



A mixed methods study of challenges in the implementation and use of the surgical safety checklist[☆]



Tahrin Mahmood, MD^a, Maria Mylopoulos, PhD^{a,b}, Darius Bagli, MDCM, FRCSC, FAAP, FACS^b, Rita Damignani, MSc, BScPT^b, Faizal Aminmohamed Haji, MD, PhD, FRCSC^{c,*}

^a University of Toronto, ON, Canada

^b Hospital for Sick Children, Toronto, ON, Canada

^c Queen's University, Kingston, ON, Canada

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ABSTRACT

Background: The surgical safety checklist is an evidence-based global initiative designed to reduce perioperative morbidity and mortality. However, the expounded benefits of the surgical safety checklist have not been realized in naturalistic settings. This may be related to the *quality* of surgical safety checklists being performed in operating rooms.

Methods: In this explanatory, sequential, mixed-methods study, 2 trained observers used a standardized tool to record the compliance and quality of the surgical safety checklist completed during 51 surgeries performed at a pediatric academic hospital. We compared compliance with each phase of the surgical safety checklist, the number of checklist items completed, and professionals initiating the surgical safety checklist across surgical specialties and case urgency levels. Interviews with nurses, anesthesiologists, and surgeons ($n = 18$) were subsequently conducted to explore and contextualize the findings.

Results: Hospital-recorded surgical safety checklist compliance (94%, 100%, and 100% on briefing, time out, and debriefing) was higher than the proportion of checklist items completed in matched cases (26%, 59%, and 42%, respectively). Thematic analysis of the interview data suggests this may result from limited staff “buy in,” arising from the “top-down” mandated nature of the surgical safety checklist, the perceived lack of benefit in surgical safety checklist completion, and redundancies with other operating room processes. This has led to the surgical safety checklist becoming “an exercise in box ticking” (ie, compliance is recorded without ensuring quality), thereby obfuscating potential safety benefits.

Conclusion: These results highlight that compliance data are insufficient for monitoring surgical safety checklist quality. Our study suggests that surgical safety checklist quality may be enhanced through better calibration of the surgical safety checklist with existing procedures and staff expectations through a bottom-up implementation strategy.

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Introduction

The safe surgery checklist (SSC) is a global initiative introduced by the World Health Organization (WHO) in 2009, designed to reduce perioperative morbidity and mortality. The SSC is divided into 3 “moments”: briefing, time out, and debriefing. Briefing occurs before induction of anesthesia, time out occurs before the start of the surgical procedure, and debriefing occurs after the procedure is completed. Ideally, during these 3 moments, the entire health care team is engaged in a discussion about the procedure and

potential safety concerns to mitigate near misses and avert potential complications.

The landmark global cohort study by Haynes et al.¹ showed a marked reduction in perioperative morbidity and mortality after implementation of the SSC in 8 geographically dispersed hospitals. After this, the SSC was taken up as a standard of care by health ministries around the world. However, despite high levels of hospital-reported compliance with the SSC, recent studies have failed to demonstrate the expected reduction in surgical morbidity or mortality after implementation of the checklist.^{2–6}

A potential explanation for these discrepant findings is that some surgical teams may be only completing part of the SSC.^{7–9} These teams may be viewed as *compliant* with the SSC; however the quality of the safety check (as defined by the number of items completed) may vary.^{7,8} This argument is supported by studies

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* Corresponding author. Department of Surgery, Division of Neurosurgery, Kingston General Hospital, Victory 3 Kingston, ON K7L 2V7, Canada
E-mail address: faizal.a.haji@gmail.com (F. Aminmohamed Haji).

demonstrating that, although all the items in the SSC are rarely completed, when the checklist is fully completed, a positive impact on health outcomes is observed.^{10,11}

Although variations in checklist item completion have been documented in other studies, there is relatively limited data regarding why such variation exists.^{7–9} The present study was designed to explore both the compliance and quality of the SSC completed among health care teams working at a tertiary-care hospital. Our goals were to investigate potential discrepancies between compliance and quality to determine whether the quality of SSC completion varied by the procedure type or surgical specialties and to understand *why* such discrepancies occur. We hypothesized that the lack of compliance is attributable to safety culture and efficiency-driven culture, which disengages the members from fully participating in the SSC. A mixed-methods study was believed to best answer this question.

