Quality Improvement Study

Development and content validation of the Safe Surgery Organizational Readiness Tool: A quality improvement study

Tuna C. Hayirli a,1, John G. Meara a,1,1, David Barash d, Bwire Chirangi e, Augustino Hellar f, Benard Kenemo g, Innocent Kissima h, Sarah Maongezi i, Cheri Reynolds j, Hendry Samky i, Mpoki Ulisubisya l, John E. Varallo k, Chloe B. Warinner k, Shehnaz Alidina a,2, Ntuli A. Kapologwe l,2

a Program in Global Surgery and Social Change, Harvard Medical School, Boston, USA
b Harvard Business School, Boston, USA
c Department of Plastic and Oral Surgery, Boston Children’s Hospital, Boston, USA
d GE Foundation, Boston, MA, USA
e Shirati KMT Hospital, Shirati, Tanzania
f Jhpiego, Baltimore, MD, USA
g Bugando Medical Centre, Mwanza, Tanzania
h Assist International, Ripon, CA, USA
i Ministry of Health, Community Development, Gender, Elderly & Children, Dodoma, Tanzania
j Center for Reform, Innovation, Health Policies and Implementation Research, Dodoma, Tanzania
k Harvard Medical School, Boston, USA
l President’s Office – Regional Administration and Local Government Directorate of Health, Social Welfare and Nutrition Services, Dodoma, Tanzania

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ABSTRACT

Background: Recent efforts to increase access to safe and high-quality surgical care in low- and middle-income countries have proven successful. However, multiple facilities implementing the same safety and quality improvement interventions may not all achieve successful outcomes. This heterogeneity could be explained, in part, by pre-intervention organizational characteristics and lack of readiness of surgical facilities. In this study, we describe the process of developing and content validating the Safe Surgery Organizational Readiness Tool.

Materials and methods: The new tool was developed in two stages. First, qualitative results from a Safe Surgery 2020 intervention were combined with findings from a literature review of organizational readiness and change. Second, through iterative discussions and expert review, the Safe Surgery Organizational Readiness Tool was content validated.

Results: The Safe Surgery Organizational Readiness Tool includes 14 domains and 56 items measuring the readiness of surgical facilities in low- and middle-income countries to implement surgical safety and quality improvement interventions. This multi-dimensional and multi-level tool offers insights into facility members’ beliefs and attitudes at the individual, team, and facility levels. A panel review affirmed the content validity of the Safe Surgery Organizational Readiness Tool.

Conclusion: The Safe Surgery Organizational Readiness Tool is a theory- and evidence-based tool that can be used by change agents and facility leaders in low- and middle-income countries to assess the baseline readiness of surgical facilities to implement surgical safety and quality improvement interventions. Next steps include assessing the reliability and validity of the Safe Surgery Organizational Readiness Tool, likely resulting in refinements.
1. Introduction

Access to safe and high-quality surgical care is a necessary component of universal health care coverage. The Lancet Commission on Global Surgery reported in 2015 that 5 billion people do not have access to safe, timely, and affordable surgical and anesthesia care, 90% of people in low- and middle-income countries (LMICs) do not have access to such care, and merely 6% of surgical procedures are performed in emerging countries where a third of the world’s poorest population lives [1]. Recent efforts have drawn attention to the urgent need to address the lack of access to safe and high-quality surgical care in LMICs [2]; however, not all interventions intended to improve quality and safety in LMICs achieve successful outcomes. Take, for example, the implementation of clinical checklists. While an analysis of pre-post trends after the implementation of the World Health Organization Surgical Safety Checklist showed an improvement in surgical practices and complications [3], a randomized controlled trial of the coaching-based implementation of the Safe Childbirth Checklist showed increased complications [4].

More strikingly, multiple facilities implementing the same intervention may not all achieve success [5,6]. Previous research has demonstrated that pre-intervention characteristics can set the trajectory for high and low-performing organizations [7]. This heterogeneity in achieving success could be explained, in part, by pre-intervention organizational characteristics and lack of readiness of surgical facilities to implement safety and quality improvement interventions. Although lack of readiness is not a problem uniquely found in LMICs, assessing such characteristics would be helpful in low-resource settings where scaling surgical quality interventions takes place in a resource-constrained setting.

