A Systematic Review of the Effectiveness, Compliance, and Critical Factors for Implementation of Safety Checklists in Surgery

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Objective: A systematic literature review was conducted to assess the effectiveness of, compliance with, and critical factors for the implementation of safety checklists in surgery.

Background: With the aim of increasing patient safety, checklists have gained growing attention. Information about effectiveness, compliance, and critical factors for implementation is crucial for whether and which of the available instruments to use.

Data Sources: Medline including Premedline (OvidSP), Embase, and Cochrane Collaboration Library, hand search, a search of reference lists of key articles, and tables of content.

Study Selection: Electronic databases returned 4997 citations, of which 84 articles were chosen for full-text review. Finally, 22 articles were included in this review.

Data Extraction: Data relating to care setting, study methods and design, sample population, survey response rate, type of checklist, aim, effectiveness, compliance, attitudes, and critical factors were extracted from the studies. A random effects meta-analysis of effectiveness data was conducted if 2 or more studies reported a specified outcome.

Results: With the use of checklists, the relative risk for mortality is 0.57 [95% confidence interval (CI): 0.42–0.76] and for any complications 0.63 (95% CI: 0.58–0.67). The overall compliance rate ranged from 12% to 100% (mean: 75%) and for the Time Out from 70% to 100% (mean: 91%).

Conclusions: Checklists are effective and economic tools that decrease mortality and morbidity. Compliance of surgical staff with checklists was good overall. Further research in particular relating to implementation is needed.

Keywords: compliance, critical factors and attitudes, effectiveness, Surgical surgical safety checklist, effectiveness, compliance, critical factors and attitudes

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Surgery is a central element of health care with an estimated 234 million surgical procedures performed each year worldwide.[1] Since the publication of the Institute of Medicine report, safety of surgery and the prevention of adverse events have gained increasing attention.[2] Studies from industrialized countries indicate that permanent disability or mortality rates range between 0.4% to 0.8% of all surgical procedures. Complications are common and occur in 3% to 16% of all surgical procedures. In summary, this suggests that a minimum of at least 1 million patients die after surgery and 7 million patients are injured by surgical complications annually.[1] Several studies report that approximately 50% of surgical adverse events can be considered preventable.[3–5]

Checklists or protocols are a common tool for preventing human errors in complex and high intensity areas of work.[6] Checklists summarize 4 of the most important aspects of safety: correct identification of the patient and surgical site/side, safe anesthesia and airway or respiratory function, prevention of infection, and successful teamwork.[7,8] Whereas in fields such as aviation or aeronautics the use of checklists is widespread and have been at least partially used for more than 30 years, their adoption in the field of medicine is comparatively recent, beginning in 1999 with the recommendations made by the Institute of Medicine report "To err is human."[6,9–11] Use of checklists is associated with changes in systems and changes in the culture in operating theater teams.[12,13] Those cultural changes increase communication and teamwork within the surgical team by delegating the responsibility for patient safety to the whole team away from a purely hierarchical system and enhancing work satisfaction of health care professionals.[3,4,14–17] In addition, the use of checklists helps to determine each person's function during the surgical procedure.[3,18,19]

Several studies have shown that team communication and teamwork are critical factors for patient safety and quality and could prevent many deaths and major complications in surgery.[3,12,20] Neily et al[21] reported that the Medical Team Training program implemented in the Veterans Health Administration that includes pre- and postoperative team debriefings was associated with an 18% reduction in annual surgical mortality.

Haynes et al[22] showed that with the implementation of the World Health Organization (WHO) checklist the safety of surgery increases both in low- and high-income countries. On the basis of these results, the WHO estimated that with the implementation of the WHO checklist 500,000 lives could be saved annually worldwide.[22,23] Currently, 25 countries[24] and more than 3000 hospitals or health care facilities[25] have already implemented the WHO Surgical Safety checklist, and many countries are planning to use this checklist.[26] The Universal Protocol was used in 2257 US hospitals certified by the Joint Commission,[27,28] and the SURgical PAtient Safety System (SURPASS) checklist was used in 16 hospitals in the Netherlands.[29] The Universal Protocol was developed and implemented in 2003 to 2004,[27] SURPASS in 2007 to 2009,[4] and the WHO checklist in 2007 to 2008.[1,22] The SURPASS checklist covers the whole surgical pathway from admission to discharge,[30] whereas the Universal Protocol includes preprocedure verification, site marking, and a Time Out[31] and the WHO checklist focuses on the period before induction of anesthesia (Sign In), the period after induction and before surgical incision (Time Out), and the period during or immediately after wound closure (Sign Out).[1] As different instruments are available, each institution (or country) has to make a decision on which checklist

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to implement. Information on effectiveness of the checklist, compliance of staff, and critical factors for implementation are crucial for guiding this decision.

