National Institute for Health and Care Excellence

Consultation

Perioperative care in adults

[L] Evidence review for management systems to promote safety in operating theatres

NICE guideline

Intervention evidence review

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Draft for Consultation

This evidence review was developed by the National Guideline Centre

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1 Intraoperative management systems

1.1 Review question: What is the clinical and cost effectiveness of management systems to promote safety in operating theatres?

1.2 Introduction

Safety management systems aim to mitigate risk for patients undergoing invasive procedures. They do this by highlighting safe practice. They are particularly beneficial in pressured environments to ensure all integral aspects of care are considered. The World Health Organisation (WHO) safety checklist is the commonly used operative safety management system in the United Kingdom. It was introduced to encourage and support team working and communication, flatten hierarchy and empower staff to speak up with concerns.

The WHO safety checklist is mandated across the country and is a three staged check. The three stages carried out with multiple members of the operating team are in the anaesthetic room, before the start of surgery and immediately postoperatively. Part of the checklist also includes a team brief and team debrief. There may be local deviations governed by local policy, these fluctuations are dependent on previous lessons learnt or types of surgery such as day case.

The effectiveness of the checklist may be affected by attitudes and behaviours around its appropriate utilisation. These attitudes are important in ensuring compliance and determining whether the use of safety management systems actually reduce errors would confirm its validation.

1.3 PICO table

For full details see the review protocol in appendix A.

Table 1: PICO characteristics of review question

Population	Adults 18 years and over having surgery.
Intervention	Management systems: • World Health Organisation (WHO) surgical safety checklist • national safety standards for invasive procedures • pre-surgery briefings • post-surgical debrief • combinations of these interventions
Comparison	• no management system (usual care) • each other
Outcomes	Critical outcomes: • health-related quality of life • mortality • patient, family and carer experience of care • adverse events and complications ○ Clavien-Dindo, postoperative morbidity score (POMS) • never events • serious incidents • compliance

	Important outcomes: • length of hospital stay • hospital readmission • unplanned ICU admission • ICU length of stay (planned and unplanned)
Study design	Randomised controlled trials (RCTs), systematic reviews of RCTs. Observational studies if no RCT evidence is identified.

1.4 Clinical evidence

1.4.1 Included studies

Five studies on four randomised controlled trials were included in the review;[23, 26, 44, 46, 81] these are summarised in Table 2 below. Evidence from these studies is summarised in the clinical evidence summary below (Table 3).

See also the study selection flow chart in appendix C, study evidence tables in appendix D, forest plots in appendix E and GRADE tables in appendix F.

1.4.2 Excluded studies

See the excluded studies list in appendix I.

1.4.3 Summary of clinical studies included in the evidence review

Table 2: Summary of studies included in the evidence review

Study	Intervention and comparison	Population	Outcomes	Comments
Calland 2011[23]	**Pre-surgery briefing/ national safety standards for invasive procedures:** Preoperative steps included a briefing with instructions of all team members, review of patient's history, laboratory, and radiographic studies, and discussion of any unusual case circumstances such as need for an intraoperative cholangiogram. Surgeons in the intervention group were provided instructions on the use of checklist and reminded of the need to review the review before each case. In addition a checklist copy was posted on the anaesthesia monitor in the operating room discussing cases and participants were instructed to use call-and-repeat method to ensure critical steps from the checklist were neither omitted nor performed suboptimally. N=33 **Usual care:** Attending surgeons and operating teams in the control	All adult non-emergent LC (laparoscopic cholecystectomy) cases at the academic tertiary care centre institution were screened for study eligibility from April 2001 to July 2002. Age: not reported Country: USA	• Post-operative length of stay (1 day) • Post-operative length of stay (2 days) • Post-operative length of stay (2 -7 days) • Hospital readmission	RCT

Study	Intervention and comparison	Population	Outcomes	Comments
	group performed the LC procedure in their normal fashion without any normalized checklist or pre-briefing N=32			
Chaudhary 2015[26]	**WHO Surgical safety checklist:** Modified WHO checklist It includes the preoperative (sign in), intra-operative (time out) and postoperative (sign out) periods. 1. Sign in phase—whether the imaging studies had been discussed with a radiologist. 2. Time out phase—whether prophylactic measures against deep venous thrombosis had been administered when indicated. The checklist was used on three separate occasions: before anaesthesia (sign in), before the skin incision (time out) and before the patient was shifted out of the operating room (sign out). The surgical resident (and not the nurse as in the WHO study) was responsible for the completion of the checklist. N=350 **Usual care:** not specified	All patients undergoing a surgical procedure between February 2012 and April 2013 were included in a prospective, randomized and controlled trial. Age: Intervention group: 50; control group 48 Country: India	• Mortality • Complications (total) • Clavien-Dindo 3 – 4 • Compliance • Length of hospital stay	RCT Compliance was reported as a proportion within the intervention group.

Study	Intervention and comparison	Population	Outcomes	Comments
	N=350			
Haugen 2015[44] (Haugen 2019[46])	**WHO surgical safety checklist:** The WHO SSC was first adapted to fit into the Norwegian surgical care pathway. In the Norwegian checklist version, items to prevent hypothermia are listed both under the Sign in and under Time out parts. The Checklist consisted of 20 items and as per WHO guidelines was performed at 3 critical steps of the surgical procedure: the “sign in” before induction of anaesthesia, the “time out” before start of surgery, and the “sign out” before the head surgeon left the operating room. N=2304 **Usual Care:** not specified N=1398	Patients of all age groups and elective or emergency surgery were included. Mean age (SD): 54.2 years (23.2) Norway	• Mortality • Complications • Length of hospital stay • Compliance	Haugen 2019 secondary analysis from parent study (Haugen 2015). Two studies have been merged for analysis. Cluster RCT Compliance was reported as a proportion within the intervention group.
Naidoo 2017[81]	**WHO surgical safety checklist:** The intervention on the use of the Modified Surgical Safety Checklist (MSSCL)	Study sites were 18 hospitals offering maternal surgical services in the public health sector.	• Mortality	All outcomes were reported as change in incidence rate (RR) per 1000 procedures, intervention group vs control from baseline to

Study	Intervention and comparison	Population	Outcomes	Comments
	consisted of training by the principal investigator of doctors and nurses working in maternity operating theatres during May 2013. The MSSCL used was the SSCL adapted by the provincial health department of the Western Cape Province of SA and further modified by the investigator (deleted an item on scalp vein electrodes). The MSSCL consists of three sections, the sign-in phase, the time-out phase and the sign-out phase. Before induction of anaesthesia (sign in) - During this phase the identity of the woman, the procedure and consent is confirmed. The anaesthetist and paediatrician/ midwife confirm that the anaesthetic and neonatal safety checks are complete with no problems. Before the skin incision (time out) - This occurs after induction of the anaesthetic. During this phase all members would have introduced themselves. The patient identity and procedure are again confirmed. Before the patient leaves the operating room (sign out) - This occurs after induction of the anaesthetic. During this phase all members would have	Public sector hospitals were stratified into district hospitals (DHs) or regional hospitals (RHs), with the DHs being further classified as large or small based on the number of CDs performed per month. Further geographical stratification occurred based on the three demarcated health areas in the province Age: not reported Country: South Africa	• Complications (surgical) • Complications (Intraoperative) • ICU admission	post intervention. Cluster RCT

Study	Intervention and comparison	Population	Outcomes	Comments
	introduced themselves. The patient identity and procedure are again confirmed. The surgeon reviews whether additional procedures are planned and whether there are concerns about the placental site. N=9 **Usual care:** not specified N=9			

See appendix D for full evidence tables.

1.4.4 Quality assessment of clinical studies included in the evidence review

Table 3: Clinical evidence summary: World Health Organization compared to usual care

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with WHO versus usual care (95% CI)
Mortality	4511 (2 studies) 30 days	⨁⨁⊖⊖ LOW1,2 due to risk of bias, imprecision	RR 0.61 (0.41 to 0.88)	Moderate	
				58 per 1000	23 fewer per 1000 (from 7 fewer to 34 fewer)
Complications	4402 (2 studies) 30 days	⨁⊖⊖⊖ VERY LOW1,3 due to risk of bias, inconsistency	RR 0.65 (0.61 to 0.69)	Moderate	
				660 per 1000	231 fewer per 1000 (from 205 fewer to 257 fewer)

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with WHO versus usual care (95% CI)
Complications (Clavien-Dindo Grade III-IV)	700 (1 study) 30 days	⊕⊕⊖⊖ LOW1,2 due to risk of bias, imprecision	RR 0.7 (0.54 to 0.89)	Moderate	
				331 per 1000	99 fewer per 1000 (from 36 fewer to 152 fewer)
Length of hospital stay	3811 (1 study)	⊕⊕⊕⊕ HIGH		The mean length of hospital stay in the control groups was 7 days.	The mean length of hospital stay in the intervention groups was 0.8 lower (1.49 to 0.11 lower)
1 Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias 2 Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs 3 Downgraded by 1 or 2 increments because: The point estimate varies widely across studies, unexplained by subgroup analysis. The confidence intervals across studies show minimal or no overlap, unexplained by subgroup analysis Heterogeneity, I2=50%, p=0.04, unexplained by subgroup analysis.					

Table 4: Clinical evidence summary: Surgical safety standards compared to usual care

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Surgical safety standards versus usual care (95% CI)
Postoperative length of stay (number of patients with same day discharge)	47 (1 study)	⊕⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision	RR 1.02 (0.59 to 1.29)	Moderate	
				696 per 1000	14 more per 1000 (from 285 fewer to 202 more)
Postoperative length of stay (number of patients with next day discharge)	47 (1 study)	⊕⊖⊖⊖ VERY LOW1,2	RR 0.68 (0.21 to	Moderate	
				304 per	97 fewer per 1000

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Surgical safety standards versus usual care (95% CI)
		due to risk of bias, imprecision	1.64)	1000	(from 240 fewer to 195 more)
Postoperative length of stay (number of patients with 2-7 days discharge)	47 (1 study)	⊕⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision	Peto OR 7.4 (0.45 to 122.11)	Moderate	
				0 per 1000	Not-estimable
Readmission	47 (1 study) 30 days	⊕⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision	Peto OR 7.09 (0.14 to 357.5)	Moderate	
				0 per 1000	Not-estimable

1 Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
2 Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

See appendix F for full GRADE tables.

Table 5: Evidence not suitable for GRADE analysis: WHO checklist compared to usual care

Outcome	Study (no. of participants)	Risk of bias	Usual care results	Intervention results	*P* value
Length of hospital stay (days)	Chaudhary 2015 (700)	High	9 (median)	9 (median)	0.54
Mortality	Naidoo 2017 (47 medical centres)	High	Change in incidence rate per 1000 procedures, intervention group vs control from baseline to post intervention IRR: 0.655, 95% CI (0.221 - 1.938)		0.444

Outcome	Study (no. of participants)	Risk of bias	Usual care results	Intervention results	*P* value
Complications (surgical)		High	Change in incidence rate per 1000 procedures, intervention group vs control from baseline to post intervention IRR: 0.592 95% CI (0.323 - 1.085)		0.090
Complications (intraoperative)		High	Change in incidence rate per 1000 procedures, intervention group vs control from baseline to post intervention IRR: 1.154 95% CI (0.8 - 1.664)		0.443
ICU admission (referral to higher level of care)		High	Change in incidence rate per 1000 procedures, intervention group vs control from baseline to post intervention IRR: 1.409 95% CI (1.066 - 1.862)		0.016
Compliance	Chaudhary 2015 (700)	High	Fully completed checklist 85% (n=298) Partially completed checklist (at least one of the items filled) 10 % (n=34) Not completed checklist (none of the 24 items filled) 5% (n=18)		n/a
	Haugen 2019[46] (3702)	High	Surgical Safety Checklist compliance: • none of the three (sign in, time out, sing out) parts used: 256 • 1 part used:109 • 2 parts used: 196 • 3 parts used: 1743 • any parts used: 2048		n/a

1.5 Economic evidence

1.5.1 Included studies

No health economic studies were included.