Scholars of organizational change who study modifications to organizational structure, process, and behavior have previously studied why so many change initiatives fail. Beer and Nohria [8] note that efforts to change are successful less than 30% of the time, with Kotter arguing that more than half of failure initiatives have roots in lack of preparedness to change [9,10]. Complicating many interventions is the fact that there is no one size fits all solution to successful change [11]. In response to such findings, organizational readiness for change has emerged as a critical concept within implementation science (Table 1). Readiness is a multi-dimensional and multi-level construct with social-psychological and organizational-contextual components measurable at the individual or collective levels. Simply put, “the concept of readiness in everyday discourse connotes a state of preparedness for future action” [18].

In this paper, we aimed to develop a theory- and evidence-based tool to assess surgical care facilities’ readiness in low-resource settings to implement safety and quality improvement interventions. The purpose of the Safe Surgery Organizational Readiness Tool (SSORT) is to evaluate surgical facility members’ baseline beliefs and attitudes toward such interventions and their implementation. The long-term goal is to use the SSORT to identify potential barriers to implementation such that interventions can be better tailored to promote success.

2. Methods

For the development and content validation of this tool, approaches outlined by Lynn [19] and Hinkin [20] were followed, and findings are reported using the Standards for Quality Improvement Reporting Excellence (SQUIRE) framework [21]. Tool development proceeded in two main stages. The developmental stage consisted of domain identification and item generation following both inductive and deductive approaches. An expert panel was consulted in the content validation stage, using a commonly utilized quantification method [19]. An overview of the steps is presented in Fig. 1.

Table 1

<table>
<thead>
<tr>
<th>Definitions of readiness.</th>
<th>Source</th>
<th>Theoretical foundation</th>
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<tbody>
<tr>
<td>Readiness is the “beliefs, attitudes, and intentions regarding the extent to which changes are needed and the organization’s capacity to successfully undertake those changes”</td>
<td>Armenakis et al., 1993 [12]</td>
<td>Lewin’s (1947) field theory and work on group and change dynamics [13]</td>
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<td>Readiness for change refers to organizational members’ shared resolve to implement a change (change commitment) and shared belief in their collective capability to do so (change efficacy)”</td>
<td>Weiner, 2009 [10]</td>
<td>Bandura’s (1997) self-efficacy and social cognitive theory [4], and Vroom’s (1964) theory of motivation [15]</td>
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<tr>
<td>Readiness is defined as the degree to which those involved are individually and collectively primed, motivated, and technically capable of executing the change”</td>
<td>Holt et al., 2010 [16]</td>
<td>Extension of Armenakis et al.’s (1993) model [12]</td>
</tr>
<tr>
<td>Organizational readiness involves (a) the motivation to implement an innovation, (b) the general capacities of an organization, and (c) the innovation-specific capacities needed for a particular innovation”</td>
<td>Scacca et al., 2015 [17]</td>
<td>Practical extension of Weiner’s (2009) model [10]</td>
</tr>
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</table>

2.1. Developmental stage

The foundation for this project’s development came out of the larger Safe Surgery 2020 program, a collaborative initiative launched in 2015 aimed to strengthen health systems and surgical services in Ethiopia, Tanzania, and Cambodia [22]. This multi-component program was designed to improve surgical safety practices, teamwork and communication, and data quality in order to lower surgical complications related to surgical site infections, postoperative sepsis, and maternal sepsis [23]. Accompanying program intervention, a longitudinal, mixed-methods study comparing high and low performing facilities took place in Tanzania’s Lake Zone region. The qualitative component of this study included 101 interviews with leaders, surgical and anesthesia providers, and nurses in six facilities [7]. The analysis of these interviews specified some domains and informed the literature review and theory building that followed.

