

1 **A Systematic Review of Interventions Used to Enhance Compliance and**  
2 **Implementation of the WHO Surgical Safety Checklist in adult surgery**

3

4 **Abstract**

5 This systematic review aimed to identify and synthesize the evidence for  
6 effectiveness of interventions on compliance of the WHO Surgical Safety Checklist  
7 (SSC) in adult surgery. Databases searched included CINAHL, MEDLINE,  
8 PsycINFO and Cochrane Central. Our review was limited to 24 peer-reviewed  
9 articles with quantitative (N=17), qualitative (N=4) and mixed methods design (N=3)  
10 published in English from 2008 to 2020. Intervention models were: 1) Modifying the  
11 ways of delivering the SSC; 2) Integrating or tailoring SSC to local contexts or  
12 existing practice; 3) Promoting clinician awareness and engagement; 4) Institutional  
13 policy management. Despite a lack of common outcome measures, all 17  
14 quantitative studies and three mixed method studies found a significant intervention  
15 effect on SSC compliance. A few studies reported insignificant or negative changes  
16 in certain aspects with the interventions. Further studies must address compliance  
17 measures and outcomes in developing countries.

18 **Key Words:** WHO Surgical Safety Checklist, Compliance, Adult Surgery, Systematic  
19 review

20 **Background**

21 Approximately 234 million surgical procedures are undertaken across the world  
22 every year<sup>1</sup> with an estimate of more than 7 million people suffering post-operative  
23 complications each year<sup>1</sup>, including at least 1 million deaths. As many as 50 percent

24 of those deaths and complications are preventable, as they are due to human  
25 errors<sup>2</sup>. It is reported that one in six safety incidents are related to perioperative  
26 adverse events in the UK, and half of them are potentially avoidable<sup>1</sup>. Preventable  
27 adverse events represent significant economic burden in healthcare system and also  
28 have detrimental impact in patients. The UK Department of Health estimates that  
29 iatrogenic harm costs the National Health Service more than £1 billion (£1 =  
30 approximately \$1.33) each year, NHS errors costing billions per year<sup>1,3</sup>.

31

32 Checklists have been utilized in complex and high intensity areas of work such as  
33 aviation to prevent accidents due to human errors since the 1930s.<sup>4</sup> At the  
34 beginning of 1999, the use of checklists was recommended to prevent human error,  
35 by the Institute of Medicine report "To err is human".<sup>5</sup> Subsequently, several  
36 surgical safety checklists have been developed in the 2000s. The Universal Protocol  
37 was first developed and implemented in 2003 and consists of three elements: 1) A  
38 pre-procedure verification process. 2). Surgical site marking. 3). Surgical "time out"  
39 immediately prior to starting the procedure. In 2004, the *Joint Commission*  
40 introduced The Universal Protocol as a mandatory quality standard<sup>6,7</sup>.

41

42 Another checklist named SURgical PATient Safety System (SURPASS) checklist was  
43 developed in 2007 to enhance standardization in the surgical pathway and improve  
44 surgical patient safety, and was subsequently validated by observation of the  
45 surgical pathway and practical evaluation<sup>8</sup>. This multidisciplinary checklist involves  
46 the entire surgical pathway alongside many other items, such as administration of  
47 antibiotic prophylaxis in the operating room before induction of anaesthesia.

48

49 In 2008, the World Health Organization (WHO) launched the “Safe Surgery Saves  
50 Lives” campaign and created a Surgical Safety Checklist (SSC)<sup>9</sup>. It consists of 19  
51 items and is used at three critical perioperative points: (1) before anaesthesia - the  
52 sign in, (2) before incision - the time out (3) before the patient leaves the operating  
53 room - the sign out. The 19-item WHO SSC is shown in Appendix I. The items  
54 contain verbal confirmation by the surgical team of the completion of some key steps  
55 for ensuring safe delivery of anaesthesia, antibiotic prophylaxis, effective teamwork  
56 and other essential practices in surgery<sup>9</sup>.

