Systematic review

Systematic review and meta-analysis of the effect of the World Health Organization surgical safety checklist on postoperative complications

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Background: **The World Health Organization (WHO) surgical safety checklist (SSC) was introduced to improve the safety of surgical procedures. This systematic review evaluated current evidence regarding the effectiveness of this checklist in reducing postoperative complications.**

Methods: **The Cochrane Library, MEDLINE, Embase and CINAHL were searched using predefined inclusion criteria. The systematic review included all original articles reporting a quantitative measure of the effect of the WHO SSC on postoperative complications. Data were extracted for postoperative complications reported in at least two studies. A meta-analysis was conducted to quantify the effect of the WHO SSC on any complication, surgical-site infection (SSI) and mortality. Yule's *Q* contingency coefficient was used as a measure of the association between effectiveness and adherence with the checklist.**

Results: **Seven of 723 studies identified met the inclusion criteria. There was marked methodological heterogeneity among studies. The impact on six clinical outcomes was reported in at least two studies. A meta-analysis was performed for three main outcomes (any complication, mortality and SSI). Risk ratios for any complication, mortality and SSI were 0·59 (95 per cent confidence interval 0·47 to 0·74), 0·77 (0·60 to 0·98) and 0·57 (0·41 to 0·79) respectively. There was a strong correlation between a significant decrease in postoperative complications and adherence to aspects of care embedded in the checklist ($Q = 0·82$; $P = 0·042$).**

Conclusion: **The evidence is highly suggestive of a reduction in postoperative complications and mortality following implementation of the WHO SSC, but cannot be regarded as definitive in the absence of higher-quality studies.**

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Introduction

Hospitals are not as safe as generally believed[1]. Overall, the incidence of in-hospital adverse events is about 10 per cent, of which three-quarters are related to surgery. At least half of these adverse events are considered preventable within the current standards of care[2–4]. The rate of patients experiencing an adverse event is even expected to increase over time[5]. The incidence of surgery-related adverse events combined with the increasing volume of surgery[6] results in an important healthcare problem.

With the aim of improving patient safety following surgery, a checklist was developed by the World Health Organization (WHO) patient safety programme, similar to those used in aviation, aeronautics and product manufacturing. The surgical safety checklist (SSC) consists of 19 items and is used at three critical perioperative moments: induction, incision and before the patient leaves the operating theatre. The items contain an oral confirmation by the surgical team of the completion of some key steps for ensuring safe delivery of anaesthesia, antibiotic prophylaxis, effective teamwork and other essential practices in surgery[7].

Previous studies[8,9] suggested that implementation compliance was low, despite checklist awareness by the theatre team. The knowledge that checklists are executed

incompletely makes the evaluation of a team's compliance with the checklist as important as evaluating clinical outcomes[9,10]. However, to date, only one single-centre study[11] has examined the extent to which the WHO SSC effectiveness is related to checklist adherence.

The aim of this review was to assess the effectiveness of the WHO SSC. The first objective was to assess the effect of the checklist on postoperative complications and mortality following implementation; the second was to assess the relationship between clinical outcome and adherence with the WHO SSC.

Methods

Data sources

The Cochrane Library, MEDLINE, Embase and Cumulative Index to Nursing and Allied Health Literature (CINAHL) databases were searched systematically for all publications until February 2013. The following medical subject heading (MeSH) search terms and keywords were used, either individually or in combination: 'Postoperative complications'[MeSH], 'Checklist'[MeSH], 'Postoperative complications, prevention and control'[MeSH]. The MEDLINE search strategy (*Appendix S1*, supporting information) was adjusted to the dictionary of the other databases as appropriate. This was accompanied by a checklist-specific query using the following keywords: 'Safety Management'[MeSH], 'Risk Management'[MeSH], 'Checklist'[MeSH]. In addition, bibliographies of included articles were hand searched for other relevant articles. During the preparation of the manuscript, the MEDLINE strategy was consulted weekly in order to identify potentially new relevant publications. Grey literature was not considered.

Study selection

Only English-language studies were included. Potentially included study designs were: randomized clinical trials, non-randomized controlled trials, controlled before–after studies, interrupted time series (ITS) and repeated-measures studies. Only studies with a quantitative evaluation regarding the impact of the WHO SSC on postoperative complications, including postoperative mortality, were included. Studies were excluded if they addressed only a particular issue or complication, such as those solely focusing on the effectiveness of surgical-site marking.