Methodology

A sequential mixed-methods study¹² at a tertiary-care pediatrics hospital in Ontario, Canada, was conducted. Initially, direct structured observations of operative cases, using a standardized tool, were completed. In the subsequent qualitative phase, semistructured interviews with operating room (OR) staff were conducted. Institutional approval was obtained from the Quality Management Department at our institution.

Phase 1: Direct observation of the OR

Data collection

To understand the quality of the SSC being conducted at the hospital, a custom tool based on the local version of the SSC was developed. This tool included all the components of the local SSC, and therefore was deemed to represent the current standard of practice related to the SSC at the hospital. The tool was further elaborated after a detailed review of existing checklists from the literature. Specifically, the items on the tool were cross-referenced with the WHO checklist to ensure that all relevant items were included.^{9,13} The final tool was presented to a panel of key informants ($n=5$) and was iteratively revised until consensus was achieved (Appendix 1).

Two student observers were recruited and trained in the use of this tool, including a detailed discussion on what each item in the custom tool meant and how to grade observations. The students were believed to be unbiased and unlikely to be viewed as intrusive by OR teams. The training was conducted by a resident (PGY4) involved in developing the tool. The students observed 3 pilot procedures and reviewed their observations with the project team. Key informants and the project team clarified any discrepancies or questions in the use of the tool. SSC items were graded as being completed (1) or not completed (0). In addition, observers recorded who (nursing, anesthesia, or surgery) initiated each moment of the SSC (briefing, time out, and debriefing).

A purposive sampling strategy was used to select cases for observation to understand the utility of SSC in various circumstances.¹² First, a variety of specialties were included in the observations based on which ORs were available and willing to participate in the study. Contingent upon availability of the observers and procedures, additional observations of emergency cases were included to facilitate a comparison of SSC quality based on case acuity.

Data analysis

Data were analyzed using SPSS (IBM Corp, Armonk, NY, USA). First, mean compliance in the 3 sections of the checklist was calculated by determining the proportion of observed cases in which

compliance with the section was observed. Specifically, if the surgical team was observed to engage in any of the checklist items under a section (briefing, time out, or debriefing), the team was considered to be compliant with that section, with overall compliance occurring when all 3 moments were observed during a single procedure. This observed compliance level was case-matched with hospital-recorded compliance data and the Mann-Whitney U test was used to compare hospital and observed compliance. Second, the proportion of checklist items completed was calculated as a measure of quality of the SSC. Items deemed inapplicable to a procedure (ie, implants) were removed to ensure accuracy of the assessment. The mean proportion of items completed for each case was compared across surgical specialties and between elective and emergent cases, using one-way ANOVA (post hoc testing using the Tukey test) and the Student t test, respectively. Finally, the one-sample Kolmogorov-Smirnov test was used to compare the professions initiating the 3 sections of the SSC.

Phase 2: Interviews with OR team members

Data collection

Interviews with OR staff were conducted to gain insight into their experiences with the SSC and to explore potential explanations for the pattern of results obtained during the structured observations. These semistructured interviews were conducted by a medical student (T.M.) between June 2014 and December 2014, with support from a surgeon (F.H.) and an education scientist (M.M.).

We developed an initial interview guide based on the results from Phase 1 (Appendix 2). The guide explored the dynamics of the OR and how this would affect SSC utility. For instance, some checklist items were noted to be used less frequently than others across all observed cases; potential reasons for this were discussed with participants.

Participants were recruited through a snowball sampling method, beginning with our key informants who played a leadership role in implementation of the SSC. Suggestions for other participants were elicited from these individuals and through E-mail suggestions from other individuals who work in the OR. Interviews were audiorecorded, deidentified, and transcribed verbatim. In total, 18 participants were recruited (6 from each of surgery, nursing, and anesthesia).