57

58 Among these checklists, the Universal Protocol is reported to be too limited to  
59 reduce deaths and overall complications<sup>5</sup>. The WHO and SURPASS checklists have  
60 both been found to reduce significantly patient mortality and any complications<sup>5, 10-  
61 14</sup>. However, the SURPASS checklist has been reported as being more complex to  
62 implement. Additionally, the effectiveness of this tool has been mainly investigated in  
63 one European country, and generalization to other countries and health systems is  
64 uncertain<sup>8, 12</sup>. The WHO SSC has advantages in terms of effectiveness and  
65 generalisability to a variety of settings and health care systems.<sup>15</sup> Indeed, a large  
66 amount of data suggests that the WHO SSC reduces preventable mistakes in the  
67 operating room together with reductions in mortality and postoperative complications.  
68<sup>1, 10, 16</sup> Weiser and colleagues carried out a prospective cohort study to  
69 assess the effect of implementing WHO SSC on mortality and postoperative  
70 complications. They analysed outcomes of 1750 consecutively enrolled patients

71 undergoing urgent noncardiac surgeries, before and after the introduction of the  
72 WHO SSC in eight hospitals around the world. They found that the death rate  
73 decreased from 3.7% to 1.4%, and the complication rate decreased from 18.4% to  
74 11.7% after introducing the WHO SSC.<sup>16</sup> Based on the number of 234 million  
75 operations undertaken each year globally, at least half a million deaths per year  
76 worldwide could be prevented with effective implementation of the WHO SSC.<sup>1</sup>

77 Since its inception, the WHO SSC has been rapidly adopted more than in 3900  
78 hospitals across 122 countries worldwide before 2011<sup>15</sup>. In the UK, the WHO SSC  
79 was introduced into the NHS in February 2010, and supported by the National  
80 Patient Safety Agency and the Royal Colleges of Surgeons across the UK<sup>17</sup>. In the  
81 United States, the Centres for Medicare and Medicaid Services has made “safe  
82 surgery checklist use” one of the measures in the Ambulatory Surgical Centre  
83 Quality Reporting payment program since 2015. While the WHO SSC has been used  
84 across the world and many hospitals adopted it as a standard practice, previous  
85 studies suggested that any positive effects of SSC on patient outcomes were  
86 dependent on the checklist being fully complied with. For instance, Abbott and  
87 colleagues (2018) conducted a large sample cohort study including 44,814 patients  
88 from 4,997 hospitals in 27 countries together with a systematic review of a further 11  
89 studies. They concluded that patients exposed to the use of the WHO SSC had  
90 significantly reduced mortality and postoperative complications<sup>1</sup>. However, they  
91 suggested such positive effects only reflected that the checklist was being properly  
92 implemented, indicating the importance of good staff compliance. Likewise, Bergs  
93 and colleagues (2014) conducted a systematic review of seven non-randomized  
94 clinical studies and performed a meta-analysis for three main outcomes (any  
95 complication, mortality and Surgical Site Infection rate<sup>12</sup>. They found significant

96 reductions in postoperative complications and mortality following implementation of  
97 the WHO SSC. Again, their findings also showed that significant decrease in  
98 postoperative complications was strongly associated with compliance to the items in  
99 the checklist.

100 In contrast, poor compliance with the items on the WHO SSC has been associated  
101 with a failure in improving surgical patient outcomes<sup>5,18-20</sup>. For example, in the UK,  
102 NHS England initiated a programme of work to understand why surgical never  
103 events persist despite the requirement in the NHS to use the WHO SSC as standard  
104 practice. They analysed 38 surgical never event cases occurring in English hospitals  
105 between April 2016 and March 2017. Their findings indicated that failing to comply  
106 with using the SSC at different stages by all levels of the surgical team were key  
107 factors contributing to those cases<sup>21</sup>. Similarly, a lack of staff acceptance and  
108 surgeon engagement of SSC has been shown to contribute to the failure in  
109 improving surgical complications or 30-day mortality rates in the checklist-based  
110 quality improvement program in Michigan<sup>22</sup>.