Data extraction

After removal of duplicates, a first selection of references was made based on title and abstract. Papers selected for full-text review were screened according to the inclusion and exclusion criteria. Two independent reviewers carried out data extraction and critical assessment of included studies, with disagreements settled by a third reviewer. Study setting, design, selection and measurement bias, baseline outcome measurements and characteristics, risk of contamination, data analysis, selective outcome reporting, other risks of bias, and issues relating to generalizability and sustainability were extracted and recorded. Assessment for risk of bias and critical appraisal was conducted using the Cochrane Collaboration's Effective Practice and Organisation of Care Group guidelines[12].

Data synthesis and analysis

Data were analysed using R (a language and environment for statistical computing)[13]. All reported P values are two-sided; $P < 0{\cdot}050$ was considered to indicate statistical significance.

Postoperative complications discussed in at least two studies were included in the narrative synthesis. Meta-analysis was performed for three main patient outcome measures: occurrence of any postoperative complication, surgical-site infection (SSI) and death. If a study provided data for more than one site, data from the individual sites were used in order to overcome the effect of aggregated data reporting as well as to limit in-study heterogeneity. Risk ratios (RRs) with 95 per cent confidence intervals (c.i.) were calculated as summary estimates of the effects using a random-effects model, as proposed by DerSimonian and Laird[14]. Heterogeneity of the study results was assessed using the Cochran Q test and the Higgins I^2 test. $P < 0{\cdot}100$ in Cochran's Q test and an I^2 value exceeding 50 per cent were considered to show significant heterogeneity.

Yule's Q contingency coefficient was used as a measure of association between effectiveness and adherence. Yule's Q is a transformation of the odds ratio (OR) designed to vary, not from 0 to infinity with 1 indicating no effect, but from -1 to $+1$ with 0 indicating no effect, as the Pearson correlation. Conceptually, this is the number of pairs in agreement (ad) minus the number in disagreement (bc) divided by the total number of paired observations[15]. Effectiveness of the WHO SSC was represented using a binary variable indicating the occurrence of a significant RR for any complication.

All authors reviewed the measures of adherence individually and determined whether adequate adherence to the SSC could be expected. Adequate adherence was defined as adherence to the provided measures for at least 90 per cent of all patients. Following these individual assessments, a consensus meeting was held at

each site, at which consensus was sought in cases of disagreement. Throughout this procedure the authors were blinded to outcome data and study references. Agreement between the authors regarding their interpretation of checklist adherence was assessed using Fleiss' κ. The resulting decision was expressed as a binary variable representing presence or absence of adequate adherence to the WHO SSC.

Results

In total, 723 potentially relevant articles were retained. After critical assessment of title and abstract, nine papers were selected for full-text evaluation of which two[16,17] were excluded because they did not meet the inclusion criteria. Finally, seven[11,18–23] papers were considered for further analysis. One study[19] was excluded from meta-analysis as it was a reanalysis of a subcohort of patients undergoing non-elective surgery already reported in another study (*Fig. 1*).

Included studies

Haynes and colleagues[18] assessed the effectiveness of the WHO SSC at eight hospitals worldwide. This study, with an ITS design, included patients aged 16 years or older undergoing non-cardiac surgery. After a first exploratory baseline measurement, each institution received feedback about areas of deficiencies identified and was subsequently asked to implement the WHO SSC. The checklist was introduced to the operating theatres over a 1-week to 1-month interval. To facilitate implementation, the checklist was translated to the local language and adjusted to fit into the care process at each institution. A local dedicated study team guided the introduction of the checklist to the staff. Effectiveness was measured as the reduction in any major complication, including death, during the postoperative hospital stay (up to 30 days) or until hospital discharge. Weiser and co-workers[19] conducted a reanalysis of a subsample of adult patients undergoing urgent, non-cardiac surgery. The subsample was drawn from the data used by Haynes and colleagues[18].

Sewell *et al.*[20] evaluated the use of the WHO SSC before and after implementation of an educational programme in one hospital in the UK[20]. This study, with an ITS design, considered trauma and orthopaedic surgery. The programme, which was designed to improve checklist use, consisted of the following measures: SSC forms were placed in the operating theatre so staff members could become more familiar with their use; a compulsory training video was produced, detailing the correct way to fulfil the checklist; and educational sessions were delivered, discussing the main causes of adverse events associated with surgery, and explaining how to use the checklist appropriately. Effectiveness was measured as the reduction in any major complication, including death, during the postoperative hospital stay, up to 30 days or until hospital discharge.