1.5.2 Excluded studies

No relevant health economic studies were excluded due to assessment of limited applicability or methodological limitations.

See also the health economic study selection flow chart in Appendix G:.

1.6 Evidence statements

1.6.1 Clinical evidence statements

No evidence was found for was found for health-related quality of life, patient/family/ carer experience of care, never events, serious incidents and ICU length of stay.

WHO checklist compared to usual care

Mortality

Two studies found a clinically important benefit of WHO on mortality compared to usual care (2 studies, n=4511, low quality of evidence).

Adverse events

Two studies found a clinically important benefit of on complications WHO compared to usual care (2 studies, n=4402, very low quality of evidence).

A single study demonstrated a clinically important benefit of WHO on complications (Clavien-Dindo grade 3-4) compared to usual care (1 study, n=700, low quality of evidence).

Length of hospital stay

One study showed no clinically important difference of WHO for length of hospital stay compared to usual care (1 study, n=3811, high quality of evidence)

Outcomes not suitable for GRADE analysis:

One study showed no statistically significant difference between WHO checklist and usual care for mortality (reported as change in incidence rate per 1000 procedures) (1 study, n=47 medical centres, high risk of bias).

One study showed no statistically significant difference between WHO checklist and usual care for surgical complications (reported as change in incidence rate per 1000 procedures) (1 study, n=47 medical centres, high risk of bias).

One study showed no statistically significant difference between WHO checklist and usual care for intraoperative complications (reported as change in incidence rate per 1000 procedures) (1 study, n=47 medical centres, high risk of bias).

One study showed a statistically significant difference between WHO checklist and usual care for ICU admissions (reported as change in incidence rate per 1000 procedures) (1 study, n=47 medical centres, high risk of bias).

One study showed no statistically significant difference between WHO checklist and usual care for length of hospital stay (1 study, n=700, high risk of bias).

Two studies reported compliance, but these results could not be compared to usual care (n=4402, high risk of bias)

Surgical safety standards compared to usual care.

Length of hospital stay

One study showed no clinically important difference between surgical safety standards and usual care on postoperative length of stay (number of patients with the same day discharge), (1 study, n=47, very low quality of evidence)

A single study showed a clinically important benefit of surgical safety standards on postoperative length of stay (number of patients with next day discharge) compared to usual care (1 study, n=47, very low quality of evidence)

One study reported no clinically important difference between surgical safety standard and usual care for postoperative length of stay (number of patients with next day discharge) (1 study, n=47, very low quality of evidence)

One study reported a clinically important benefit with surgical safety standard for postoperative length of stay (number of patients with discharge at days 2 to 7) compared to usual care (1 study, n=47, very low quality of evidence)

Readmissions

One study reported a clinically important harm for readmission comparing surgical safety standard to usual care (1 study, n=47, very low quality of evidence)

1.6.2 Health economic evidence statements

- No relevant economic evaluations were identified.

1.7 The committee's discussion of the evidence

Please see recommendations 1.4.8 – 1.4.9 in the guideline.

1.7.1 Interpreting the evidence

1.7.1.1 The outcomes that matter most

The committee considered that the purpose of this review was to assess the efficacy of safety management systems, which aim to mitigate risk for patients undergoing invasive procedures. As such, the critical outcomes for decision making to be health-related quality of life, mortality, patient, family and carer experience of care, adverse events and complications, never events, serious incidents and compliance. Length of hospital stay, unplanned intensive care unit admission, length of stay in intensive care unit and hospital readmission were also thought to be important outcomes.

A Never Event is a term used to describe certain serious patient safety incidents which can occur in hospital. What sets Never Events apart from other types of serious incidents is that they are regarded as being wholly preventable when appropriate safety protocols are followed by healthcare professionals.

No evidence was identified for critical outcomes such as health-related quality of life, patient family and carer experience of care, never events, serious incidents, compliance. No evidence was identified for important outcomes such as unplanned ICU admission, and ICU length of stay.

While there was evidence for critical outcomes such as mortality and complications, the committee suggested that Never Events should also be considered when reviewing surgical safety checklists. The committee stressed that there is still some work to be done to identify the reasons that Never Events still occur and how they occurred in the presence of the checklist.

1.7.1.2 The quality of the evidence

The quality of evidence that was suitable for GRADE ranged from very low to high. The majority of outcomes were graded as very low quality. This was mostly due to risk of bias, inconsistency and impression. Only length of hospital stay had high quality of evidence, however, there was no clinically important difference for this outcome. As such, the committee felt that they could not make any strong recommendations based on the evidence presented alone.

Outcomes which were not suitable for GRADE analysis were all high risk of bias.

1.7.1.3 Benefits and harms

The committee discussed the evidence on effectiveness of management systems to promote safety in operating theatres.

The committee discussed the evidence from two studies showing reduced mortality, and total number of complications while using WHO SSC compared to usual care. This benefit was considered by the committee to be clinically important.

The committee also discussed the evidence from one study showing reduced complications (Clavien-Dindo grade 3-4) while using WHO SSC compared to usual care. This benefit was considered by the committee to be clinically important.

Evidence reviewed by the committee showed no clinically important difference in length of stay between WHO checklist compared to usual care.

The committee also discussed the evidence from one study showing no clinically important difference in postoperative length of stay between surgical safety standards compared to usual care.

Evidence reviewed by the committee from one study showed an increased risk of readmission with surgical safety checklist, although the committee noted the very low quality of the outcome due to risk of bias and significant imprecision resulting from a small sample size and low event rate.

The committee noted that on the balance of the evidence presented and consensus agreement, the WHO surgical safety checklists has a real capacity to reduce mortality and complication rate. The committee considered that this benefit was more significant than the potential increased rate of readmissions reported by one study, and supported a recommendation for the WHO checklists. Although not directly reported by the studies included in the review, the committee agreed that surgical safety checklists may have the capacity to reduce the occurrence of Never Events. The committee considered that this may reduce the risk of serious patient harm or death. The committee were unaware of any harms associated with the checklists.

1.7.2 Cost effectiveness and resource use

No economic evaluations were identified for this question.

There are no costs involved in the checklists themselves, although they would require some staff time to implement for every patient.

The clinical review identified a reduction in mortality due to the WHO surgical safety checklist, which would lead to additional QALYs compared to not using the checklist. Additionally, there was a reduction in complications. The committee felt that this reduction would lead to downstream savings. In particular, there was a reduction in complications that

were classified as grade III-IV on the Clavien-Dindo scale. These complications would result in a very high cost, for example grade III requires a surgical, endoscopic or radiological intervention, and grade IV includes life threatening complications that would typically require intensive care. Therefore, implementing the WHO surgical safety checklist which does not require a substantial resource use can result in significant savings. This checklist is also commonly used in practice already as it is mandatory.

The committee felt that Never Events were not captured by the review but were an essential driver of the implementation of a surgical safety checklist. It was discussed that complications may be covering these events but that a recommendation to address them was essential. Although the WHO surgical safety checklist is mandatory there are still cases of Never Events occurring in England. If hospitals adapt the checklist in order to address Never Events and NHS National Patient Safety alerts then it may require some staff training on how to use the adapted checklist, but this is unlikely to lead to a significant increase in NHS costs. Surgical Never Events can include events such as wrong site surgery or retention of a foreign object post procedure. These events can have a large cost associated with them and can potentially cause serious harm or death. Therefore a recommendation that could lead to the reduction of these events will have a positive clinical impact as well as a reduction in costs.

The committee acknowledged that the recommendations would not lead to a substantial resource impact as the WHO surgical safety checklist is already mandatory in current practice.

1.7.3 Other factors the committee took into account

Committee discussed whether the term Never Events is internationally recognised as a concept and how recognised Never Events may vary. The committee suggested that from the available evidence, mortality and complications were the closest alternative and may inform the occurrence of Never Events.

The committee noted that safety checklists are in use across surgical teams and all members should be aware of the process. The committee noted that the recommendation was applicable to people undergoing dental surgery.

The committee was aware of literature reviewing staff attitudes towards surgical safety checklists but these did not meet this reviews inclusion criteria.

The committee agreed that a recommendation to modify the WHO checklist would enable local practices to add appropriate concepts to the WHO checklist to reduce Never Events and surgical near-misses.

The committee was in agreement that there is a need for full engagement/attention when completing checklists and that this may require an organisational/departmental cultural change similar to that experienced in the aviation industry

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Appendices

Appendix A: Review protocols

Table 6: Review protocol: safety management systems

ID	Field	Content
0.	PROSPERO registration number	Not registered on PROSPERO
1.	Review title	What is the clinical and cost effectiveness of management systems to promote safety in operating theatres?
2.	Review question	What is the clinical and cost effectiveness of management systems to promote safety in operating theatres?
3.	Objective	To determine the clinical and cost effectiveness of management systems to promote safety in operating theatres.
4.	Searches	• Cochrane Central Register of Controlled Trials (CENTRAL) • Cochrane Database of Systematic Reviews (CDSR) • Embase • MEDLINE The searches may be re-run 6 weeks before the final committee meeting and further studies retrieved for inclusion if relevant. The full search strategies will be published in the final review.
5.	Condition or domain being studied	Perioperative care
6.	Population	Inclusion: Older people 60 years and over having surgery. Exclusion: • children and young people aged 17 years and younger • surgery for burns, traumatic brain injury or neurosurgery
7.	Intervention/Exposure/Test	Management systems: • World Health Organisation (WHO) surgical safety checklist • National safety standards for invasive procedures • Pre-surgery briefings

		• Post-surgical debrief • Combinations of these interventions
8.	Comparator/Reference standard/Confounding factors	• no management system (usual care) • each other
9.	Types of study to be included	Randomised controlled trials (RCTs), systematic reviews of RCTs. Observational studies if no RCT evidence is identified.
10.	Other exclusion criteria	Exclusions: • non-English language studies • cross-over randomised controlled trials • studies published before 2000
11.	Context	n/a
12.	Primary outcomes (critical outcomes)	• health-related quality of life • mortality • patient, family and carer experience of care • adverse events and complications (Clavien-Dindo, postoperative morbidity score (POMS)) • never events • serious incidents • compliance The committee did not agree to on any established minimal clinically important differences, therefore the default MIDs will be used and any difference in mortality will be considered clinically important.
13.	Secondary outcomes (important outcomes)	• length of hospital stay • hospital readmission • unplanned ICU admission • ICU length of stay (planned and unplanned) The committee did not agree to on any established minimal clinically important differences, therefore the default MIDs will be used and any difference in mortality will be considered clinically important.
14.	Data extraction (selection and coding)	EndNote will be used for reference management, sifting, citations and bibliographies. All references identified by the searches and from other sources will be screened for inclusion. 10% of the abstracts will be reviewed by two reviewers, with any disagreements resolved by discussion or, if necessary, a third independent reviewer. The full text of potentially eligible studies will be retrieved and will be assessed in line with the criteria outlined above. Data extractions performed using EviBase, a platform designed and maintained by the

		National Guideline Centre (NGC)
15.	Risk of bias (quality) assessment	Risk of bias will be assessed using the appropriate checklist as described in Developing NICE guidelines: the manual. • Systematic reviews: Risk of Bias in Systematic Reviews (ROBIS) • Randomised Controlled Trial: Cochrane RoB (2.0) • Non randomised study, including cohort studies: Cochrane ROBINS-I • Case control study: CASP case control checklist • Controlled before-and-after study or Interrupted time series: Effective Practice and Organisation of Care (EPOC) RoB Tool • Cross sectional study: JBI checklist for cross sectional study • Case series: Institute of Health Economics (IHE) checklist for case series 10% of all evidence reviews are quality assured by a senior research fellow. This includes checking: • papers were included /excluded appropriately • a sample of the data extractions • correct methods are used to synthesise data • a sample of the risk of bias assessments Disagreements between the review authors over the risk of bias in particular studies will be resolved by discussion, with involvement of a third review author where necessary.
16.	Strategy for data synthesis	Pairwise meta-analyses will be performed using Cochrane Review Manager (RevMan5). GRADEpro will be used to assess the quality of evidence for each outcome, taking into account individual study quality and the meta-analysis results. The 4 main quality elements (risk of bias, indirectness, inconsistency and imprecision) will be appraised for each outcome. Publication bias is tested for when there are more than 5 studies for an outcome. The risk of bias across all available evidence was evaluated for each outcome using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group http://www.gradeworkinggroup.org/ • Where meta-analysis is not possible, data will be presented and quality assessed individually per outcome.

