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Adapting the World Health Organization's Surgical Safety Checklist to High-Income Settings: A Hybrid Effectiveness-Implementation Trial Protocol

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Objectives: The proposed study aims to assess users' perceptions of a surgical safety checklist (SSC) reimplementation toolkit and its impact on SSC attitudes and operating room (OR) culture, meaningful checklist use, measures of surgical safety, and OR efficiency at 3 different hospital sites.

Background: The High-Performance Checklist toolkit (toolkit) assists surgical teams in modifying and implementing or reimplementing the World Health Organization's SSC. Through the explore, prepare, implement, and sustain implementation framework, the toolkit provides a process and set of tools to facilitate surgical teams' modification, implementation, training on, and evaluation of the SSC.

Methods: A pre–post intervention design will be used to assess the impact of the modified SSC on surgical processes, team culture, patient experience, and safety. This mixed-methods study includes quantitative and qualitative data derived from surveys, semi-structured interviews, patient focus groups, and SSC performance observations. Additionally, patient outcome and OR efficiency data will be collected from the study sites' health surveillance systems.

Data analysis: Statistical data will be analyzed using Statistical Product and Service Solutions, while qualitative data will be analyzed thematically using NVivo. Furthermore, interview data will be analyzed using the Consolidated Framework for Implementation Research and reach, effectiveness, adoption, implementation, maintenance implementation frameworks.

Setting: The toolkit will be introduced at 3 diverse surgical sites in Alberta, Canada: an urban hospital, university hospital, and small regional hospital.

Anticipated impact: We anticipate the results of this study will optimize SSC usage at the participating surgical sites, help shape and refine the toolkit, and improve its usability and application at future sites.

INTRODUCTION

The World Health Organization's (WHO) surgical safety checklist (SSC) provides surgeons, anesthesiologists, nurses, and other surgical personnel with checks and prompts for improving patient safety through enhanced communication and teamwork.[1] The global adoption of the SSC is widespread: a recent study of 1464 facilities in 94 countries between 2014 and 2016 reported SSC use in 75.4% of surgeries.[2]

The SSC is customizable, allowing diverse surgical teams to develop an SSC tailored to their customs, practices, and workflow to maximize utility and buy-in, which, leads to reduced perioperative complications and improved patient safety.[3] However, despite intended adaptability, there are few tools to

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FIGURE 1. The High-Performance Checklist toolkit.

help teams effectively modify the SSC and develop implementation strategies to meet their needs. Lacking these essential tools may contribute to poorly designed checklists and poor clinical engagement. Customization is not required for effective SSC usage in all cases, but inadequate tailoring and ineffective implementation strategies may diminish the consistent benefits observed in the literature.[4,5]

For implementation effectiveness, the "how" and "why" factors are vital and interconnected with the inner context (where the intervention takes place) and outer context (environment outside the boundaries of where the intervention takes place).[6] Regarding the outer context, for example, the Ontario SSC implementation was mandated by the provincial government without a developed implementation strategy or collaboration with local stakeholders, which may explain why the SSC failed to achieve its desired results.[7] For the inner context, implementation effectiveness is influenced by teams' awareness of the SSC's purpose[8] and workload constraints.[7] As such, a poor understanding of the benefits of the SSC influences its effectiveness. Moreover, some organizations may desire to modify and reimplement the SSC to improve its effectiveness. So, context may be more critical in reimplementation efforts to account for the existing attitudes and practices around the SSC.[9,10]

This interplay of "how", "why", inner, and outer contexts expose a gap between individual perceptions and the practical implementation of the SSC in healthcare settings, which influences its effectiveness. Despite recognizing the SSC's value, healthcare professionals use it inconsistently, which results in difficulty in integrating the SSCs into hospital workflows.[11] Additionally, hospitals face implementation challenges in translating checklist adoption into meaningful patient safety outcomes due to team dynamics, limited communication, and resistance to top-down initiatives.[12]

This proposed study is part of a multi-stage project. Stage 1 captured SSC perceptions from surgical personnel in 5 high-income countries: Australia, the United States, Canada, the United Kingdom, and New Zealand, through interviews and surveys. Barriers to, facilitators of SSC use, and user perceptions of SSC were explored. Our analyses identified the need to better tailor SSC checklists to meet contextual demands and address ongoing gaps in leadership and team performance.[13,14] In December 2019, these findings were reviewed at a meeting in Boston involving an international group of participants; the meeting was designed to identify strategies for improving SSC performance. Attendees included patients and subject-matter experts in surgery, anesthesiology, nursing, and human factors. Most attendees were checklist users, and some developed the original SSC. The convening identified the need for a centralized effort to improve SSC performance and support contemporary teams in modifying, implementing, training, and evaluating their SSC. As a result, attendees envisioned a toolkit with tools and best practices for addressing these areas.

