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Impact of the WHO Surgical Safety Checklist Relative to Its Design and Intended Use: A Systematic Review and Meta-Meta-Analysis

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BACKGROUND: The aim of this study was to identify what parts of the World Health Organization Surgical Safety Checklist (WHO SSC) are working, what can be done to make it more effective, and to determine if it achieved its intended effect relative to its design and intended use.

STUDY DESIGN: We conducted a qualitative thematic analysis and meta-meta-analyses of findings in WHO SSC systematic reviews following Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines.

RESULTS: Twenty systematic reviews were included for qualitative thematic analysis. Narrative information was coded in 4 primary areas with a focus on impact of the WHO SSC. Four themes—Clinical Outcomes, Process Measures, Team Dynamics and Communication, and Safety Culture—pertained directly to the aims or purposes behind the development of the SSC. The other 2 themes—Efficiency and Workload involved in using the checklist and Checklist Impact on Institutional Practices—are associated with SSC use, but were not focal areas considered during its development. Included in the 20 systematic reviews were 24 unique observational cohort studies that reported pre-post data on a total of 18 clinical outcomes. Mortality, morbidity, surgical site infection, pneumonia, unplanned return to the operating room, urinary tract infection, blood loss requiring transfusion, unplanned intubation, and sepsis favored the use of the WHO SSC. Deep vein thrombosis was the only postoperative outcome assessed that did not favor use of the WHO SSC.

CONCLUSIONS: The WHO SSC positively impacts the things it was explicitly designed to address and does not positively impact things it was not explicitly designed for. (J Am Coll Surg 2021;233: 794−810. © 2021 The Author(s). Published by Elsevier Inc. on behalf of the American College of Surgeons. This is an open access article under the CC BY-NC-ND license [http://creativecommons.org/licenses/by-nc-nd/4.0/].)

The operating room is a fast-paced and detail-oriented environment requiring highly skilled multidisciplinary staff to deliver the care necessary to treat a wide variety of patients and conditions. The technical skills required to safely perform complex procedures, including the setup and use of numerous items of equipment, and coordination of the surgical team to ensure the safety and care of each patient, provide multiple opportunities for errors. Approximately 313 million surgical procedures are performed annually worldwide,[1] with an estimated adverse event rate of 10% and mortality rate of 7.3%. Half of these adverse events are likely preventable.[2]

As part of a global effort to reduce the number of adverse events and postoperative deaths, the World Health Organization (WHO) developed and implemented the Surgical Safety Checklist (SSC).[3] The WHO SSC is composed of 19 items divided into 3 sections, 1 for use at 3 critical perioperative moments—before induction of anesthesia, before skin incision, and before the patient leaves the room. The items within the checklist are a mix of process checks,

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Abbreviations and Acronyms

CD	= cannot determine
DVT	= deep vein thrombosis
NA	= not applicable
NR	= not reported
OR	= odds ratio
PRISMA	= Preferred Reporting Items for Systematic Reviews and Meta-Analysis
SSC	= Surgical Safety Checklist
SSI	= surgical site infection
UTI	= urinary tract infection

intended to reinforce accepted safety practices, and items to foster better communication between clinical disciplines. The initial trial of the WHO SSC at 8 hospitals worldwide resulted in significant reductions of complication rates from 11% at baseline to 7% ($p < 0.001$) after WHO SSC implementation, as well as a reduction in mortality rates from 1.5% to 0.8% ($p = 0.003$).[4]

Similar studies[5,6] have demonstrated comparable results across a wide variety of settings. However, these substantial claims and the sustainability of the SSC overall effectiveness has been challenged.[7,8] Indeed, several studies[9-11] found no statistically significant reductions in mortality. Reasons for this variability in outcomes can be ascribed, in part, to inconsistency in implementation across facilities.[12]

Since its inception, the WHO SSC has been implemented in healthcare facilities in 70% of countries[13] and has become standard practice in most. The outcomes of a majority of studies give insight to the SSC's effectiveness at an institutional level. This study was conducted as part of a larger project focused on accentuating facilitators and minimizing barriers of WHO SSC implementation, modification, training, and evaluation in high-resource, English-speaking countries. The aim of this study was to perform a systematic review, thematic analysis, and meta-analyses of other systematic reviews and meta-analyses (ie, a meta-meta-analysis) on WHO SSC impacts and outcomes across multiple sites to identify what parts are working, what can be done to make it more effective, and to determine if it achieved its intended effect relative to its design and intended use.

METHODS

We conducted an analysis of systematic reviews and meta-analyses reporting on impacts and clinical outcomes associated with WHO SSC use, through a qualitative thematic analysis[14] and quantitative meta-analyses (ie a meta-meta-analysis), following the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines (Fig. 1).[15]

Data sources

Author KS conducted a systematic search of all articles from January 2008 until February 2021 contained in PubMed and the World Health Organization Global Index Medicus using the following search terms: "WHO Surgical Safety Checklist Literature Review," "WHO Surgical Safety Checklist Systematic Review," "WHO Surgical Safety Checklist Thematic Analysis," "World Health Organization Surgical Safety Checklist Review," "WHO Surgical Checklist AND Barriers," "Surgical Safety Checklist," "Perioperative AND Checklist AND Systematic Review," "Safety AND Checklist AND Systematic Review," and "Surgical AND Checklist AND Systematic Review."

Study selection

Titles and abstracts of citations between January 2008 and February 2021 were identified by an author (KS) for full text screening. Full-length articles were retrieved for abstracts that did not provide sufficient information to determine eligibility, and were reviewed for inclusion by 2 reviewers (KS and BB). Disagreements were settled by a third reviewer (MB) if consensus was not met between the reviewers. Systematic reviews that contained extractable data on performance of the WHO SSC were included for full-text review. Any outcome measures were considered (eg clinical outcomes, process measures, attitudes, etc). For the search, we also included systematic reviews that explored implementation considerations, which we retained for future study. Those excluded were duplicates, non-English articles, those that were not systematic reviews, and studies whose focus was on other surgical safety checklists (eg SURPASS Checklist, Universal Protocol). See Figure 1 for a PRISMA diagram depicting the study selection process.

Analyses

Quality assessment and risk of bias in individual studies

Risk of bias within each systematic review was independently assessed by 2 reviewers (KS and MB) using the Quality Assessment of Systematic Reviews and Meta-Analyses tool developed by the National Institutes of Health.[16] The tool consists of 8 items focusing on key concepts for critical appraisal of the internal validity of each systematic review. Each systematic review was assessed for the following criteria: a focused question, eligibility criteria, search strategy, dual review for inclusion/exclusion of studies, quality appraisal for internal

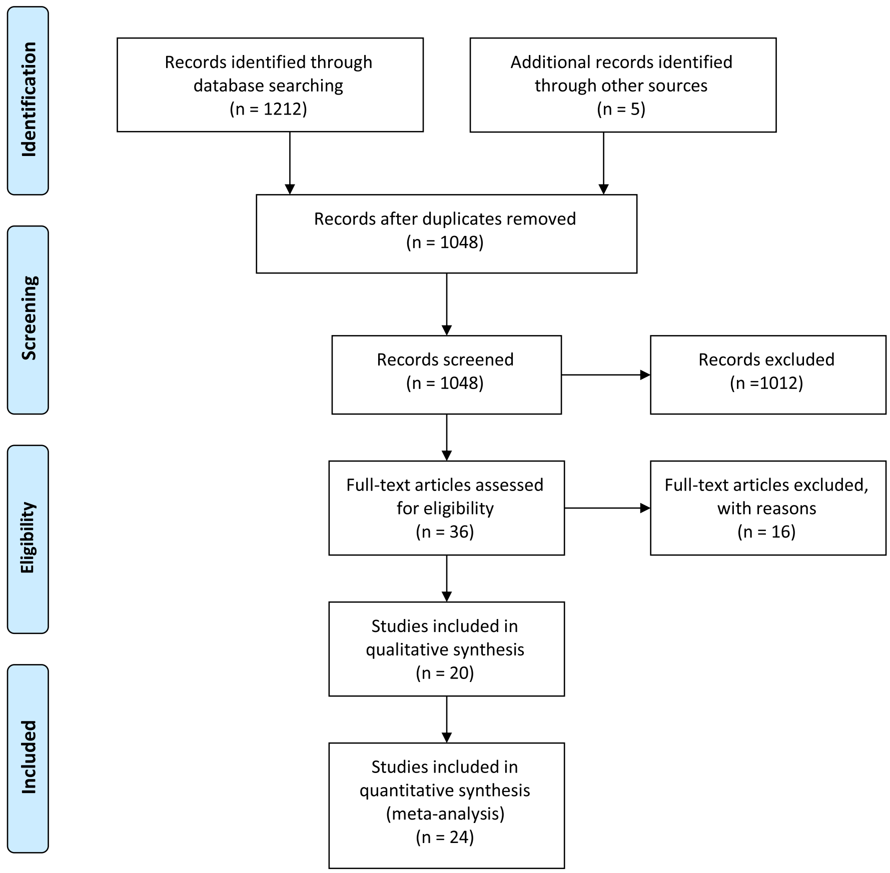

Figure 1. Preferred reporting items for systematic review and meta-analyses flow diagram.

validity, key characteristics of included studies, assessment of publication bias, and assessment of heterogeneity if a meta-analysis was conducted. Reviewers selected either "yes," "no," or "cannot determine (CD)/not applicable (NA)/not reported (NR)" for each item. Items for which "no/CD/NR" was selected were noted as potential risk of bias and/or potential flaws in study design. An overall quality rating of "good" (least risk of bias), "fair" (susceptible to some bias), or "poor" (significant risk of bias and considered for exclusion) was given to each systematic review based on the overall assessment of the 8 items. Disagreements were settled by a third reviewer (BB) if consensus was not met between the reviewers.