111 Taken together, the successful implementation and full compliance with the checklist  
112 is critical to ensuring positive outcomes for patient safety. Yet poor compliance of  
113 checklists has been widely reported in the literature<sup>12,18-20,23</sup>. The key challenges  
114 associated with poor compliance and implementation of the checklist have been  
115 addressed in the literature. These include a lack of understanding of the purpose and  
116 ownership of the SSC, lack of clarity about roles and responsibilities of team  
117 members, lack of leadership and institutional support.<sup>23-26</sup> While these exploratory  
118 studies are essential in understanding barriers and identify potential facilitators of the  
119 use of SSC, it is important to utilize these studies to develop and evaluate  
120 interventions designed to improve the compliance and successful implementation of

121 the WHO SSC. Different strategies or interventions may be required by the  
122 heterogeneous settings, surgical procedures and patient populations. Thus far, there  
123 is a lack of clear descriptions of how SSCs have been introduced within  
124 organizations in practice settings, and a lack of evidence of the effectiveness of  
125 implementation processes in surgical checklist literature. It is difficult for clinicians  
126 and healthcare providers to know what works, in terms of ensuring meaningful  
127 compliance and successful implementation of WHO SSC among surgical teams.  
128 Previous study suggested that when staff did not understand the rationale behind  
129 SSC implementation, or were inadequately prepared to use the checklist, it lead to  
130 frustration, disinterest, and eventual abandonment<sup>27</sup>. In an era of evidence-based  
131 practice, clinical practice should be informed by the best available scientific  
132 evidence. We therefore conducted this systematic review to identify the updated  
133 evidence on what interventions work in implementing the WHO SSC, in terms of  
134 enhancing compliance and implementation, and to make recommendations for future  
135 studies on implementing the use of the WHO SSC for surgical safety enhancement.

136 We sought to address three specific research questions:

- 137 1) What intervention methods are used to promote compliance and implementation  
138 of WHO SSC?
- 139 2) How has the compliance of WHO SSC been measured?
- 140 3) What is the efficacy and/or effectiveness of the interventions used for promoting  
141 compliance and implementation of WHO SSC?

142

## 143 **Method**

144 We devised a full systematic review protocol for article identification and retrieval,  
145 alongside evidence appraisal. The systematic review was registered in the  
146 PROSPERO database in September 2019 ([http://www.crd.york.ac.uk/ PROSPERO/](http://www.crd.york.ac.uk/PROSPERO/))  
147 with registration number CRD42019150649. The search strategies in each database  
148 are available on request.

149

## 150 **Search methods for identification of studies**

### 151 **Electronic databases searches**

152 We searched all relevant literature published from 2008 to 2020 up to 8<sup>th</sup> July 2020  
153 in four databases without any language restrictions. We used free-text and  
154 keyword/MESH terms for each of the following databases: Medline, CINAHL,  
155 PsycINFO, and the Cochrane Central Register of Controlled Trials. We entered  
156 subject sub-headings and word truncations according to database requirements in  
157 order to map all possible keywords. Search strategies: we applied no language  
158 restrictions during searches. We used free-text and keyword/MESH terms for each  
159 database. Search terms for surgery included surgery, surgical or procedure. Search  
160 terms for checklist included WHO Safety checklist, SSC, check list, questionnaires.  
161 Search terms for compliance included compliance, adherence, concordance and  
162 acceptance. Search terms for implementation included implement\*, application,  
163 administrat\*, complet\*. Searches for other resources included National Institute for  
164 Health and Clinical Excellence (NICE) and Scottish Intercollegiate Guidelines  
165 Network (SIGN), and WHO websites were searched for relevant published  
166 guidelines. In addition, we screened the reference list of included studies and other  
167 available reviews for any potential studies meeting our criteria.