Data analysis

After the first 3 interviews, the project team reviewed these transcripts separately, using NVivo (QSR International, Inc, Burlington, MA, USA) and then met to review the emerging themes and develop a coding scheme. Disagreements between team members were resolved through discussion until consensus was reached. The major themes that surfaced from this preliminary review were then used to iteratively revise the interview guide to facilitate a purposeful exploration of the data obtained (Appendix 2). Additional interviews were subsequently conducted, and this iterative process was repeated until data saturation was achieved.

Results

Phase 1: Direct observation of the OR

The surgical specialties represented in the sample are presented in Table 1. Of the 57 observed procedures, 6 were excluded: 4 were excluded because of incomplete observations, and 2 were excluded because the number of observations in the given specialty were insufficient for subsequent analysis ($n=1$ for neurosurgery and plastic surgery, respectively).

Table 1
Specialties observed during phase 1.

Specialties	Number of cases observed
Cardiac surgery	9
Dentistry	7
General surgery	9
Neurosurgery	1
Ophthalmology	4
Orthopedic surgery	7
Otolaryngology	10
Plastic surgery	1
Urology	9
Total	57

Table 2
Hospital-recorded compliance, observed compliance, and quality of the SSC.

Sections	Hospital-recorded compliance %	Observed compliance (case matched) %	Proportion of checklist items completed %
Briefing	94	89	26
Time out	100	96	59
Debriefing	100	94	42
Overall	94	85	40

Table 3
Average proportion of items completed among different specialties and acuity levels as observed.

Specialties	Average proportion of checklist items completed %
Cardiac	33
Dentistry	33
ENT	44
General surgery	45
Orthopedics	35
Urology	43
Ophthalmology	19
Acuity	Average proportion of checklist items completed %
Elective	36.9
Urgent	44.7

Hospital and observed compliance versus proportion of items completed

The overall compliance and items completed are presented in Table 2. Across the 51 cases, hospital-recorded compliance was higher than the observed compliance ($P=.11$). However, the proportion of checklist items completed was markedly lower than either the hospital-recorded or observed compliance rate ($P < .05$)¹³.

SSC quality across specialty and case acuity

The proportion of items completed, stratified by surgical specialty and case acuity are presented in Table 3. On average, general surgery completed the highest number of items, whereas ophthalmology completed the least. However, no surgical specialty achieved an average item completion rate greater than 50%.

When comparing elective and emergency cases, we did not observe a significant difference in either the compliance with SSC ($P=.49$) or its quality ($P=.81$).

Checklist initiation by various professions

Table 4 summarizes the results of which professional cadre initiated each moment of the SSC. At the institution, nursing was deemed responsible for briefing, surgery for time out, and anesthesia for debriefing. On average, nurses most frequently initiated the briefing and debriefing moments, whereas surgeons most often initiated the time out ($P < .0001$ at all 3 moments).

Table 4
Initiating profession for each section of the SSC.

	Briefing %	Time out %	Debriefing %
Nursing	84.8	45.2	62.2
Surgery	8.70	50.9	35.6
Anesthesia	6.52	3.77	2.22

Phase 2: Interviews with OR team members

The interviews revealed 4 factors that impacted the quality of the SSC: the mandated nature of SSC implementation, the imperative of efficiency in the OR, the frequent redundancy and irrelevancy of the SSC, and the team hierarchies and responsibility for SSC completion. Participants indicated that because of these factors, the SSC was perceived as an exercise in “box-ticking.”