		• CERQual will be used to synthesise data from qualitative studies. • WinBUGS will be used for network meta-analysis, if possible given the data identified. • List any other software planned to be used. Heterogeneity between the studies in effect measures will be assessed using the I^2 statistic and visually inspected. An I^2 value greater than 50% will be considered indicative of substantial heterogeneity. Sensitivity analyses will be conducted based on pre-specified subgroups using stratified meta-analysis to explore the heterogeneity in effect estimates. If this does not explain the heterogeneity, the results will be presented pooled using random-effects.	
17.	Analysis of sub-groups	Subgroups: • older adults (over 60) • capacity to consent (including dementia, learning difficulties)	
18.	Type and method of review	☒	Intervention
		☐	Diagnostic
		☐	Prognostic
		☐	Qualitative
		☐	Epidemiologic
		☐	Service Delivery
		☐	Other (please specify)
19.	Language	English	
20.	Country	England	
21.	Anticipated or actual start date	To be added	
22.	Anticipated completion date	To be added	
23.	Stage of review at time of this submission	Review stage	Started / Completed
		Preliminary searches	☐ / ☐
		Piloting of the study selection process	☐ / ☐
		Formal screening of search results against eligibility criteria	☐ / ☐
		Data extraction	☐ / ☐
		Risk of bias (quality) assessment	☐ / ☐

		Data analysis	☐	☐
24.	Named contact	5a. Named contact National Guideline Centre 5b Named contact e-mail perioperativecare@nice.org.uk 5e Organisational affiliation of the review National Institute for Health and Care Excellence (NICE) and the National Guideline Centre		
25.	Review team members	From the National Guideline Centre: Ms Kate Ashmore Ms Kate Kelley Ms Sharon Swain Mr Ben Mayer Ms Maria Smyth Mr Vimal Bedia Mr Audrius Stonkus Ms Madelaine Zucker Ms Margaret Constanti Ms Annabelle Davis Ms Lina Gulhane		
26.	Funding sources/sponsor	This systematic review is being completed by the National Guideline Centre which receives funding from NICE.		
27.	Conflicts of interest	All guideline committee members and anyone who has direct input into NICE guidelines (including the evidence review team and expert witnesses) must declare any potential conflicts of interest in line with NICE's code of practice for declaring and dealing with conflicts of interest. Any relevant interests, or changes to interests, will also be declared publicly at the start of each guideline committee meeting. Before each meeting, any potential conflicts of interest will be considered by the guideline committee Chair and a senior member of the development team. Any decisions to exclude a person from all or part of a meeting will be documented. Any changes to a member's declaration of interests will be recorded in the minutes of the meeting. Declarations of interests will be published with the final guideline.		
28.	Collaborators	Development of this systematic review will be		

		overseen by an advisory committee who will use the review to inform the development of evidence-based recommendations in line with section 3 of Developing NICE guidelines: the manual. Members of the guideline committee are available on the NICE website.	
29.	Other registration details	n/a	
30.	Reference/URL for published protocol	n/a	
31.	Dissemination plans	NICE may use a range of different methods to raise awareness of the guideline. These include standard approaches such as: • notifying registered stakeholders of publication • publicising the guideline through NICE's newsletter and alerts • issuing a press release or briefing as appropriate, posting news articles on the NICE website, using social media channels, and publicising the guideline within NICE.	
32.	Keywords	Perioperative care	
33.	Details of existing review of same topic by same authors	n/a	
34.	Current review status	☐	Ongoing
		☐	Completed but not published
		☐	Completed and published
		☐	Completed, published and being updated
		☐	Discontinued
35..	Additional information	n/a	
36.	Details of final publication	www.nice.org.uk	

1

2 **Table 7: Health economic review protocol**

Review question	All questions – health economic evidence
Objectives	To identify health economic studies relevant to any of the review questions.
Search criteria	• Populations, interventions and comparators must be as specified in the clinical review protocol above. • Studies must be of a relevant health economic study design (cost–utility analysis, cost-effectiveness analysis, cost–benefit analysis, cost–consequences analysis, comparative cost analysis). • Studies must not be a letter, editorial or commentary, or a review of health economic evaluations. (Recent reviews will be ordered although not reviewed. The bibliographies will be checked for relevant studies, which will then be ordered.) • Unpublished reports will not be considered unless submitted as part of a call for evidence. • Studies must be in English.

Search strategy	A health economic study search will be undertaken using population-specific terms and a health economic study filter – see appendix B below.
Review strategy	Studies not meeting any of the search criteria above will be excluded. Studies published before 2003, abstract-only studies and studies from non-OECD countries or the USA will also be excluded. Each remaining study will be assessed for applicability and methodological limitations using the NICE economic evaluation checklist which can be found in appendix H of Developing NICE guidelines: the manual (2014).[82] **Inclusion and exclusion criteria** • If a study is rated as both 'Directly applicable' and with 'Minor limitations' then it will be included in the guideline. A health economic evidence table will be completed and it will be included in the health economic evidence profile. • If a study is rated as either 'Not applicable' or with 'Very serious limitations' then it will usually be excluded from the guideline. If it is excluded then a health economic evidence table will not be completed and it will not be included in the health economic evidence profile. • If a study is rated as 'Partially applicable', with 'Potentially serious limitations' or both then there is discretion over whether it should be included. **Where there is discretion** The health economist will make a decision based on the relative applicability and quality of the available evidence for that question, in discussion with the guideline committee if required. The ultimate aim is to include health economic studies that are helpful for decision-making in the context of the guideline and the current NHS setting. If several studies are considered of sufficiently high applicability and methodological quality that they could all be included, then the health economist, in discussion with the committee if required, may decide to include only the most applicable studies and to selectively exclude the remaining studies. All studies excluded on the basis of applicability or methodological limitations will be listed with explanation in the excluded health economic studies appendix below. The health economist will be guided by the following hierarchies. *Setting:* • UK NHS (most applicable). • OECD countries with predominantly public health insurance systems (for example, France, Germany, Sweden). • OECD countries with predominantly private health insurance systems (for example, Switzerland). • Studies set in non-OECD countries or in the USA will be excluded before being assessed for applicability and methodological limitations. *Health economic study type:* • Cost–utility analysis (most applicable). • Other type of full economic evaluation (cost–benefit analysis, cost-effectiveness analysis, cost–consequences analysis). • Comparative cost analysis. • Non-comparative cost analyses including cost-of-illness studies will be excluded before being assessed for applicability and methodological limitations. *Year of analysis:* • The more recent the study, the more applicable it will be. • Studies published in 2003 or later but that depend on unit costs and resource data entirely or predominantly from before 2003 will be rated as 'Not applicable'. • Studies published before 2003 will be excluded before being assessed for applicability and methodological limitations.

	Quality and relevance of effectiveness data used in the health economic analysis: • The more closely the clinical effectiveness data used in the health economic analysis match with the outcomes of the studies included in the clinical review the more useful the analysis will be for decision-making in the guideline. For example, economic evaluations based on observational studies will be excluded, when the clinical review is only looking for RCTs,

1

Appendix B: Literature search strategies

The literature searches for this review are detailed below and complied with the methodology outlined in Developing NICE guidelines: the manual 2014, updated 2018.[82]

For more detailed information, please see the Methodology Review.

B.1 Clinical search literature search strategy

Searches were constructed using a PICO framework where population (P) terms were combined with Intervention (I) and in some cases Comparison (C) terms. Outcomes (O) are rarely used in search strategies for interventions as these concepts may not be well described in title, abstract or indexes and therefore difficult to retrieve. Search filters were applied to the search where appropriate.

Table 8: Database date parameters and filters used

Database	Dates searched	Search filter used
Medline (OVID)	1946 – 30 May 2019	Exclusions Randomised controlled trials Systematic review studies Observational studies
Embase (OVID)	1974 – 30 May 2019	Exclusions Randomised controlled trials Systematic review studies Observational studies
The Cochrane Library (Wiley)	Cochrane Reviews to 2019 Issue 5 of 12 CENTRAL to 2019 Issue 5 of 12 DARE, and NHSEED to 2015 Issue 2 of 4 HTA to 2016 Issue 4 of 4	None

Medline (Ovid) search terms

1.	Operating Rooms/
2.	(operat* adj2 (theatre* or theater* or room* or suite* or facility or facilities or environment* or space*)).ti,ab.
3.	exp Specialties, Surgical/
4.	or/1-3
5.	letter/
6.	editorial/
7.	news/
8.	exp historical article/
9.	Anecdotes as Topic/
10.	comment/
11.	case report/
12.	(letter or comment*).ti.
13.	or/5-12
14.	randomized controlled trial/ or random*.ti,ab.
15.	13 not 14

16.	animals/ not humans/
17.	exp Animals, Laboratory/
18.	exp Animal Experimentation/
19.	exp Models, Animal/
20.	exp Rodentia/
21.	(rat or rats or mouse or mice).ti.
22.	or/15-21
23.	4 not 22
24.	limit 23 to English language
25.	exp Safety management/
26.	Checklist/
27.	Equipment safety/
28.	Patient safety/
29.	Patient Harm/
30.	Containment of Biohazards/
31.	((surg* or manage*) adj3 (check* or safe* or procedure* or standard* or protocol* or brief* or debrief* or system* or equipment*)).ti,ab.
32.	(equipment* adj3 (check* or safe* or procedure* or standard* or protocol*)).ti,ab.
33.	(patient* adj2 (harm* or check* or safe* or procedure* or standard* or protocol* or verif* or verificat*)).ti,ab.
34.	(quality adj2 (assurance or care or caring or check* or safe* or procedure* or standard* or protocol*)).ti,ab.
35.	or/25-34
36.	24 and 35
37.	randomized controlled trial.pt.
38.	controlled clinical trial.pt.
39.	randomi#ed.ab.
40.	placebo.ab.
41.	randomly.ab.
42.	clinical trials as topic.sh.
43.	trial.ti.
44.	or/37-43
45.	Meta-Analysis/
46.	Meta-Analysis as Topic/
47.	(meta analy* or metanaly* or metaanaly* or meta regression).ti,ab.
48.	((systematic* or evidence*) adj2 (review* or overview*)).ti,ab.
49.	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.
50.	(search strategy or search criteria or systematic search or study selection or data extraction).ab.
51.	(search* adj4 literature).ab.
52.	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.
53.	cochrane.jw.
54.	((multiple treatment* or indirect or mixed) adj2 comparison*).ti,ab.
55.	or/45-54
56.	Epidemiologic studies/

57.	Observational study/
58.	exp Cohort studies/
59.	(cohort adj (study or studies or analys* or data)).ti,ab.
60.	((follow up or observational or uncontrolled or non randomi#ed or epidemiologic*) adj (study or studies or data)).ti,ab.
61.	((longitudinal or retrospective or prospective or cross sectional) and (study or studies or review or analys* or cohort* or data)).ti,ab.
62.	Controlled Before-After Studies/
63.	Historically Controlled Study/
64.	Interrupted Time Series Analysis/
65.	(before adj2 after adj2 (study or studies or data)).ti,ab.
66.	or/56-65
67.	exp case control study/
68.	case control*.ti,ab.
69.	or/67-68
70.	66 or 69
71.	Cross-sectional studies/
72.	(cross sectional and (study or studies or review or analys* or cohort* or data)).ti,ab.
73.	or/71-72
74.	66 or 73
75.	66 or 69 or 73
76.	36 and (44 or 55 or 75)
77.	WHO Surgical Safety Checklist.ti,ab.
78.	National Safety Standards for Invasive Procedures.ti,ab.
79.	76 or 77 or 78