168 **Inclusion criteria for this review**

169 To capture all relevant evidence, we included both qualitative studies and  
170 quantitative studies as eligible studies. Quantitative studies refer to experimental  
171 studies such as randomized controlled trials, nonrandomized controlled trials, pre-  
172 and post- studies, and observational studies defined as cohort studies, case series  
173 and case control studies. Further study inclusion criteria were applied as follows:  
174 primary research studies published in peer-reviewed journals; Studies with a target  
175 population including any Operating Room personnel or any type of surgical  
176 procedures for adults aged above 18 years old; Studies exploring or evaluating any  
177 type of interventions, strategies or approaches aimed to enhance WHO SSC  
178 compliance or implementation; Studies measuring the compliance or implementation  
179 of WHO SSC. Outcomes of compliance including frequency and item or domain  
180 completeness. We excluded literature reviews, book chapters, conference  
181 proceedings, dissertations/thesis, letters or editorial opinions, paediatric surgery, and  
182 non-English articles. We also excluded the studies that did not explore or examine  
183 any of intervention, strategies or approaches aimed to enhance compliance or  
184 implementation of WHO SSC checklist.

185 **Data extraction and analysis**

186 We exported all articles searched from the databases to Endnote to enable removing  
187 of duplicates and sifting of abstracts. The first reviewer (L.Q.L) identified all articles  
188 that met the inclusion criteria first and then the second reviewer (SM) verified all  
189 articles. The first reviewer (L.Q.L) extracted the following data from eligible articles  
190 and the second reviewer (SM) double-checked for accuracy: author, year of  
191 publication, country of origin, sample characteristics (sample size and participants

192 included operation room role, type of surgical procedures), type of study design,  
193 description of intervention and outcome measures and findings.

194 We assessed the findings to determine whether meta-analysis was possible. Meta-  
195 analysis requires common intervention types, uniform outcome measures and  
196 homogenous populations. It was impossible for us to perform a formal meta-analysis  
197 with statistical pooling of results across studies because of the absence of both a  
198 uniform mode of intervention and standardization of outcome measures.

199

## 200 **Results**

### 201 **Search results and description of studies**

202 We identified a total of 1196 unique references from the literature search, which  
203 were all exported to Endnote (Endnote version X9.2 for Windows, Thomson Reuters,  
204 Philadelphia, PA, USA). We identified three additional articles from other sources. Of  
205 these 1199 articles, 653 were identified as duplicates, thus resulting in 546 abstracts  
206 and titles that were available for sifting for eligibility.

207

208 We further screened all 546 abstracts, and this subsequently generated 64 abstracts  
209 that were potentially relevant. We retrieved the full texts of these 64 abstracts and  
210 considered for eligibility for inclusion in the final systematic review. The outcome  
211 following this procedure was that a total of 24 studies met the inclusion criteria and  
212 were subjected to full-data extraction. Figure 1 provides a flow chart of the process  
213 and results for screening eligibility and study selection.

214

## 215 **Sample characteristics**

216 All 24 articles <sup>27-50</sup> described the intervention or facilitators to enhance WHO SSC  
217 compliance or successful implementation. Of the 24 studies, six of the studies were  
218 conducted in the USA, five of the studies were conducted in the UK, two studies in  
219 New Zealand and Switzerland respectively; the other nine studies were conducted  
220 in Austria, Benin (in collaboration with UK), Brazil, Canada, Cameroon (in  
221 collaboration with UK), Congo, India, and Thailand respectively. **Table 1** illustrates  
222 the distribution of countries where the studies were carried out.