Mandated SSC implementation

Given the top-down implementation, although participants recognized the stated purpose, they did not feel that the implementation was driven by a local need. A surgeon described how the top-down approach affects the OR culture: “Probably most of them don’t want to do it. I don’t think everyone is sold on how useful it is. It was brought on more as a provincial mandate because of the book that was put out there. I don’t think it is done in an evidence-based manner or in an efficient way.” This impression that the SSC was just a mandated requirement perpetuated a “box-ticking” approach to the checklist among some staff, resulting in a superficial engagement with the SSC. As stated by one nurse: “Some are on board 100%—actively participate. Some are doing it because it is required and it is mandated and you gotta do it—so they pretend.” Moreover, some staff believed the checklist served as a lowest common denominator for team communication, and its implementation replaced the need for critical awareness of patient safety throughout the procedure. Team members fear that this would produce boxed-in thinking and over-reliance on the checklist. A surgeon mentioned: “I do think that sometimes the culture of checklist versus actually 100% attention—They are conflicted right? Wouldn’t it be better, if you didn’t have a checklist but everybody absolutely, at all times during the procedure...once the patient has entered the operating room, you know, the patient has our undivided attention.”

Imperative of efficiency

Participants believed that an efficiency-driven OR culture, where time is a valuable commodity, makes the pause to complete the SSC onerous. A nurse described the culture of the OR: “We are in such a time sensitive area...not to say that it would be a waste of time, but you would be going through all of these questions and people will be like, ‘Okay let’s go—I just wanna go and do it.’”

Other professionals perceived that, because of existing system inefficiencies and shortage of surgical time, any potential value of the SSC was obfuscated by the reduction in efficiency resulting from its implementation. A surgeon mentioned that “...the OR is not very efficient anyway. So, it [the checklist] may add to the inefficiencies of things, if this ... adds to the efficiency in some way, then that would be easier to adapt.”

Given that the SSC was not believed to improve the efficiency of team communication, but was required to ensure appropriate “compliance,” teams would often complete the SSC in a haphazard fashion without spending too much time.

Redundancy and irrelevancy of the SSC

Interviewees highlighted that one potential explanation of the observed variance in compliance between surgical specialties was the potential for redundancy with other processes. Specifically, it

was noted that the SSC reproduced some of the processes already implemented within certain specialties. For example, in cardiac surgery, a nurse noted that, “In cardiac we have our own checklist, so the one that is hanging on the wall [WHO checklist] is really just a dust collector. We fill ours out—It’s a whiteboard and we physically fill it out every day. So, that one is used 100%... To be honest, I don’t read the checklist that is on the wall that often—I go by the one that we use.”

The dynamic nature of the cardiac surgery checklist has been very successful in engaging team members because it was developed by them owing to their unique perceived needs. In settings like these, an additional checklist seems to have marginal benefits, therefore reducing engagement in the process. However, there is the sense that checklists in general make procedures safer.

Similarly, participants described instances where the components of checklist were inapplicable to them. In ophthalmology, where the surgeries often utilize advanced technologic tools, a surgeon mentioned that, “Maybe some specialties see less relevance of some of the items to their specialty than others. Less of them immediately apply. For example, ophthalmology doesn’t need blood ever really. Having to go through that—it gets skipped all the time.”

It was believed that the generic nature of the checklist that did not cater to specific concerns, based on the specialty (or case) in question, decreased compliance because the less utilized items made the checklist seem impersonal. This sentiment was echoed by a surgeon, who said, “If you have extra things that are completely useless, then people won’t do them and it drowns out the effectiveness of what is really important for the patient.”

Given the variations in practice, participants suggested that a more specific checklist might be more effective, as described by an ophthalmologist: “I personally feel that compliance is going to be better if it is more tailored to what we do. You know, we always get asked about antibiotics, but we never use antibiotics in any of our surgeries.”

All of these factors led to low-quality compliance with the checklist, which further cemented the perception of a checklist as an institutional requirement. Perfectly summarized by a participant, “Actually, the compliance data have very little value because what compliance is and what we do are very different.”

Team hierarchy and responsibility for SSC completion

An additional concern raised by some participants relates to the impact of hierarchies within surgical teams on compliance and quality of the SSC. Specifically, the finding from phase 1, that the SSC is most often initiated by nursing staff, was reinforced by interviewees. However, nursing staff (particularly junior nurses), who are expected to document compliance with the SSC, often find it difficult to get other team members to participate in the process. As one anesthesiologist commented:

I mean, I see people trying to do the time out, and, as soon as somebody says, “We will do a time out now,” I see 3 people in the corner turn around and start having a conversation, and those 3 people will be the entire “surgical” team. While the nurse, who is probably the youngest, newest edition to the room, who is maybe 22 years old and has a very soft voice and is very embarrassed about speaking is being listened to by one of her colleagues.