Literature on organizational change and readiness to change was retrieved from PubMed, Google Scholar, and Web of Science database searches. Two recently published and very comprehensive systematic reviews assessing organizational readiness instruments proved most helpful in identifying domains and existing questionnaire items [18,24]. Three authors (Author1, Author2, Author3) considered domains identified from the literature in light of theories of change management and findings from the preceding qualitative analysis, resulting in a preliminary list of domains.

Due to the geographic dispersion of the research team, principles of the Delphi technique were adapted to further develop the tool and reach a consensus on the domains and questions that were ultimately included in the tool [25]. First, all members of the research team were presented the conceptual framework and preliminary domains, and were asked to independently comment on the findings and propose additional domains. These meetings were led by a member of the research team (Author1), and were conducted over the Zoom platform. The feedback collected from all authors resulted in changes to content domains for which items were either constructed or adapted from existing instruments. Next, using an online survey, members of the research team commented on each domain and item, and provided feedback on
whether domains and items should be removed, kept, or changed. The feedback collected was synthesized by the first authors (Author1 and Author2), and looped back to all authors. After this round of comments, the research team agreed that the tool was ready for review by an expert panel.

2.2. Content validation stage

Content validity is a measure of “whether or not the items sampled for inclusion on the tool adequately represent the domain of content addressed by the instrument” [26] and provides evidence for the soundness of a tool. Although there is no standard way of establishing content validity, we followed recent content validation efforts in the health care literature making use of expert panel validation techniques employing the Content Validity Index (CVI) [19]. Seven panelists were selected based on their training in surgery, organizational behavior, healthcare management, or global surgical research.

For the CVI method, panelists were presented the domains in detail and were asked to rate the relevance of each item to that domain on a scale of one to four, ranging from “not relevant” to “very relevant.” Panelists were also asked to provide feedback on each domain, item, and the overall tool. Items receiving a score of one or two were deemed content invalid, while items scored three or four were considered content valid. The validity of each item (I-CVI) was calculated as the proportion of experts giving that item a content valid rating. The validity of the overall scale was calculated in two ways. In the average method (S-CVI/Ave), the I-CVI scores for the whole tool was averaged. In the universal agreement method (S-CVI/UA), the proportion of items that all panelists rated as content valid was calculated, though the S-CVI/Ave method is preferred for establishing content validity [27]. Accounting for chance agreement on relevance, I-CVI scores greater than 0.78 and S-CVI/Ave scores greater than 0.9 establish excellent content validity with any number of panelists [28]. Items receiving an I-CVI less than 0.78 are considered candidates for revision by the research team.

3. Results

3.1. Results of the development stage

The qualitative findings from the Safe Surgery 2020 intervention in Tanzania highlighted seven themes that distinguished high performing surgical facilities from low performing ones: starting organizational context, engagement with interventions, teamwork and communication, collective learning, organizational leadership, perceived intervention impact, and vision beyond the intervention [7]. The research team streamlined these seven themes into measurable scales, resulting in seven domains (Fig. 2).

In conjunction with this inductive approach, the deductive approach

Fig. 1. Steps in the development and content validation of SSORT
An overview of the steps taken to develop the SSORT, beginning with insights from qualitative results and literature on organizational change and readiness, to using a common quantification method for content validation.

Fig. 2. Results of the development stage. Domains included in the SSORT were either inductively proposed by the investigator team, or derived out of qualitative findings from the Safe Surgery 2020 program and literature on organizational change and readiness. Out of the two additional domains proposed by the investigators, only political governance context was deemed content valid.
from the literature provided an organizing framework for the readiness construct. Theoretical developments in assessing organizational readiness point out that readiness is a multi-level phenomenon that should be measured at the individual, work-group, and organizational levels [29, 30]. Scholarship on readiness also suggests that readiness has cognitive, structural, and emotional components that vary across the three levels [10,16,29]. The two comprehensive systematic reviews identified in our literature review additionally provided six common domains extracted from 23 tools that had either been used or designed for use in the healthcare setting (Appendix 1), and two domains suggested in response to a lack of emotional assessments in previously existing domains [18, 29].