Quantitative analysis. All quantifiable outcome measures were identified and categorized. Unique studies within meta-analyses were identified and collated within each outcome measure. Outcome measures for which data were available from 2 or more individual studies across systematic review were identified for meta-analysis.

Each outcome was pooled using a random-effects model. Pooled analyses were reported as odds ratios with a 95% confidence interval. Tests for overall effect were reported as Z-scores. A value of $p < 0.05$ indicated statistical significance. Heterogeneity was calculated using Higgin's I^2. I^2 values of 25%, 50%, and 75% were interpreted as low, moderate, and high heterogeneity, respectively.[17] All analyses were performed using Comprehensive Meta-Analysis software (Version 3.0, Biostat, Inc.).

Risk of bias across studies (publication bias). Risk of bias across studies (publication bias) was evaluated through visual inspection of funnel plot symmetry, if there were a sufficient number of trials ($n \geq 10$).[18] Egger's regression tests were conducted to further assess for funnel plot asymmetry. A 2-tailed p value < 0.05 indicated statistical significance and potential for publication bias. Funnel plots and Egger's regression tests were performed using Comprehensive Meta-Analysis software (Version 3.0, Biostat, Inc.).

Thematic analysis. We included all identified systematic reviews that specifically explored outcomes measures in our thematic analysis of the impact of the WHO SSC. Themes were developed both deductively and inductively through line-by-line coding of each systematic review using QSR International NVivo software (Version 12, QRS International), performed by author KS and refined with author BB. Similar themes were further grouped into 4 major areas or categories, described below. A 1-way, chi-square goodness-of-fit test was conducted for each major area or category and each theme using IBM SPSS Statistics for Macintosh (Version 25.0, IBM Corp). This study will report the results and findings on the categories and themes identified that focus on the impact and outcomes of the WHO SSC.

RESULTS

We identified 1,048 articles for tile and abstract screening. After applying inclusion and exclusion criteria, we excluded 1,012 articles. The remaining 36 full-text articles were reviewed, and 20 systematic reviews were included for our review (Fig. 1).

Risk of bias in individual studies

Table 1 displays a summary of quality assessment ratings for each systematic review and meta-analysis included in our study. Risk of bias was low for each systematic review included in our study. Of the 20 systematic reviews included in our study, 15 systematic reviews[19-33] were given an overall quality of "good" (least risk of bias) and 5 systematic reviews[34-38] were rated as "fair" (susceptible to some bias).

Quantitative analysis

The 20 systematic reviews included, contained 24 unique observational cohort studies that reported pre-post data on a total of 18 clinical outcomes (Table 2). Each outcome was assessed in anywhere from 2 to 19 studies. The most common outcomes evaluated were surgical site infection (n = 19 studies), mortality (n = 18), and morbidity or any complication (n =17). The overall effect for each outcome was further categorized into 3 categories: favors WHO SSC, favors control, and no impact. Table 3 displays a summary of the results for each outcome analyzed.

Postoperative outcomes that favor the use of the WHO SSC

Nine postoperative outcomes—surgical site infection (SSI; Fig. 2), mortality (Fig. 3), morbidity (eFig. 1), pneumonia (eFig. 2), unplanned return to the operating room (eFig. 3), urinary tract infection (UTI; eFig. 4), blood loss requiring transfusion (eFig. 5), unplanned intubation (eFig. 6), and sepsis (eFig. 7)—favored the use of the WHO SSC. For example, 19 studies reported data on postoperative SSI, which included a total of 289,845 patients. Pooled analysis revealed that 1,750 of 142,743 (1.2%) patients in the intervention group compared with 2,512 of 147,102 (1.7%) patients in the control group experienced an SSI. A meta-analysis (Fig. 2) revealed that WHO SSC use was associated with a significant reduction of SSIs [odds ratio (OR) 0.62 (0.47–0.81), Z = -3.51 ($p < 0.001$)], and there was a high level of heterogeneity across trials ($I^2 = 92\%$).

Eighteen studies reported data on mortality, including a total of 373,385 patients. Pooled analysis revealed that 1,587 of 187,196 (0.8%) patients in the intervention group compared to 1,853 of 186,189 (1.0%) patients in the control group died. A meta-analysis (Fig. 3) revealed that WHO SSC use was associated with a significant reduction of deaths [odds ratio (OR) 0.82 (0.72–0.94), Z = -2.90 ($p = 0.004$)] with a moderate level of heterogeneity across trials ($I^2 = 44\%$). The most significant impact of the checklist was seen in a composite measure of morbidity [OR 0.60 (0.49–0.74), Z = -4.88 ($p < 0.001$)].

Postoperative outcomes that do not favor use of the WHO SSC

Deep vein thrombosis (DVT) was the only postoperative outcome assessed that did not favor use of the WHO SSC. Five studies reported DVT occurrence data. Pooled analysis revealed that 81 of 121,625 (0.07%) patients in the intervention group, compared with 53 of 126,762 (0.04%) patients in the control group, experienced DVT. A meta-analysis (Fig. 4) revealed that WHO SSC use was associated with a significant increase of DVT cases [OR 2.00 (1.37–2.92), Z = 3.61 ($p < 0.001$)]; there was a low heterogeneity across trials ($I^2 = 0\%$).

Postoperative outcomes on which the WHO SSC had no impact

We found that the WHO SCC had no impact on the remaining 8 postoperative outcomes evaluated in the studies we included—renal complications (eFig. 8), ventilation >48 hours (eFig. 9), cardiac arrest (eFig. 10), myocardial infarction (eFig. 11), stroke/cerebrovascular accident (eFig. 12), pulmonary embolism (eFig. 13), DVT combined with pulmonary embolism and embolism (eFig. 14), and septic shock (eFig. 15). For example, 5 studies reported rates of ventilation greater than 48 hours, and included 224,090 patients. Pooled analysis revealed that 154 of 109,574 (0.14%) patients in the intervention group compared with 198 of 114,516 (0.17%) patients in the control group were ventilated for more than 48 hours. A meta-analysis revealed that the WHO SCC had no significant impact on prolonged ventilation rates [OR 0.72 (0.36–1.44), Z = -0.94

Table 1. Quality Assessment of Systematic Reviews and Meta-Analyses Included in our Study

Study	Criteria								
	Review based on a focused question that is adequately formulated and described	Eligibility criteria for included and excluded studies predefined and specified	Literature search strategy used a comprehensive, systematic approach	Titles, abstracts, and full-text articles dually and independently reviewed for inclusion and exclusion to minimize bias	Quality of each included study rated independently by $\geq$2 reviewers using a standard method to appraise internal validity	Included studies listed along with important characteristics and results of each study	Publication bias assessed	Heterogeneity assessed[*]	Quality assessment
Abbott et al 2018	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Good
Bergs et al 2014	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Good
Bergs et al 2015	Yes	Yes	Yes	Yes[†]	Yes	Yes	NA	NA	Good
Biccard et al 2016	Yes	Yes	Yes	Yes	Yes	Yes	NA	Yes	Good
Borchard et al 2012	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Good
Boyd et al 2017	Yes	Yes	Yes	Yes	Yes	Yes	NA	Yes	Good
de Jager et al 2016	Yes	Yes	Yes	Yes[†]	Yes	Yes	NA	NA	Good
Gillespie et al 2014	Yes	Yes	Yes	Yes[†]	Yes	Yes	Yes	Yes	Good
Lagoo et al 2017	Yes	Yes	Yes	Yes	Yes	Yes	NA	NA	Good
Lau et al 2016	Yes	Yes	Yes	Yes[†]	Yes[†]	Yes	Yes	Yes	Fair
Mafra et al 2018	Yes	Yes	Yes	Yes[†]	No	Yes	NA	NA	Fair
McDowell et al 2014	Yes	Yes	Yes	Yes[†]	No	Yes	No	NA	Fair
Patel et al 2014	Yes	Yes	Yes	Yes	No	Yes	NA	NA	Good
Russ et al 2013	Yes	Yes	Yes	Yes	Yes[†]	Yes	NA	NA	Good
Tang et al 2014	Yes	Yes	Yes	Yes[†]	Yes	Yes	NA	NA	Good
Thomassen et al 2014	Yes	Yes	Yes	Yes	Yes	Yes	NA	NA	Good
Treadwell et al 2014	Yes	Yes	NR	No	No	Yes	NA	NA	Fair
Wangoo et al 2016	Yes	Yes	Yes	Yes	Yes	Yes	NA	NA	Good
Westman et al 2020	Yes	Yes	Yes	Yes[†]	No	Yes	NA	NA	Fair
White et al 2020	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Good

*This question applies only to meta-analyses.
†Titles, abstracts, and full-text articles reviewed; unable to determine if reviewed dually and independently.
NA, not applicable; NR, not reported.