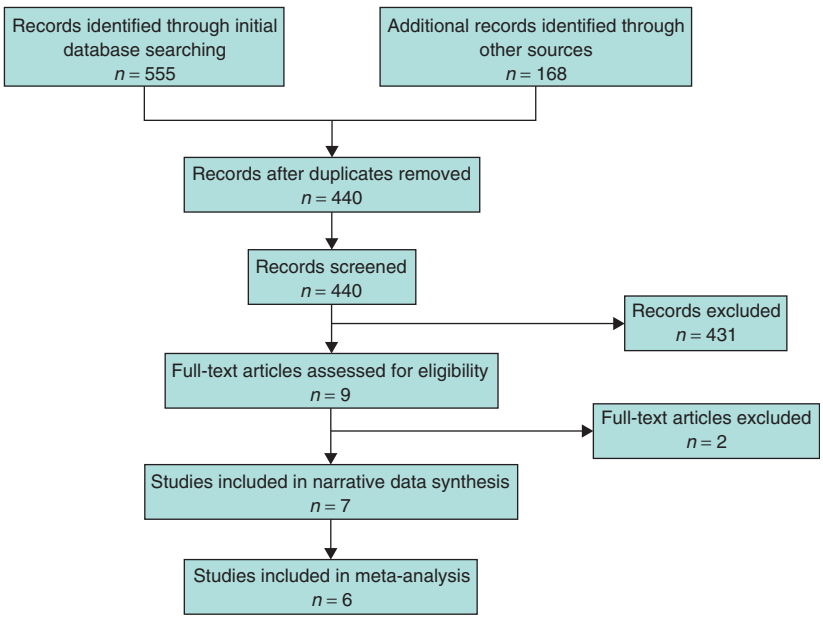

Fig. 1 PRISMA diagram showing selection of articles for review

Askarian and colleagues[21] evaluated the effect of the WHO SSC on postoperative morbidity and mortality rates in a tertiary-care hospital in Iran. This study, with an ITS design, included patients aged at least 16 years undergoing elective general surgery. End-stage and immunocompromised patients were excluded. Baseline assessment was carried out during the first 3 months of the study; postoperative complications were recorded in four hospital wards until hospital discharge. The checklist was introduced during meetings, and an educational package, containing the checklist and accompanying guidelines, was provided to operating theatre personnel. Effectiveness was measured as the reduction in postoperative complications.

van Klei and co-workers[11] evaluated the effect of an adapted version of the WHO SSC on in-hospital mortality, together with the impact of checklist compliance on outcome, in a tertiary hospital in the Netherlands. This retrospective cohort study included all adult patients who underwent a surgical procedure. Modifications of the WHO SSC were made to enhance local applicability, resulting in a 22-item checklist. The entire surgical and anaesthesia team briefly reviewed each surgical patient, replacing the sign-in part of the WHO SSC. To ensure that checklist items were also available to caregivers before a patient entered and left the operating theatre, structured handovers were implemented from the ward to the theatre holding area as well as from the theatre to the recovery room. Implementation information was provided both at regular meetings and during extra meetings with the entire staff (surgeons, anaesthetists and nurses), where the importance of the checklist was emphasized. In addition, the checklist was made available in poster format in every operating theatre and electronically in the scheduling system. Effectiveness was measured as any reduction in in-hospital mortality within 30 days of surgery.

Bliss *et al.*[22] evaluated the effects of the Association of Perioperative Registered Nurses Comprehensive Surgical Checklist at a 600-bed tertiary-care facility and major teaching hospital in the USA. This checklist incorporates mandated clinical practice required by the WHO, the Joint Commission, and the Centers for Medicare and Medicaid Services. This study used an ITS design with historical controls, and included all patients aged 18 years or older undergoing high-risk surgical procedures. Implementation of the checklist involved a three-session team-based training programme. Surgical services staff were oriented to the use of the checklist, and barriers to checklist use were discussed at the training session. Effectiveness was evaluated as any reduction in 30-day mortality and/or postoperative complications.