This lack of engagement by team members, particularly surgeons and anesthesiologists, was perceived to devalue the SSC. Moreover, participants indicated that a single team member would find it difficult to advocate for completion of the SSC when the rest of the group demonstrated disregard for the process, especially if that team member were a nurse, because traditional hierarchies

relegate nurses into a supporting role, limiting their power to engage team members in the SSC.

Discussion

In this mixed-methods study, we observed a significant discrepancy between hospital-recorded compliance and the number of checklist items completed. Our study also revealed numerous factors that result in the SSC being viewed as an “exercise in box-ticking,” thereby limiting its value. These challenges related to SSC implementation may help explain why the established mortality reduction demonstrated in controlled studies have not been observed in the “real world.”^{1,2–6,14}

Several studies have found that hospital-recorded compliance rates do not reflect the true quality of the SSC. These studies have shown that, despite >90% compliance with the SSC in hospital-recorded data, true item completion ranges 30% to 64%.^{7,8} Our study corroborates and expands on the discordance between compliance and quality of the SSC. Together, these data provide evidence for the assertion that hospital-recorded compliance is not a reliable way to judge quality of the SSC.^{8,13}

The interview data reveal that frontline health workers believe that the mandated implementation of the SSC was not driven by a perceived need with respect to perioperative safety practices. This disconnect between mandated implementation of the checklist and perceived need was further exacerbated by the variations in practice among various specialties; some of which already had similar checklist-procedures (e.g., a pre-existing daily huddle and time out) already in place at our institution. These created redundancies that, combined with the efficiency-driven culture of the OR, led to the SSC becoming onerous, and deterred teams from fully engaging in the checklist process, thereby potentially reducing its effectiveness.^{15–20} This phenomenon relates to the previously described concept of “checklist fatigue.”²¹ Similar barriers to implementation of the SSC have been identified in the literature: lack of time, excess workload, redundancy in the system, poor communication and hierarchical structure within surgical teams, and lack of a clearly identified profession responsible for the checklist have all been noted to affect the quality of the SSC.^{7,10}

In our study we used item-level compliance as a quality measure. However, some surgical teams adapted the SSC to make it shorter and harmonize it with existing processes in their ORs.²² Given that some teams deliberately decided not to complete low-yield items because of their perceived irrelevance, it is difficult to determine whether the proportion of checklist items completed truly reflects a lack of engagement in the SSC process or is simply an acceptable variation in practice.^{20,23} Furthermore, it is unclear from our data and the current literature whether these adapted checklists undermine the effectiveness of the SSC. Given that completion of all SSC items is associated with a reduction in adverse outcomes, further study is necessary to determine whether adapting the SSC based on local needs can achieve similar gains and to further delineate “acceptable” versus “unacceptable” variation in practice.^{10,24}

These factors highlight the tension between acceptable variation (achieved through adapting the SSC to team needs) and standardization inherent in SSC implementation.²⁵ The goal of standardization is undoubtedly appealing because it establishes a minimum benchmark that may be particularly useful in regions with less-established processes for team communication and complication avoidance.^{26–28} However, our results suggest that the top-down implementation of such a standard, without consideration for how it fits with existing practices, is a flawed approach that may undermine the utility of the tool.²⁰ Another unintended consequence of standardization is the potential for it to disengage team members from maintaining situational awareness and atten-

tion to patient safety by creating a false sense of security.^{6,29} This was identified by our interviewees, who believed that standardization cannot ensure excellence because it distills many situations to one generalized instance. These issues may be avoided if the SSC is implemented as the “lowest common denominator,” whereby the checklist is simplified and distilled to essential elements that prevent common and harmful errors but does not replace existing safety procedures or staff vigilance.^{9,30}