Table 2. Characteristics of Studies Included for Quantitative Analysis

Author, year	Country	Study design	Type of checklist	Outcomes measured	Duration of follow-up
Haynes et al, 2009	Canada, India, Jordan, New Zealand, Philippines, Tanzania, England, US	Prospective cohort	WHO SSC	SSI, unplanned return to operating room, pneumonia, mortality, any complication	In-hospital 30 d
Weiser et al, 2010	Jordan, India, US, Tanzania, Philippines, Canada, UK, New Zealand	Prospective cohort	WHO SSC (modified as needed)	Any complication, mortality, SSI, blood loss	In-hospital 30 d
Askarian et al, 2011	Iran	Prospective cohort	WHO SSC	SSI, pneumonia, acute renal failure, any complication	In-hospital—discharge
Bliss et al, 2012	US	Prospective cohort with historical controls	WHO SSC (modified)	Any complication, SSI, blood loss, DVT, pulmonary embolism, UTI, pneumonia, ventilator >48 h	30 d postoperatively
van Klei et al, 2012	Netherlands	Retrospective cohort	WHO SSC (modified)	Mortality	In-hospital 30 d postoperatively
Yuan et al, 2012	Liberia	Prospective cohort	WHO SSC (modified)	SSI, any complication, mortality	In-hospital 30 d from procedure
Kwok et al, 2013	Moldova	Prospective cohort	WHO SSC	Mortality, any complication, SSI, pneumonia, unplanned return to operating room, unplanned intubation, sepsis, cardiac arrest, stroke/cerebrovascular accident	In-hospital 30 d postoperatively
Lepanluoma et al, 2013	Finland	Retrospective cohort	WHO SSC (modified)	Any complication, SSI, pneumonia, unplanned return to operating room, blood loss, DVT, ventilation >48 h	In-hospital 30 d postoperatively
Lubbeke et al, 2013	Switzerland	Prospective cohort	WHO SSC (modified)	Mortality, SSI, unplanned return to operating room	In-hospital 30 d postoperatively
Tillman et al, 2013	US	Retrospective cohort	WHO SSC (modified)	SSI, mortality	In-hospital
Boaz et al, 2014	Israel	Cross-sectional	WHO SSC (modified)	Mortality, any complication, SSI	In-hospital postoperatively
Prakash et al, 2014	India	Prospective cohort	WHO SSC	SSI, blood loss, mortality, any complication	In-hospital 30 d postoperatively
Urbach et al, 2014	Canada	Retrospective cohort	WHO SSC (modified)	Mortality, any complication, SSI, pneumonia, unplanned return to operating room, blood loss, sepsis, DVT, renal complication, ventilation >48 h, cardiac arrest, stroke/cerebrovascular accident, pulmonary embolism, septic shock	30 d postoperatively
Chaudhary et al, 2015	India	Prospective randomized controlled study	WHO SSC (modified)	Mortality, any complication, blood loss, sepsis, renal complication	In-hospital 30 d postoperatively
Haugen et al, 2015	Norway	Step wedge cluster randomized controlled study	WHO SSC (modified)	Mortality, any complication, SSI, pneumonia, unplanned return to operating room, UTI, blood loss, sepsis, ventilation >48 h, cardiac arrest, MI,	In-hospital 30 d postoperatively

(Continued)

Table 2. Continued

Author, year	Country	Study design	Type of checklist	Outcomes measured	Duration of follow-up
				DVT, pulmonary embolism, and embolism (combined)	
Kim et al, 2015	Moldova	Prospective cohort	WHO SSC	Mortality, any complication, SSI, pneumonia, unplanned return to operating room, sepsis	In-hospital 30 d postoperatively
Lepanluoma et al, 2015	Finland	Retrospective cohort	WHO SSC	Unplanned return to operating room	Reoperation due to a neurosurgical complication
Rodrigo-Rincon et al, 2015	Spain	Retrospective cohort	WHO SSC (modified)	Mortality, any complication, SSI, pneumonia, unplanned return to operating room, UTI, blood loss, unplanned intubation, sepsis, DVT, renal complication, ventilation >48 h, cardiac arrest, MI, stroke/cerebrovascular accident, pulmonary embolism	30 d postoperatively
Toor et al, 2015	Pakistan	Prospective cohort	WHO SSC	SSI	In-hospital 30 d postoperatively
Biskup et al, 2016	US	Retrospective cohort	WHO SSC (modified)	Mortality, any complication, SSI, pneumonia	In-hospital 30 d postoperatively
Lacassie et al, 2016	Chile	Retrospective cohort	WHO SSC (modified)	Mortality	In-hospital
Mayer et al, 2016	UK	Prospective cohort/ longitudinal study	WHO SSC	Mortality, any complication	In-hospital
O'Leary et al, 2016	Canada	Retrospective cohort	WHO SSC (modified)	Mortality, any complication, SSI, pneumonia, unplanned return to operating room, sepsis, DVT, renal complications, stroke/cerebrovascular accident, pulmonary embolism, septic shock	30 d postoperatively
Westman et al,2018	Finland	Retrospective cohort	WHO SSC	SSI	30 d postoperatively

DVT, deep vein thrombosis; SSC, Surgical Safety Checklist; SSI, surgical site infection; UTI, urinary tract infection.

Table 3. Forest Plot Statistics Summary by Outcome

Outcome, study	n	Intervention		Control		OR (random) 95%CI	Effect Size		Heterogeneity				
		Event	Total	Event	Total		*Z*	*P*	*Q*	df (*Q*)	*P*	I^2, %	τ^2
Favors WHO SSC													
Mortality[4-6,9-11,41-52]	18	1,587	187,196	1,853	186,189	0.82 (0.72 - 0.94)	-2.90	0.004	30.43	17	0.023	44	0.02
Any complication[4-6,9,10,41,42,45-49,51-55]	17	6,965	142,327	7,917	141,099	0.60 (0.49 - 0.74)	-4.88	<0.001	273.30	16	<0.001	94	0.15
SSI[4-6,9,10,41-45,47-49,52-57]	19	1,750	142,743	2,512	147,102	0.62 (0.47 - 0.81)	-3.15	<0.001	216.16	18	<0.001	92	0.27
Pneumonia[4,9,10,41,47-49,52-55]	11	554	133,046	770	139,003	0.70 (0.52 - 0.94)	-2.35	0.019	34.29	10	<0.001	71	0.13
Unplanned return to operating room[4,9,10,41,43,47,48,52,55,58]	10	2,280	135,084	2,570	137,888	0.78 (0.66 - 0.92)	-2.98	0.003	19.25	9	0.023	53	0.03
UTI[9,48,54]	3	48	3,137	133	5,092	0.59 (0.41 - 0.86)	-2.76	0.006	2.06	2	0.357	3	0.004
Blood loss requiring transfusion[5,6,9,10,46,48,54,55]	8	844	110,912	1,083	115,780	0.70 (0.50 - 0.98)	-2.09	0.036	23.05	7	0.002	70	0.10
Unplanned intubation[41,48,54]	3	7	2,980	69	4,873	0.41 (0.17 - 0.96)	-2.05	0.041	1.37	2	0.505	0	0
Sepsis[9,10,41,46-48,52,54]	8	232	126,914	382	133,227	0.65 (0.48 - 0.90)	-2.61	0.009	13.54	7	0.060	48	0.08
Favors control													
DVT[10,48,52,54,55]	5	81	121,625	53	126,762	2.00 (1.37 - 2.92)	3.61	<0.001	3.47	4	0.482	0	0
No impact													
Renal complication[10,46,48,52-54]	6	149	122,058	137	127,173	0.78 (0.38 - 1.62)	-0.66	0.510	9.21	5	0.101	46	0.33
Ventilation >48 h[9,10,48,54,55]	5	154	109,574	198	114,516	0.72 (0.36 - 1.44)	-0.94	0.349	14.97	4	0.005	73	0.39
Cardiac arrest[9,10,41,48,54]	5	160	111,613	158	116,426	0.99 (0.64 - 1.53)	-0.03	0.974	6.31	4	0.177	37	0.08
MI[48,54]	3	12	3,137	26	5,092	0.78 (0.24 - 2.50)	-0.42	0.674	2.51	2	0.285	20	0.34
Stroke and cerebrovascular accident[10,41,48,52,54]	5	174	123,664	175	128,672	1.06 (0.86 - 1.31)	-0.53	0.595	2.39	4	0.664	0	0
PE[10,48,52,54]	4	33	121,558	39	126,679	0.97 (0.61 - 1.54)	-0.13	0.894	2.57	3	0.463	0	0
DVT, PE, and embolism (combined)[9,54]	2	5	2,336	26	4,291	0.48 (0.18 - 1.30)	-1.44	0.151	0.22	1	0.642	0	0
Septic shock[10,52,54]	3	60	120,757	88	125,878	1.00 (0.70 - 1.43)	0.03	0.980	1.13	2	0.569	0	0

DVT, deep vein thrombosis; OR, odds ratio; PE, pulmonary embolism; SSC, surgical safety checklist; SSI, surgical site infection; UTI, urinary tract infection.

Study or Subgroup	WHO SSC Events	WHO SSC N	No WHO SSC Events	No WHO SSC N	Weight, %	OR, Random, (95% CI)
Haynes et al., 2009	134	3955	231	3733	6.56	0.53 (0.43 - 0.66)
Weiser et al., 2010	120	908	94	842	6.35	1.21 (0.91 - 1.62)
Askarian et al., 2011	8	150	15	144	3.90	0.48 (0.20 - 1.18)
Bliss et al., 2012	4	73	129	2079	3.43	0.88 (0.31 - 2.44)
Kwok et al., 2012	98	2106	297	1993	6.50	0.28 (0.22 - 0.35)
Yuan et al., 2012	24	249	63	232	5.49	0.29 (0.17 - 0.48)
Lepanluoma et al., 2013	3	67	8	83	2.46	0.44 (0.11 - 1.73)
Lubbeke et al., 2013	30	1818	18	609	5.14	0.55 (0.30 - 1.00)
Tillman et al., 2013	107	3616	104	3319	6.39	0.94 (0.72 - 1.24)
Boaz et al., 2014	8	380	12	380	3.84	0.66 (0.27 - 1.63)
Prakash et al., 2014	1	80	6	72	1.27	0.14 (0.02 - 1.19)
Urbach et al., 2014	681	106370	667	109341	6.78	1.05 (0.94 - 1.17)
Haugen et al., 2015	34	2263	49	2212	5.78	0.67 (0.43 - 1.05)
Kim et al., 2015	18	637	297	1993	5.60	0.17 (0.10 - 0.27)
Rodrigo-Rincon et al., 2015	48	801	57	801	5.96	0.83 (0.56 - 1.24)
Toor et al., 2015	47	310	99	303	5.98	0.37 (0.25 - 0.55)
Biskup et al., 2016	38	2310	28	2166	5.57	1.28 (0.78 - 2.09)
O'Leary et al., 2016	243	14314	243	14458	6.65	1.01 (0.84 - 1.21)
Westman et al., 2018	104	2336	95	2342	6.36	1.10 (0.83 - 1.46)
Total	**1750**	**142743**	**2512**	**147102**	**100.00**	**0.62 (0.47 - 0.81)**

Heterogeneity: $Tau^2 = 0.27$; $Q = 216.16$, $df(Q) = 18$ ($p < 0.001$); $I^2 = 92\%$
Test for overall effect: $Z = -3.51$ ($p < 0.001$)

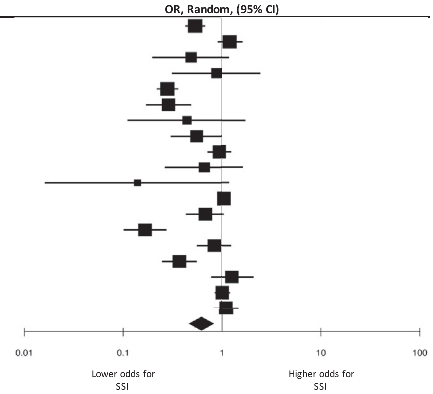

Figure 2. Forest plot: surgical site infection (SSI). OR, odds ratio; SSC, surgical safety checklist.