Kwok and colleagues[23] evaluated the effectiveness of the WHO SSC at a public, university-affiliated general and trauma hospital in Chisinau, Moldova, using an ITS design. The intervention comprised a hospital-wide implementation of the WHO SSC. A local implementation team was created consisting of hospital administrators and representatives from the surgical, anaesthesia and nursing departments. The implementation team was trained during four weekly 30–60-min video conferences, using checklist and oximetry training materials developed by the WHO, Harvard School of Public Health, the World Federation of Societies of Anaesthesiologists, and the Association of Anaesthetists of Great Britain and Ireland. These materials included presentations, manuals, clinical scenarios and videos. Thirty-day complication data were collected as defined by the American College of Surgeons National Surgical Quality Improvement Program.

Risk of bias of included studies

All studies were prone to confounding and bias owing to methodological decisions. All papers reported the results of non-randomized studies, resulting in potential bias. As methodological information was difficult to find, many questions concerning bias and confounding were unanswered. The following potential sources of bias and confounding could be generalized. A first source concerns compliance with checklist use. Six studies[18–23] reported a measure of a subgroup of safety indicators that reflect compliance with the checklist, with a range between 0 and 97·3 per cent. All studies demonstrated variability in compliance between checklist items. This incomplete implementation makes it difficult to attribute the measured effect to the WHO SSC alone. A second source of bias is the implementation strategy used in the studies. Various, often unclear, implementation approaches were used, possibly resulting in different levels of compliance with the WHO SSC. Third, in some studies direct observation was used to evaluate compliance, potentially leading to a Hawthorne effect.

Effects of checklist use on postoperative complications

Any complication

Six studies[18–23] reported data on any complication within 30 days following surgery or until hospital discharge (*Table 1*). Five studies found decreasing complication rates: 11·0 *versus* 7·0 per cent ($P < 0·001$)[18], 18·4 *versus* 11·7 per cent ($P = 0·001$)[19], 22·9 *versus* 10·0 per cent ($P = 0·03$)[21], 23·6 *versus* 8 per cent ($P < 0·001$)[22] and 21·5

Table 1 Summary of major clinical outcomes before and after checklist implementation

	Any complication (%)			Mortality (%)			Surgical-site infection (%)		
	Before	After	*P*	Before	After	*P*	Before	After	*P*
Haynes *et al.*[18]	11·0	7·0	< 0·001	1·5	0·8	0·003	6·2	3·4	< 0·001
Site 1	11·6	7·0	< 0·050	1·0	0	< 0·050	4·0	2·0	< 0·050
Site 2	7·8	6·3	> 0·050	1·1	0·3	> 0·050	2·0	1·7	> 0·050
Site 3	13·5	9·7	> 0·050	0·8	1·4	> 0·050	5·8	4·3	> 0·050
Site 4	7·5	5·5	> 0·050	1·0	0·6	> 0·050	3·1	2·6	> 0·050
Site 5	21·4	5·5	< 0·050	1·4	0·0	< 0·050	20·5	3·6	< 0·050
Site 6	10·1	9·7	> 0·050	3·6	1·7	> 0·050	4·0	4·0	> 0·050
Site 7	12·4	8·0	< 0·050	2·1	1·7	> 0·050	9·5	5·8	> 0·050
Site 8	6·1	3·6	> 0·050	1·4	0·3	> 0·050	4·1	2·4	> 0·050
Weiser *et al.*[19]	18·4	11·7	0·001	3·7	1·4	0·007	11·2	6·6	< 0·001
Sewell *et al.*[20]	8·5	7·6	RR 0·89 (0·58,1·37)	1·9	1·6	RR 0·88 (0·34, 2·26)	4·4	3·5	n.a.
Askarian *et al.*[21]	22·9	10·0	0·03	n.a.	n.a.	n.a.	10·4	5·3	0·1
van Klei *et al.*[11]	n.a.	n.a.	n.a.	3·1	2·9	OR 0·91 (0·78, 1·05)	n.a.	n.a.	n.a.
Bliss *et al.*[22]	23·6	8	< 0·001	n.a.	n.a.	n.a.	6·2	5	0·845
Kwok *et al.*[23]	21·5	8·8	< 0·001	4·0	3·1	0·151	14·9	4·7	< 0·001

Values in parentheses are 95 per cent confidence intervals. RR, risk ratio; n.a., not available; OR, odds ratio.