Our second stage involved building the "High-Performance Checklist" toolkit ("HPC toolkit"/"toolkit"). The toolkit's content was developed and curated by working groups, including convening members, surgical safety experts, and implementation scientists. The explore, prepare, implement, and sustain (EPIS) framework[15] provided a structure for a toolkit that aids users in effectively customizing and reimplementing their SSC (Figure 1).

The purpose of this proposed study is to gather users' perceptions of the toolkit at 3 different hospital sites and assess its impact on surgical team attitudes and culture, meaningful SSC use, surgical safety, and operative efficiency. By sharing SSC knowledge and implementation best practices, this initiative will empower surgical teams to design and launch custom SSCs.

In this article, we turn our attention to the study's third stage. We propose and describe our methods for evaluating the acceptability of a toolkit for modifying and reimplementing SSCs and its impact on surgical team attitudes and culture, SSC engagement, surgical safety, and operative efficiency.

HPC TOOLKIT

The toolkit consists of steps and tools for designing and reimplementing a tailored SSC and is packaged as an interactive PDF, which facilitates offline access to content through built-in links. The toolkit is intended to be used by an implementation team. It employs Aaron et al.'s[6] EPIS framework and instructs users on addressing challenges and leveraging opportunities in organizations' inner and outer contexts for customizing and reimplementing SSCs.[6] Meant for diverse users, from hospital leadership to operating staff, the toolkit includes guidance material, checklists, forms, and surveys for modifying and implementing SSCs. Since SSC customization encompasses changing content, attitudes, and behaviors, the toolkit's content is structured so that intra-organizational and individual characteristics are reflected in its work, which is designed to be accomplished as a team.[16] We anticipate implementation teams will be able to customize the WHO SSC or redevelop their existing SSC according to their needs by working through the toolkit phases:

1. *Explore*. This element focuses on the organizational context, considering clinician use and perceptions of their sites' existing SSC. It acknowledges that (1) implementation depends on sites' resources and external factors and (2) external challenges such as public health crises may emerge and shape customization. To understand the inner organizational context, implementation teams will use surveys and interviews to explore their site's safety culture. In this phase, research personnel will observe and measure the quality of clinicians' use of the SSC. For the outer organizational context, the implementation teams will examine health system opportunities and constraints for tailoring SSCs.

2. *Prepare*. Using information collected during the explore phase, teams design an updated checklist, reimplementation strategy, and pilot their draft SSC.
3. *Implementation*. In this phase, teams train and coach on their modified SSC's use. Once trained, teams launch their SSC and run ongoing training to ensure proper usage.
4. *Sustainment*. Teams leverage resources within and outside their teams and organizations to sustain modified SSC usage, and then evaluate its efficacy and impact. Teams will regularly return to the explore stage and repeat the toolkit process, so their SSCs consistently match their requirements.

METHODS AND ANALYSIS

Methods

This proposed study stage involves the implementation of the toolkit at 3 sites in Alberta, Canada. We are using Curran et al's[17] third type of effectiveness-implementation hybrid designs, which simultaneously tests clinical and implementation interventions. Mixed methods will be used to evaluate the implementation of the toolkit and its users' experiences. Four data collection phases will occur at each site: a baseline measure of SSC usage, an intervention phase where the toolkit is used, and the customized SSC is launched, followed by postimplementation data collection and follow-up phase. Figure 2 provides an overview of our approach at each site.

Primary and Secondary Outcome Measures

Primary Outcomes

Our 4 primary outcome measures are perceptions of the toolkit, SSC attitudes and operating room (OR) culture, meaningful checklist use, and measures of surgical safety.