The purpose of this systematic review was to determine the effectiveness, compliance, and critical factors for the successful initiation and implementation of checklists or protocols in surgical theaters. The following questions should be answered:

1. What is the effectiveness of checklists or protocols in terms of complications and mortality?
2. What is the compliance with checklists (frequency and completeness)?
3. Which factors influence the compliance and effectiveness of checklists or protocols?

METHODS

A systematic review concerning the effectiveness of, staff compliance with, and critical factors for the successful implementation of safety checklists in surgery was conducted.

Data Sources

A comprehensive systematic search of the English, French, and German language literature was performed for articles published between 1995 and April 2011 in Medline including Premedline (OvidSP), Embase, and Cochrane Collaboration Library. This search was complemented by a hand search, an intensive search of tables of content of surgical journals, and a search in reference lists of key articles. To investigate our 3 questions, 4 search fragments were constructed on the basis of the inclusion criteria:

1. Surgery (surgery or surgical or surgical procedures)
2. Checklist or protocol (checklist or protocol or universal protocol)
3. Effectiveness (hospital mortality, surgical procedures, postoperative or intraoperative complications, medical errors, safety management, surgical procedures, adverse event or effect, surgical complication or surgery complication, surgical safety or surgery safety, iatrogenic injury, patient identification, correct patient or site or patients or sites, patient safety, teamwork or wrong site)
4. Compliance (compliance, compliancy or guideline adherence).

Investigations into the critical factors of implementation were captured along with the other search strategies. Searches with the search strings of each fragment as Medical Subject Heading (MeSH) or free-text were conducted.

The search fragments (1) to (4) were then combined using Boolean operators: surgery AND checklist AND effectiveness OR compliance. The detailed search strategies are available from the authors.

Study Selection

Citations were identified through our initial electronic database search for possible inclusion. All studies provided with a title and abstract were screened by 2 independent reviewers (A.Bo., A.Ba.) to select reports for full textual review. Disagreement between them was resolved by consensus with input from a third author (D.L.B.S.). The selection criteria for inclusion and exclusion are presented below.

Inclusion Criteria

Studies were included if they empirically investigated the effectiveness of surgical safety checklists, staff compliance with, or critical factors for implementation of the safety checklist in surgery. The following definitions were used to develop the search strategy and during the review of candidate articles:

Definitions

1. *Checklists*. Checklists or protocols are instruments that are completed or marked preoperatively or during the operation from one or more responsible persons with the aim of increasing the safety of surgical interventions. They consist of a verbal verification by operating teams in terms of implementing the basic steps ensuring the safe delivery of anesthesia, effective teamwork, and other substantial steps or practices within the range of surgical interventions, which pass a well-defined process.[1] All studies that used the WHO, the SURPASS checklist, or the Universal Protocol or any adaptations or modifications of these checklists were included.
2. *Effectiveness*. Effectiveness was defined as preventing and reducing complications such as wrong site surgery, anesthetic complications, surgical site infections, and the intra and postoperative mortality rate, through the use of checklists. All studies that determined the effectiveness of 1 or more of these endpoints were included. For definition of our endpoints of effectiveness, we referred to the "Ten essential objectives for safe surgery," as defined in the program from the World Alliance for Patient Safety "Safe Surgery Saves Lives."[1]
3. *Compliance*. This is the frequency and completeness of checklist usage. All studies were included which cover information about compliance, as well as studies that described factors associated with a high compliance rate or reasons for a poor compliance were included.
4. *Critical factors and attitudes*. These are any actions or behaviors, attitudes or training associated with a highly effective checklist implementation or compliance. All studies were included if they assessed empirically any factors associated with effectiveness of or staff compliance with surgical safety checklists. Studies were also included if they assessed the attitudes of staff members using the checklist.

Exclusion Criteria

Studies were excluded from the review if they examined only parts of checklists, for example, studies regarding the effectiveness of the team briefing or correct surgical site marking.

Data Synthesis

To describe the included studies, the following data were extracted and documented in a spread sheet: Care setting, study design and methods, sample size and sample characteristics, response rate for survey studies, aim of the study, and quality of the studies. Morbidity and mortality rates and data on compliance were extracted and documented. Information on critical factors was extracted if their association with effectiveness or compliance had been empirically investigated. A random effects meta-analysis of the effectiveness data was conducted when 2 or more studies reported a specific outcome. Chi-square tests for heterogeneity of the study results and I^2 statistics for inconsistency were performed. The meta-analyses were conducted using STATA 10.0 statistical software (StataCorp, College Station, TX).

Study Quality

Most of the guidance on quality assessment criteria has been developed for randomized controlled trials,[32] cohorts and case control[33,34] or cross-sectional studies[34,35] and not for the assessment of qualitative and quantitative observational studies. To be able to compare qualitative and quantitative studies with wide heterogeneity, for example, in research design, metrics, and populations, Nagpal et al[36] developed an assessment criteria of the study quality based on the available recommendations (The details of the assessment criteria are available at: http://links.lww.com/SLA/A57). This system was the most comprehensive and practical for the purpose of this review. The

quality assessments were performed by 2 independent investigators (A.B. and D.L.B.S.) on the basis of the criteria by Nagpal et al[36] for all the studies. The agreement of the quality assessment of the 2 independent reviewers was assessed with the Cohen kappa coefficient.