Upon review of the 13 domains identified up to this stage, iterative discussions between members of the research team resulted in the addition of two domains related to community engagement and political governance. Items for each domain were either sourced from previously existing tools and scales, or generated to better match the LMIC surgical setting (Appendix 2). At the end of this stage, a preliminary list of domains and items was deemed ready for expert panel review (Fig. 2).

3.2. Results of the panel review

All content validity calculations are presented in detail in Appendix 3. For the 15 domains, panelists rated a total of 65 items. I-CVI scores ranged from 0.43 to 1, with 52 out of 65 items (80%) meeting the threshold for excellent content validity. The S-CVI/Ave score of 0.88 was close to meeting the threshold for excellent content validity.

Based on feedback from panelists, a number of changes were made to improve the tool. Panelists reported that two out of 52 items receiving an excellent I-CVI scores were repetitive and unnecessary for inclusion. These two items were dropped. Further, panelists did not find community engagement to be a relevant domain for the SSORT. Out of the 13 items not meeting the excellence threshold, six were revised and included in the SSORT, while seven items were dropped. The finalized version of the SSORT included 14 domains and 56 items, of which 50 were retained in the SSORT, while seven items were dropped. The finalized version of the SSORT included 14 domains and 56 items, of which 50 were retained in the SSORT, while seven items were dropped. The finalized version of the SSORT included 14 domains and 56 items, of which 50 were retained in the SSORT, while seven items were dropped.

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As a conservative measure that does not allow for the I-CVI scores of revised items to increase, we again calculated the S-CVI/Ave using only the included items. This S-CVI/Ave score of 0.90 establishes excellent content validity for the SSORT.

4. Discussion

The aim of this study was to describe the development and content validation of the Safe Surgery Organizational Readiness Tool (Appendix 4). The SSORT measures facility members’ attitudes and beliefs regarding 14 domains at the individual, team, and organizational levels, providing insight into the readiness of surgical facilities in LMICs to implement surgical safety and quality improvement interventions. Further, results of the CVI confirm that the domains and items included in the SSORT are relevant and appropriate.

The SSORT provides facility leaders and change agents a tool to uncover cultural factors at the individual, team, and organizational levels (Table 3). Conceptualizing readiness as a multi-level construct [29,30] is especially important for surgical facilities in LMICs. Performance, learning, and improvement in the surgical theatre are impacted by teamwork and leadership capabilities at the individual [40–42] and collective levels [43–46]. Capabilities required by interventions face unique constraints in LMICs compared to high-income countries [47], as surgical care in LMICs often takes place in settings with high burden of disease, inadequate opportunities for training, inadequate staff and supplies, and lack of funding [48]. Because of such contextual factors, team-based approaches to improving quality and safety, as emphasized by the SSORT, may lead to greater success [49].

The SSORT should be used one to two weeks after the change intervention has been proposed to facility members. This timeframe will

<table>
<thead>
<tr>
<th>Table 2</th>
<th>SSORT domains and descriptions.</th>
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<tbody>
<tr>
<td>Domain</td>
<td>Description</td>
</tr>
<tr>
<td>Discrepancy</td>
<td>Belief that the facility is in need of change.</td>
</tr>
<tr>
<td>Appropriateness</td>
<td>Belief that the proposed change is appropriate in addressing discrepancy.</td>
</tr>
<tr>
<td>Individual efficacy</td>
<td>Individual belief that the person has the ability to perform necessary tasks successfully with respect to the proposed change.</td>
</tr>
<tr>
<td>Individual valence</td>
<td>Measures whether the individual values the proposed change.</td>
</tr>
<tr>
<td>Emotional reaction</td>
<td>Measures whether the individual feels positively toward the proposed change.</td>
</tr>
<tr>
<td>Resistance to change</td>
<td>Measures whether the person may resist change.</td>
</tr>
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Table 2 (continued)