1. *Toolkit Perceptions*. We will assess whether the implementation teams' completion of the toolkit improves surgical teams' SSC use and collect their perceptions of its value. Semi-structured interviews will occur before and after the sites' toolkit application. These interviews will indicate how participants' SSC needs are met. Furthermore, a user experience survey capturing the implementation teams' impressions on the toolkit's usability and utility will be administered postimplementation. These data will allow us to evaluate the toolkit's most and least valued aspects (eg, layout, format, and tools, etc.), and the sustainability of customized SSC use. In our study, "completing the toolkit" is defined by the implementation team working through its recommended activities in all 4 phases.
2. *SSC Attitudes and OR Culture*. The implementation team and OR team's perceptions of SSC and OR culture will be surveyed 3 times: at baseline, postimplementation, and follow-up. The SSC attitudes survey probes dispositions toward the SSC, whereas the OR culture survey queries team dynamics and communication. As Mahmood et al[18] noted, SSC attitudes and OR culture are influenced by SSC execution quality and perceived effectiveness: objectives the toolkit aims to address. This outcome will be supplemented by patient focus group data.
3. *Meaningful Checklist Use*. This will be measured with CheckPOINT, an observation tool that captures checklist performance and item completion. CheckPOINT is described later in this article.
4. *Surgical Safety*. We will use health systems surveillance data, including National Surgical Quality Improvement Program (NSQIP) indicators, averted errors, and provincial health data, to explore how revised SSC use affects the rate of adverse events and other safety metrics before and after the intervention. International Classification of Disease (ICD)-10 codes have been used to define surgical complications in previous studies[19,20] and will similarly be used in this study.

Secondary outcome

Our secondary outcome, efficiency, will be measured before and after toolkit use focusing on turnover rates, timed duration of similar cases, and time between cases. The turnover rate is the daily number of surgeries completed in an operating room; the case duration and time between cases are measured in minutes.[21] Although scant research specifically examines turnover rate and checklist use, there is concern that checklist use diminishes efficiency. However, Papaconstantinou et al's[22] pre–post study of the SSC at a large, multispecialty tertiary care hospital observed no difference regarding OR time, operation time, first start time, and same-day cancelations.[22] Likewise, Gillespie et al[23] found SSC implementation and use in day surgery produced no change in clinical efficiencies and surgical delays.[23] Therefore, to test for similar results, we will compare surgical services using the toolkit SSC to those that do not. As multiple services share operating rooms, we will isolate turnover rates and timed metrics via the study sites' health surveillance systems. These rates and times will be compared with services of similar patient volumes not undergoing the toolkit-guided SSC reimplementations.

A list of the various data metrics and their definitions is provided in Supplemental Table 1, http://links.lww.com/AOSO/A350.

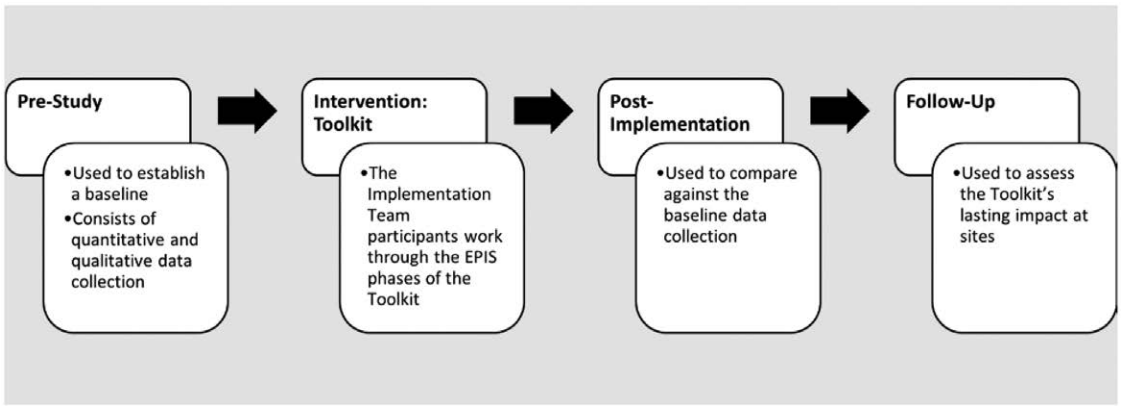

FIGURE 2. Summary of HPC toolkit evaluation at each site.