RESULTS

A total of 4997 citations were identified for possible inclusion through the initial electronic database search (Fig. 1). In addition, 15 citations were identified in the manual searches. After in-depth review, 22 articles met the inclusion criteria and were finally included in the systematic review (Table 1). Of these, 20 were quantitative[3,4,15,16,22,28,30,31,37–48] and 2 were qualitative studies.[14,17] The majority of studies were prospective observational studies, surveys, or analyses of claim reports data. Nine studies had a prepost design.[3,4,16,22,38,40–42,48] Seventeen studies used either the Universal Protocol or the WHO checklist or a newly developed protocol on the basis of one or both of these 2 protocols. In f4 studies, the SURPASS checklist was used. Details of the investigated outcomes by checklist or protocol type are presented in Table 2. Quality assessments and data extraction were conducted for only 21 studies, because 2 articles presented primary data from the same study.[46,47] Detailed result tables are available in supplemental tables upon request.

Study Quality

The quality assessments of the studies by 2 independent investigators were in moderate agreement (kappa score for 0.646; $P < 0.001$). Quantitative studies fulfilled on average 7.6 of 18 criteria, and qualitative studies fulfilled on average 9.5 of 24 criteria. Fifty percent of the qualitative studies (1 of 2) achieved a score $\geq$ 12/24 and 40% of the quantitative studies (8 of 20) achieved a score $\geq$ 9/18. The analysis for each of the studies is available on request.

Effectiveness of Checklists or Protocols in Terms of Complication and Mortality Rates

Thirteen articles were identified that reported the effectiveness of checklists or protocols. Of these, 5 studies reported data about mortality, 4 reported data about any complications (Table 3), and all but 1[16] described 1 or more "other specified outcome." The study by Weiser et al[48] is a reanalysis of a subsample (urgent patients) of the data reported by Haynes et al[22] and is therefore not included in the meta-analysis. All studies which were included in the meta-analysis used either the WHO or the SURPASS checklist, none used the Universal Protocol. The quality assessments of the 3 studies combined in the meta-analysis were moderate with a mean score of 11.3/18.

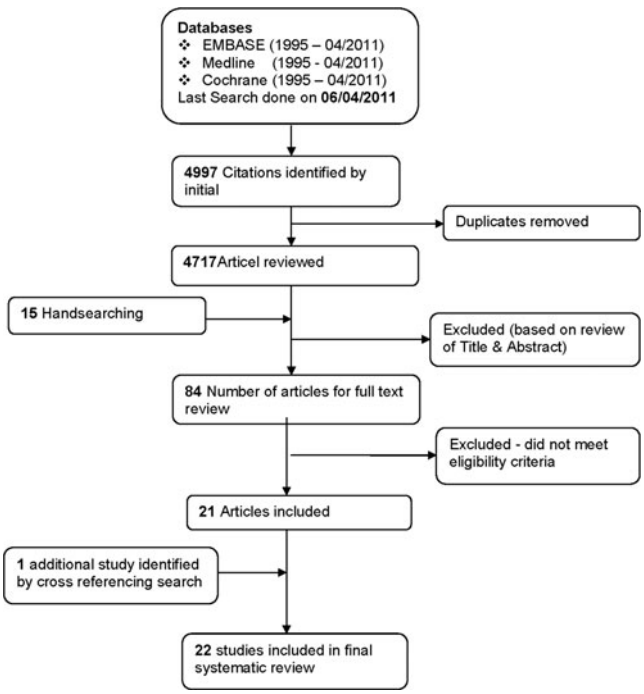

FIGURE 1. Consort diagram for search strategy.

Meta-analysis revealed that across the 3 prospective prepost observational studies the relative risk for mortality with the use of the checklist is 0.57 [95% confidence interval (CI): 0.42–0.76] (Fig. 2).[3,4,22] One study found no significant differences in results of mortality before and after implementing the checklist.[16] A retrospective claim report review reported that 40% of deaths claimed were deemed preventable by use of the checklist.[15]

In the 3 prospective prepost observational studies, the relative risk for any complication with checklist usage is 0.63 (95% CI: 0.58–0.67).[3,4,22]

Many studies also assessed checklist effectiveness in terms of other specified outcomes. In 3 prospective prepost observational studies, the surgical site infection rate was determined. With the use of the checklist, the relative risk for surgical site infection is 0.62 (95% CI: 0.53–0.72).[3,4,22]

Two prospective prepost observational studies showed that with the use of the WHO[3] or SURPASS[22] checklist the relative risk for unplanned return to the operating room using the checklist is 0.76 (95% CI: 0.56–1.02).[3,22] The quality assessments of these studies were moderate (mean score: 11/18). The relative risk for respiratory complications such as pneumonia with use of the checklist is 0.87 (95% CI: 0.67–1.13)[4,22] with a mean score of 13/18 for the quality assessment.