($p = 0.349$)]; there was a moderate level of heterogeneity between trials ($I^2 = 73\%$). With the exception of renal complications, postoperative outcomes for which the WHO SSC had no impact included data from 5 or fewer studies.

Risk of bias across studies (publication bias)

Visual evaluation of funnel plots and Egger's tests for mortality ($p = 0.453$; Fig. 5), SSI ($p = 0.077$), pneumonia ($p = 0.118$), and unplanned return to the operating room ($p = 0.057$) showed no signs of asymmetry, indicating no presence of publication bias. A funnel plot and significant Egger's test for morbidity ($p = 0.004$) showed signs of asymmetry, indicating a potential presence of publication bias. Funnel plots for all other outcomes—UTI, blood loss, unplanned intubation, sepsis, DVT, renal complications, ventilation >48 hours, cardiac arrest, myocardial infarction, stroke/cerebrovascular accident, pulmonary embolism, septic shock, and DVT combined with pulmonary embolism, and embolism were not conducted due to a small number of studies ($n < 10$) included for meta-analyses.

Thematic analysis

Narrative information from the original studies included in the 20 systematic reviews[19-38] used in this study were deductively coded in 4 primary areas of interest to the investigators: impact of the WHO SSC; barriers and facilitators to checklist adoption, implementation, or use; operational issues and compliance with checklist use; and local modifications made to the checklist. In this article, we focus only on the first area—studies that explore checklist impact on outcomes related to the patient, healthcare team, and health system.

Subthemes under the umbrella theme of impact were identified inductively, from the data, and deductively, based on previous work.[39] These included: Clinical Outcomes, Process Measures (eg time tracking), Effects on Team Dynamics and Communication, Influence of or on Safety culture, Efficiency and Workload Involved in Using the Checklist, and Checklist Impact on

Study or Subgroup	WHO SSC Events	WHO SSC N	No WHO SSC Events	No WHO SSC N	Weight, %	OR, Random, (95% CI)
Haynes et al., 2009	32	3955	56	3733	6.45	0.54 (0.35 - 0.83)
Weiser et al., 2010	13	908	31	842	3.49	0.38 (0.20 - 0.73)
Kwok et al., 2012	66	2106	79	1993	9.03	0.78 (0.56 - 1.09)
van Klei et al., 2012	318	11151	450	14362	16.32	0.91 (0.78 - 1.05)
Yuan et al., 2012	7	249	5	232	1.26	1.31 (0.41 - 4.20)
Lubbeke et al., 2013	108	1818	26	609	6.42	1.42 (0.91 - 2.20)
Tillman et al., 2013	36	3616	30	3319	5.54	1.10 (0.68 - 1.79)
Boaz et al., 2014	10	380	3	380	1.02	3.40 (0.93 - 12.44)
Prakash et al., 2014	0	80	1	72	0.17	0.30 (0.01 - 7.38)
Urbach et al., 2014	691	106370	776	109341	18.06	0.91 (0.83 - 1.01)
Chaudhary et al., 2015	20	350	35	350	4.36	0.55 (0.31 - 0.97)
Haugen et al., 2015	23	2263	35	2212	4.89	0.64 (0.38 - 1.08)
Kim et al., 2015	20	637	79	1993	5.34	0.79 (0.48 - 1.29)
Rodrigo-Rincon et al., 2015	7	801	12	801	1.87	0.58 (0.23 - 1.48)
Biskup et al., 2016	1	2310	1	2166	0.23	0.94 (0.06 - 15.00)
Lacassie et al., 2016	178	29250	231	29250	14.12	0.77 (0.63 - 0.94)
Mayer et al., 2016	56	6494	3	220	1.24	0.63 (0.20 - 2.03)
O'Leary et al., 2016	1	14458	0	14314	0.18	2.97 (0.12 - 72.92)
Total	**1587**	**187196**	**1853**	**186189**	**100.00**	**0.82 (0.72 - 0.94)**

Heterogeneity: $Tau^2=0.02$; $Q=30.43$, $df(Q) = 17$ ($p = 0.023$); $I^2=44\%$
Test for overall effect: $Z=-2.90$ ($p=0.004$)

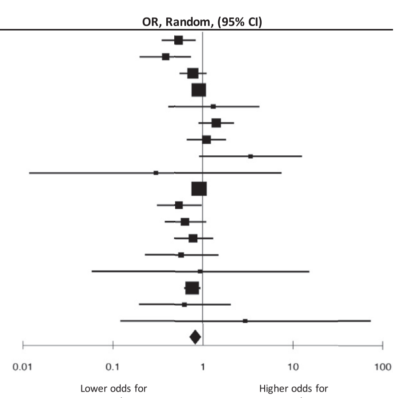

Figure 3. Forest plot: mortality. OR, odds ratio; SSC, surgical safety checklist.

Study or Subgroup	WHO SSC Events	WHO SSC N	No WHO SSC Events	No WHO SSC N	Weight, %	OR, Random, (95% CI)
Bliss et al., 2012	0	73	12	2079	1.76	1.13 (0.07 - 19.19)
Lepanluoma et al., 2013	0	67	1	83	1.37	0.41 (0.02 - 10.16)
Urbach et al., 2014	74	106370	33	109341	84.23	2.31 (1.53 - 3.48)
Rodrigo-Rincon et al., 2015	3	801	4	801	6.30	0.75 (0.17 - 3.36)
O'Leary et al., 2016	4	14314	3	14458	6.33	1.35 (0.30 - 6.02)
Total	**81**	**121625**	**53**	**126762**	**100.00**	**2.00 (1.37 - 2.92)**

Heterogeneity: $Tau^2 = 0$; $Q = 3.47$, $df(Q) = 4$ ($p = 0.482$); $I^2 = 0\%$
Test for overall effect: $Z = 3.61$ ($p < 0.001$)

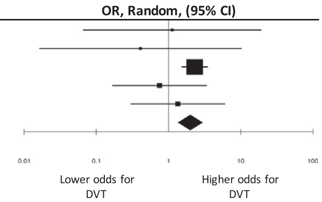

Figure 4. Forest plot: deep vein thrombosis (DVT). OR, odds ratio; SSC, surgical safety checklist.

Institutional Practices. The number of positive, neutral, and negative items coded in these themes and related subthemes are shown in Figure 6; Table 4 shows the key findings for each impact theme, as well as the designs of the studies from which the narrative data were obtained and the relationship of the impact findings to the WHO SSC.

Overall impact

Within the publications, more than twice as many items pertaining to the impact of the WHO SSC were positive (n = 58), as compared to neutral (n = 24) or negative (n = 23). A 1-way chi-square goodness of fit test revealed that the direction of the qualitative themes for overall impact of the SSC was statistically more positive, X^2 (2, N = 105) = 22.686, $p < 0.001$.

Themes associated with specific aims of SSC

Four of the 6 themes pertained directly to the aims or purposes behind the development of the SSC[3]: Clinical Outcomes, Process Measures, Team Dynamics and Communication, and Safety Culture. In all 4 themes, narrative information described the SSC as having overwhelming positive effects rather than neutral or negative effects.

Under the Clinical Outcomes theme, the SSC was credited with greatly reducing mortality, morbidity, and never events[40] (eg wrong patient, wrong site surgery, and retained foreign objects), X^2 (2, N = 61) = 28.557, $p < 0.001$ (Table 4). However, some studies included in the systematic reviews we analyzed found no statistically significant reductions in mortality and morbidity, though these were few in number.

Process measures in the operating room are closely associated with surgical safety. In this study, we found mostly positive (n = 15), but a few neutral (n = 2) and negative (n = 2) reports of the WHO SSC on clinical processes, such as decreased nontechnical surgical errors and increased situation awareness and knowledge about patients, X^2 (2, N = 19) = 17.789, $p < 0.001$.