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<tr>
<th>Domain</th>
<th>Description</th>
<th>Items</th>
<th>Item sources</th>
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</table>
| Team efficacy                           | Team level belief in ability to perform necessary tasks successfully with respect to the proposed change. | ● I would rather not change the way I do things at work.  
● Achieving this change as a team is well within our reach.  
● This team can support its members as they adjust to change.  
● This team can handle the challenges that might arise in implementing this change.  
● This team can coordinate tasks so that implementation goes smoothly.                                                                 | (Edmondson, 1999 [36]; Shea et al., 2014 [37])                                                                                                                                            |
| Team valence                            | Measures whether the team values the proposed change. | ● This team believes this change will be beneficial for our facility.  
● This team wants to implement this change.  
● This team values this change.  
● If you make a mistake on this team, it is often held against you.  
● Members of this team are able to bring up problems and tough issues.  
● It is safe to take a risk on this team.  
● It is difficult to ask other members of this team for help.  
● This team looks for opportunities to develop new skills and knowledge.  
● This team likes challenging and difficult assignments that teach new things.  
● This team is willing to take risks on new ideas in order to find out what works.  
● This team sees learning and developing skills as very important.  
● In this facility, people are open to alternative ways of getting work done.  
● In this facility, people value new ideas.  
● This facility frequently seeks new information that leads us to decision makers actively involved with the changes.  
● Our facility’s top decision makers have put all their support behind this change effort.                                                                 | (Shea et al., 2014 [37])                                                                                                                                                                                      |
| Psychological safety                    | Shared team belief that it is safe to take risks, characterized by interpersonal trust and respect. | ● Our leaders and officers would agree that formal leaders have explicitly bought in and support the proposed change.  
● Our leaders believe the facility can sustain the proposed change long-term and institutionalize changes.  
● Our leaders have a long-term vision beyond this change to strengthen our facility.  
● Our leaders and staff are committed to ensure the success of this change moving forward.  
● This change aligns well with the priorities of national, regional, and district medical officers.  
● Our senior leaders have encouraged all of us to embrace this change.  
● Information provided to us about the change is clear.  
● We are sufficiently informed of the progress of change.  
● Our leaders are able to address concerns and provide clarity about the change process.                                                                 | (Holt et al., 2007 [32]; Boukennooghe et al., 2009 [33])                                                                                                                                                    |
| Team learning orientation                | Shared team belief that team behaviors facilitate learning. | ● Communication about change  
● Measures factory about change  
● Attitudes toward communication about the proposed change within the facility.  
● Make important changes.  
● Our senior leaders have encouraged all of us to embrace this change.  
● Information provided to us about the change is clear.  
● We are sufficiently informed of the progress of change.  
● Our leaders are able to address concerns and provide clarity about the change process.  
● Facility members were sufficiently consulted during the design of this change.  
● Leaders (Holt et al., 2007 [32]; Boukennooghe et al., 2009 [33])  
● Facility members (Shea et al., 2007 [31])  
● Regional, and district medical officers.  
● National, regional, and district medical officers would support this change and commit to its success.                                                                 | (Holt et al., 2007 [32]; Boukennooghe et al., 2009 [33])                                                                                                                                                    |

(continued on next page)
SSORT should be used to better characterize the readiness of facilities for interventions only in facilities that are more prepared for change, the widen existing disparities. Instead of comparing facilities and pursuing tantly, the SSORT should not be used as a screening tool that could members to have both formal and informal discussions about the allow time for knowledge about the intervention to spread, and facility members to have both formal and informal discussions about the intervention, providing more meaningful inputs for the SSORT. Importantly, the SSORT should not be used as a screening tool that could widen existing disparities. Instead of comparing facilities and pursuing interventions only in facilities that are more prepared for change, the SSORT should be used to better characterize the readiness of facilities for planned interventions.

Data for the SSORT can be collected in a few ways. Facility leaders and change agents may choose to employ electronic or pen-and-paper surveys for self-reporting, or have a designated person set up a time with facility members to go over the tool together. We suggest that along with the items in the SSORT, facility members’ demographic information should also be recorded. Specifically, data on age, gender, role at the facility and in a team, tenure in that role, and tenure at the facility can be analytically helpful. For instance, collecting data on team membership can help an analyst reconstruct teams, thereby allowing facility leaders to compare team-level measures across groups and role measures across the facility.