Setting

This proposed study takes place at 3 surgical sites in Alberta, Canada: an urban hospital, a university hospital, and a regional hospital. The urban and university hospitals are in Alberta's largest city, the regional hospital is situated in rural Alberta. The city hospitals perform myriad surgical procedures, whereas the regional hospital is limited. Sites were chosen through convenience sampling: surgical teams' self-identification and approaching the provincial surgery strategic clinical network.

Participants

There are 3 participant types: implementation and OR team members, and patients, providing organizational, clinician, and patient perspectives. The implementation teams represent toolkit "users" and include participating clinicians, quality and safety staff, and members of hospital organizations who will customize and reimplement their SSC. The customized SSCs are utilized by surgical team members (surgeons, anesthesiologists, and nurses) at participating sites.

Patient perspectives will be collected to ensure their priorities are reflected in perioperative communication processes. Patient participation in the SSC is limited but may highlight recent changes in patient health, acknowledge patient priorities in the case of an averse intraoperative event, and identify family contacts to discuss outcomes of surgery. It also allows patients to meet their OR team, offering opportunities to use the SSC to address patient priorities and convey critical information. Patients' experiences during the first pause point of the checklist can mirror clinicians' meaningful SSC engagement. Effective doctor-patient interactions in these critical moments contribute to patients' sense of safety. Dixon et al's[24] survey of 345 patients who received elective surgery found a positive association between surgeons' interactions with patients in the preoperative area and patients' sense of safety. Table 1 outlines the participants' activities.

Recruitment

We will recruit implementation and OR teams through presentations and meetings at each study site. Patients will be recruited through advertisements and during appointments. Since it is not feasible to measure the same patient participants' experiences both before and after reimplementation, we will recruit different patients before and after toolkit use.

Guiding the Toolkit Process

As this project marks an early application of the toolkit, we will help implementation teams navigate it, but allow them to complete its tasks according to their priorities. We will use Zoom and in-person meetings to present toolkit phases to the implementation team for discussion and feedback. Individual meetings with implementation team members ensure inclusive perspectives that will be aggregated and shared with the larger implementation team for prioritization and action.

Data Collection Instruments

The toolkit's impact on the primary and secondary outcomes will be assessed using surveys, semi-structured interviews, patient focus groups, SSC performance observations, and health system surveillance data. Table 1 shows the data collection instruments' sequencing.

To mitigate the Hawthorne effect, we will use operational controls. First, health system surveillance data will be collected during times when research personnel are absent. Second, private online surveys will capture participants' perceptions of the toolkit and its impact on their use of the SSC.

SSC and OR Safety Culture Attitudes Surveys

We used the SSC and OR safety culture attitude surveys in our data-gathering stage.[14] They are adapted from previous studies of the SSC and explore surgical teams' use of SSC, patient safety, and team dynamics.[25–27] They will be administered to the implementation team and OR team participants as online surveys before and after toolkit use and at follow-up. We aim to administer 50 pre–postimplementation and follow-up surveys at sites ($50 \times 3 \times 3 = 450$) to evaluate the acceptability of the new SSC's reimplementation process, attitudes towards it, and impact on operating room culture. Understanding the multiple commitments of clinicians and historically poor response rates to surveys, our response rate may not reach the target of 50 clinicians per site. Nevertheless, we will collect enough data to refine the SSC and toolkit rather than seek generalization. We will limit nonresponse bias by ensuring

TABLE 1.

Study Phases and Data Instruments

	Data Collection Phases and Participant Activities			
	Baseline	**Intervention (HPC Toolkit)**	**Postimplementation**	**Follow-Up**
Participant groups				
Implementation team	SSC attitudes and OR culture survey, interviews	Toolkit meetings	HPC toolkit user experience survey, SSC attitudes and OR culture survey, interviews	SSC attitudes and OR culture survey
Operating room members	SSC attitudes and OR culture survey, interviews	NA	SSC attitudes and OR culture survey, interviews	SSC attitudes and OR culture survey
Surgical patients	Focus groups	NA	Focus groups	NA
Health system surveillance data	Yes, 1 year before implementation	NA	NA	Yes, up to 18 months after implementation
CheckPOINT observations by research team	Yes	During sustain phase	Yes	Yes
	Legend	Baseline SSC assessment HPC toolkit assessment Assessing for impact of the HPC toolkit	Blue text Green text Purple text	

surveys take approximately 10 minutes to complete and issuing reminders.