1 **Embase (Ovid) search terms**

1.	operating room/
2.	(operat* adj2 (theatre* or theater* or room* or suite* or facility or facilities or environment* or space*)).ti,ab.
3.	*surgery/ or cancer surgery/ or general surgery/ or orthopedic surgery/ or plastic surgery/ or thorax surgery/ or urologic surgery/
4.	or/1-3
5.	letter.pt. or letter/
6.	note.pt.
7.	editorial.pt.
8.	case report/ or case study/
9.	(letter or comment*).ti.
10.	or/5-9
11.	randomized controlled trial/ or random*.ti,ab.
12.	10 not 11
13.	animal/ not human/
14.	nonhuman/
15.	exp Animal Experiment/
16.	exp Experimental Animal/
17.	animal model/
18.	exp Rodent/

19.	(rat or rats or mouse or mice).ti.
20.	or/12-19
21.	4 not 20
22.	limit 21 to English language
23.	safety/ or material safety data sheet/
24.	checklist/
25.	device safety/
26.	patient safety/
27.	patient harm/
28.	hazardous waste/
29.	((surg* or manage*) adj3 (check* or safe* or procedure* or standard* or protocol* or brief* or debrief* or system* or equipment*)).ti,ab.
30.	(equipment* adj3 (check* or safe* or procedure* or standard* or protocol*)).ti,ab.
31.	(patient* adj2 (harm* or check* or safe* or procedure* or standard* or protocol* or verif* or verificat*)).ti,ab.
32.	(quality adj2 (assurance or care or caring or check* or safe* or procedure* or standard* or protocol*)).ti,ab.
33.	or/23-32
34.	22 and 33
35.	random*.ti,ab.
36.	factorial*.ti,ab.
37.	(crossover* or cross over*).ti,ab.
38.	((doubl* or singl*) adj blind*).ti,ab.
39.	(assign* or allocat* or volunteer* or placebo*).ti,ab.
40.	crossover procedure/
41.	single blind procedure/
42.	randomized controlled trial/
43.	double blind procedure/
44.	or/35-43
45.	systematic review/
46.	Meta-Analysis/
47.	(meta analy* or metanaly* or metaanaly* or meta regression).ti,ab.
48.	((systematic* or evidence*) adj2 (review* or overview*)).ti,ab.
49.	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.
50.	(search strategy or search criteria or systematic search or study selection or data extraction).ab.
51.	(search* adj4 literature).ab.
52.	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.
53.	cochrane.jw.
54.	((multiple treatment* or indirect or mixed) adj2 comparison*).ti,ab.
55.	or/45-54
56.	Epidemiologic studies/
57.	Observational study/
58.	exp Cohort studies/
59.	(cohort adj (study or studies or analys* or data)).ti,ab.

60.	((follow up or observational or uncontrolled or non randomi#ed or epidemiologic*) adj (study or studies or data)).ti,ab.
61.	((longitudinal or retrospective or prospective or cross sectional) and (study or studies or review or analys* or cohort* or data)).ti,ab.
62.	Controlled Before-After Studies/
63.	Historically Controlled Study/
64.	Interrupted Time Series Analysis/
65.	(before adj2 after adj2 (study or studies or data)).ti,ab.
66.	or/56-65
67.	exp case control study/
68.	case control*.ti,ab.
69.	or/67-68
70.	66 or 69
71.	Cross-sectional studies/
72.	(cross sectional and (study or studies or review or analys* or cohort* or data)).ti,ab.
73.	or/71-72
74.	66 or 73
75.	66 or 69 or 73
76.	34 and (44 or 55)
77.	WHO Surgical Safety Checklist.ti,ab.
78.	National Safety Standards for Invasive Procedures.ti,ab.
79.	76 or 77 or 78

1 **Cochrane Library (Wiley) search terms**

#1.	MeSH descriptor: [Operating Rooms] this term only
#2.	(operat* near/2 (theatre* or theater* or room* or suite* or facility or facilities or environment* or space*)):ti,ab
#3.	MeSH descriptor: [Specialties, Surgical] explode all trees
#4.	(OR #1-#3)
#5.	MeSH descriptor: [Safety Management] explode all trees
#6.	MeSH descriptor: [Checklist] this term only
#7.	MeSH descriptor: [Equipment Safety] this term only
#8.	MeSH descriptor: [Patient Safety] this term only
#9.	MeSH descriptor: [Patient Harm] this term only
#10.	MeSH descriptor: [Containment of Biohazards] this term only
#11.	((surg* or manage*) near/3 (check* or safe* or procedure* or standard* or protocol* or brief* or debrief* or system* or equipment*)):ti,ab
#12.	(equipment* near/3 (check* or safe* or procedure* or standard* or protocol*)):ti,ab
#13.	(patient* near/2 (harm* or check* or safe* or procedure* or standard* or protocol* or verif* or verificat*)):ti,ab
#14.	(quality near/2 (assurance or care or caring or check* or safe* or procedure* or standard* or protocol*)):ti,ab
#15.	(OR #5-#14)
#16.	WHO Surgical Safety Checklist:ti,ab
#17.	National Safety Standards for Invasive Procedures:ti,ab
#18.	#4 AND #15
#19.	#16 OR #17 OR #18

B.2 Health Economics literature search strategy

Health economic evidence was identified by conducting a broad search relating to the perioperative care population in NHS Economic Evaluation Database (NHS EED – this ceased to be updated after March 2015) and the Health Technology Assessment database (HTA) with no date restrictions. NHS EED and HTA databases are hosted by the Centre for Research and Dissemination (CRD). Additional health economics searches were run on Medline and Embase.

Table 9: Database date parameters and filters used

Database	Dates searched	Search filter used
Medline	2014 – 30 May 2019	Exclusions Health economics studies
Embase	2014 – 30 May 2019	Exclusions Health economics studies
Centre for Research and Dissemination (CRD)	HTA - Inception – 02 May 2019 NHSEED - Inception to 02 May 2019	None

Medline (Ovid) search terms

1.	exp Preoperative Care/ or exp Perioperative Care/ or exp Perioperative Period/ or exp Perioperative Nursing/
2.	((pre-operative* or preoperative* or preop* or pre-op* or pre-surg* or presurg*) adj3 (care* or caring or treat* or nurs* or monitor* or recover* or medicine)).ti,ab.
3.	((perioperative* or peri-operative* or intraoperative* or intra-operative* or intrasurg* or intra-surg* or peroperat* or per-operat*) adj3 (care* or caring or treat* or nurs* or monitor* or recover* or medicine)).ti,ab.
4.	((postoperative* or postop* or post-op* or post-surg* or postsurg*) adj3 (care* or caring or treat* or nurs* or monitor* or recover* or medicine)).ti,ab.
5.	((care* or caring or treat* or nurs* or recover* or monitor*) adj3 (before or prior or advance or during or after) adj3 (surg* or operat* or anaesthes* or anesthes*)).ti,ab.
6.	1 or 2 or 3 or 4 or 5
7.	(intraoperative* or intra-operative* or intrasurg* or intra-surg* or peroperat* or per-operat* or perioperat* or peri-operat*).ti,ab.
8.	((during or duration) adj3 (surg* or operat* or anaesthes* or anesthes*)).ti,ab.
9.	7 or 8
10.	postoperative care/ or exp Postoperative Period/ or exp Perioperative nursing/
11.	(postop* or post-op* or post-surg* or postsurg* or perioperat* or peri-operat*).ti,ab.
12.	(after adj3 (surg* or operat* or anaesthes* or anesthes*)).ti,ab.
13.	(post adj3 (operat* or anaesthes* or anesthes*)).ti,ab.
14.	10 or 11 or 12 or 13
15.	exp Preoperative Care/ or Preoperative Period/
16.	(pre-operat* or preoperat* or pre-surg* or presurg*).ti,ab.
17.	((before or prior or advance or pre or prepar*) adj3 (surg* or operat* or anaesthes* or anesthes*)).ti,ab.
18.	15 or 16 or 17
19.	6 or 9 or 14 or 18
20.	letter/
21.	editorial/

22.	news/
23.	exp historical article/
24.	Anecdotes as Topic/
25.	comment/
26.	case report/
27.	(letter or comment*).ti.
28.	or/20-27
29.	randomized controlled trial/ or random*.ti,ab.
30.	28 not 29
31.	animals/ not humans/
32.	exp Animals, Laboratory/
33.	exp Animal Experimentation/
34.	exp Models, Animal/
35.	exp Rodentia/
36.	(rat or rats or mouse or mice).ti.
37.	or/30-36
38.	19 not 37
39.	limit 38 to English language
40.	(exp child/ or exp pediatrics/ or exp infant/) not (exp adolescent/ or exp adult/ or exp middle age/ or exp aged/)
41.	39 not 40
42.	economics/
43.	value of life/
44.	exp "costs and cost analysis"/
45.	exp Economics, Hospital/
46.	exp Economics, medical/
47.	Economics, nursing/
48.	economics, pharmaceutical/
49.	exp "Fees and Charges"/
50.	exp budgets/
51.	budget*.ti,ab.
52.	cost*.ti.
53.	(economic* or pharmaco?economic*).ti.
54.	(price* or pricing*).ti,ab.
55.	(cost* adj2 (effectiv* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)).ab.
56.	(financ* or fee or fees).ti,ab.
57.	(value adj2 (money or monetary)).ti,ab.
58.	or/42-57
59.	41 and 58

1 **Embase (Ovid) search terms**

1.	*preoperative period/ or *intraoperative period/ or *postoperative period/ or *perioperative nursing/ or *surgical patient/
2.	((pre-operative* or preoperative* or preop* or pre-op* or pre-surg* or presurg*) adj3 (care* or caring or treat* or nurs* or monitor* or recover* or medicine)).ti,ab.
3.	((perioperative* or peri-operative* or intraoperative* or intra-operative* or intrasurg* or intra-surg* or peroperat* or per-operat*) adj3 (care* or caring or treat* or nurs* or

	monitor* or recover* or medicine)).ti,ab.
4.	((care* or caring or treat* or nurs* or recover* or monitor*) adj3 (before or prior or advance or during or after) adj3 (surg* or operat* or anaesthes* or anesthes*)).ti,ab.
5.	1 or 2 or 3 or 4
6.	peroperative care/ or exp peroperative care/ or exp perioperative nursing/
7.	(intraoperative* or intra-operative* or intrasurg* or intra-surg* or peroperat* or per-operat* or perioperat* or peri-operat*).ti,ab.
8.	((during or duration) adj3 (surg* or operat* or anaesthes* or anesthes*)).ti,ab.
9.	6 or 7 or 8
10.	postoperative care/ or exp postoperative period/ or perioperative nursing/
11.	(postop* or post-op* or post-surg* or postsurg* or perioperat* or peri-operat*).ti,ab.
12.	(after adj3 (surg* or operat* or anaesthes* or anesthes*)).ti,ab.
13.	(post adj3 (operat* or anaesthes* or anesthes*)).ti,ab.
14.	10 or 11 or 12 or 13
15.	exp preoperative care/ or preoperative period/
16.	(pre-operat* or preoperat* or pre-surg* or presurg*).ti,ab.
17.	((before or prior or advance or pre or prepar*) adj3 (surg* or operat* or anaesthes* or anesthes*)).ti,ab.
18.	15 or 16 or 17
19.	5 or 9 or 14 or 18
20.	letter.pt. or letter/
21.	note.pt.
22.	editorial.pt.
23.	case report/ or case study/
24.	(letter or comment*).ti.
25.	or/20-24
26.	randomized controlled trial/ or random*.ti,ab.
27.	25 not 26
28.	animal/ not human/
29.	nonhuman/
30.	exp Animal Experiment/
31.	exp Experimental Animal/
32.	animal model/
33.	exp Rodent/
34.	(rat or rats or mouse or mice).ti.
35.	or/27-34
36.	19 not 35
37.	limit 36 to English language
38.	(exp child/ or exp pediatrics/) not (exp adult/ or exp adolescent/)
39.	37 not 38
40.	health economics/
41.	exp economic evaluation/