223

224 Seventeen studies were designed as quantitative studies to examine the  
225 effectiveness of interventions or approaches to enhance compliance or successful  
226 implementation of WHO SSC. Four studies were designed as qualitative studies to  
227 explore strategies or facilitators to enhance compliance or implementation of the  
228 checklist. The remaining three studies adopted mixed methods, using both  
229 quantitative and qualitative research methods. Among those seventeen quantitative  
230 studies, one study was a randomized control trial (RCT), two studies were  
231 descriptive studies, and the other fourteen studies were either non-RCT, prospective,  
232 retrospective or cross-sectional cohort studies. Details of sample characteristics are  
233 shown in Table 2.

234

## 235 **Quality of Methodology**

236 We used the mixed methods appraisal tool (MMAT version 2018) to determine the  
237 methodological quality of each study.<sup>51, 52</sup> The MMAT is a critical appraisal tool that  
238 is designed for the appraisal of systematic reviews including qualitative, quantitative

239 and mixed methods studies. We assessed the methodological quality of each study  
240 using seven criteria based on different type of study design.<sup>51,52</sup>  
241 We ranked the methodology of studies included in this review as moderate or low as  
242 we included any type of studies that explored or examined the effectiveness of  
243 interventions to enhance the compliance of WHO SSC. It appears that most studies  
244 used observational or descriptive research methods such as retrospective studies or  
245 cross-sectional survey methods rather than interventional prospective controlled trial  
246 methods, with four studies using qualitative research methods. None of the studies  
247 met all seven criteria, five out of 24 studies met six criteria, and four studies only met  
248 three out seven criteria. Numbers of criteria met by each study were shown in Table  
249 2.

250

### 251 **Intervention features /models and effectiveness**

252 For the four qualitative studies, potential strategies to enhance the compliance of  
253 SSC recommended by the participants are: organizational support and policy  
254 management, staff training, increasing self-awareness of SSC, incentives to prompt  
255 SSC use or consequences associated with non-adherence. Others include having  
256 senior surgeons and anaesthesiologists lead the review of the SSC,  
257 modifying/adapting SSC implementation to the hospital's context and incorporating it  
258 into existing practice, and including patient involvement. Feedback from local data  
259 and anecdotal evidence focusing on the beneficial impact of the checklist helps  
260 reinforce to staff that it is not just a tick-box exercise.

261

262 The interventional procedures reported by the quantitative and mixed method studies  
263 include: staff education and training, deliberately allocating leadership responsible  
264 for each domain, using digital SSC or aviation-style computerized format, integrating  
265 the SSC into the electronic health record with build-in clinical decision support,  
266 displaying the checklist on large wall-mounted posters or a centrally located screen  
267 in the **operating room**, using audio prompt to deliver the questions in the checklist,  
268 and ongoing feedback for sustainability of SSC implementation.

269

270 With respect to intervention effectiveness, all quantitative studies examined the  
271 effect of an intervention on either compliance or successful implementation. **We**  
272 **noted positive changes in compliance with some elements of the SSC process** in all  
273 17 quantitative studies and three mixed method studies. The significant  
274 improvements seen in compliance and implementation include: increased completion  
275 rate of SSC items **30,32,33,42,44,45,47**, increased use of or attempt of using SSC **39\_41,48-50**,  
276 improved team communications **37,42, 44**; improved completion of team brief <sup>36</sup>, and  
277 decreased specimen labelling error. **38**

278 Although all quantitative and mixed method studies reported improvement in some  
279 elements of compliance or implementation of SSC, a few studies reported  
280 insignificant changes with the intervention in other outcomes. Kieffer and colleagues  
281 <sup>38</sup>reported that their intervention, which involved assigning a dedicated person, the  
282 **operating room** co-ordinator, to arrange a briefing with the team before each list  
283 began improved completion of the Team Briefing significantly. However, there was  
284 no statistically significant change in the completion of the team de-brief and WHO  
285 SSC completion rate after this intervention was introduced. In another study carried