### Table 2 (continued)

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<thead>
<tr>
<th>Domain</th>
<th>Description</th>
<th>Items</th>
<th>Item sources</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facility capacity</td>
<td>Beliefs regarding organizational resource availability related to funds, human resources, equipment and supplies, infrastructure, and information management.</td>
<td>• This change clashes with national, regional, and district policies. • This facility has enough funds to make this change work. • We have the right staff in this facility to make this change work. • This facility can manage the data and information necessary to make this change work. • This facility has the infrastructure to implement this change. • This facility has the right equipment and supplies to implement this change.</td>
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Surgical leaders can use the SSORT as a diagnostic tool of self-reported readiness measures, which can be complemented by other quantitative tools that place an emphasis on measuring facility capacity. For instance, the Surgical Assessment Tool can be used to assess elements regarding infrastructure, service delivery, workforce, information management, and financing [50]. The SSORT would provide surgeons with additional context-specific data regarding their teams’ beliefs and attitudes. For instance, the SSORT could reveal that while surgical team members believe their facility capacity for change is adequate, they do not believe that communication about the change was strong. Surgeons could then work with their teams and facilities to tailor implementation by providing more information and addressing concerns about the change.

Many organizational readiness tools exist, though they have either been developed for and in high-income country settings or for non-healthcare/non-surgical settings. LMICs contexts provide unique challenges when implementing interventions [51]. SSORT employs findings from a study of surgical facilities in a LMIC to better respond to some of these challenges. Organizational context assessments in LMICs also exist [52,53], though combining inductive and deductive approaches led to the discovery of cultural domains that are relevant to implementation success that do not exist in such tools. Namely, the importance of team-level learning measures and concern for sustainability of interventions are some new additions the SSORT makes to the literature on readiness.

#### 4.1. Limitations

The SSORT has not yet been tested in the field. It’s reliability and construct validity have not yet been tested. Hence, it is still a preliminary tool that is being actively tested. Future directions include pilot testing, as well as assessing reliability and construct and criterion validation which will likely result in refinements. Further, the SSORT assesses facility member perceptions and offers insight into their cultural habits, values, and basic assumptions, and is not a collection tool for measuring hospital size, capacity, or other metric measurable through direct observation. Lastly, there are other factors that may be important for the successful implementation of safety and quality interventions that the SSORT is not intended to measure, such as change agent characteristics, the initial introduction of the change intervention, gender and professional dynamics, and resource availability. Such factors would require measurements relying on archival sources, observations, or interviews with facility members.

#### 5. Conclusion

This paper describes the development and content validation of the Safe Surgery Organizational Readiness Tool, a theory- and evidence-based tool designed to assess the readiness of surgical care facilities in low- and middle-income countries to implement surgical safety and quality improvement interventions. We hope that this tool will serve to aid global surgical initiatives and enable more effective implementation of interventions in low- and middle-income countries by facilitating the recognition and mitigation of barriers to implementation. To this end, the research team plans to assess the reliability and validity of the Safe Surgery Organizational Readiness Tool by testing the tool’s psychometric properties, which will likely result in refinements. Further work will also address and provide guidelines for how the Safe Surgery Organizational Readiness Tool can be used in surgical facilities to remedy readiness weaknesses and strengthen surgical quality and safety interventions.

**CRediT authorship contribution statement**

**Tuna C. Hayirli:** Conceptualization, Methodology, Formal analysis, Investigation, Writing – original draft. **John G. Meara:**

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijsu.2021.105944.

“Provenance and peer review

Not commissioned, externally peer-reviewed.

Data statement

All data generated and used in this study is made available as supplementary materials.

International journal of surgery author disclosure form

The following additional information is required for submission. Please note that failure to respond to these questions/statements will mean your submission will be returned. If you have nothing to declare in any of these categories, this should be stated.

Declaration of competing interest