42.	exp health care cost/
43.	exp fee/
44.	budget/
45.	funding/
46.	budget*.ti,ab.
47.	cost*.ti.
48.	(economic* or pharmaco?economic*).ti.
49.	(price* or pricing*).ti,ab.
50.	(cost* adj2 (effectiv* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)).ab.
51.	(financ* or fee or fees).ti,ab.
52.	(value adj2 (money or monetary)).ti,ab.
53.	or/40-52
54.	39 and 53

1 **NHS EED and HTA (CRD) search terms**

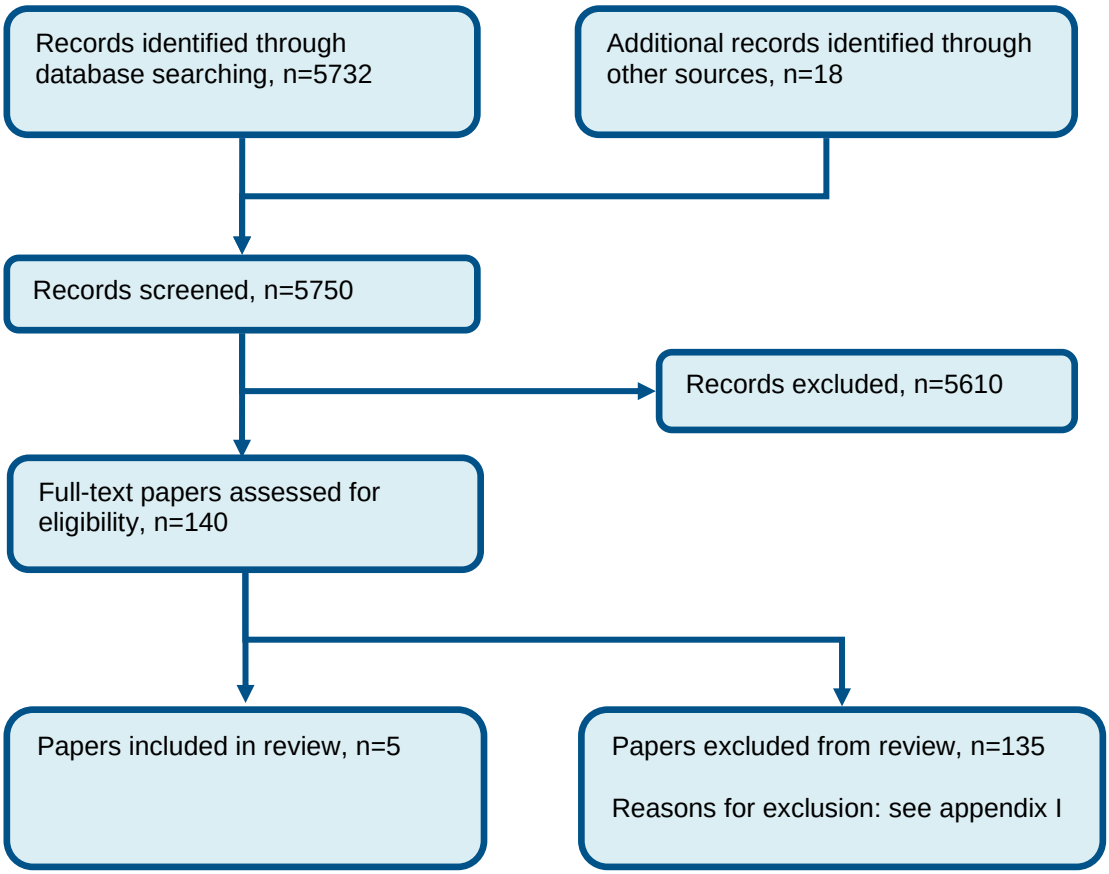
#1.	MeSH DESCRIPTOR Preoperative Care EXPLODE ALL TREES
#2.	MeSH DESCRIPTOR Perioperative Care EXPLODE ALL TREES
#3.	MeSH DESCRIPTOR Perioperative Period EXPLODE ALL TREES
#4.	MeSH DESCRIPTOR Perioperative Nursing EXPLODE ALL TREES
#5.	(((perioperative* or peri-operative* or intraoperative* or intra-operative* or intrasurg* or intra-surg* or peroperat* or per-operat*) adj3 (care* or caring or treat* or nurs* or monitor* or recover* or medicine)))
#6.	(((care* or caring or treat* or nurs* or recover* or monitor*) adj3 (before or prior or advance or during or after) adj3 (surg* or operat* or anaesthes* or anesthes*)))
#7.	(((pre-operative* or preoperative* or preop* or pre-op* or pre-surg* or presurg*) adj3 (care* or caring or treat* or nurs* or monitor* or recover* or medicine)))
#8.	(((postoperative* or postop* or post-op* or post-surg* or postsurg*) adj3 (care* or caring or treat* or nurs* or monitor* or recover* or medicine)))
#9.	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8
#10.	(* IN HTA)
#11.	(* IN NHSEED)
#12.	#9 AND #10
#13.	#9 AND #11
#14.	MeSH DESCRIPTOR Intraoperative Care EXPLODE ALL TREES
#15.	#1 OR #2 OR #3 OR #4 OR #14
#16.	((intraoperative* or intra-operative* or intrasurg* or intra-surg* or peroperat* or per-operat* or perioperat* or peri-operat*))
#17.	(((during or duration) adj3 (surg* or operat* or anaesthes* or anesthes*)))
#18.	((postop* or post-op* or post-surg* or postsurg* or perioperat* or peri-operat*))
#19.	((after adj3 (surg* or operat* or anaesthes* or anesthes*)))
#20.	((post adj3 (operat* or anaesthes* or anesthes*)))
#21.	((pre-operat* or preoperat* or pre-surg* or presurg*))
#22.	(((before or prior or advance or pre or prepar*) adj3 (surg* or operat* or anaesthes* or anesthes*)))
#23.	#15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22
#24.	#10 AND #23

#25.	#11 AND #23
#26.	#12 OR #13 OR #24 OR #25

1
2

Appendix C: Clinical evidence selection

Figure 1: Flow chart of clinical study selection for the review of postoperative recovery in specialist areas.



Appendix D: Clinical evidence tables

Study	Haugen 2015[44] (Haugen 2019[46])
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=3702)
Countries and setting	Conducted in Norway; Setting: This study was conducted in 2 Norwegian hospitals, a community hospital and a tertiary teaching hospital, and included 5 surgical specialties (orthopedic, cardiothoracic, neurosurgery, urology, and general surgery)
Line of therapy	Not applicable
Duration of study	
Method of assessment of guideline condition	Unclear method of assessment/diagnosis: unclear
Stratum	Overall: n/a
Subgroup analysis within study	Not applicable: n/a
Inclusion criteria	Data from all age groups and elective or emergency surgery are included.
Exclusion criteria	Surgical procedures which the SSC was not adapted for were excluded (ie, donor surgery)
Recruitment/selection of patients	Not specified
Age, gender and ethnicity	Age - Mean (SD): intervention group 53.9 (23.4) control 53.5 (23.3). Gender (M:F): males intervention group 1247 (54.1%); males control group 759 (54.3%). Ethnicity: Norwegian
Further population details	1. Age: Not applicable 2. Capacity to consent (including dementia, learning difficulties): Not applicable
Indirectness of population	No indirectness: n/a
Interventions	(n=2304) Intervention 1: Management system - World Health Organisation (WHO) surgical safety checklist. The SSC consists of 3 parts, the Sign in before anesthesia induction, the Time out before incision, and the Sign out at the end of the surgical procedure—before transfer to postoperative care unit. The SSC adapted for use in Norwegian operating rooms is presented online via http://links.lww.com/SLA/B343. In the Norwegian checklist version, items to prevent hypothermia are listed both under the Sign in and under Time out parts.. Duration 3 month baseline period and 3 months after clusters received an intervention. Concurrent medication/care: n/a. Indirectness: No indirectness; Indirectness comment: n/a

Study	Haugen 2015[44] (Haugen 2019[46])
	(n=1398) Intervention 2: Usual care - No management system. not specified. Duration 3 month baseline period and 3 months after clusters received an intervention. Concurrent medication/care: n/a. Indirectness: No indirectness
Funding	Academic or government funding (This study received departmental support. ASH and HVW received postdoctoral and PhD grants from the Western Norwegian Regional Health Authority with grant numbers, respectively: HV1172 and HV1174. NS' research is funded by the NIHR via the ''Collaboration for Leadership in Applied Health Research and Care South London'' at King's College Hospital NHS Foundation Trust, London, UK)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: WORLD HEALTH ORGANISATION (WHO) SURGICAL SAFETY CHECKLIST versus NO MANAGEMENT SYSTEM

Protocol outcome 1: Mortality
- Actual outcome: Total deaths; Group 1: 20/2033, Group 2: 28/1778; Comments: Results from parent study [44]
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: no indirectness;

Protocol outcome 2: Perioperative complications
- Actual outcome: Complications at Surgery till 3 months; Group 1: 443/2304, Group 2: 488/1398
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: no indirectness;

Protocol outcome 3: Compliance
- Actual outcome: Compliance at Intervention +3 months after the intervention; Proportion; , Comments: SCC compliance
none of the parts used: 256
1 part used: 109
2 parts used: 196
3 parts used: 1743
any parts used: 2048
Risk of bias: All domain - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: no indirectness;

Protocol outcome 4: Length of hospital stay
- Actual outcome: Length of hospital stay at n/a; Group 1: mean 7 days (SD 10.78); n=2033, Group 2: mean 7.8 days (SD 10.78); n=1778; Comments: Data from Parent study[44]. SE calculated from p value (0.022).

Study	Haugen 2015[44] (Haugen 2019[46])
Risk of bias: All domain - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: no indirectness;	
Protocol outcomes not reported by the study	Quality of life ; Patient, family, and carer experience of care ; Never events ; Serious incidents ; Hospital readmission ; Unplanned ICU admission ; Length of stay in intensive care unit

Study	Chaudhary 2015[26]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=700)
Countries and setting	Conducted in India; Setting: Department of Surgical Gastroenterology and Liver Transplantation, Sir Ganga RamHospital, New Delhi, India,
Line of therapy	Not applicable
Duration of study	Intervention + follow up:
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: all patients undergoing surgical procedure were included
Stratum	Overall: n/a
Subgroup analysis within study	Not applicable: n/a
Inclusion criteria	All patients undergoing a surgical procedure in the unit between February 2012 and April 2013 were included in a prospective, randomized and controlled trial.
Exclusion criteria	Patients who were below 16 years of age, recipients and donors of living related liver transplantation procedures and those from other departments where the investigators provided intra-operative assistance were excluded
Recruitment/selection of patients	Seven hundred consecutive patients were included in the study
Age, gender and ethnicity	Age - Median (range): intervention group 50 control group 48. Gender (M:F): intervention group male 211 (60.2%); control group male 190 (54.2% . Ethnicity: Indian
Further population details	1. Age: Not applicable 2. Capacity to consent (including dementia, learning difficulties): Not applicable
Extra comments	.
Indirectness of population	No indirectness: n/a
Interventions	(n=350) Intervention 1: Management system - World Health Organisation (WHO) surgical safety checklist. modified WHO checklist It includes the preoperative (sign in), intra-operative (time out) and postoperative

Study	Chaudhary 2015[26]
	(sign out) periods. 1. Sign in phase—whether the imaging studies had been discussed with a radiologist. 2. Time out phase—whether prophylactic measures against deep venous thrombosis had been administered when indicated. The checklist was used on three separate occasions: before anaesthesia (sign in), before the skin incision (time out) and before the patient was shifted out of the operating room (sign out). The surgical resident (and not the nurse as in the WHO study) was responsible for the completion of the checklist.. Duration 1 year. Concurrent medication/care: n/a. Indirectness: No indirectness (n=350) Intervention 2: Usual care - No management system. Not specified. Duration 1 year. Concurrent medication/care: n/a. Indirectness: No indirectness; Indirectness comment: n/a
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: WORLD HEALTH ORGANISATION (WHO) SURGICAL SAFETY CHECKLIST versus NO MANAGEMENT SYSTEM

