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Outcomes of a multicomponent safe surgery intervention in Tanzania's Lake Zone: a prospective, longitudinal study

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Abstract

Background: Evidence-based strategies for improving surgical quality and patient outcomes in low-resource settings are a priority.

Objective: To evaluate the impact of a multicomponent safe surgery intervention (Safe Surgery 2020) on (1) adherence to safety practices, teamwork and communication, and documentation in patient files, and (2) incidence of maternal sepsis, postoperative sepsis, and surgical site infection.
Methods: We conducted a prospective, longitudinal study in 10 intervention and 10 control facilities in Tanzania's Lake Zone, across a 3-month pre-intervention period in 2018 and 3-month post-intervention period in 2019. SS2020 is a multicomponent intervention to support four surgical quality areas: (i) leadership and teamwork, (ii) evidence-based surgery, anesthesia and equipment sterilization practices, (iii) data completeness and (iv) infrastructure. Surgical team members received training and mentorship, and each facility received up to a $10 000 infrastructure grant. Inpatients undergoing major surgery and postpartum women were followed during their stay up to 30 days. We assessed adherence to 14 safety and teamwork and communication measures through direct observation in the operating room. We identified maternal sepsis (vaginal or cesarean delivery), postoperative sepsis and SSIs prospectively through daily surveillance and assessed medical record completeness retrospectively through chart review. We compared changes in surgical quality outcomes between intervention and control facilities using difference-in-differences analyses to determine areas of impact.
Results: Safety practices improved significantly by an additional 20.5% (95% confidence interval (CI), 7.2–33.7%; $P = 0.003$) and teamwork and communication conversations by 33.3% (95% CI, 5.7–60.8%; $P = 0.02$) in intervention facilities compared to control facilities. Maternal sepsis rates reduced significantly by 1% (95% CI, 0.1–1.9%; $P = 0.02$). Documentation completeness improved by 41.8% (95% CI, 27.4–56.1%; $P < 0.001$) for sepsis and 22.3% (95% CI, 4.7–39.8%; $P = 0.01$) for SSIs.
Conclusion: Our findings demonstrate the benefit of the SS2020 approach. Improvement was observed in adherence to safety practices, teamwork and communication, and data quality, and there was a reduction in maternal sepsis rates. Our results support the emerging evidence that improving surgical quality in a low-resource setting requires a focus on the surgical system and culture. Investigation in diverse contexts is necessary to confirm and generalize our results and to understand how to adapt the intervention for different settings. Further work is also necessary to assess the long-term effect and sustainability of such interventions.

Key words: surgical quality, surgical site infections, sepsis, surgical safety checklist, data quality, outcomes

Introduction

Poor surgical quality in low- and middle-income countries (LMICs) contributes to significant morbidity and mortality. Patients in Africa are twice as likely to die [1], and women undergoing cesarean delivery are 100 times more likely to die [2] after surgery when compared to their global counterparts. Infection is the most common postoperative complication in African countries; one in 10 patients develop an infection [1], a rate 2–10 times higher than in high-income countries (HICs) [3]. The disparities are worse for women. One in six African women develops a surgical site infection (SSI) following cesarean delivery [4], and one in 10 develops maternal sepsis [5]. Improving surgical quality in LMICs is an urgent priority.

Safe, high-quality surgical care is increasingly asserted as a universal right. Quality should be 'the DNA' of surgical systems [6]. However, improving surgical quality in LMICs is fraught with challenges: a high unmet burden of surgically treatable conditions, insufficient providers, weak health systems, and shortages of essential equipment and supplies.

Postoperative infections are proxies of surgical quality in LMICs [7]. While sepsis and SSIs are preventable, the evidence on how to prevent them in LMICs is low. Data to evaluate impact are derived from single centers, observational studies and retrospectively collected datasets [8]. Interventions to reduce postsurgical infection rates in LMICs are scarce, single-component and largely ineffective [9]. Recent efforts have focused on multicomponent strategies. A study at five African hospitals that combined SSI prevention measures with strategies to improve teamwork and safety climate found a decline in SSI incidence [10]. Another intervention in Ethiopia focusing on teamwork, compliance assessment and process mapping found improved adherence to six perioperative infection standards and a significant decline in postoperative infections [11]. Strengthening surgical systems is essential to improving surgical quality.

Tanzania faces significant challenges in providing high-quality surgical services, including limited use of evidence-based practices [12] and high surgical infection rates [13]. Tanzania was among the first countries to develop a National Surgical, Obstetric, and Anaesthesia Plan [14], garnering significant buy-in to strengthen surgical services. In 2017, Safe Surgery 2020 (SS2020), a multi-partner intervention, initiated an effort in Tanzania's Lake Zone region to reduce maternal sepsis, postoperative sepsis and SSIs. SS2020 in Tanzania was designed following consultation with global surgical experts, scoping visits and drawing lessons from initial implementation in Ethiopia. It was conceived as a multicomponent intervention addressing four surgical quality areas: (i) leadership, teamwork and communication; (ii) evidence-based surgery, anesthesia and equipment sterilization practices; (iii) quality of documentation in patient files and (iv) surgical infrastructure.