Semi-structured Interviews

Before and after toolkit implementation, approximately 40 interviews will be conducted with clinician participants. The interviews will be run and recorded by research personnel using Zoom. These interviews will collect implementation team members' perspectives on the SSC and toolkit and OR participants' perceptions of their existing and customized SSCs.

SSC Performance Observations

The CheckPOINT observation tool will be used to observe live SSC performances.[28] Adapted from the World Health Organization Behaviourally Anchored Rating Scale evaluation tool,[29] CheckPOINT quantifies team SSC performance using Likert scales. Rating the 3 SSC sections (sign-in, time-out, and sign-out), CheckPOINT evaluates checklist adherence, communication effectiveness, attitude, and engagement. Two research assistants will record CheckPOINT observations during each data collection phase. CheckPOINT observations will illustrate teams' baseline performance, use of their customized SSCs, and postimplementation performance and meaningful use. The observations also illuminate team dynamics and workflow, which facilitate SSC design and implementation.

Toolkit User Experience Survey

The implementation team will complete a user experience survey in the postimplementation phase. This survey asks questions about participants' general experience with the toolkit and the SSC customization work they complete. This survey feedback will facilitate the toolkit's iterative improvement.

Patient Focus Groups

Adult patients will participate in focus groups before and after the toolkit's use. Focus groups will comprise 5 to 8 participants recruited within 3 months postsurgery. These groups will discuss the first section of the SSC and explore SSC familiarity, presurgery concerns, postanesthesia considerations, and overall surgical experience. Focus groups will be facilitated and recorded by research personnel and then transcribed and analyzed thematically.

Health System Surveillance Data

To evaluate the toolkit's impact on patient outcomes and operative efficiency, we will gather health system data from participating sites using Alberta's provincial data analytics. These measures will be collected retrospectively for a year before and up to 18 months after sites' toolkit use. NSQIP indicators will be collected at sites' participating surgical services to assess the toolkit's impact on surgical safety. These metrics include the rate of surgical site infection, 30-day in-hospital mortality, and unplanned emergency department visits within 30 days of surgery. NSQIP data samples of 8 to 12% of relevant cases and will be supplemented by comprehensive provincial health data that permits complete collection and identification of sites' occurrence of "never events" (ie, incorrect site/side/location/procedures) adjusted for total case volume. International Classification of Disease-10 codes will help identify rates of important and common postoperative complications in the study populations' provincial electronic health records.[19,20] Supplemental Table 1, http://links.lww.com/AOSO/A350 details our health system data collection.

Analytical considerations

Data Analysis

This is a mixed-methods study, so quantitative and qualitative data analyses will be performed. Details for each data collection tool are included below and in Table 2. As the toolkit's EPIS structure mandates sequentially completing each phase to develop and reimplement a customized SSC, our analysis encompasses a study of the entire toolkit and its effects.

Surveys, Health Systems Surveillance Data, and CheckPOINT Data

The surveys, health system data, and CheckPOINT observation data will be analyzed using Statistical Product and Service Solutions. Subgroup analyses will be performed on user and site characteristics. Since 2 research assistants will conduct the CheckPOINT observations, interrater reliability will be measured using Cohen's kappa statistic.[30]

Interviews and Focus Groups

Qualitative data from the interviews and focus groups will be analyzed on computers using NVivo. We will employ a deductive coding approach using the Consolidated Framework for Implementation Research (CFIR) and reach, effectiveness, adoption, implementation, maintenance (RE-AIM) framework, and an inductive lens for identifying additional themes.[31,32] The 5 contextual domains of CFIR—intervention, outer setting, inner setting, individuals, and process—will serve as high-level coding schemes. Focusing on facilitators and barriers, CFIR describes factors contributing to the implementation of a health program, tool, or process.[33] Its 5 domains "interact in rich and complex ways to influence implementation effectiveness".[34] Whereas, RE-AIM targets implementation outcomes concerning individual and setting-level domains.[35] The individual-level domains consist of implementation reach, effectiveness, and maintenance, while the framework's setting-level domains are adoption, implementation, and maintenance.[35]

Two reviewers will iteratively read and compare the interview and focus group transcripts to develop a coding framework together. They will individually read some of the same transcripts, create memos on their thoughts, and then meet to

TABLE 2.