286 out by Dixon and colleagues, in which they assessed the digital version of SSC on  
287 compliance, they found that the duration of time-outs increased significantly using  
288 the digital version of SSC (49 seconds with standard version vs 79 seconds with  
289 digital version). However, there was significant improvement in the performance of  
290 key safety elements and most participants preferred to use the digital version of  
291 SSC<sup>28</sup>. A survey was taken of 742 participants who completed the attitudes-  
292 questionnaire before a SSC implementation program, which included a series of  
293 mandatory training activities, and 660 participants who completed after the  
294 intervention, Mascherek and colleagues reported that there were no significant  
295 differences in attitudes and acceptance of SSC use although the intervention  
296 significantly increased in knowledge of SSC and frequency of checklist use, showing  
297 that the main impact of the intervention was in closing the gap between what was  
298 considered a relevant tool in theory and what was actually applied for use in practice.

299

### 300 **WHO SSC Compliance measurement**

301 Seven quantitative studies and three mixed method studies assessed the WHO SSC  
302 across all three phases including 'sign in', 'sign out' and 'time out'. The other ten  
303 quantitative studies assessed selected one or two SSC phases. All seventeen  
304 quantitative and three mixed method studies measured the compliance in different  
305 ways such as evaluating the usage of SSC, completion rate of SSC items 30,32,33,42,  
306 44,47, directly observing whether SSC sign-in, time-out and sign-out were attempted,  
307 and whether fully complied with 39-41,48,49, or the presence and engagement of staff  
308 during checklist administration 37,42,44. Other studies reported perioperative risk  
309 events and key safety elements in checklists such as specimen labelling error,

310 incorrect counts, wrong site, and wrong procedure and patient identification<sup>28,30,38</sup>.

311 Table 2 shows details of intervention and outcomes of compliance in the 24 studies.

312

## 313 Discussion

314 In appraising current available evidence of interventions used to enhance WHO SSC

315 compliance in adult surgery, diverse aims were described for the different type of

316 interventions in the literature. This reflects the broad outcome measures in

317 compliance and implementation of the WHO SSC.

318 In this systematic review of 24 studies, 20 of them (80%) investigated the

319 effectiveness of interventional procedures to enhance SSC compliance by using

320 either a quantitative research method (17 studies) or a mixed method (three studies),

321 while the other four (20%) qualitative studies explored the facilitators to enhance

322 SSC compliance. The quality of methodology was moderate or weak, as we

323 included all types of studies. It appears that most of the studies were underpowered

324 using observational methods rather than prospective controlled trials. Seventeen

325 studies (71%) were carried out in high income countries. De Jager and colleagues

326 carried out a systematic review of 25 studies: to examine the effects of the SSC on

327 postoperative outcomes<sup>13</sup>. They found that postoperative mortality rates were

328 significantly decreased in most of studies conducted in developing countries, but

329 this changes were not found in those studies carried in developed countries. While

330 there is a lack of evidence to explain such findings, different societal, cultural aspects

331 or implementation of SSC methods may be contributing factors. More evidence on

332 SSC implementation strategies in developing countries are needed.

333

334 We identified the heterogeneous descriptions of interventional methods among the  
335 studies included in our review. On the whole, the interventional methods described in  
336 this review fall into four types: 1) Modifying the ways of delivering the SSC, e.g.  
337 using digital SSC instead of a paper version, displaying the checklist on large wall-  
338 mounted posters or operating room flight boards, for the whole process, using audio  
339 prompts to deliver the questions in the checklist; 2) Integrating or tailoring SSC to  
340 local contexts or existing practice, e.g. integrating patients electronic health records  
341 with clinical decision support built into SSC; 3) Promoting clinician awareness and  
342 engagement, i.e. staff education, training and coaching, allocating leadership  
343 responsibility for SSC, physicians' and surgeons' involvement and ongoing feedback;  
344 4) Institutional policy management, i.e. evaluation, mandatory activities, incentives to  
345 promote SSC use and highlighting consequences of non-compliance. Our findings  
346 support the explanatory models identified previously by Gillespie and colleagues,  
347 who reported a realist synthesis of the evidence, that implementation interventions  
348 improve adherence of the use of safety checklists in surgery<sup>53</sup>. They described the  
349 model as 'the sustained use of surgical checklists is discipline-specific and is more  
350 successful when physicians are actively engaged and leading implementation.  
351 Secondly, involving clinicians in tailoring the checklist to their context and  
352 encouraging them to reflect on and evaluate the implementation process enabled  
353 greater participation and ownership'<sup>53</sup>.