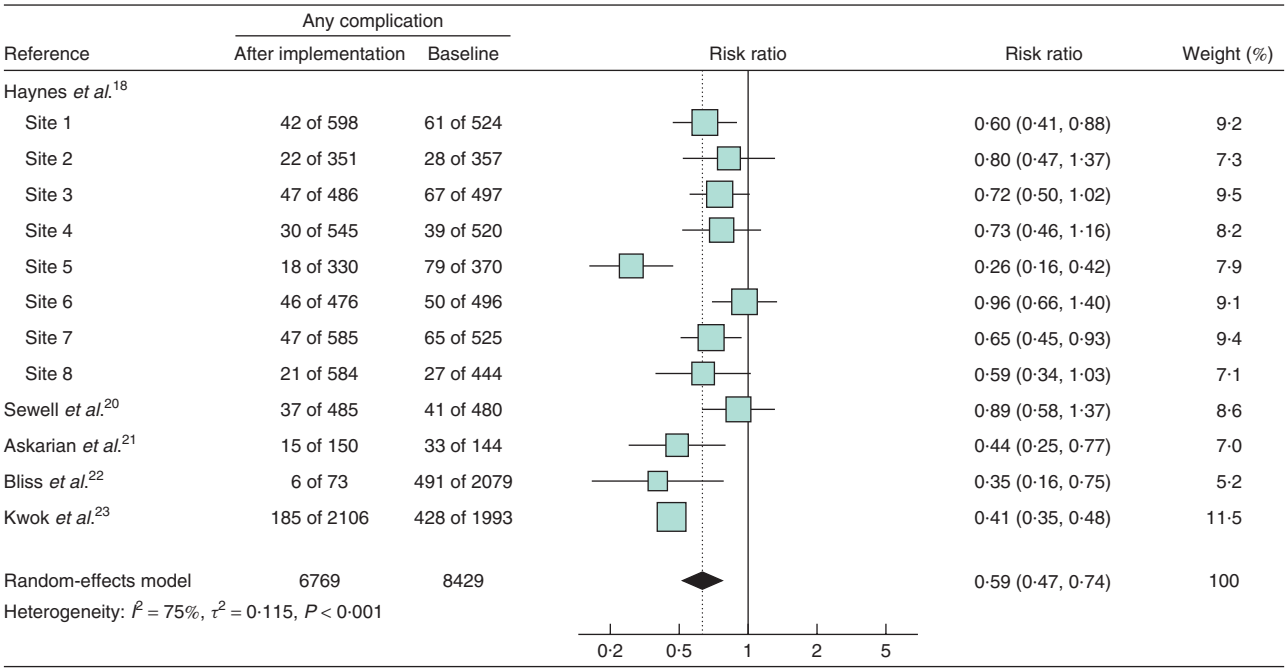

Fig. 2 Forest plot showing the effectiveness of the World Health Organization surgical safety checklist in reducing any complication. A random-effects model was used for meta-analysis. Risk ratios are shown with 95 per cent confidence intervals

versus 8·8 per cent ($P < 0·001$)[23]. One study[20] did not demonstrate a significant difference between evaluation intervals (8·5 *versus* 7·6 per cent; RR 0·89, 95 per cent c.i. 0·58 to 1·37). Meta-analysis for any complication across five studies yielded a RR of 0·59 (95 per cent c.i. 0·47 to 0·74; $P < 0·001$). There was significant heterogeneity (Cochran's Q = 44·07, 11 d.f., $P < 0·001$; $I^2 = 75$ (95 per cent c.i. 56 to 86) per cent) (*Fig. 2*).

Mortality rates

Thirty-day mortality was reported in five studies[11,18–20,23] (*Table 1*). A significant effect on mortality following SSC implementation was found in two: 1·5 *versus* 0·8 per cent ($P = 0·003$)[18] and 3·7 *versus* 1·4 per cent ($P = 0·007$)[19]. van Klei and colleagues[11] reported a decrease in crude mortality rates from 3·1 to 2·9 per cent, but this was not statistically significant ($P = 0·19$). After adjustment