Another interesting finding from our data is that, although the burden of initiating the SSC falls mainly to nursing staff, often these individuals are in positions with the least authority in the OR and, as a result, may experience significant challenges in engaging other team members. This is not a unique finding; nurses in Norway charged with coordinating the SSC faced similar challenges.³¹ Wähle et al.³¹ found that the main barrier to nurses being able to successfully navigate this role related to how best to obtain professional and social acceptance within the surgical team. To do so, nurses utilized a variety of strategies to adjust team involvement when encountering resistance to the SSC from members of the surgical team, including avoiding completing the checklist entirely, or selectively completing some items with specific team members. Both strategies resulted in decreased quality of the SSC process. Given supportive data indicating that nurses may not consider the surgical environment to be collaborative, when nursing staff are left to lead the SSC without adequate support from the surgical team, the result may bring to the forefront the hierarchies in the OR, rather than allaying them.³²

A combination of these reasons has been leading to an increasing sense that the SSC is not yielding expected results, in part, because it is viewed as a requirement rather than as a tool to facilitate team communication and improve care.³³ This highlights the importance of considering the manner in which the SSC is implemented.¹⁰ A recent systematic review identified that compliance with surgical checklists improved when surgical staff were directly engaged in the checklist development process in a multidisciplinary team.¹⁸ Furthermore, clearly communicating “why” and “how” the checklist should be used was identified as essential to successful implementation, as it generates enthusiasm leading to buy-in.¹⁸ This process may also allow for necessary organizational changes to take place, such as the harmonization between the SSC and the existing processes to ensure patient-centered care.⁷

Based on these factors, we contend that in institutions where the SSC has been implemented, improved checklist compliance may be facilitated by eliciting feedback from surgical staff on how to tailor the content and process the safety check to maximize its relevance for each surgical team. This may help ensure that the SSC aligns with actual needs, facilitates “buy-in” from OR staff, and establishes a collaborative environment where potential hierarchies within surgical teams can be addressed.^{5,20,34} We anticipate that the subsequent length of the checklist at each institution may vary based on local needs. In fact, at our institution, resorting to a simplified checklist (eg, the WHO’s 5SSS checklist) may be the best strategy because this may avoid redundancies and help harmonize the checklist with existing processes in place.^{5,20,34} Conversely, institutions that do not have pre-established safety processes may require a more extensive SSC. Furthermore, the results from this study call for an effort to better document the benefits of the checklist by investigating near misses and pooling data at a regional level, given the rare occurrence of morbidity and mortality events in high-resource settings.

Our study has several important limitations should be noted. First, this study was conducted in a single tertiary pediatrics health care center in Ontario, Canada, where the implementation of the SSC resulted from a provincial mandate. Moreover, the observation phase was limited to 51 cases, which did not include all surgical

specialties, limiting the team to convenience-based sampling. This limits the transferability of our findings. In addition, the interviews conducted were not specifically with surgical team members involved in the observation phase. Therefore, we cannot provide data on why some items were not completed in those specific cases. Finally, although we have generated some insight regarding factors influencing SSC quality, these data do not provide direct evidence of the influence of any specific variable on the SSC. Future studies investigating the impact of interventions on the factors identified may provide additional insight. However, it is important to keep in mind that there may not be one answer to these questions and a single implementation strategy may not be effective across disparate health care institutions and systems.

In conclusion, this mixed-method study reveals that hospital-recorded compliance does not accurately represent the quality of the SSC (defined by checklist-item completion). This discrepancy was attributed to the mandated nature of SSC implementation, redundancies between the SSC and existing procedures, an imperative of efficiency, and hierarchies among OR team members that make it difficult for those responsible to ensure the checklist is completed to do so. Together, these factors result in the SSC being viewed as an exercise in “box-ticking,” making the checklist onerous to complete. Our data suggest that, rather than a top-down implementation strategy, engagement of front-line surgical staff may optimize understanding and buy-in, providing the opportunity to harmonize the checklist with existing practices. Accordingly, investigating the effect of standardization on team function and surgical safety are important avenues for future inquiry.

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Supplementary materials

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