Compliance With Checklists (Frequency and Completeness)

Fifteen studies evaluated the compliance with checklists or protocols. The mean quality score of the 14 quantitative studies that investigated compliance with the checklist was 7.1/18 and the quality score for the 1 qualitative study[14] was better with 12/24. Ten studies[3,4,14,16,22,37,40,42,43,48] collected data about compliance in real time or in the assessment and 5 studies[30,31,38,39,44] by surveying or interviewing surgical staff members. Whereas 11 studies[3,4,14,16,30,37,40,42–44,48] assessed the overall compliance, only 4 studies[14,37,38,42] assessed the Time Out and 3 studies described failures of compliance of the Time Out[39] or the compliance of different aspects[22] or the compliance and frequency for using a special checklist.[31]

Of the studies that collected data in real time or in the assessment, all but 1[22] reported the overall compliance with a range between 12%[14] and 100%[37] (mean: 75%). In the 2 studies which surveyed or interviewed surgical staff members about their overall compliance with the checklist, the fraction of responders that reported being "always or mostly" compliant with the checklist or specific required procedures ranged between 20% and 98%.[30,44]

The compliance rates for the Time Out were identified in 4 articles.[14,37,38,42] In the 3 studies that collected the compliance rates as real time data, completed Time Out ranged between 70%[42] and 100%[14] (mean: 91%).[14,37,42] In the study by Blanco et al,[38] compliance with the Time Out was 95%, calculated on the basis of reports. Although Blanco et al[38] showed no relevant differences in compliance for the Time Out between surgical staff members (between 94% and 96%), de Vries et al[30] observed differences in compliance of completion of the checklist between surgeons and anesthesiologists. Sixty-seven percent of surgeons completed the checklist almost

TABLE 1. Summary of Included Studies

Study	Country/Place/Year	Study Methods/Study Design	Study Sample Populations/Composition/ Survey Response Rate	Quality Assessment
Altpeter et al[37]	USA, Louisville, Kentucky 2006	Quantitative: Observational study	290 patients	1/18
Blanco et al[38]	USA, Pennsylvania 2007–2008	Quantitative: Survey (Prepost)	203 reports	3/18
Clarke et al[39]	USA, Pennsylvania 2004–2006	Quantitative: Analysis of wrong site surgery reports	433,528 reports	7/18
Conley et al[17]	USA, Washington 2009	Qualitative: Semistructured interviews	5 Checklist implementation leaders who were not a member of the implementation group	7/24
de Vries et al[4]	The Netherlands, Amsterdam 2007–2009	Quantitative: Prospective observational study (Prepost)	Baseline: 3760 patients with 4364 surgical procedures After implementation: 3820 patients with 4387 procedures	12/18
de Vries et al[15]	The Netherlands, 2004–2005	Quantitative: Retrospective claims record review	294 claims	9/18
de Vries et al[30]	The Netherlands, Amsterdam 2003–2004	Quantitative: Observational validation study and qualitative interview	171 surgical procedures Interviews with: 21 surgeons or surgical residents and 17 anesthesiologists	6/18
de Vries et al[40]	The Netherlands, Amsterdam 2008	Quantitative: Observational study (Prepost)	772 elective and urgent surgeries: Baseline: 369 patients After implementation: 403 patients	10/18
Haynes et al[22]	USA, Boston, Massachusetts 2007–2008	Quantitative: Prospective observational study (Prepost)	7688 patients: Baseline: 3733 patients After implementation: 3955 patients	14/18
Haynes et al[41]	USA, Boston, Massachusetts 2007–2008	Quantitative: Observational study and clinician survey (Prepost)	Baseline: 281 respondents After implementation: 257 respondents	13/18
Johnston et al[42]	Canada, Saskatoon Health Region 2006–2007	Quantitative: Prospective observational study (Prepost)	Baseline: 48 procedures Intervention: 231 procedures	9/18
Knight and Aucar[31]	USA, Urbana, Illinois 2004–2009	Quantitative: Survey	Survey sent to 205 users: Response rate: 21% (43/205)	4/18
Kwaan et al[28]	USA, Massachusetts 1985–2004	Quantitative: Retrospective claims record review and analysis of site marking protocols	Among 1153 malpractice claims and 259 loss observations, there are 40 cases of wrong site surgery. Medical records were available for 13 non–spine surgery cases.	9/18
Lyons[43]	USA, Arizona 2002–2010	Quantitative: Prospective observational study	6313 operative checklists for 6345 patients	3/18
Mody et al[44]	USA, other countries 2006	Quantitative: Survey	3505 members of the society Response rate: 12% (415/3505)	7/18
Nilsson et al[45]	Sweden, Östergötland 2007	Quantitative: Survey	704 persons from the operating departments Response rate: 47% (331 persons)	8/18
Sewell et al[3]	UK, London 2009	Quantitative: Prospective observational study (Prepost, Audit)	Baseline: 480 patients After implementation: 485 patients	8/18
Simon[46]	USA, New York 1985–2005	Quantitative: Retrospective claims record review	106 claims	7/18
Spence et al[14]	Canada, Winnipeg 2009	Qualitative: Observation focus group discussion*	130 students visiting 65 operating rooms in pairs	12/24
Vats et al[16]	UK, London 2008	Quantitative: Prospective observational study (Prepost)	Baseline: 152 operations respectively patients Intervention: between 70–141 operations respectively patients It is not mentioned how many operating staff members they interviewed	1/18
Weiser et al[48]	USA, Boston, Massachusetts 2007–2008	Quantitative: Prospective observational study (Prepost)	Baseline: 842 patients with urgent operations, Implementation: 908 patients with urgent operations	14/18