Protocol outcome 1: Mortality
- Actual outcome: mortality at Death occuring within 30 days of the operation; Group 1: 20/350, Group 2: 35/350; Comments: intervention group 5.7 % control group 10%
p= 0.04
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: no indirectness; Baseline details: Seven hundred consecutive patients were included in the study. There was no crossover of participants from one group to the other (parallel group study design).; Group 1 Number missing: 0; Group 2 Number missing: 0

Protocol outcome 2: Perioperative complications
- Actual outcome: Adverse events and complications at Surgery till the discharge or death; Group 1: 280/350, Group 2: 340/350; Comments: number of people experiencing complications
intervention group 162 (48 %) ; control group 182 (52%)
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: no indirectness; Baseline details: Seven hundred consecutive patients were included in the study. There was no crossover of participants from one group to the other (parallel group study design).; Group 1 Number missing: 0; Group 2 Number missing: 0
- Actual outcome: Clavien-Dindo 3/4 at Surgery till the discharge or death; Group 1: 81/350, Group 2: 116/350
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low,

Study	Chaudhary 2015[26]
Crossover - Low; Indirectness of outcome: No indirectness, Comments: no indirectness; Baseline details: Seven hundred consecutive patients were included in the study. There was no crossover of participants from one group to the other (parallel group study design).; - Actual outcome: Charlson morbidity score at Surgery till the discharge or death; Intervention arm 1.43 control arm 1.42; Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: no indirectness; Baseline details: Seven hundred consecutive patients were included in the study. There was no crossover of participants from one group to the other (parallel group study design).; Protocol outcome 3: Compliance - Actual outcome: Compliance at Surgery till the discharge or death; Proportion; , Comments: Checklist compliance in the intervention group Fully completed 85% (n=298) Partially completed (at least one of the items filled) 10 % (n=34) Not completed (none of the 24 items filled) 5% (n=18); Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: no indirectness; Baseline details: Seven hundred consecutive patients were included in the study. There was no crossover of participants from one group to the other (parallel group study design).; Protocol outcome 4: Length of hospital stay - Actual outcome: length of hospital stay at admission to discharge or death; p: 0.54, Comments: median intervention group 9; control group 9); Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: no indirectness; Baseline details: Seven hundred consecutive patients were included in the study. There was no crossover of participants from one group to the other (parallel group study design).;	
Protocol outcomes not reported by the study	Quality of life ; Patient, family, and carer experience of care ; Never events ; Serious incidents ; Hospital readmission ; Unplanned ICU admission ; Length of stay in intensive care unit

Study	Naidoo 2017[81]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=47 medical centres)
Countries and setting	Conducted in South Africa; Setting: Study sites were 18 hospitals offering maternal surgical services in the public health sector. Patients requiring maternal surgical intervention at the study sites were included
Line of therapy	Unclear
Duration of study	Intervention + follow up: March to November 2013

Study	Naidoo 2017[81]
Method of assessment of guideline condition	Unclear method of assessment/diagnosis: n/a
Stratum	Overall: n/a
Subgroup analysis within study	Not applicable: n/a
Inclusion criteria	Study sites were 18 hospitals offering maternal surgical services in the public health sector. Public sector hospitals were stratified into district hospitals (DHs) or regional hospitals (RHs), with the DHs being further classified as large or small based on the number of CDs performed per month. Further geographical stratification occurred based on the three demarcated health areas in the province
Exclusion criteria	Central and tertiary hospitals were excluded, as they are not found in all the three areas.
Recruitment/selection of patients	As this was a cluster-randomised control trial, the sample size was worked out by first estimating the average number of CDs done in hospitals that met the eligibility criteria. This was calculated as 85 CDs per month per site.
Age, gender and ethnicity	Age - Other: not reported. Gender (M:F): Not reported. Ethnicity: Not reported
Further population details	1. Age: Not applicable 2. Capacity to consent (including dementia, learning difficulties): Not applicable
Indirectness of population	No indirectness: n/a
Interventions	(n=9) Intervention 1: Management system - World Health Organisation (WHO) surgical safety checklist . The intervention on the use of the MSSCL consisted of training by the principal investigator (MN) of doctors and nurses working in maternity operating theatres during May 2013. The MSSCL used was the SSCL adapted by the provincial health department of the Western Cape Province of SA and further modified by us (we deleted an item on scalp vein electrodes). The MSSCL consists of three sections, the sign-in phase, the time-out phase and the sign-out phase. Before induction of anaesthesia (sign in) - During this phase the identity of the woman, the procedure and consent is confirmed. The anaesthetist and paediatrician/midwife confirm that the anaesthetic and neonatal safety checks are complete with no problems. Before the skin incision (time out) - This occurs after induction of the anaesthetic. During this phase all members would have introduced themselves. The patient identity and procedure are again confirmed. Before the patient leaves the operating room (sign out) - This occurs after induction of the anaesthetic. During this phase all members would have introduced themselves. The patient identity and procedure are again confirmed. The surgeon reviews whether additional procedures are planned and whether there are concerns about the placental site.. Duration Period of 9 months – 3 months before intervention (baseline) and 6 months after intervention.. Concurrent medication/care: n/a. Indirectness: No indirectness; Indirectness comment: n/a Comments: No. randomized is clusters rather than patients

Study	Naidoo 2017[81]
	(n=9) Intervention 2: Usual care - No management system. not specified. Duration Period of 9 months – 3 months before intervention (baseline) and 6 months after intervention.. Concurrent medication/care: n/a. Indirectness: No indirectness; Indirectness comment: n/a Comments: No. randomized is clusters rather than patients
Funding	Academic or government funding (The UKZN Medical Education Partnership Initiative (MEPI), Enhancing Training, Research and Education (ENTRÉE) programme (grant no. 5R24TW008863).)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: WORLD HEALTH ORGANISATION (WHO) SURGICAL SAFETY CHECKLIST versus NO MANAGEMENT SYSTEM

Protocol outcome 1: Mortality
- Actual outcome: Mortality (total change in incidence rate per 1000 procedures) at period of 9 months – 3 months before intervention (baseline) and 6 months after intervention.; RR; (95% CI: (0.221 - 1.938)) change in incidence rate per 1000 procedures, intervention group vs control from baseline to post intervention, Comments: total deaths 0.655, p=0.444);
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: n/a; Baseline details: n/a;

Protocol outcome 2: Perioperative complications
- Actual outcome: Surgical complications (total change in incidence rate per 1000 procedures) at period of 9 months – 3 months before intervention (baseline) and 6 months after intervention.; RR; (95% CI: (0.323 - 1.085)) change in incidence rate per 1000 procedures, intervention group vs control from baseline to post intervention, Comments: Surgical complications - 0.592, p=0.090);
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: n/a; Baseline details: n/a;
- Actual outcome: Intraoperative complications (total change in incidence rate per 1000 procedures) at period of 9 months – 3 months before intervention (baseline) and 6 months after intervention.; RR; (95% CI: (0.8 - 1.664)) change in incidence rate per 1000 procedures, intervention group vs control from baseline to post intervention, Comments: Intraoperative complications 1.154, p=0.443);
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: n/a; Baseline details: n/a;

Protocol outcome 3: Unplanned ICU admission
- Actual outcome: ICU admission ('higher level of care' total change in incidence rate per 1000 procedures) at period of 9 months – 3 months before intervention (baseline) and 6 months after intervention.; RR; (95% CI: (1.066 - 1.862)) change in incidence rate per 1000 procedures, intervention group vs control from baseline to post intervention, Comments: Referal to higher level of care 1.409, p=0.016);
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover

Study	Naidoo 2017[81]
- Low; Indirectness of outcome: No indirectness, Comments: n/a; Baseline details: n/a;	
Protocol outcomes not reported by the study	Quality of life ; Patient, family, and carer experience of care ; Never events ; Serious incidents ; Compliance ; Length of hospital stay ; Hospital readmission ; Length of stay in intensive care unit

Study	Calland 2011[23]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=65)
Countries and setting	Conducted in USA; Setting: Academic tertiary care centre
Line of therapy	Not applicable
Duration of study	Intervention + follow up: 30 days follow up
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: all nonemergent LC cases were included
Stratum	Overall: n/a
Subgroup analysis within study	Not applicable: n/a
Inclusion criteria	All adult nonemergent LC (laparoscopic cholecystectomy) cases at the academic tertiary care centre institution were screened for study eligibility from April 2001 to July 2002.
Exclusion criteria	Emergent procedures and those involving children, hospitalized patients, prison inmates and the investigators patients were excluded
Recruitment/selection of patients	All laparoscopic cholecystectomy cases were included
Age, gender and ethnicity	Age - Other: not reported. Gender (M:F): not specified. Ethnicity: not stated
Further population details	1. Age: Not applicable 2. Capacity to consent (including dementia, learning difficulties): Not applicable
Indirectness of population	No indirectness: n/a
Interventions	(n=33) Intervention 1: Management system - National safety standards for invasive procedures. the intervention group made use of an intraoperative procedural checklist that reviewed critical steps of the LC procedure. Preoperative steps included a briefing with instructions of all team members, review of patient's history, laboratory, and radiographic studies, and discussion of any unusual case circumstances such as need for an intraoperative cholangiogram. Surgeons in the intervention group were provided instructions on the use of checklist and reminded of the need to review the review before each case. In addition a checklist copy was posted on the anesthesia monitor in the operating room discussing cases and participants were instructed to use call-and-repeat method to ensure critical steps from the checklist were neither omitted nor

Study	Calland 2011[23]
	performed suboptimally.. Duration pre surgery +30 day follow up. Concurrent medication/care: n/a. Indirectness: No indirectness (n=32) Intervention 2: Usual care - No management system. Attending surgeons and operating teams in the control group performed the LC procedure in their normal fashion without any normalized checklist or prebriefing,. Duration pre surgery +30 day follow up. Concurrent medication/care: n/a. Indirectness: No indirectness
Funding	Academic or government funding (funded by The National Patient Safety foundation, 268 Summer st., 6th floor, Boston, MA 02210.)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: NATIONAL SAFETY STANDARDS FOR INVASIVE PROCEDURES versus NO MANAGEMENT SYSTEM

Protocol outcome 1: Length of hospital stay
- Actual outcome: Post-operative length of stay (1 day) at Surgery till discharge; Group 1: 17/24, Group 2: 16/23; Comments: Intervention group (70.8%) control group (69.6%)
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: not reported; Group 1 Number missing: 8, Reason: No Av equipment, cancelled, clinician request, conversion to open; Group 2 Number missing: 9, Reason: No Av equipment, cancelled, clinician request, conversion to open
- Actual outcome: Post-operative length of stay (2 days) at Surgery till discharge; Group 1: 5/24, Group 2: 2/23; Comments: Intervention group (20.8%) control group (30.4%)
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: not reported; Group 1 Number missing: 8, Reason: No Av equipment, cancelled, clinician request, conversion to open; Group 2 Number missing: 9, Reason: No Av equipment, cancelled, clinician request, conversion to open

Protocol outcome 2: Hospital readmission
- Actual outcome: Postoperative length of stay (2 - 7 days) at Surgery till discharge; Group 1: 2/24, Group 2: 0/23; Comments: Intervention group (8.3%) control group (0%)
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: not reported; Group 1 Number missing: 8, Reason: No Av equipment, cancelled, clinician request, conversion to open; Group 2 Number missing: 9, Reason: No Av equipment, cancelled, clinician request, conversion to open
- Actual outcome: Hospital readmission at pre surgery +30 day follow up; Group 1: 1/24, Group 2: 0/23; Comments: Intervention group (4.2%) control group (0%)
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: not reported; Group 1 Number missing: 8; Group 2 Number missing: 9