> Specifically, team members reported that the SSC provided brief pertinent information about patient's history and risk, as well as the required procedure, increasing overall situational awareness.[32(p.44)]

Our thematic analysis also found overwhelmingly positive reports (Table 4) of the checklist on Team Dynamics and Communication within the operating room, X^2 (2, N = 24) = 42.250, $p < 0.001$. The checklist was reported

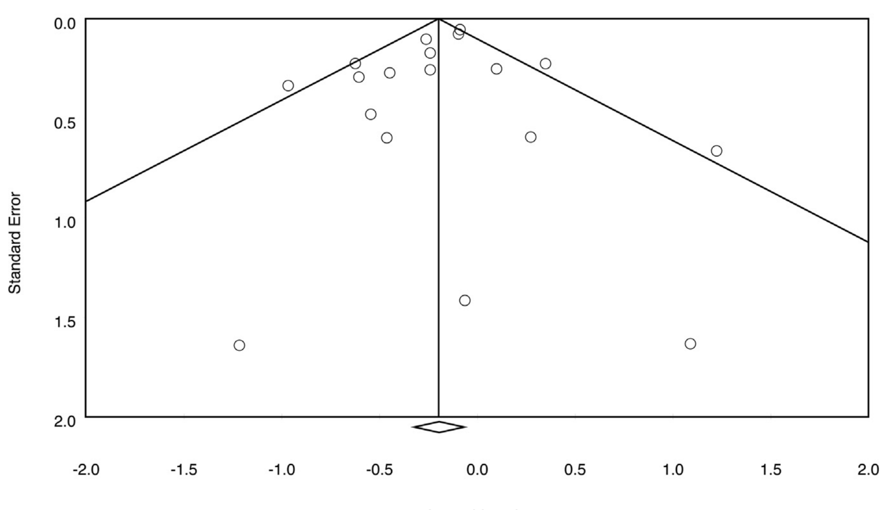

Figure 5. Funnel plot of standard error by log odds ratio (observed values) for mortality.

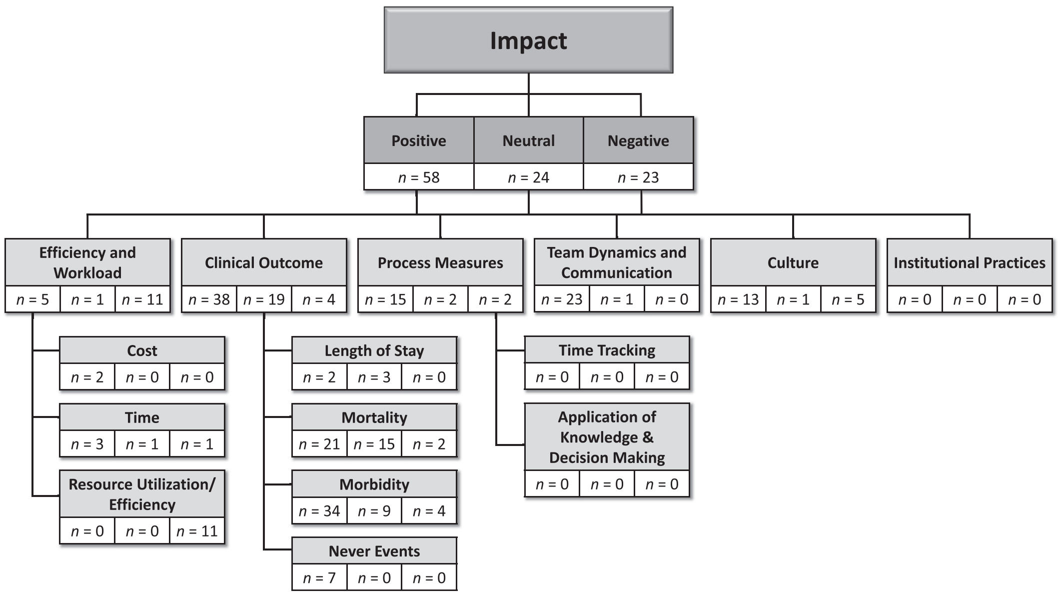

Figure 6. Themes, subthemes, and frequencies of positive, neutral, and negative impacts of the WHO Surgical Safety Checklist.

to improve both teamwork and communication, as its developers intended.

Finally, more than twice as many items reported a positive effect of the SCC on Safety Culture in the operating room (n = 13), as compared with negative effects (n = 5); X^2 (2, N = 19) = 11.789, p = 0.003. Interestingly, some who reported negative cultural effects (n = 5) felt the use of the SSC might actually widen professional hierarchies and accentuate power differentials among operating room staff—the opposite effect that SSC developers intended.

> Furthermore, if OR staff place differing importance to SSC adherence, SSC completion might actually antagonize team relationships/interactions and widen pre-existing power differentials."[32(p.45)]

> Importantly in some studies, SSC implementation did not mitigate the professional hierarchy, but can actually accentuate the power differential due to its perceived 'staged' nature.[32(p.45)]

Themes not directly associated with SSC aims

The other 2 themes we identified—Efficiency and Workload involved in using the checklist and Checklist Impact on Institutional Practices—are associated with SSC use, but were not focal areas considered during its development.

In contrast with the findings of the 4 themes addressed in the SSC's development, more negative (n = 11) than positive (n = 5) items related to Efficiency in the operating room and Perceived Workload were found; this difference was statistically significant, X^2 (2, N = 17) = 8.941, p = 0.011. For example, individuals felt that introduction of the checklist was disruptive to established work routines and did not fit into workload flow, especially during emergency operations. Additionally, some found the checklist to duplicate existing safety procedures.

> The introduction of a checklist in the operating theatre involves doctors and nurses changing existing routines. Workflows on the individual, professional, or team level have to be altered and aligned in order to create a brief moment of reflection to review the safety checks collectively. The workflow introduced by the checklist often collides with existing routines. This creates conflicts as existing workflows are established in function of different priorities (e.g., efficiency or productivity).[21(p.6)]

The last theme—Checklist Impact on Institutional Practices—was developed deductively based on reviews of the larger SSC literature, but no items pertaining to this theme were identified in the systematic reviews included in this study.

DISCUSSION

The aim of the WHO SCC is to reduce the frequency of surgical morbidities and mortality globally by "reinforcing accepted safety practices and fostering better communication between clinical disciplines."[3] Our systematic review

Table 4. Impact of WHO Surgical Safety Checklist: Key Findings and Study Design

Theme, study design	No. of studies	Key findings
Efficiency and workload		
Positive (n = 5)		Decrease in OR time; reduced delays in OR; reduced healthcare-associated cost
Pre-post study	1	
Cohort study	1	
Decision analysis	1	
Interview and survey study	1	
Pre-post survey	1	
Negative (n = 11)		Disrupts existing routine and creates conflicting priorities; duplicates existing safety procedures; creates challenges during emergency procedures
Interview study	3	
Case series	2	
Systematic review	2	
Ethnographic study	1	
Observation study	1	
Pre-post study	1	
Review	1	
Clinical outcome		
Positive (n = 38)		Decrease in mortality rate; decreased rate of wrong-side/wrong-site surgery; decreased length of stay; decrease in morbidity rate (eg decreased rate of infection, transfusion for blood loss, unplanned return to OR, respiratory complication)
Pre-post study	13	
Systematic review	1	
Review	4	
Cohort study	7	
Case series	2	
Pre-post survey	2	
Randomized controlled trial	2	
Article	1	
Meta-analysis	1	
Systematic review and meta-analysis	5	
Neutral (n = 19)		No significant difference in mortality rate, length of stay, or morbidity rate (eg infection rate, SSI, sepsis, transfusion for blood loss, respiratory complication)
Pre-post study	11	
Cohort study	2	
Randomized controlled trial	2	
Retrospective review	2	
Case series	1	
Systematic review	1	
Negative (n = 4)		Increased mortality and morbidity (eg increased rate of lower respiratory tract infection)
Pre-post study	3	
Time series	1	
Process measure		
Positive (n = 15)		Decreased non-technical surgical error; knowledge about patients improved; increased situational awareness
Pre-post survey	8	
Post-implementation survey	2	
Pre-post study	1	
Pre-post survey/ observation	1	
Prospective cohort study	2	
Review	1	
Team dynamics and communication		
Positive (n = 23)		Improves teamwork; decrease in communication failure/ improvement in communication
Post-implementation survey	7	
Pre-post survey	4	
Pre-post study	2	
Review	4	
Observation study	1	
Case series	1	
Cohort study	1	
Interview and survey study	1	
Pre-post survey/ observation	1	
Survey study	1	

(Continued)

Table 4. Continued

Theme, study design	No. of studies	Key findings
Culture		
Positive (n = 13)		Improved safety culture in the OR; can eliminate hierarchy or encourage a nonhierarchical team-based approach
Pre-post implementation survey	4	
Case series	2	
Pre-post study	1	
Cohort study	1	
Post-implementation survey	1	
Pre-post implementation survey/observation	1	
Review	1	
Prospective cohort study	1	
Systematic review and meta-analysis	1	
Neutral (n = 1)		No change in entrenched hierarchy and relationship of OR staff
Pre-post study	1	
Negative (n = 5)		Widens professional hierarchy and accentuates power differential
Interview study	1	
Direct observation	1	
Interview and survey	1	
Pre-post survey	1	
Review	1	

OR, operating room; SSI, surgical site infection.

and meta-analysis analyzed impacts and clinical outcomes associated with WHO SSC use through a thematic analysis and meta-meta-analyses. Our principal findings can be summarized as: the WHO SSC positively impacts the things it was explicitly designed to address and does not positively impact the things it was not explicitly designed for.

The thematic analysis revealed 4 themes that are emphasized by the authors—clinical outcomes, process measures, team dynamics and communication, and safety culture—in which the direction of the narrative of the overall impact of the WHO SSC was positive; these are directly related to the original aims of the WHO SSC. Our meta-meta-analysis directly supports these findings and the primary goal of the WHO SSC to decrease surgical complications and mortality. Not surprisingly, postoperative outcomes that favored the use of the WHO SSC were addressed by specific items within the checklist (eg SSI, unplanned intubation). All infectious outcomes (ie SSI, pneumonia, UTI, and sepsis), with the exception of septic shock, favored the use of the WHO SSC. This is unsurprising because the WHO SSC contains a check for antibiotic prophylaxis administration. Conversely, postoperative outcomes that did not favor the use of WHO SSC (DVT) or where the WHO SSC had no impact (renal complications) were conditions for which no specific items appeared in the SSC. Surprisingly, a majority of these items are both directly and indirectly related to cardiovascular functioning (eg cardiac arrest, myocardial infarction, stroke/cerebrovascular accident, and pulmonary embolism). These findings suggest that content—the specific items included in the checklist—does matter; it is not just the change in culture induced through checklist use that influences positive surgical outcomes.