354 In this systematic review, we reported a comprehensive synthesis of multiple study  
355 designs and pooled the data from peer reviewed articles on any form of  
356 interventional procedures aiming to enhance SSC compliance and implementation.  
357 The findings of this review provided enriched subjective data on a range of  
358 international methods described in the literature to enhance SSC compliance since

359 its inception. Whilst the patient involvement and incentive/disincentive associating  
360 with adherence or non-adherence of SSC was suggested to promote SSC  
361 compliance by the qualitative studies reviewed, there were no studies looking at the  
362 effectiveness of them as interventional methods in any quantitative or mixed method  
363 studies.

364 In terms of the effectiveness of the interventional procedures, all quantitative and  
365 mixed method studies examined the effect of an intervention on SSC compliance.  
366 Positive changes were reported as increased completion rate of SSC items, or  
367 increased attempts of using SSC, improved team communications<sup>37,42,44</sup>, completion  
368 of team brief<sup>36</sup> and decreased perioperative risk events<sup>38</sup>. Despite all these studies  
369 reporting positive changes related to compliance, a few studies reported insignificant  
370 or negative changes with the interventional procedures. For instance, Dixon and  
371 colleagues found that duration of time-outs increased significantly using digital  
372 version of SSC in comparison with the paper version of SSC<sup>28</sup>. Kieffer et al 2013  
373 reported that there were no statistically significant changes in completion of the team  
374 de-brief and WHO SSC completion rate after assigning a dedicated person who  
375 arranged the briefing with the team<sup>36</sup>. Moreover, Mascherek and colleagues reported  
376 that there were no significant differences in attitudes and acceptance of SSC use  
377 although implementing SSC with mandatory training activities significantly increased  
378 staff knowledge of SSC and the frequency of checklist use<sup>39</sup>. Team members'  
379 engagement did not significantly vary using audio delivery of the time-out and sign-  
380 out sections<sup>44</sup>.

381

382 Regardless of the methodological challenges, or whatever the compliance measures  
383 applied, 20 of the 24 (83%) quantitative and mixed method studies found significant  
384 differences between intervention and comparison groups or pre- and post-  
385 intervention. This suggests that the success of the use of SSC is dependent on  
386 planning interventions in introducing it to staff. However, the diversity of interventions  
387 and lack of ability to conduct a full meta-analysis means that we should interpret the  
388 findings with caution. Our findings provided an insight for clinicians and stakeholders  
389 to consider those interventional procedures that could fit into their practice to  
390 enhance the SSC implementation and compliance, with the aim, ultimately, of  
391 improving patient safety.

392

393 With respect to SSC compliance measurements, the definition of compliance among  
394 the studies is inconsistent in the 17 quantitative studies and three mixed method  
395 studies reviewed. As a result, the measurement of compliance varies among studies  
396 included here. Some studies reported the completion rate of SSC either in all three  
397 phases through audit, i.e. sign in, sign out and time out, or in selected phases;  
398 whereas others used a self-assessment scale or were evaluated by use of direct  
399 observation with measures of SSC compliance, such as communications within the  
400 team for all specified information and presence of all the team member. Other  
401 studies<sup>36,38</sup> measured perioperative risk events, such as incorrect counts, wrong  
402 site, wrong specimen labelling, and wrong procedure to determine the effectiveness  
403 of interventions for SSC compliance. The purpose of developing SSC was to reduce  
404 surgical error and improve patient care. It has been well established that SSC  
405 compliance is associated with improved patient outcomes<sup>1,10,16</sup>. In appraising the  
406 compliance measurement, we recognise the challenges of selecting appropriate