*The study was assessed as a qualitative study based on the focus group discussion whereas the observation of the compliance rate was quantitative method.

always, and only 35% of anesthesiologists did so. De Vries et al[30] interviewed surgical staff members about reasons for non-compliance with the Universal Protocol. The most frequent reasons were having "forgotten" with 66% and "logistics" with 45%. "Lack of time" was stated in 34% of cases, whereas "motivation" and "other" comprised only 11% of reasons for noncompliance. Adherence to an appropriate timely use of prophylactic antibiotics increased in all studies but with marked differences.[14,16,22,37,40,48] Patients not receiving antibiotics until after incision decreased from 12% to 6% of patients with the use of the checklist.[40] Weiser et al[48] showed that prophylactic antibiotics given appropriately increased from 37% to 83% of patients with the use of the checklist.

Factors Influencing Compliance and Effectiveness

Whereas most of the included studies described 1 or more critical factors or attitudes for the successful implementation of a checklist, only 5 studies[3,17,38,41,45] quantitatively or qualitatively assessed them. The mean quality score of the 4 quantitative studies

TABLE 2. Investigated Outcomes of the Included Studies by Checklist or Protocol Type

Checklist/Protocol	Mortality	Any Complications	Other Specified Outcomes	Compliance	Critical Factors
SURPASS	de Vries et al[4] de Vries et al[15]*	de Vries et al[4]	de Vries et al[4] de Vries et al[15],* de Vries et al[40]	de Vries et al[4] de Vries et al[30] de Vries et al[40]	
WHO-Checklist	Haynes et al[22] Sewell et al[3] Vats et al[16] Weiser et al[48]	Haynes et al[22] Sewell et al[3] Vats et al[16] Weiser et al[48]	Haynes et al[22] Sewell et al[3] Spence et al[14]* Weiser et al[48]	Haynes et al[22] Johnston et al[42] Sewell et al[3] Spence et al[14] Vats et al[16] Weiser et al[48]	Conley et al[17] Haynes et al[41] Sewell et al[3]
Universal Protocol			Clarke et al[39] Knight and Aucar[31] Kwaan et al[28]* Simon[46]*	Altpeter et al[37] Blanco et al[38] Clarke et al[39] Knight and Aucar[31] Mody et al[44]	Blanco et al[38]
Adaptions of the WHO checklist or the Universal Protocol			Lyons[43]	Lyons[43]	Nilsson et al[45]

*Describing hypothetical effectiveness, that is, the potential effects of the checklist, would this checklist have been used.

TABLE 3. Effectiveness of Checklist Use

Study	Mortality	Any complications
de Vries et al[4]	1.5% (95% CI: 1.2–2.0) → 0.8% patients (95% CI: 0.6–1.1) $P = 0.003$	27.3% (95% CI: 25.9–28.7) → 16.7% patients (95% CI: 15.6–17.9) $P < 0.001$
de Vries et al[15]*	40% claims were deemed preventable by use of the checklist	
Haynes et al[22]	1.5%→0.8% patients $P = 0.003$	11.0% → 7.0% patients $P < 0.001$
Sewell et al[3]	1.9% → 1.6% patients RR = 0.88 (95% CI: 0.34 – 2.26)	8.5% → 7.6% patients RR = 0.89 (95% CI: 0.58 -1.37)
Vats et al[16]	Data not published. Differences were reported as non-significant	Data not published. Differences were reported as non-significant
Weiser et al[48]	3.7% → 1.4% patients $P = 0.0067$	18.4% → 11.7% patients $P = 0.0001$

*Describing hypothetical effectiveness, that is, the potential effects of the checklist, would this checklist have been used.
RR indicates relative risk.

that investigated compliance with the checklist were moderate with 8/18, and the quality score for the 1 qualitative study[17] was moderate with 7/24.