Our thematic analysis also revealed another theme—efficiency and workload—in which the direction of the narrative was negative. For example, checklist users often felt that the checklist slowed down processes within the operating room. This effect is common when a new quality improvement program is initiated and workflow must be adjusted to accommodate. This concern, however, also indicates that users may not be aware that the WHO SSC is actually intended to slow down processes in the operating room—the very notion of a "time out" is to set aside other tasks to focus attention on something else, in this case, addressing items and issues of concern related to patient safety and surgical outcomes.

Based on the studies included for analysis, it is evident that there is widespread use of the WHO SSC across countries with both low and high human development indices. The findings from our thematic analysis were mostly positive. Neutral and negative findings (eg efficiency and workload) indicate that there is room for improvement in training and implementation of the WHO SSC. The content of the SSC may also need to be reconsidered in some types of circumstances, such as emergency operations, in which some of the patient data (eg allergies, comorbidities) may not be known. Furthermore, the urgent or emergent nature of emergency conditions may take greater precedence over pausing for a "time out" to conduct the checklist.

The majority of clinical outcomes analyzed in our meta-analyses also favor the use of the WHO SSC. Though these findings were significant, in most outcomes, the pooled effect comes considerably close to the line of no effect (eg Fig. 2); we had expected to see a more robust effect in favor of the WHO SSC.

To our knowledge, this study is the first meta-meta-analysis consisting of a thematic analysis and meta-analysis of the WHO SSC. Consistent findings discovered through both qualitative and quantitative analyses indicate that faith can be placed in the robustness of this study's results.

There are, however, some limitations to this study. There is moderate to high heterogeneity in the pooled results, which could limit the generalizability of our findings. However, some degree of heterogeneity is always anticipated in meta-analyses and can reflect differences in study populations, methods of outcome measurement, analytic methods, and numerous other factors.

Many of the original studies included in the systematic reviews analyzed are relatively old at this point and were conducted not long after the WHO SSC was first introduced. Furthermore, the effectiveness of the checklist in developing or low-resource countries, as compared to in developed or high-resource countries, is an important consideration, but beyond the scope of this study.

CONCLUSIONS

Although largely positive, there was some variability in impact and outcome findings in both the thematic analysis and meta-analyses. The variability across outcomes implies that there is no single determinant for SSC success; rather, there are multiple determinants that affect checklist impact and outcomes, such as the specific content included, the way it is implemented, its training, and how it is used in practice. Our findings suggest that users may need to revisit their WHO SSC to determine if there is a need for modification and changes to implementation strategies and methods for ensuring compliance and its use as intended. The overall purposes and goals of the WHO SSC must remain at the forefront during these processes; however, improving operating room team communication and reducing errors leading to patient mortality or morbidity are critical.

Author Contributions

Study conception and design: Sotto, Burian, Brindle
Acquisition of data: Sotto
Analysis and interpretation of data: Sotto, Burian, Brindle
Drafting of manuscript: Sotto, Burian, Brindle
Critical revision: Sotto, Burian, Brindle

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Invited Commentary

Examining Quality Improvement in Medicine and Business

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Over the past 20 years, the medical community has been forced to invest in quality assurance programs. Surgery, in particular, has worked to develop a workforce educated in quality improvement methods and to formalize existing efforts in quality and safety in surgery. The article, "Impact of the WHO Surgical Safety Checklist relative to its design and intended use: a systematic review and meta-meta-analysis" provides a nice opportunity to consider the general benefits and limitations of quality improvement programs in surgery in the context of the lessons learned in business, where formal efforts in quality assurance are better established.[1]

The World Health Organization (WHO) Surgical Safety Checklist (SSC)[2] may represent the most ubiquitous effort to improve surgical care globally. Despite data demonstrating significant advances in care attributed to SSC adoption,[3-5] skepticism over its effectiveness persists. The meta-meta-analysis published by Sotto and colleagues[1] provides insight into why the surgical community may question adoption of the SSC, and many other similar efforts to advance care.

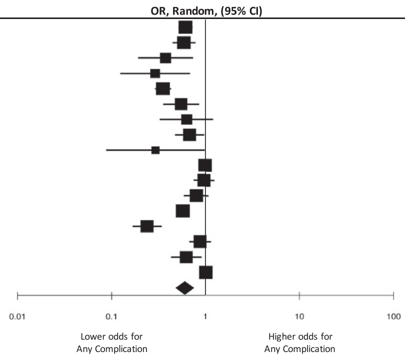
In the meta-meta-analysis, Sotto and colleagues[1] identified 9 outcomes metrics that improved after SSC adoption (mortality, morbidity, surgical site infection, pneumonia, unplanned return to the operating room, urinary tract infection, blood loss requiring transfusion, unplanned intubation, and sepsis), 7 metrics unaffected by the SSC (renal complication, prolonged ventilation, cardiac arrest, MI, stroke, venous embolism, and septic shock), and one measure for which outcomes were worse after SSC adoption (deep venous thrombosis). Additionally, the thematic assessment found that SSC was negatively associated with both staff workload and overall efficiency, two core concepts highly valued within surgical culture.

If we place these findings in the context of what has been learned within business, it may be possible to develop a mature infrastructure for quality and safety efforts that minimize inefficiency and excessive workload to accelerate buy-in from surgeons and clinicians involved in patient care. To begin, we have to accept that the time has come to invest in the infrastructure of quality and safety in Surgery. Dating back to almost two decades before the release of the SSC, the business world battled the idea that investment in quality improvement would lead to rising cost and inefficiency.[6] After arduous debate, the business community ultimately accepted the notion that investment in quality assurance and, research and development was instrumental to the optimization of performance.[7] As such, investments in these efforts have been steadily climbing over time in Business. In 2018, top performing businesses invested up to 45.5% of revenue into research and development to improve product quality.[8] It remains unclear how much hospitals currently invest in efforts to improve their product: the ability to deliver optimal care to patients. However, what is clear is that investments in the domains of quality and safety infrastructure are necessary to offset the impact of inefficiencies and waste on our patients and on the surgeons and clinicians who provide care to them. Moreover, a part of the investment must include the support of surgeons who work on the front lines of the quality and safety programs within our institutions.

A recent systematic review by Psarommatis and colleagues[9] summarized the critical failures and successes associated with implementation of quality improvement programs within the field of business. Among the top three causes of failure, Psarommatis and colleagues[9] report a lack of training in quality improvement methodology among staff, lack of commitment to quality improvement by top management, and resistance to change among stakeholders. Lack of resources and data control infrastructure are also cited as top reasons for failure. In surgery, there is a commitment among management to improve outcomes, yet skilled personnel with the time and resources to perform quality initiatives and the infrastructure to support these efforts are limited. As such, the burden of work placed on clinicians often dampens enthusiasm for these activities. Many of the other critical

Clinical Outcome: Any Complication (Morbidity)

Study or Subgroup	WHO SSC Events	WHO SSC N	No WHO SSC Events	No WHO SSC N	Weight, %	OR, Random, (95% CI)
Haynes et al., 2009	277	3955	411	3733	7.09	0.61 (0.52 - 0.71)
Weiser et al., 2010	106	908	155	842	6.59	0.59 (0.45 - 0.77)
Askarian et al., 2011	15	150	33	144	4.21	0.37 (0.19 - 0.72)
Bliss et al., 2012	6	73	491	2079	3.32	0.29 (0.12 - 0.67)
Kwok et al., 2012	185	2106	429	1993	6.99	0.35 (0.29 - 0.42)
Yuan et al., 2012	46	249	68	232	5.62	0.55 (0.36 - 0.84)
Lepanluoma et al., 2013	31	67	48	83	4.27	0.63 (0.33 - 1.20)
Boaz et al., 2014	72	380	98	380	6.14	0.67 (0.48 - 0.95)
Prakash et al., 2014	4	80	11	72	2.13	0.29 (0.09 - 0.96)
Urbach et al., 2014	4063	106370	4221	109341	7.38	0.99 (0.95 - 1.03)
Biskup et al., 2015	133	2310	129	2166	6.68	0.96 (0.75 - 1.24)
Chaudhary et al., 2015	162	350	182	350	6.42	0.80 (0.59 - 1.07)
Haugen et al., 2015	382	3083	440	2212	7.13	0.57 (0.49 - 0.66)
Kim et al., 2015	39	637	429	1993	6.16	0.24 (0.17 - 0.33)
Rodrigo-Rincon et al., 2015	130	801	145	801	6.62	0.88 (0.68 - 1.14)
Mayer et al., 2016	724	6494	37	220	6.03	0.62 (0.43 - 0.89)
O'Leary et al., 2016	590	14314	590	14458	7.23	1.01 (0.90 - 1.14)
Total	**6965**	**142327**	**7917**	**141099**	**100.00**	**0.60 (0.49 - 0.74)**

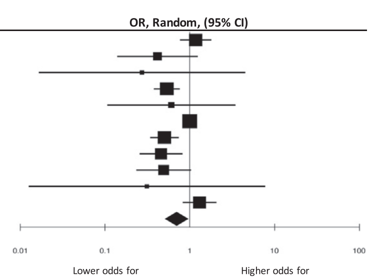


Heterogeneity: Tau^2 = 0.15; Q = 273.30, df(Q) = 16 (p < 0.001); I^2 = 94%
Test for overall effect: Z = -4.88 (p < 0.001)

eFigure 1. Clinical outcome: any complication (morbidity). OR, odds ratio; SSC, surgical safety checklist.