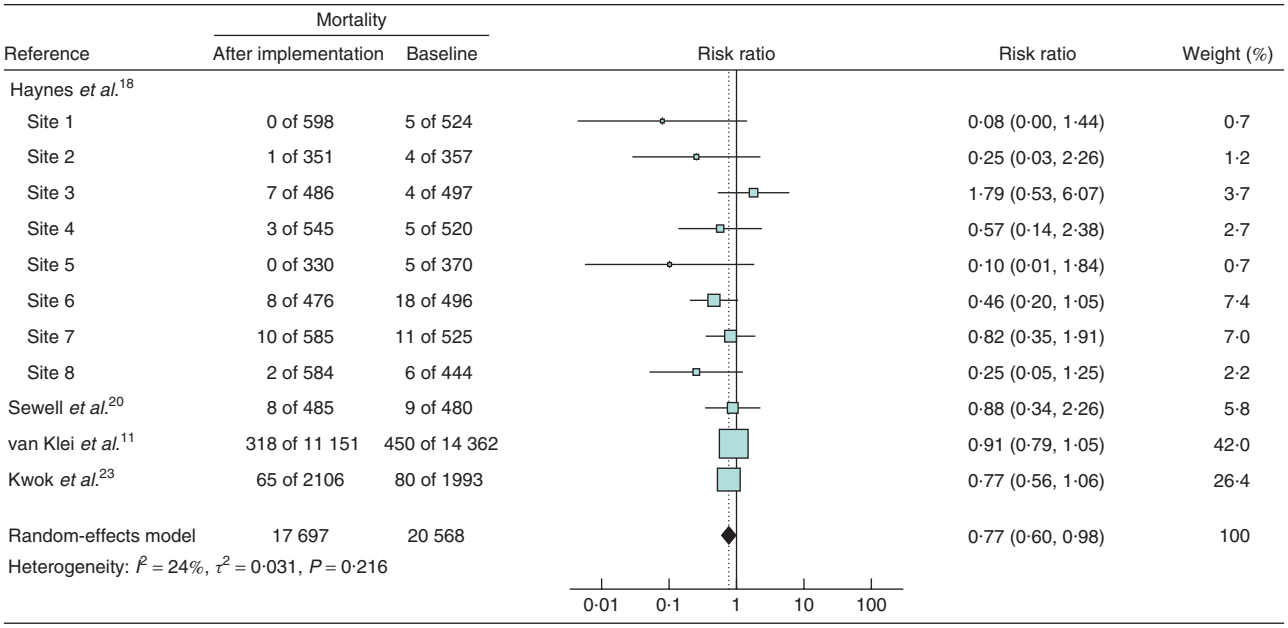

Fig. 3 Forest plot showing the effectiveness of the World Health Organization surgical safety checklist in reducing mortality. A random-effects model was used for meta-analysis. Risk ratios are shown with 95 per cent confidence intervals

for baseline differences, mortality decreased significantly after checklist implementation (OR 0·85; 95 per cent c.i. 0·73 to 0·98). This effect was strongly related to checklist compliance; the OR was 0·44 (0·28 to 0·70) if the checklist was completed fully, compared with 1·09 (0·78 to 1·52) and 1·16 (0·86 to 1·56) for partial and non-compliance respectively[11]. Two studies[20,23] did not demonstrate a significant reduction in mortality. Meta-analysis for crude mortality revealed that across four studies the RR for mortality with the use of the WHO SSC was 0·77 (0·60 to 0·98; $P = 0·035$), without significant heterogeneity (Cochran's $Q = 13·15$, 10 d.f., $P = 0·216$; $I^2 = 24$ (0 to 62) per cent) (*Fig. 3*).

Surgical-site infections

SSIs were reported in six studies (*Table 1*)[18–23]. Three reported a significant decrease in SSI rates following SSC implementation: from 6·2 to 3·4 per cent ($P < 0·001$)[18], 11·2 to 6·6 per cent ($P < 0·001$)[19] and 14·9 to 4·7 per cent ($P < 0·001$)[23]. The other studies did not demonstrate a significant change in SSI rate after implementation of the WHO SSC: 4·4 *versus* 3·5 per cent[20], 10·4 *versus* 5·3 per cent ($P = 0·1$)[21] and 6·2 *versus* 5 per cent ($P = 0·845$)[22]. Meta-analysis revealed that across five studies the RR for SSI with the use of the WHO SSC was 0·57 (95 per cent c.i. 0·41 to 0·79; $P < 0·001$). There was significant heterogeneity (Cochran's $Q = 41·74$, 11 d.f., $P < 0·001$; $I^2 = 74$ (53 to 85) per cent) (*Fig. 4*).

Blood loss

Two studies[19,22] reported on blood loss. In the article by Weiser and colleagues[19], the proportion of patients with estimated blood loss greater than 500 ml declined from 20·3 to 13·3 per cent ($P < 0·001$). Bliss *et al.*[22], however, did not demonstrate a significant difference in the percentage that required transfusion for bleeding (6·1 to 5·5 per cent; $P = 0·392$)[22].

