspects of checklist use results in low compliance and poor quality of its completion, risking it becoming a rote task (Levy et al 2012). This needs addressing with the provision of successful educational and implementation strategies to ensure its continued success and further development and should avoid sole dissemination of guidelines (Conley et al 2011, Gonzales et al 2012, Putnam et al 2014). Key points in doing this is that education must be continual and multidisciplinary (NHS England 2014), and it should

also be tailored to address local needs and local barriers (Whyte et al 2008, Russ et al 2015b). Such education should be targeted to abolish negative issues surrounding the checklist and should ideally employ multiple methods using a team approach (Putnam et al 2014). Staff need to fully understand the purpose of the checklist, be provided with evidence be it research, or data from their own institute regarding safety incidents to facilitate its use. This helps build an appreciation for how and why the checklist works which increases 'buy-in' (Conley et al 2011). Although this may lead to increased time and financial costs for the training of staff to be delivered appropriately and effectively, the priority should remain on patient safety and delivering optimum care to patients.

Efficiency

Use of the checklist can be said to have a positive impact on theatre efficiency yet staff do not notice this. There appears to be a perception that the checklist imposes delays, yet the little evidence available so far shows this not to be the case and that checklist use actually reduces operating time (Bliss et al 2012, Papaconstantinou et al 2013b). Whilst not able to prevent every possible time delay, it is easy to see how the checklist is able to achieve this reduction. Staff are more likely to be better prepared for each case as a result of improved communication, for example having equipment available in theatre to address potential events rather than having to retrieve it later when an event happens thus causing a delay. In addition to this, items relating to site marking, patient identification, allergies, and blood loss help ensure that both patients and staff are appropriately prepared for theatre and so avoid imposing delays later on.

There is little available literature available examining the financial impact of the checklist, with this review only retrieving one paper in its search (Papaconstantinou et al 2013b). However, this single paper reported a significantly reduced theatre disposable cost by a mean value of \$68/operation ($P < 0.0001$). They concluded based on 18,000 procedures per year, this would lead to savings over \$1.2 million at their site thus demonstrating its value as a cost saving mechanism (Papaconstantinou et al 2013b). Whilst these findings should be treated with caution with it being a single study at a single site, such findings should equally not be completely ignored. If nothing else they justify the need for further research in this area. In these current times of austerity and funding cuts, such evidence could provide managers and other staff with the incentive to address ongoing negative issues to optimise checklist use as a potential cost saving mechanism. It appears obvious how such savings can be made despite increased costs incurred through educational provision and interventions to improve its use. Work by Semel et al (2010) found that estimated implementation costs of the checklist were cheaper than the estimated costs involved in a single major complication (\$12,635 versus \$13,372). Savings through checklist use arise through a variety of mechanisms. Firstly the checklist allows for clarification of procedures and potential events, thus ensuring that the correct equipment and drugs are opened and prepared. The identification of 'near misses' thus preventing critical and never events such as confirmation of instrument and swab counts, prevents additional costs from theatre returns and subsequent legal costs in dealing with the result of these. In addition, there is a potential reduction in costs to the wider hospital, for example checking that appropriate antibiotic prophylaxis has taken place and confirmation of the sterility of

instruments help reduce the incidence of surgical site infection and therefore additional treatment and/or hospital stay. Cumulatively, these small reductions in costs could generate a significant saving for theatre departments.

Limitations

As with other review studies, the limitations of this study are influenced by those of the included studies themselves. One of the main limitations occurring across numerous studies was that of an observed, or a potential, Hawthorne effect when the performance of staff is altered, usually positively, due to their being observed (Gosall & Gosall 2009). Publication bias also needs to be considered as a limitation to this review, as well as language bias as only studies published in English were considered.

Data analysis for all areas proved difficult due to the limitation imposed by the heterogeneity in study methods, designs and measures. It would have been useful if data could have been aggregated but given the differing data, trying to do this would have yielded unreliable results. Therefore thematic analysis was the most appropriate way to analyse data but even this had its problems due to the multiple impacts of the checklist and the way in which these are all interlinked with each other. As much as studies were categorised into themes, it is not as simple as a study showing only one impact. Each impact often leads to another and so on giving numerous, complex, interwoven impacts making it difficult to assign many concepts to single, clear themes.

Studies included in this review were carried out in predominantly developed countries and so not really representative of the global population which the checklist aims to apply to. One of the key factors for this lack of available research is the possible lack of infrastructure, resources, and funding for research to be carried out in less developed countries. This therefore needs addressing for the impact of the checklist to be evaluated and for it to be continually advocated as applicable to a global population, as at present there are few studies providing evidence to support this.

Conclusions

This literature review has shown that the introduction of surgical safety checklists has had many impacts, predominantly positive, on theatre departments. The available evidence shows that use of the checklist reduces patient morbidity and mortality, improves staff teamwork and communication, reduces operating time and reduces theatre costs. Staff however, do not appear to be fully aware of all of this evidence and have many negative perceptions surrounding the checklist which are demonstrably false. Overall this suggests that the checklist is a valid and appropriate safety tool and every effort should be made to pursue its development and improved use through addressing the negative perceptions held by staff.

Future research

The majority of the available research understandably focuses on patient safety, and teamwork and communication. This work is essential to increase the evidence base and emphasise the relevance to clinical practice to address some of the barriers that exist to checklist use (resistance and negative perceptions). This seems to be more of an immediate need for developed countries. In contrast, in developing countries there appears to be a lack of existing research in relation to all aspects of checklist use which needs to be addressed.

Research focusing on compliance and implementation strategies would be beneficial to both developed and developing countries alike. Identifying the barriers and facilitators to compliance and addressing each one would be invaluable in increasing compliance and therefore observing the extent of the checklists' impact more accurately. Establishing successful implementation strategies from evaluating different models would also help achieve this. Some of this has recently been carried out in the NHS by Imperial College, London as part of the Surgical Checklist Implementation Project funded by the NIHR (National Institute for Health Research) with papers from this project published at the time of writing included and greatly informing this review (Russ et al 2013, Russ et al 2015a) and subsequent discussion (Russ et al 2015b). Such work on a national or large scale needs to continue to build the knowledge base so that outcomes from checklist research can then be applied to practice more effectively through proven successful models for implementation strategies. Cumulatively this research will help confirm and maintain applicability and ensure that the checklist and related strategies continue to evolve to generate best practice and ensure the safety of surgical patients worldwide.

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