Clinical Outcome: Pneumonia

Study or Subgroup	WHO SSC Events	WHO SSC N	No WHO SSC Events	No WHO SSC N	Weight, %	OR, Random, (95% CI)
Haynes et al., 2009	51	3955	41	3733	13.20	1.18 (0.78 - 1.78)
Askarian et al., 2011	5	150	11	144	5.27	0.42 (0.14 - 1.23)
Bliss et al., 2012	0	73	50	2079	1.06	0.27 (0.02 - 4.47)
Kwok et al., 2012	54	2106	93	1993	14.38	0.54 (0.38 - 0.76)
Lepanluoma et al., 2013	2	67	4	83	2.52	0.61 (0.11 - 3.42)
Urbach et al., 2014	330	106370	339	109341	16.97	1.00 (0.86 - 1.16)
Haugen et al., 2015	43	2263	82	2212	13.85	0.50 (0.35 - 0.73)
Kim et al., 2015	14	637	93	1993	10.74	0.46 (0.26 - 0.81)
Rodrigo-Rincon et al., 2015	11	801	22	801	8.55	0.49 (0.24 - 1.02)
Biskup et al., 2016	0	2310	1	2166	0.82	0.31 (0.01 - 7.67)
O'Leary et al., 2016	44	14314	34	14458	12.64	1.31 (0.84 - 2.05)
Total	**554**	**133046**	**770**	**139003**	**100.00**	**0.70 (0.52 - 0.94)**

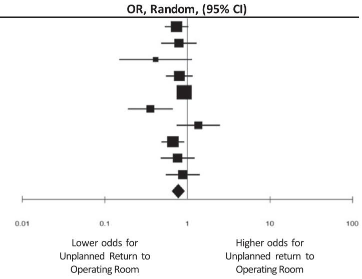


Heterogeneity: Tau^2 = 0.13; Q = 34.29, df(Q) = 10 (p < 0.001); I^2 = 71%
Test for overall effect: Z = -2.35 (p = 0.019)

eFigure 2. Clinical outcome: pneumonia. OR, odds ratio; SSC, surgical safety checklist.

Clinical Outcome: Unplanned Return to Operating Room

Study or Subgroup	WHO SSC Events	WHO SSC N	No WHO SSC Events	No WHO SSC N	Weight, %	OR, Random, (95% CI)
Haynes et al., 2009	71	3955	90	3733	12.97	0.74 (0.54 - 1.01)
Kwok et al., 2012	31	2106	37	1993	8.02	0.79 (0.49 - 1.28)
Lepanluoma et al., 2013	6	67	16	83	2.49	0.41 (0.15 - 1.12)
Lubbeke et al., 2013	109	1818	45	609	11.34	0.08 (0.56 - 1.15)
Urbach et al., 2014	1893	106370	2121	109341	23.27	0.92 (0.86 - 0.98)
Haugen et al., 2015	14	2263	38	2212	5.63	0.36 (0.19 - 0.66)
Kim et al., 2015	16	637	37	1993	5.95	1.36 (0.75 - 2.47)
Lepanluoma et al., 2015	72	2753	103	2665	13.30	0.67 (0.49 - 0.91)
Rodrigo-Rincon et al., 2015	34	801	44	801	8.54	0.76 (0.48 - 1.21)
O'Leary et al., 2016	34	14314	39	14458	8.49	0.88 (0.56 - 1.40)
Total	**2280**	**135084**	**2570**	**137888**	**100.00**	**0.78 (0.66 - 0.92)**

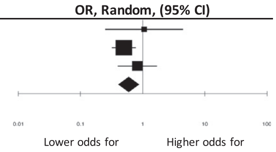


Heterogeneity: $Tau^2 = 0.03$; $Q = 19.25$, df(Q) = 9 ($p = 0.023$); $I^2 = 53\%$
Test for overall effect: $Z = -2.98$ ($p = 0.003$)

eFigure 3. Clinical outcome: unplanned return to operating room. OR, odds ratio; SSC, surgical safety checklist.

Clinical Outcome: Urinary Tract Infection

Study or Subgroup	WHO SSC Events	WHO SSC N	No WHO SSC Events	No WHO SSC N	Weight, %	OR, Random, (95% CI)
Bliss et al., 2012	2	73	54	2079	6.60	1.06 (0.25 - 4.42)
Haugen et al., 2015	32	2263	62	2212	67.53	0.50 (0.32 - 0.77)
Rodrigo-Rincon et al., 2015	14	801	17	801	25.88	0.82 (0.40 - 1.68)
Total	**48**	**3137**	**133**	**5092**	**100.00**	0.59 (0.41 - 0.86)



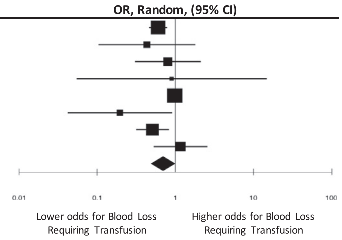
Heterogeneity: $Tau^2 = 0.004$; $Q = 2.06$, df(Q) = 2 ($p = 0.357$); $I^2 = 3\%$
Test for overall effect: $Z = -2.76$ ($p = 0.006$)

eFigure 4. Clinical outcome: urinary tract infection (UTI). OR, odds ratio; SSC, surgical safety checklist.

Clinical Outcome: Blood Loss Requiring Transfusion

Study or Subgroup	WHO SSC Events	WHO SSC N	No WHO SSC Events	No WHO SSC N	Weight, %	OR, Random, (95% CI)
Weiser et al., 2010	120	908	170	842	24.28	0.60 (0.47 - 0.78)
Bliss et al., 2012	2	73	127	2079	4.70	0.43 (0.10 - 1.79)
Lepanluoma et al., 2013	8	67	12	83	8.57	0.80 (0.31 - 2.09)
Prakash et al., 2014	1	80	1	72	1.38	0.90 (0.06 - 14.64)
Urbach et al., 2014	670	106370	700	109341	27.45	0.98 (0.88 - 1.09)
Chaudhary et al., 2015	2	350	10	350	4.15	0.20 (0.04 - 0.90)
Haugen et al., 2015	27	2263	51	2212	18.20	0.51 (0.32 - 0.82)
Rodrigo-Rincon et al., 2015	14	801	12	801	11.26	1.17 (0.54 - 2.54)
Total	**844**	**110912**	**1083**	**115780**	**100.00**	**0.70 (0.50 - 0.98)**

Heterogeneity: $Tau^2 = 0.10$; $Q = 23.05$, $df(Q) = 7$ ($p = 0.002$); $I^2 = 70\%$
Test for overall effect: $Z = -2.09$ ($p = 0.036$)

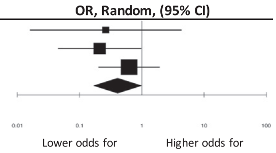


eFigure 5. Clinical outcome: blood loss requiring transfusion. OR, odds ratio; SSC, surgical safety checklist.

Clinical Outcome: Unplanned Intubation

Study or Subgroup	WHO SSC Events	WHO SSC N	No WHO SSC Events	No WHO SSC N	Weight, %	OR, Random, (95% CI)
Bliss et al., 2012	0	73	52	2079	9.50	0.26 (0.02 - 4.30)
Kwok et al., 2013	2	2106	9	1993	31.55	0.21 (0.05 - 0.97)
Rodrigo-Rincon et al., 2015	5	801	8	801	58.96	0.62 (0.20 - 1.91)
Total	**7**	**2980**	**69**	**4873**	**100.00**	**0.41 (0.17 - 0.96)**

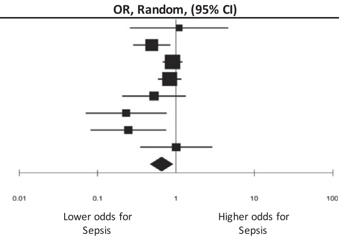
Heterogeneity: $Tau^2 = 0$; $Q = 1.37$, $df(Q) = 2$ ($p = 0.505$); $I^2 = 0\%$
Test for overall effect: $Z = -2.05$ ($p = 0.041$)



eFigure 6. Clinical outcome: unplanned intubation. OR, odds ratio; SSC, surgical safety checklist.

Clinical Outcome: Sepsis

Study or Subgroup	WHO SSC Events	WHO SSC N	No WHO SSC Events	No WHO SSC N	Weight, %	OR, Random, (95% CI)
Bliss et al., 2012	2	73	52	2079	4.29	1.10 (0.26 - 4.60)
Kwok et al., 2012	21	2106	40	1993	17.02	0.49 (0.29 - 0.84)
Urbach et al., 2014	96	106370	109	109341	26.12	0.91 (0.69 - 1.19)
Chaudhary et al., 2015	92	350	105	350	24.04	0.83 (0.60 - 1.16)
Haugen et al., 2015	7	2263	13	2212	8.73	0.52 (0.21 - 1.32)
Kim et al., ,2015	3	637	40	1993	5.97	0.23 (0.07 - 0.75)
Rodrigo-Rincon et al., 2015	4	801	16	801	6.65	0.25 (0.08 - 0.74)
O'Leary et al., 2016	7	14314	7	14458	7.18	1.01 (0.35 - 2.88)
Total	**232**	**126914**	**382**	**133227**	**100.00**	**0.65 (0.48 - 0.90)**

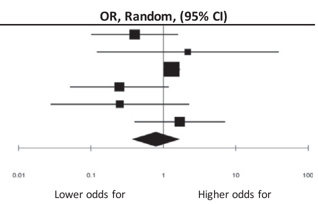


Heterogeneity: $Tau^2 = 0.08$; $Q = 13.54$, df(Q) = 7 ($p = 0.060$); $I^2 = 48\%$
Test for overall effect: $Z = -2.61$ ($p = 0.009$)

eFigure 7. Clinical outcome: sepsis. OR, odds ratio; SSC, surgical safety checklist.