Study	Calland 2011[23]
Protocol outcomes not reported by the study	Quality of life ; Mortality ; Patient, family, and carer experience of care ; Perioperative complications ; Never events ; Serious incidents ; Compliance ; Unplanned ICU admission ; Length of stay in intensive care unit

Appendix E: Forest plots

E.1 World Health Organization Checklist compared to usual care

Figure 2: Mortality

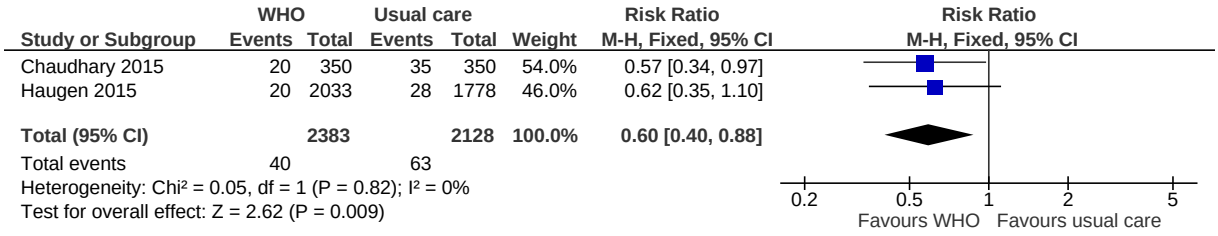


Figure 3: Complications

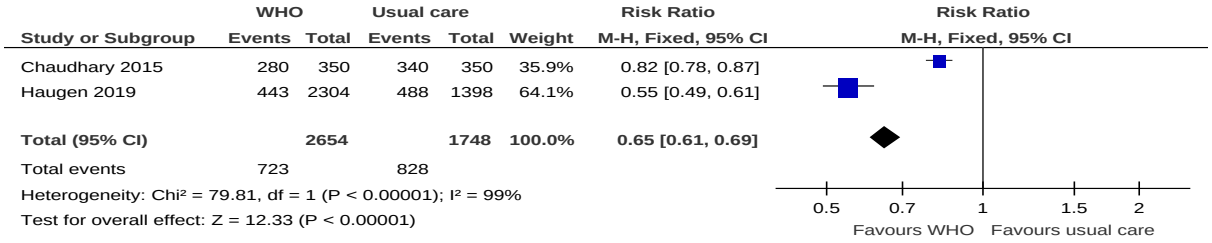


Figure 4: Complications (Clavien-Dindo Grade III-IV)

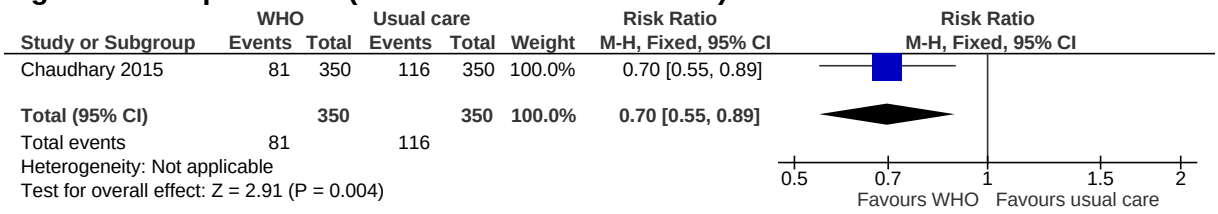
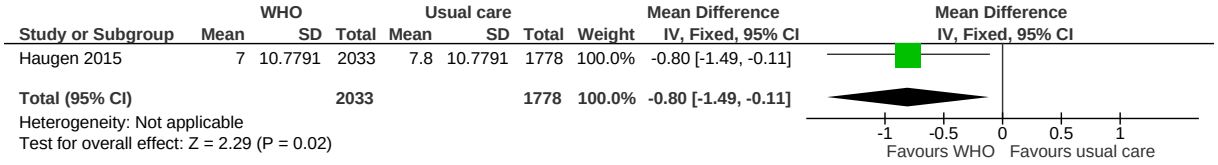


Figure 5: Length of stay



E.2 Surgical safety standards compared to usual care

Figure 6: Postoperative length of stay (same day discharge)

Study or Subgroup	SSS Events	SSS Total	Usual care Events	Usual care Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Calland 2011	17	24	16	23	100.0%	1.02 [0.70, 1.48]
Total (95% CI)		**24**		**23**	**100.0%**	**1.02 [0.70, 1.48]**
Total events	17		16			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.09 (P = 0.92)

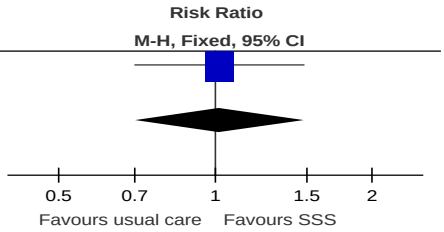


Figure 7: Postoperative length of stay (next day discharge)

Study or Subgroup	SSS Events	SSS Total	Usual care Events	Usual care Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Calland 2011	5	24	7	23	100.0%	0.68 [0.25, 1.85]
Total (95% CI)		**24**		**23**	**100.0%**	**0.68 [0.25, 1.85]**
Total events	5		7			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.75 (P = 0.46)

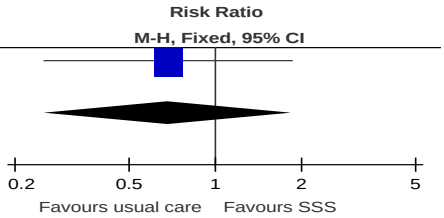


Figure 8: Postoperative length of stay (day 2-7 discharge)

Study or Subgroup	SSS Events	SSS Total	Usual care Events	Usual care Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Calland 2011	2	24	0	23	100.0%	7.40 [0.45, 122.11]
Total (95% CI)		**24**		**23**	**100.0%**	**7.40 [0.45, 122.11]**
Total events	2		0			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.40 (P = 0.16)

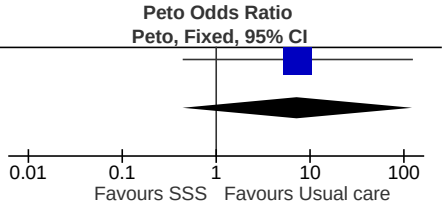
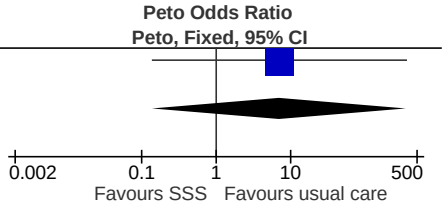


Figure 9: Readmission

Study or Subgroup	SSS Events	SSS Total	Usual care Events	Usual care Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Calland 2011	1	24	0	23	100.0%	7.09 [0.14, 357.50]
Total (95% CI)		**24**		**23**	**100.0%**	**7.09 [0.14, 357.50]**
Total events	1		0			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.98 (P = 0.33)



Appendix F: GRADE tables

Table 10: Clinical evidence profile: World Health Organization compared to usual care

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	WHO versus usual care	Control	Relative (95% CI)	Absolute		
Mortality (follow-up 30 days)												
2	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	40/2383 (1.7%)	5.8%	RR 0.61 (0.41 to 0.88)	23 fewer per 1000 (from 7 fewer to 34 fewer)	⊕⊕OO LOW	CRITICAL
Complications (follow-up 30 days)												
2	randomised trials	serious[1]	very serious[3]	no serious indirectness	no serious imprecision	none	723/2654 (27.2%)	66%	RR 0.65 (0.61 to 0.69)	231 fewer per 1000 (from 205 fewer to 257 fewer)	⊕OOO VERY LOW	CRITICAL
Complications (Clavien-Dindo Grade III-IV) (follow-up 30 days)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	81/350 (23.1%)	33.1%	RR 0.7 (0.54 to 0.89)	99 fewer per 1000 (from 36 fewer to 152 fewer)	⊕⊕OO LOW	CRITICAL
Length of hospital stay (Better indicated by lower values)												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	2033	1778	-	MD 0.8 lower (1.49 to 0.11 lower)	⊕⊕⊕⊕ HIGH	IMPORTANT

[1] Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

[2] Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

[3] Downgraded by 1 or 2 increments because: The point estimate varies widely across studies, unexplained by subgroup analysis. The confidence intervals across studies show minimal or no overlap, unexplained by subgroup analysis Heterogeneity, I2=50%, p=0.04, unexplained by subgroup analysis.

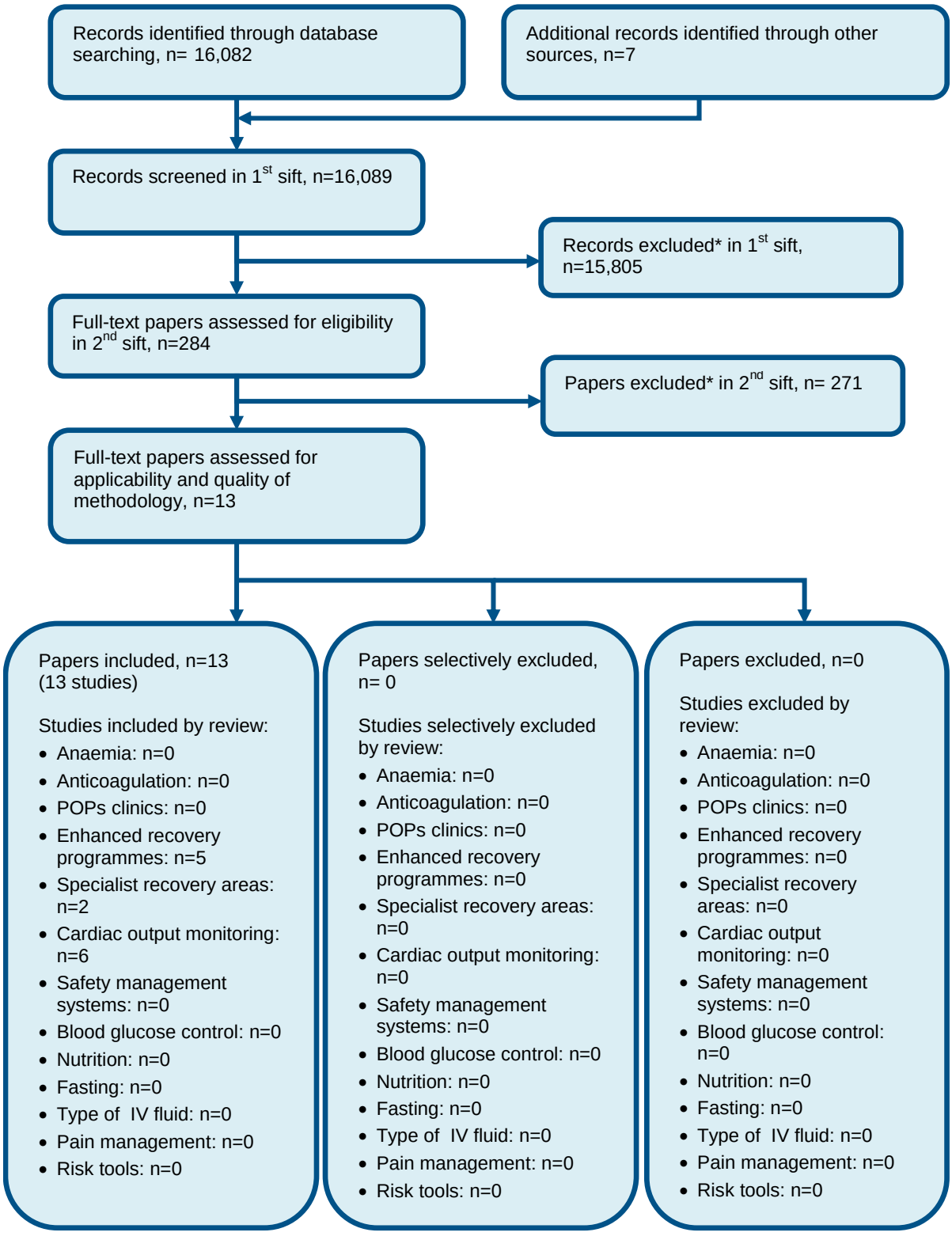
Table 11: Clinical evidence profile: Surgical safety standards compared to usual care

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Surgical safety standards versus usual care	Control	Relative (95% CI)	Absolute		
Postoperative length of stay (same day)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	17/24 (70.8%)	69.6%	RR 1.02 (0.59 to 1.29)	14 more per 1000 (from 285 fewer to 202 more)	⊕OOO VERY LOW	IMPORTANT
Postoperative length of stay (next day)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	5/24 (20.8%)	30.4%	RR 0.68 (0.21 to 1.64)	97 fewer per 1000 (from 240 fewer to 195 more)	⊕OOO VERY LOW	IMPORTANT
Postoperative length of stay (2-7 days)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	2/24 (8.3%)	0%	PETO OR 7.4 (0.45 to 122.11)	-	⊕OOO VERY LOW	IMPORTANT
Readmission (follow-up 30 days)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	1/24 (4.2%)	0%	PETO OR 7.09 (0.14 to 357.5)	-	⊕OOO VERY LOW	IMPORTANT

[1] Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
[2] Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

Appendix G: Health economic evidence selection

Figure 10: Flow chart of health economic study selection for the guideline



* Non-relevant population, intervention, comparison, design or setting; non-English language

Appendix H: Health economic evidence tables

None.