Unplanned return to operating theatre

Three studies[18,20,23] reported details on unplanned return to the operating theatre. In the Haynes study[18] the unplanned return rate dropped from 2·4 to 1·8 per cent ($P = 0·047$)[18]. Sewell and colleagues[20] reported unplanned return to the operating theatre after 1 per cent of procedures in both audits. Kwok and co-workers[23] reported that the unplanned return rate decreased from 1·9 to 1·5 per cent ($P = 0·151$).

Pneumonia

Pneumonia or lower respiratory tract infections were reported in five studies[18,20–23]. One[23] reported a significant decrease in pneumonia rates, from 4·7 to 2·6 per cent ($P < 0·001$). The others all reported a non-significant difference: 1·1 *versus* 1·3 per cent ($P = 0·46$)[18], 2·1 *versus* 2·5 per cent[20], 7·6 *versus* 3·3 per cent ($P = 0·1$)[21] and 2·4 *versus* 0 per cent ($P = 0·362$)[22].

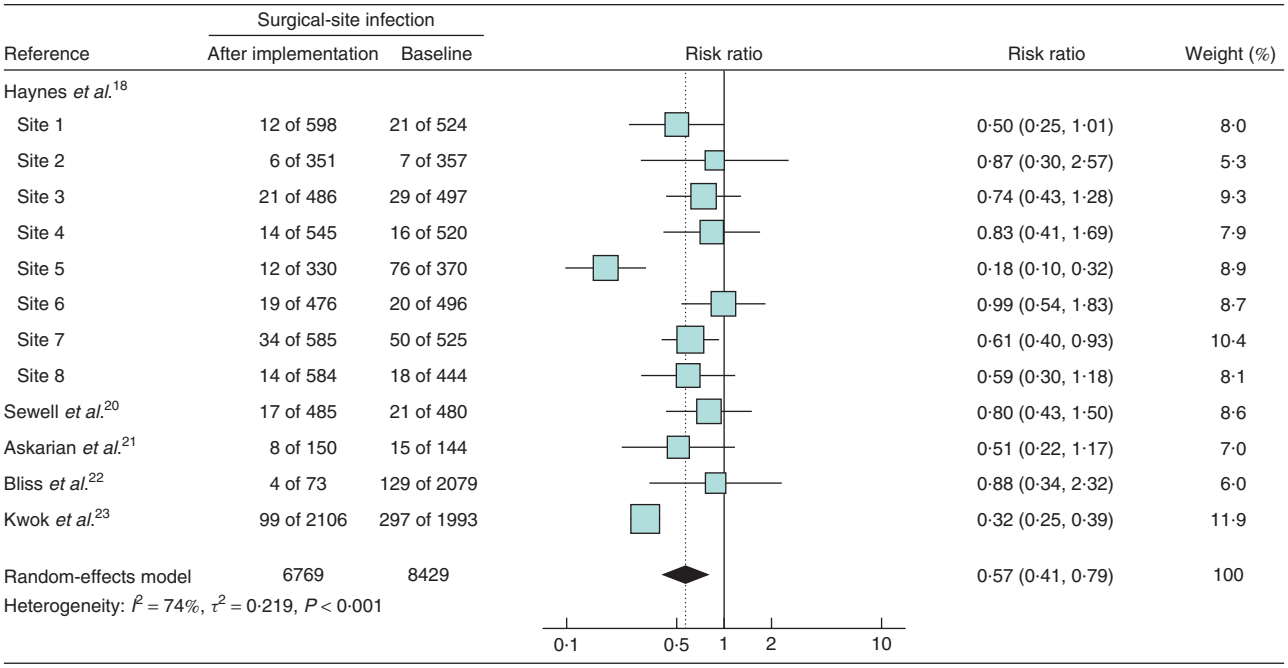

Fig. 4 Forest plot showing the effectiveness of the World Health Organization surgical safety checklist in reducing surgical-site infection. A random-effects model was used for meta-analysis. Risk ratios are shown with 95 per cent confidence intervals

Relationship between checklist compliance and effectiveness

Six studies measured adherence with the SSC. Five[18–22] reported adherence to a subgroup of six safety measures as an indicator of checklist adherence. One study[23] used a subset of five safety measures as an indicator of checklist adherence (for details see *Table S1*, supporting information).