Conley et al[17] undertook semistructured interviews with implementation leaders and surgeons using the checklist. The results showed that for a highly effective implementation it is important that it is clearly communicated "why" and "how" the checklist should be used. "How" refers not only to actual checklist execution but also to checklist introduction and support. Key points to explaining "why" were, for example, providing a rationale for checklist implementation, highlighting values that aligned the institution with the checklist and surgical staff recognizing their own role in patient safety. The conversations around "why" were very important to build enthusiasm and achieve "buy in" of the whole team. Key points to explain "showing how" were, for example, long-term support, specific education, real time coaching and feedback, reading the checklist aloud instead of reliance on memory, and directly addressing staff concerns. The success of the implementation of the checklist was much higher when it was led by a multidisciplinary team, which met regularly and spontaneously, than when the implementation was led and mandated by a single surgical staff member. Blanco et al[38] highlighted in their prepost survey that empowering staff members to speak up if there are any concerns and acknowledging these concerns are very important aspects for teamwork and leadership. Education sessions of checklist use are platforms where common causes of surgical adverse events can be discussed, as well as "how" the checklist has to be conducted to prevent those events and to answer any questions around these topics.[3]

The results of the interviews with surgeons, surgical residents, or anesthesiologists/surgical staff members conducted by De Vries et al[30] showed that 1 reason for noncompliance with the literature-based prototype checklist, which was validated and evaluated during real time observation, was "lack of time." Haynes et al[41] and Sewell et al[3] report that attitudes of staff members changed after implementing the checklist. Only 20% of the staff members interviewed by Haynes et al[41] had the opinion that the checklist took a long time to complete.

DISCUSSION

To our knowledge, this is the first systematic review covering not only the effectiveness but also the compliance of and critical factors for implementation of safety checklists in surgery.

This review shows that with the use of the checklist the relative risk for mortality is 0.57 (95% CI: 0.42–0.76) and for any complications 0.63 (95% CI: 0.58–0.67).

The mean overall compliance rate was 75% and the compliance for the Time Out was much higher with a mean of 91%. Explaining "why" and "how" the checklist should be used are the most critical

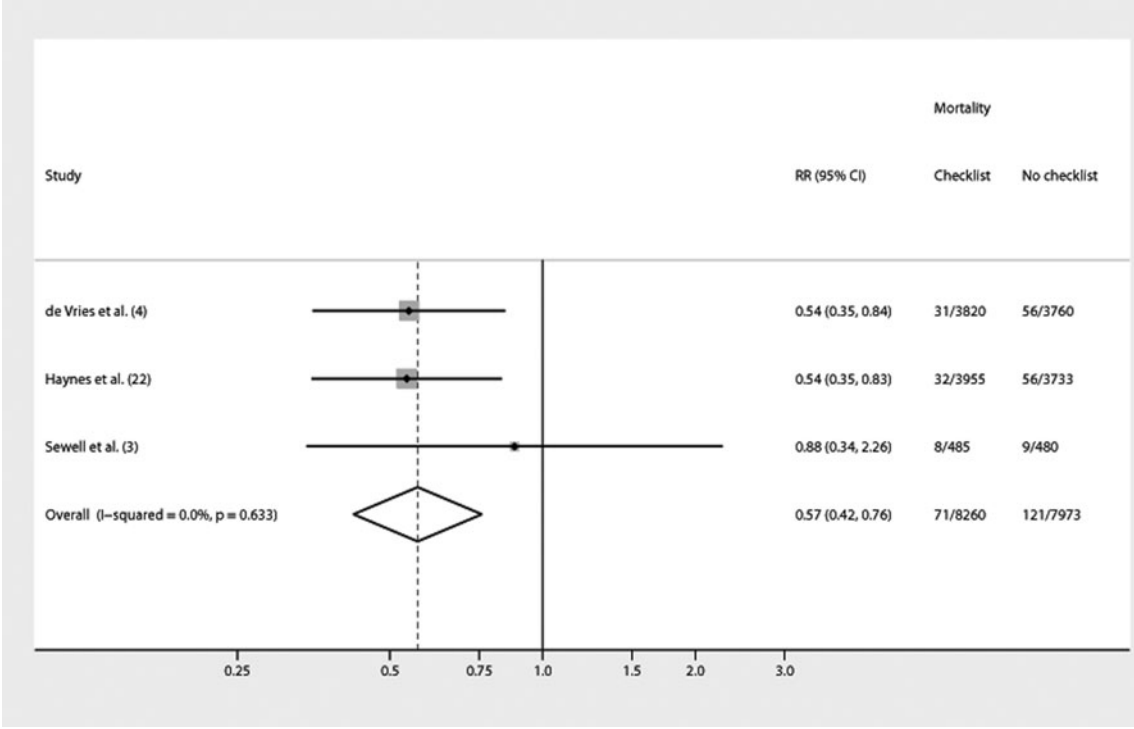

FIGURE 2. Forest plot of the pooled risk ratio for mortality with use of the checklist.