407 outcome measures for the purposes of a study to validate a tool is not usually  
408 possible. In fact, the definition of compliance and measuring true compliance has  
409 always been debatable in the literature<sup>26,52,53</sup> While it may seem easy to measure  
410 attainment of compliance with the SSC by defining completion of any item of the  
411 checklist as simply looking for a tick in the relevant box in the tool, true compliance  
412 with meaningful use of the entire checklist is more important and may not be as easy  
413 to evaluate or obtain<sup>26,54</sup>. Furthermore, in order to enable comparison, the use of  
414 commonly reported tools is usually advocated. There is no clear standardized  
415 compliance measurement that applies for surgical settings. Future work is needed to  
416 generate item banks that reflect true compliance and which can be validated for  
417 further outcome research. This may require a core tool that has additional items for  
418 different surgical produces /populations (e.g. elective surgeries, emergency surgery,  
419 and keyhole and open surgeries).

420  
421 Referring to the background literature and currently available evidence, we would  
422 advocate for future studies focus on generating and robustly evaluating a range of  
423 interventional methods for the use of SSC by designing robust prospective controlled  
424 trials or reviews of compliance in areas coupled with a revision of use / ways of  
425 updating staff. As the needs of different surgical settings are diverse, and worth to  
426 note that each institution will often adopt different models (e.g. applying new  
427 technologies, team work, staff training and incentive policy), theoretically sound  
428 models of intervention must be adapted to meet the feasibility of various settings and  
429 populations.

430

431 Limitations:

432 We are aware of several limitations inherited by the nature of systematic reviews  
433 such as publication bias (particularly against negative findings), language  
434 restrictions, and coding of keywords. However, we designed a well-structured search  
435 strategy with guidance by a clinical librarian and supplemented all “explode”  
436 functions. In addition, we carried out hand searches for grey literature to minimize  
437 the potential for publication bias. Another limitation is including qualitative studies in  
438 the review, which was classified as providing a low level of evidence in terms of the  
439 effectiveness of interventions. Including such qualitative studies in our review has  
440 undoubtedly enabled provision of a more thorough understanding and broader  
441 evidence of current interventional procedures that may confer potential benefit for  
442 and increases in SSC compliance.

443 A further limitation is that we could not perform a meta-analysis due to  
444 heterogeneous study design alongside diverse aims and outcome measures,  
445 combining heterogeneous quality of studies. Nevertheless, we conducted this  
446 systematic review with aim to identify the updated evidence, and to make  
447 recommendations for future research, implementing interventional procedures to  
448 enhance SSC compliance, ultimately improving surgical safety.

449 **Conclusion:**

450 We draw several tentative conclusions. Firstly, it appears that a range of  
451 interventional methods can be effective. These include modifying ways of delivering  
452 the SSC in the operating room, promoting team interaction, targeted staff training,  
453 and senior clinicians’ involvement/leadership/ownership of the process. Also  
454 effective is organizational policy management and ongoing evaluation/feedback.

455 Integrating SSC to existing practices by building a patient electronic health record  
456 with clinical decision support into an electronic SSC and designing interactive  
457 prompts to prevent any missing items during each phase seems to be particularly  
458 effective. Secondly, the concept of true SSC compliance with meaningful use of the  
459 entire checklist needs to be articulated. Thirdly, appropriate outcome tools need to  
460 be developed and validated to measure SSC compliance. Future work is therefore  
461 recommended and needed in the form of well-designed prospective controlled trials  
462 to confirm the beneficial effect of interventions on the enhancement of SSC  
463 compliance and patient safety. Further studies are also required to identify which  
464 interventions work among low-/middle-income countries. Research-based  
465 approaches are necessary to identify the institutional needs and styles of surgical  
466 settings to ensure that interventions harness these styles and address specific  
467 needs.

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