Clinical Outcome: Renal Complications

Study or Subgroup	WHO SSC Events	WHO SSC N	No WHO SSC Events	No WHO SSC N	Weight, %	OR, Random, (95% CI)
Askarian et al., 2011	3	150	7	144	16.63	0.40 (0.10 - 1.58)
Bliss et al., 2012	0	73	6	2079	5.47	2.17 (0.12 - 38.88)
Urbach et al., 2014	138	106370	109	109341	39.25	1.30 (1.01 - 1.67)
Chaudhary et al., 2015	2	350	8	350	14.21	0.25 (0.05 - 1.17)
Rodrigo-Rincon et al., 2015	1	801	4	801	8.63	0.25 (0.03 - 2.23)
O'Leary et al., 2016	5	14314	3	14458	15.80	1.68 (0.40 - 7.05)
Total	**149**	**122058**	**137**	**127173**	**100.00**	**0.78 (0.38 - 1.62)**

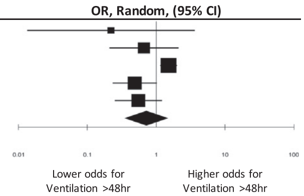


Heterogeneity: $Tau^2 = 0.33$; $Q = 9.21$, df(Q) = 5 ($p = 0.101$); $I^2 = 46\%$
Test for overall effect: $Z = -0.66$ ($p = 0.510$)

eFigure 8. Clinical outcome: renal complication. OR, odds ratio; SSC, surgical safety checklist.

Clinical Outcome: Ventilation >48hr

	WHO SSC		No WHO SSC			
Study or Subgroup	**Events**	**N**	**Events**	**N**	**Weight, %**	**OR, Random, (95% CI)**
Bliss et al., 2012	0	73	62	2079	5.17	0.22 (0.01 - 3.58)
Lepanluoma et al., 2013	5	67	9	83	17.19	0.66 (0.21 - 2.08)
Urbach et al., 2014	128	106370	87	109341	30.81	1.51 (1.15 - 1.99)
Haugen et al., 2015	11	2263	22	2212	23.87	0.49 (0.24 - 1.01)
Rodrigo-Rincon et al., 2015	10	801	18	801	22.96	0.55 (0.25 - 1.20)
Total	**154**	**109574**	**198**	**114516**	**100.00**	**0.72 (0.36 - 1.44)**

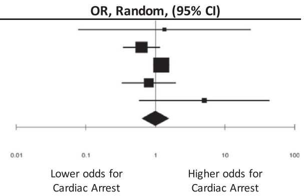


Heterogeneity: $Tau^2 = 0.39$; $Q = 14.97$, $df(Q) = 4$ ($p = 0.005$); $I^2 = 73\%$
Test for overall effect: $Z = -0.94$ ($p = 0.349$)

eFigure 9. Clinical outcome: ventilation >48 hours. OR, odds ratio; SSC, surgical safety checklist.

Clinical Outcome: Cardiac Arrest

	WHO SSC		No WHO SSC			
Study or Subgroup	**Events**	**N**	**Events**	**N**	**Weight, %**	**OR, Random, (95% CI)**
Bliss et al., 2012	0	73	10	2079	2.22	1.34 (0.08 - 23.10)
Kwok et al., 2013	18	2106	27	1993	27.72	0.63 (0.34 - 1.14)
Urbach et al., 2014	128	106370	109	109341	49.21	1.21 (0.94 - 1.56)
Haugen et al., 2015	9	2263	11	2212	17.07	0.80 (0.33 - 1.93)
Rodrigo-Rincon et al., 2015	5	801	1	801	3.78	5.03 (0.59 - 43.11)
Total	**160**	**111613**	**158**	**116426**	**100.00**	**0.99 (0.64 - 1.53)**



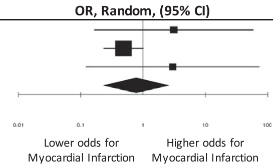
Heterogeneity: $Tau^2 = 0.08$; $Q = 6.31$, $df(Q) = 4$ ($p = 0.177$); $I^2 = 37\%$
Test for overall effect: $Z = -0.03$ ($p = 0.974$)

eFigure 10. Clinical outcome: cardiac arrest. OR, odds ratio; SSC, surgical safety checklist.

Clinical Outcome: Myocardial Infarction

Study or Subgroup	WHO SSC Events	WHO SSC N	No WHO SSC Events	No WHO SSC N	Weight, %	OR, Random, (95% CI)
Bliss et al., 2012	0	73	4	2079	13.75	3.14 (0.17 - 58.82)
Haugen et al., 2015	11	2263	22	2212	74.48	0.49 (0.24 - 1.01)
Rodrigo-Rincon et al., 2015	1	801	0	801	11.77	3.00 (0.12 - 73.84)
Total	**12**	**3137**	**26**	**5092**	**100.00**	**0.78 (0.24 - 2.50)**

Heterogeneity: $Tau^2 = 0.34$; $Q = 2.51$, $df(Q) = 2$ ($p = 0.285$); $I^2 = 20\%$
Test for overall effect: $Z = -0.42$ ($p = 0.674$)

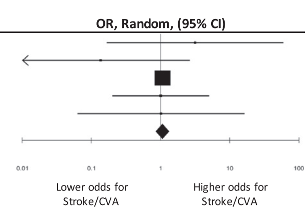


eFigure 11. Clinical outcome: myocardial infarction. OR, odds ratio; SSC, surgical safety checklist.

Clinical Outcome: Stroke/Cerebrovascular Accident

Study or Subgroup	WHO SSC Events	WHO SSC N	No WHO SSC Events	No WHO SSC N	Weight, %	OR, Random, (95% CI)
Bliss et al., 2012	0	73	4	2079	0.52	3.14 (0.17 - 58.82)
Kwok et al., 2013	0	2106	3	1993	0.51	0.13 (0.01 - 2.62)
Urbach et al., 2014	170	106370	164	109341	96.66	1.07 (0.86 - 1.32)
Rodrigo-Rincon et al., 2015	3	801	3	801	1.73	1.00 (0.20 - 4.97)
O'Leary et al., 2016	1	14314	1	14458	0.58	1.01 (0.06 - 16.15)
Total	**174**	**123664**	**175**	**128672**	**100.00**	**1.06 (0.86 - 1.31)**

Heterogeneity: $Tau^2 = 0$; $Q = 2.39$, $df(Q) = 4$ ($p = 0.664$); $I^2 = 0\%$
Test for overall effect: $Z = -0.53$ ($p = 0.595$)

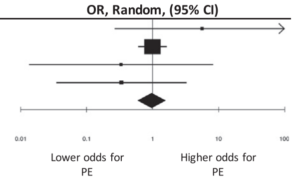


eFigure 12. Clinical outcome: stroke/cerebrovascular accident (CVA). OR, odds ratio; SSC, surgical safety checklist.

Clinical Outcome: Pulmonary Embolism

Study or Subgroup	WHO SSC Events	WHO SSC N	No WHO SSC Events	No WHO SSC N	Weight, %	OR, Random, (95% CI)
Bliss et al., 2012	0	73	2	2079	2.33	5.65 (0.27 - 118.80)
Urbach et al., 2014	32	106370	33	109341	91.35	1.00 (0.61 - 1.62)
Rodrigo-Rincon et al., 2015	0	801	1	801	2.11	0.33 (0.01 - 8.18)
O'Leary et al., 2016	1	14314	3	14458	4.22	0.34 (0.04 - 3.24)
Total	**33**	**121558**	**39**	**126679**	**100.00**	**0.97 (0.61 - 1.54)**

Heterogeneity: $Tau^2 = 0$; $Q = 2.57$, df(Q) = 3 ($p = 0.463$); $I^2 = 0\%$
Test for overall effect: $Z = -0.13$ ($p = 0.894$)

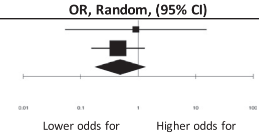


eFigure 13. Clinical outcome: pulmonary embolism (PE). OR, odds ratio; SSC, surgical safety checklist.

Clinical Outcome: Deep Vein Thrombosis, Pulmonary Embolism, and Embolism (Combined)

Study or Subgroup	WHO SSC Events	WHO SSC N	No WHO SSC Events	No WHO SSC N	Weight, %	OR, Random, (95% CI)
Bliss et al., 2012	0	73	15	2079	12.31	0.91 (0.05 - 15.29)
Haugen et al., 2015	5	2263	11	2212	87.69	0.44 (0.15 - 1.28)
Total	**5**	**2336**	**26**	**4291**	**100.00**	**0.48 (0.18 - 1.30)**

Heterogeneity: $Tau^2 = 0$; $Q = 0.22$, df(Q) = 1 ($p = 0.642$); $I^2 = 0\%$
Test for overall effect: $Z = -1.44$ ($p = 0.151$)



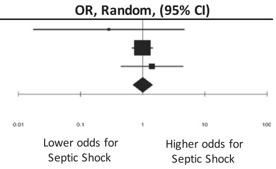
eFigure 14. Clinical outcome: deep vein thrombosis (DVT), pulmonary embolism (PE), and embolism (combined). OR, odds ratio; SSC, surgical safety checklist.

Clinical Outcome: Septic Shock

	WHO SSC		No WHO SSC			
Study or Subgroup	**Events**	**N**	**Events**	**N**	**Weight, %**	**OR, Random, (95% CI)**
Bliss et al., 2012	0	73	48	2079	1.62	0.28 (0.02 - 4.67)
Urbach et al., 2014	53	106370	55	109341	88.79	0.99 (0.68 - 1.44)
O'Leary et al., 2016	7	14314	5	14458	9.60	1.41 (0.45 - 4.46)
Total	**60**	**120757**	**108**	**125878**	**100.00**	**1.00 (0.70 - 1.43)**

Heterogeneity: $Tau^2 = 0$; $Q = 1.13$, $df(Q) = 2$ ($p = 0.569$); $I^2 = 0\%$

Test for overall effect: $Z = 0.03$ ($p = 0.980$)



eFigure 15. Clinical outcome: septic shock. OR, odds ratio; SSC, surgical safety checklist.