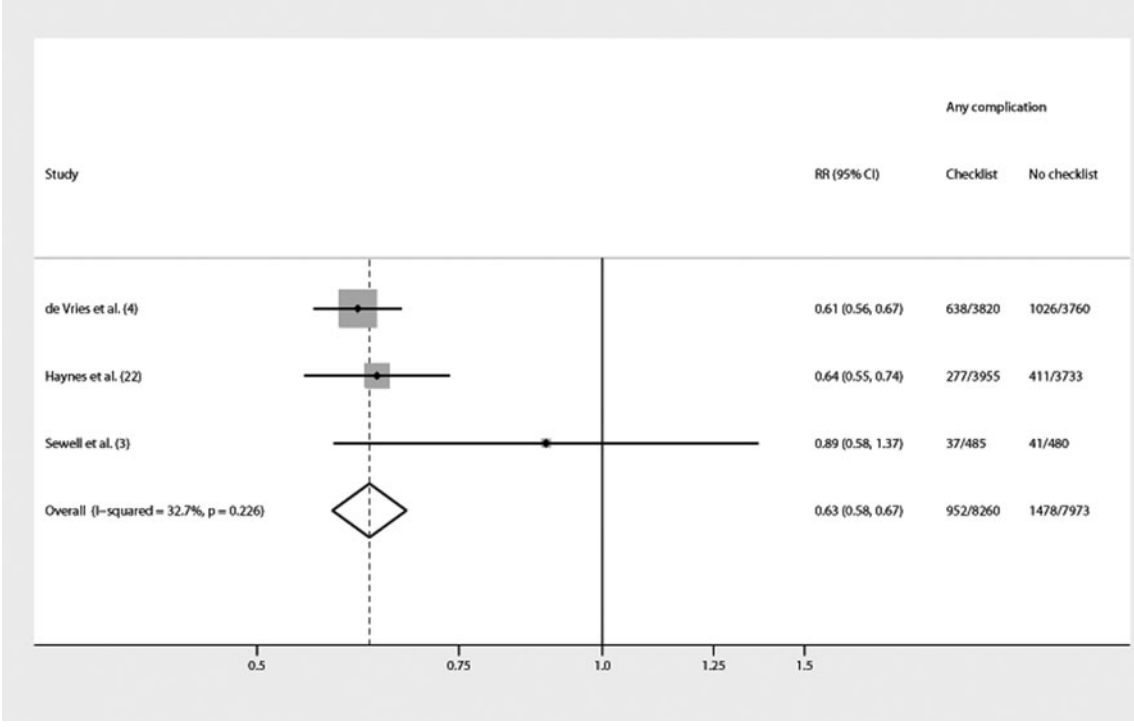

FIGURE 3. Forest plot of the pooled risk ratio for any complications with use of the checklist.

factors for successful implementation of the checklist. However, the results need to be interpreted with care because of the limited numbers of studies, their heterogeneity, and their quality.

For a highly effective implementation, the compliance of surgical staff members using the checklist is important. The results of the review show that the compliance rate differs among hospitals, surgical staff members, and on the items and parts of the checklists. The compliance rate of surgical staff members using the checklist increased if they were engaged in the development of the checklist themselves and if this happened in a multidisciplinary way.[40] In addition, simplification would increase the adherence to checklist use and allow surgical teams to focus their limited time on prevention of common and harmful errors.[28] Evidence on the effects of accompanying measures and critical factors on the compliance rates of surgical staff members using the checklists is scarce, however.

The large variance of the compliance rates suggests that accompanying measures are necessary for highly effective implementation of the checklists. Different methodologies for effective implementation exist, but 2 main steps seem vital: The initial step focuses on the development of the checklist and the items on it and their integration in the individual hospital. Checklists are only effective if the items on it match real safety risk events and if these are evidence-based without any redundant items.[49,50] De Vries et al[30] highlighted in their interviews with surgeons, surgical residents, and anesthesiologists suggestions for logistic improvements for checklists. These suggestions have also been mentioned but not evaluated by others. For some hospitals, it could be useful to integrate the checklist in the existing hospital system or adjusted in the flow of care. For other institutions, it could be important that checklists are short, simple, and as straightforward as possible or if they attach consequences to checklist use (e.g. stopping) or have an electronic list.[22,30,43,46–48] In addition to the logistic improvements, other factors exist that may increase the success of the hospitals, for example, to hang a poster in every operation room with the aim of facilitating the whole team viewing the checklist and becoming familiar with it.[3,19,51,52] Another hospital put pink Time Out flyers in sterile packs to remind surgical staff members to view the poster or publicize the checklist in the hospital newsletter, and display a checklist screen saver on all computer screens for many weeks.[52]