Appendix I: Excluded studies

I.1 Excluded clinical studies

Table 12: Studies excluded from the clinical review

Reference	Reason for exclusion
Abdel-Galil 2010[1]	Incorrect study design
Ahmed 2013[2]	Systematic review: study designs inappropriate
Al Khalifa 2013[3]	Systematic review: study designs inappropriate
Alnaib 2012[4]	Incorrect study design
Amelia Fernandez Sierra 2014[5]	Incorrect study design
Ameryoun 2019[6]	Incorrect intervention
Anderson 2015[8]	Incorrect study design
Anderson 2016[7]	Incorrect interventions
Askarian 2011[9]	Incorrect study design
Avansino 2011[10]	Incorrect study design
Babayan 2013[11]	Incorrect study design
Bashford 2014[12]	Incorrect study design
Bergs 2014[13]	Incorrect study design. Literature review
Bergs 2015[14]	Incorrect study design
Bilimoria 2016[15]	Surgical training
Binazir 2016[16]	No relevant outcome
Bliss 2012[17]	Incorrect study design
Bohmer 2012[18]	Incorrect study design. no relevant outcome
Borgmann 2015[19]	Incorrect study design
Bradley 2010[20]	Incorrect study design
Braham 2014[21]	Inappropriate comparison. Incorrect study design
Cadman 2018[22]	Incorrect study design
Catchpole 2010[24]	Incorrect study design
Challacombe 2011[25]	Incorrect study design
Cherkashin 2016[27]	Non-English language studies
Connor 2013[28]	Incorrect study design
Cornwall 2018[29]	Incorrect study design
Crawshaw 2016[30]	Clinical training
De Vries 2010[31]	Incorrect study design. Before and After
Dedy 2016[32]	Incorrect study design
Duclos 2016[33]	Incorrect study design. Before and after study
Ellis 2017[34]	Incorrect study design
Freitas 2014[35]	Non-English language studies
Fudickar 2012[36]	Literature review; references screened
Garland 2017[37]	Incorrect study design
Gillespie 2014[38]	Systematic review; references screened
Gitelis 2017[39]	Incorrect study design

GlobalSurg 2019[40]	Incorrect study design
Hales 2006[41]	Incorrect study design
Hannam 2013[42]	Incorrect study design
Hardy 2018[43]	No relevant outcomes/Anaesthesiologist performance
Haugen 2013[45]	Incorrect study design. Before and after study
Haynes 2009[48]	Incorrect study design
Haynes 2011[47]	No relevant outcome
Helmio 2011[49]	Incorrect study design. Non-comparative study design
Helmio 2012[51]	No relevant outcome
Helmio 2012[50]	No relevant outcome
Hepner 2017[52]	Non-English language studies
Humphries 2016[53]	Incorrect interventions
Hyder 2014[54]	Incorrect study design. Incorrect interventions
Igaga 2018[55]	Incorrect study design. Non-comparative study
Kasatpibal 2012[56]	Incorrect study design. Non-comparative study
Kawano 2014[57]	No relevant outcome
Kearns 2011[58]	Incorrect study design. Before and after study
Keyes 2004[59]	Incorrect interventions
Kilduff 2018[60]	Incorrect study design. Non-comparative study
Kim 2015[61]	Inappropriate comparison
Kongnyuy 2009[62]	Systematic review is not relevant to review question or unclear PICO
Lacassie 2016[63]	Incorrect study design. Before and after study
Lal 2012[64]	Incorrect interventions
Levy 2012[65]	Not review population
Lilaonitkul 2015[66]	Before and after study. Incorrect study design
Lingard 2005[67]	Incorrect study design
Lingard 2008[68]	Incorrect study design
Liu 2017[69]	Incorrect interventions
Lo 2016[70]	Incorrect study design. Paper not available
Lyndon 2006[71]	Literature review; references screened
Lyons 2014[72]	Systematic review; references screened
Makary 2006[73]	Incorrect study design. no relevant outcome
Mason 2018[74]	Incorrect study design
Mccarthy 2017[75]	Incorrect study design
Mckendy 2017[76]	Systematic review is not relevant to review question or unclear PICO
Menendez Fraga 2016[77]	Non-English language studies
Merry 2010[78]	Incorrect study design. Editorial
Montgomery 2016[79]	Incorrect interventions
Morgan 2015[80]	No relevant outcome
Neily 2010[83]	Incorrect study design
Nilsson 2010[84]	Incorrect study design. Non-comparative study design; no relevant outcomes
Nishiwaki 2014[85]	non-English language studies
Norgaard 2016[86]	non-English language studies

Ong 2016[87]	Incorrect study design. Before and after study
Osen 2011[88]	No relevant outcome
Panesar 2010[89]	Incorrect study design
Panesar 2011[90]	Incorrect study design
Papaconstantinou 2013[91]	No relevant outcome
Patel 2014[92]	Systematic review; references checked
Pattni 2019[94]	Incorrect study design
Patterson 2009[93]	No relevant outcome
Paull 2010[95]	Incorrect study design
Perry 2015[96]	Incorrect study design
Pickering 2013[97]	Incorrect study design
Pucher 2014[98]	Incorrect study design. Simulated environment
Pucher 2015[99]	Systematic review is not relevant to review question or unclear PICO
Rakoff 2018[100]	Incorrect study design. Not relevant to review question
Ramsay 2019[101]	Incorrect study design
Rydenfalt 2013[102]	Incorrect study design. Non comparative cohort study
Sabnis 2009[103]	Incorrect study design. Not relevant to review question
Sacks 2015[104]	Systematic review: quality assessment is inadequate. Systematic review is not relevant to review question or unclear PICO
Salzwedel 2016[105]	RCT not relevant to review question
Santana 2016[106]	Incorrect study design
Schwendimann 2019[107]	Incorrect study design
Senior 2009[108]	Incorrect study design
Sewell 2011[109]	Incorrect study design. Before and after study
Shams 2016[110]	Incorrect study design. No outcomes relevant to review question
Shankar 2018[111]	Incorrect study design. Before and after study
Sharma 2015[112]	Incorrect study design
Sheena 2012[113]	Incorrect study design
Singh 2013[115]	Incorrect study design
Singh 2018[114]	Incorrect study design
Sokhanvar 2018[116]	Incorrect study design
Solsky 2018[117]	No relevant outcome
Sparks 2013[118]	Incorrect study design. Not relevant to review question
Tang 2014[119]	Systematic review: study designs inappropriate
Thomasson 2016[120]	Incorrect study design
Tierney 2013[121]	Incorrect study design
Truran 2011[122]	No relevant outcome
Van Klei 2012[123]	Incorrect study design
Vandijck 2014[124]	Duplicate
Vandijck 2014[125]	Incorrect study design. Editorial
Vats 2010[126]	Incorrect study design
Verdaasdonk 2009[127]	Incorrect study design
Vogts 2011[128]	Incorrect study design
Walker 2012[129]	Incorrect study design

Wangoo 2016[130]	Incorrect study design
Weiser 2010[131]	Incorrect study design. Before and after study
Weldon 2013[132]	Systematic review is not relevant to review question or unclear PICO
Weller 2018[133]	Incorrect intervention
Westman 2018[134]	Incorrect study design. Before and after study
Wetmore 2016[135]	Simulated environment. No relevant outcomes for review question
Whitaker 2015[136]	Incorrect study design
Wilson 2009[137]	Incorrect study design
Wolf 2010[138]	Incorrect study design
Wright 2018[139]	Incorrect study design
Young-Xu 2011[140]	Incorrect study design
Yuan 2012[141]	Incorrect study design. Before and after study

I.2 Excluded health economic studies

Published health economic studies that met the inclusion criteria (relevant population, comparators, economic study design, published 2003 or later and not from non-OECD country or USA) but that were excluded following appraisal of applicability and methodological quality are listed below. See the health economic protocol for more details.

Table 13: Studies excluded from the health economic review

Reference	Reason for exclusion
None.	

Appendix J: Research recommendations

J.1 Safety management systems

What is the clinical and cost effectiveness of interventions to improve compliance to the WHO checklist?

Why this is important:

The committee found that there was little direct evidence that safety management systems reduce morbidity and mortality. There was also no evidence that never events are prevented by the use of the WHO Checklist. The committee also looked at whether there was a reduced financial burden on health services as a result of utilising the WHO Checklist and found there was no evidence to suggest that this is the case.

The WHO Checklist is a mandatory tool in perioperative care in the UK but it has been noted that compliance with its effective utilisation varies according to the safety culture of a particular organisation. It is perceived that poor compliance with its principles and utilisation is a contributing factor to never events and adverse outcomes.

Criteria for selecting high-priority research recommendations:

PICO question	Population: Adults 18 years and over having surgery. Intervention(s): The use of modified versions of the WHO Checklist depending on the nature of surgery to be performed; the use of simulation training or education to address organisational/departmental culture, human factors, health professional attitude and behaviours towards the WHO Checklist. Comparison: Standard reporting Outcome(s): health-related quality of life, mortality, patient, family and carer experience of care, adverse events and complications, Clavien-Dindo, postoperative morbidity score (POMS), never events, serious incidents, compliance, length of hospital stay, hospital readmission, unplanned ICU admission and ICU length of stay (planned and unplanned)
Importance to patients or the population	Never events and adverse outcomes as a result of non-compliance with the WHO Checklist can be devastating for patients and their carers. Apart from these potentially being life threatening events, they can also result in long term morbidity with a significant negative effect on patients' quality of life and a cost to the health services in continuing care and litigation costs. The litigation costs are often picked up by the taxpayer.
Relevance to NICE guidance	There is no robust research investigating the culture around compliance with WHO Checklists. Never events do occur despite the compulsory use of the checklist so there is a role for specific guidance in this area.
Relevance to the NHS	There would potentially be improved patient safety and reduced litigation rates. There could be mitigation in the long term costs related to significant morbidity such as permanent disability.
National priorities	Not applicable
Current evidence base	A small number of RCTs were identified comparing the use of the WHO surgical safety checklist with 'usual' care. However, since the checklist is mandatory in the NHS this research question focuses on interventions to improve compliance
Equality	Not applicable
Study design	These would ideally be assessed in 'real-life' settings with medical teams randomised to different interventions. A more pragmatic approach might involve observational studies performed before and after the introduction of a new intervention
Feasibility	Given the relative low frequency of never events, multicentre trials are likely to

	be needed. It would be impossible to blind participants with regards to the intervention or tool being used and this may introduce significant bias. There might be ethical implications in the behaviour of a team being covertly assessed for the purposes of a trial. The research could be performed at a relatively low cost.
Other comments	Nil
Importance	Medium: the research is relevant to the recommendations in the guideline, but the research recommendations are not key to future updates.

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