To contribute to the evidence on multicomponent interventions in improving adherence to evidence-based practices and reducing postsurgical infections, we began a prospective, longitudinal study in 2018 to evaluate SS2020's impact in Tanzania's Lake Zone. We hypothesized this intervention, implemented at the facility level, would (i) improve safety practice adherence, teamwork and communication, and completeness of documentation in patient files and (ii) reduce the incidence of maternal sepsis (vaginal or cesarean delivery), postoperative sepsis and SSIs.

Methods

Study design

We conducted a longitudinal, prospective study at 10 intervention and 10 control facilities in Tanzania, testing the impact of SS2020 on surgical quality processes and postsurgical and postpartum complications (Figure 1). We have described our methods elsewhere, including sample size and power considerations [15]. We received ethical approval from both Tanzania's National Institute for Medical Research and Harvard Medical School. We obtained verbal informed consent from all participants. We followed the STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) reporting guidelines for this paper.

Study setting and participants

We selected the Lake Zone's Mara and Kagera regions, with a population of 4.7 million, because they are primarily rural (59%) and impoverished (49.1% below the poverty line) [16]. We selected 10 intervention facilities including health centers, district hospitals and regional hospitals after a feasibility assessment by SS2020 and government partners. We selected 10 control facilities in Geita, Shinyanga and Simiyu based on similar socioeconomic, patient and facility characteristics [15].

We enrolled and followed all inpatients who underwent major surgery or delivery for up to 30 days. Based on the World Health Organization consensus definition for maternal sepsis, we included postpartum women who had cesarean or vaginal deliveries [17]. We did not follow patients after discharge. We excluded patients under 5 years of age, patients with minor surgeries, women with spontaneous abortions, visiting surgeons' patients, antenatal patients and surgical outpatients. We used a patient's initial surgery and excluded additional surgeries for the same patient.

Intervention

To facilitate change and embed it in surgical practice, the SS2020 intervention was implemented over 9 months in three phases. The intervention's target group included the surgical team, defined as health-care providers in the operating theater (surgical provider, anesthesia provider and nurses) and doctors and nurses in postsurgical and postnatal wards as infections could occur at any of these points. For some trainings, facility leadership and other staff in the surgical ecosystem (such as biomedical engineers) were also invited (Supplementary Table S1).

Phase 1 focused on changing culture through a week-long training session on leadership, teamwork and communication. Surgical teams also learned quality improvement (QI) techniques, which they used to identify their priorities for improving surgical quality and to develop plans to implement at their facilities over the intervention period.

Phase 2 focused on capacity building around best practices for safe surgery, anesthesia, sterilization and documentation. Training sessions included simulations demonstrating correct use of the Surgical Safety Checklist (SSC), best practices for perioperative infection prevention, safe anesthesia and equipment sterilization practices. Surgical team members also learned about using data for improvement.

Phase 3 focused on facilitating sustainability. Surgical teams received bimonthly mentorship visits from a multidisciplinary team from the zonal hospital, supplemented by virtual mentorship through Project ECHO. Finally, each facility received infrastructure support through a grant of up to $10 000 and a perioperative equipment package.

Outcomes

Outcomes included three process measures: adherence to (i) safety practices, (ii) teamwork and communication conversations and (iii) documentation in files of patients diagnosed with maternal sepsis, postoperative sepsis and SSIs, and three outcome measures: rates of (i) maternal sepsis (vaginal or cesarean delivery), (ii) postoperative sepsis and (iii) SSIs, up to a 30-day postoperative or postpartum hospitalization period. Our study outcomes are described in Supplementary Table S2.

Procedures

We trained 25 Tanzanian physicians to identify and classify our process measures and prespecified complications using standardized data