As a second step, explaining "why" and "how" the checklist will be used is critical for the success of checklist implementation. As mentioned previously, besides the evaluated critical factors there exists a large multiplicity of studies that did not quantitatively or qualitatively assess critical factors. These studies also described important points for explaining "why" the checklist should be used, for example, participation and agreement of the whole team[37] or peers who could explain the benefits of checklist use.[16,17,22] Examples for explaining "how" the checklist should be used were real time coaching, feedback and audits, education and training of surgical staff members, the support of the hospital administration and leaders, and the full agreement of all departments.[3,16,22,45] As Conley et al[17] note, it is necessary to read out the checklist item and not rely only upon memory because items could sometimes be forgotten. Often checklists were considered a chore, and staff members simply ticked off the items when in fact the items had not been completed.[28] That often happens when checklists are mandated top down without any explanation of "why" or "how" the checklist should be used[17] or when there are multiple redundant checks.[28] If surgical staff members are unaware of the underlying principle behind the implementation, this may lead to frustration and disinterest of the team members.[17] All the described critical factors are potentially relevant for individual hospitals and could improve effectiveness.

Our review is the first that covers studies of 3 different checklists, the Universal Protocol, the WHO checklist, and the SURPASS checklist. Our results indicate that the Universal Protocol is too limited to reduce deaths and overall complications. For example, antibiotic prophylaxis is not covered in the Universal Protocol, which may help to explain its limited effect on morbidity. The WHO and the SURPASS checklists have both been found to produce large reductions in harmful outcomes (mortality and any complications).[53] The SURPASS checklist has been validated; it is much more comprehensive and interdisciplinary, but also more complex to implement and often requires reorganization of care processes. The success and effectiveness of SURPASS has until now only been investigated in 1 European country[29,54] and generalization to other countries and health systems has yet to be confirmed. The generic nature and applicability to a variety of settings and health care systems is a strong advantage of the WHO checklist. The WHO checklist concentrates on focusing processes and staff in the operating room, whereas SURPASS includes care processes before and after surgery. Given that no comparative study of the 2 checklists exists, the decision as to which of the 2 checklists to introduce in a hospital will also depend on the resources available for implementation and process (re)organization. Hospitals that aim to make one large step toward patient safety in surgery and have strong support by clinicians may prefer SURPASS, whereas others may start with the WHO checklist. The WHO checklist also seems superior for use in selected departments as it requires less process redesign and has fewer interfaces with other clinical processes.

Checklists are only a supplementary tool, guiding the team members in their conduct[19] and facilitating the work of the whole surgical team, encouraging critical thinking and opening the dialog about potential risks and increasing the awareness of the whole team to focus on the ongoing case.[14,28,43] Checklists should not replace consideration of the important issues of the patient or interrupt the competency of any surgical staff member. In addition, some patients could perceive questions like "What's your name?" or "What is the site of your surgery?" as a lack of professionalism or even daunting.[55] Therefore, it is very important to inform patients about the checklist use and to involve them in the process.[31,38,56]

LIMITATIONS

This systematic review has several limitations. The primary limitations concern the method of the review: enormous free-text searches were undertaken to obtain all the important studies answering the research questions but still we may have missed studies in this evolving field of research; for example, conference proceedings or poster presentations were not included in our study.[57–60] In addition, only those studies were included, which covered 1 of the 3 species of checklists or parts of them.

The second limitation was the heterogeneity of the included studies: there was a high variability in study designs, study populations, economic circumstances, survey response rates, and methodological quality of the included studies, which makes it difficult to summarize and interpret the results. There are relatively few studies with a high-quality score and no randomized controlled studies. Observed changes could thus be influenced by secular trends, for example, changes of outcomes due to changing times[22] or the introduction of electronic anesthesia records,[40] and there could have been an improvement in implementing the checklist influenced by the knowledge of the surgical staff members being observed (Hawthorne effect).[22,43]

Third, there are only few studies which quantitatively or qualitatively assessed the critical factors for successful implementation of checklists and until now, there existed little research that assessed critical factors in relation to effectiveness or compliance of checklist use. A complete review of all studies that investigate the implementation of checklists was beyond the scope of our study. Although the results of

this review shed some light on important conditions for successful implementation of checklists, the 5 included studies[3,17,38,41,45] are insufficient to make unambiguous and evidence-based recommendations. This limitation needs to be considered when interpreting the results.

CONCLUSIONS

The implementation of a checklist in surgery not only is an effective tool for decreasing the burden of morbidity and mortality but also represents an opportunity to save costs in hospitals. Semel et al[61] estimated that with the use of the checklists $103,829 could be saved annually in a hospital conducting 4000 noncardiac operations. For highly effective implementation, the acceptance of the hospital staff and the adaption to the specific context, for example, different settings or circumstances of the hospital are important. Further research is necessary about organizational and cultural factors influencing the success of the implementation of safety checklists in surgery.

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