A significant RR, favouring use of the WHO SSC, was found in six of the 12 sites (*Fig. 2*). Within this group, four reported adequate adherence with the safety measures. Of the five sites with adequate adherence, four demonstrated a significant reduction in postoperative complications. In contrast, two of seven sites reporting inadequate adherence demonstrated a significant reduction in postoperative complications. These results suggest a correlation between a significant decrease in postoperative complications and adequate adherence to the reported safety measures ($Q = 0{\cdot}82$, $P = 0{\cdot}042$).

Discussion

The results of this meta-analysis suggest that the WHO SSC reduces postoperative complications, including mortality. Meta-analysis demonstrated a significant effect of the checklist on any complication (RR 0·59, 95 per cent c.i. 0·47 to 0·74), mortality (RR 0·77, 0·60 to 0·98) and SSI (RR 0·57, 0·41 to 0·79). The present study also suggested that sites with adequate compliance with aspects of care embedded in the checklist were more likely to demonstrate a significant reduction in postoperative complications.

Pooled analysis showed significant improvements in postoperative complications following implementation of the WHO SSC. Yet, there was variability in effect sizes among the studies. The variation becomes even more evident when the Haynes study[18] is analysed at site level (*Table 1*). Even when a uniform implementation method is used (as assumed in the Haynes study), variation in adherence and outcome is observed. It is likely that the implementation method has an impact, but it is not the only determinant. Haynes and colleagues[17] showed that improvements in postoperative outcomes were associated with improved perception of teamwork and safety climate among respondents, suggesting that changes in these aspects may be partially responsible for the effect of the checklist.

This study highlights that evaluation of a team's compliance with the checklist, which is measured by adherence, is as important as evaluating outcomes[9,10]. Hospital administrators, implementation leaders and researchers need to measure and report compliance with the checklist in association with clinical outcomes. There is a need for a reproducible method of measuring compliance

that allows a better understanding of its potential effect as a confounding variable affecting checklist efficiency[10,24]. In addition, there is a need to identify the key barriers to improve adherence to the SSC[8].

One other review[25] has dealt with the effectiveness of a checklist during surgery. This general review by Borchard and colleagues did not consider the WHO SSC exclusively. The present review excluded the SURgical PAtient Safety System (SURPASS) checklist[26], which is conceptually different from the WHO SSC. The SURPASS is a comprehensive multidisciplinary checklist divided into parts that correspond to the different phases of the entire surgical pathway (preoperative, operative, recovery or intensive care, and postoperative hospital stay); the WHO SSC covers only the perioperative phase. Inclusion of the SURPASS would therefore be methodologically incorrect here as the two instruments are different. Furthermore, this study used the impact of adherence with individual items singled out for measurement to explain the variation in effectiveness between sites. Only one other study[11] demonstrated the relationship between adherence with the WHO SSC and reduction in postoperative complications. In their study, van Klei and colleagues[11] also showed a decrease in mortality related to the degree of SSC completeness.

The present findings should be interpreted in the context of the included studies and their limitations. Several potential biasing and confounding elements must be considered. First, considerable methodological, clinical and statistical heterogeneity among studies might have hampered the meta-analysis. As a result of various methodological issues and the lack of detailed information regarding implementation and adherence, meta-regression could not be performed in order to explain statistical heterogeneity. Second, as mortality rates were relatively low, some studies[20–23] were underpowered and as such not able to detect a potential difference in mortality. Third, the size of the benefit found in these low-quality studies, expressed as a RR, is not close to the size postulated in general methodological discussions as being sufficient to rule out the need for a randomized trial[27]. Fourth, considering the different cohorts studied, paediatric patients were not investigated. Finally, the interpretation of compliance with the SSC was based on the adherence to a subgroup of safety measures. This is an important distinction as these reported measures represent adherence to specific aspects of care embedded in the WHO checklist. The full checklist probably functions in a different way to the individual items singled out for measurement. Studies emphasize the importance of team function and communication in checklist use, a factor not included in the measures of adherence in the included studies. Compliance with the subgroup of safety measures does not necessarily imply appropriate use of the checklist.

The available evidence is supportive of a reduction in postoperative complications and mortality following implementation of the WHO SSC, but cannot be regarded as definitive in the absence of higher-quality studies. Reduction in postoperative complications correlates with adherence to aspects of care embedded in the WHO SSC.

Disclosure

The authors declare no conflict of interest.

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Supporting information

Additional supporting information may be found in the online version of this article:

Appendix S1 Search strategy (MEDLINE) (Word document)

Table S1 Adherence to a subgroup of safety measures as an indicator of checklist adherence before and after implementation (Word document)