Data Collection Instruments, Analytical Approaches, and Tools

Data Collection Instrument	Analytical Approach	Tool used for Analysis
SSC attitudes and OR culture survey • HPC toolkit user experience survey • Health systems surveillance data • CheckPOINT observations • Focus groups	Descriptive statistical analysis	Statistical Product and Service Solutions NVivo
Semi-structured interviews	Thematic analysis using the CFIR and RE-AIM frameworks	NVivo

discuss interpretations. Reviewers will explain their reasoning on how coded passages and text reflect the CFIR and RE-AIM frameworks and other notable findings. These delineations will be arrived at using Glaser's (1965) constant comparative method. As the deductive and inductive codes reveal themselves in the data, reviewers will save them in NVivo, and then compare the subsequent interview and focus group transcript data to these saved codes.[36] Once the coding framework is established, reviewers will analyze the remaining transcripts and regularly discuss their interpretations of the data. This iterative and discursive process will help establish themes based on the CFIR and RE-AIM frameworks and our inductive analysis through consensus.

Sample Size Considerations

As a mixed-methods study, our sampling approach has qualitative and quantitative considerations that involve nonprobabilistic sampling.[37,38] Moreover, as this study marks an early application of the toolkit, our goal is not generalization but rather users' perceptions of the toolkit and assessment of its impact on our primary and secondary outcomes.

Across the sites and surgical services, we anticipate a total of 450 completed clinician surveys: 50 pre–post implementation and follow-up surveys from the sites ($50 \times 3 \times 3 = 450$). Considering the limited surgical staff in Alberta, we anticipate performing 40 interviews across the sites, consistent with the typical range of interviews required for thematic saturation.[39]

For patient focus groups, we will recruit 5 to 8 participants for each of the sites' 2 focus groups, for a total of 30 to 48 participants. This recruitment is not designed to achieve generalizability, but to demonstrate the range of experiences associated with sites' SSC usage.

The health system data will include relevant patient outcome data from sites. We will collect information for a period of 1 year before the toolkit's introduction and up to 18 months after. Our surveillance data captures outcomes that can be compared in an exploratory manner. Because quantitative measures will be collected to address primary and secondary outcomes, statistical differences will be regarded as exploratory.

Patient and Public Involvement

Patient advocates will contribute to toolkit activities by providing perspectives for improving surgical care. Patients focus groups participants will support the sites' customized checklists and help describe the OR teams' SSC performance.

ETHICS APPROVAL

The University of Calgary's Conjoint Health Research Ethics Board approved this study (REB21-0099).

FORESEEABLE CHALLENGES

In this proposed study, we anticipate resistance to participation from overburdened OR team members. To address this challenge, we have engaged champions and influential leaders to encourage participation and inform teams on the potential value of participating. Participants also face competing commitments, so we will run the toolkit online and in small meetings to attain adequate participation. Additionally, survey response rates may be low, so reminders will be used to bolster participation. Finally, our project collects diverse data, which poses organizational and analytical challenges. To alleviate this, we devised a data management system to separate and store data and maintain its integrity and confidentiality.

CONCLUSIONS

Despite widespread usage, the SSC is often poorly optimized for success. It is frequently not tailored to the needs and contexts of teams, and strategies supporting its reimplementation are often lacking. Given evolving surgical needs, new opportunities and perspectives can be incorporated into teams' SSCs, potentially improving engagement, patient safety, and health system efficiency.

Our proposed research will assess the impact of the toolkit for SSCs at 3 hospitals in Alberta, Canada. The toolkit is designed to aid surgical teams in assessing, modifying, and reimplementing surgical safety checklists. The resulting toolkit can be used by surgical teams worldwide to revisit and revitalize their SSCs.

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