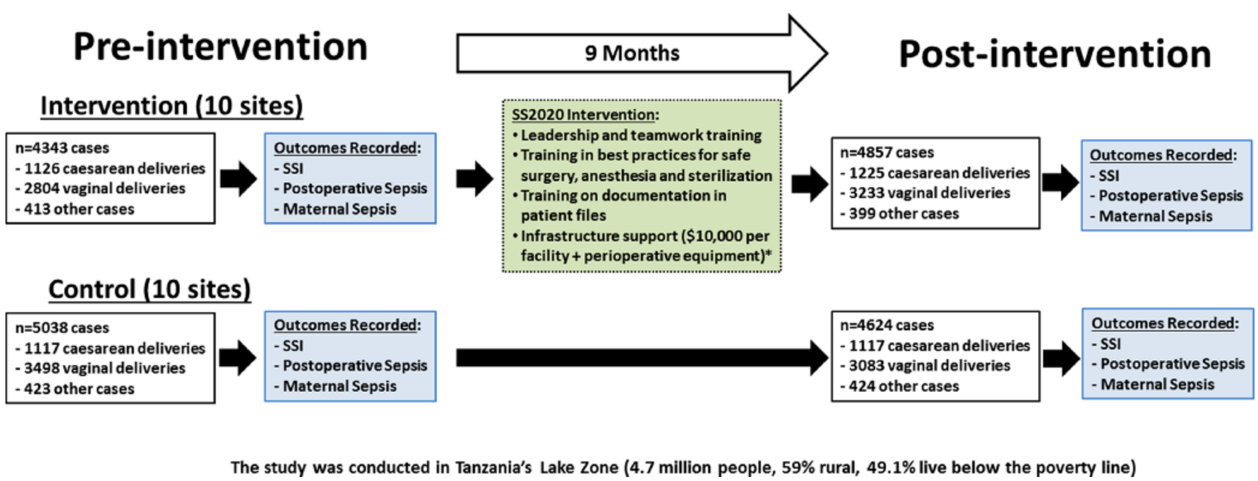

Figure 1 SS2020 Tanzania evaluation.

collection tools and assigned them to the 20 study facilities during the pre-intervention (February–April 2018) and post-intervention (March–May 2019) period. We ensured data quality by training data collectors, creating standardized operating procedures, using an electronic data collection system, and conducting weekly in-person and electronic data quality checks.

Using an adapted SSC Observation Tool [18], data collectors observed and recorded surgical teams' adherence to safety and teamwork and communication measures during surgical procedures. The tool was not used on patients who had vaginal deliveries. Data collectors followed postsurgical and postnatal patients daily until discharge or for 30 days in hospital to check for complications. We adapted postoperative and maternal sepsis tools from existing guidelines [19–21] as described in our study protocol [15]. Data collectors identified outcomes through daily patient surveillance, chart monitoring and discussion with clinical staff using paper-based tools and transferred data electronically into REDCap daily.

We assessed documentation completeness retrospectively, reviewing files of patients diagnosed with maternal sepsis, postoperative sepsis or SSI pre- and post-intervention in four domains: (i) perioperative care, (ii) sepsis diagnosis, (iii) SSI diagnosis and (iv) clinical progress [22]. Due to resource constraints, our assessment was conducted only in intervention regions.

Statistical analysis

To evaluate the SS2020 intervention's impact on surgical quality processes and maternal sepsis, postoperative sepsis and SSIs in intervention facilities as compared to the control facilities from the pre-intervention to post-intervention period, we conducted difference-in-differences analyses. Analyses were based on the assumption that trends in adherence to safety practices and teamwork and communication conversations, maternal sepsis, postoperative sepsis and SSIs would have been parallel in intervention and control facilities had the SS2020 intervention not occurred. To investigate this assumption, we conducted a visual assessment of trends in each outcome over time by intervention status. There were no statistically significant differences in pre-intervention trends between intervention and control facilities except for SSIs (Supplementary Figure S1 and Supplementary Table S3).

Multivariable difference-in-differences regression models were implemented for determining intervention effects on patient outcomes using Generalized Estimating Equations (GEEs) with a normal link function and exchangeable correlation structure while adjusting for potential confounders and baseline covariates [23]. To estimate differential changes in outcomes, each model adjusted for a treatment fixed effect to account for time constant differences between intervention and control facilities, a linear time trend to account for changes over time and important patient characteristics such as procedure type and age. Robust 'sandwich' standard errors were calculated using a first iterated jackknife procedure. Results from regression models are reported using adjusted estimates for group differences in changes from pre-intervention to post-intervention with corresponding 95% confidence intervals (CIs). We performed statistical analyses using R (version 3.5.2, R Foundation for Statistical Computing, Vienna, Austria). Analyses of all outcomes used two-tailed *a priori* criteria of $P < 0.05$ to establish statistical significance as described in our study protocol [15]. One deviation from the study protocol was the use of GEEs instead of a generalized linear model to calculate the difference-in-difference estimates. The GEE estimates account for the fact that the treatment was clustered at the hospital level and there were a relatively small number of hospitals ($n = 20$). Results from regression models are reported using adjusted estimates for group differences in changes from pre-intervention to post-intervention with corresponding 95% CIs.

Results

Facility and patient characteristics

Characteristics of the 10 intervention and 10 control facilities are shown in Table 1. The majority were district hospitals (55%) and government-operated hospitals (75%), with 101–300 inpatient beds (65%). There were no differences in characteristics between intervention and control facilities before or after the intervention. We enrolled 9381 patients during the pre-intervention period and 9483 patients after the implementation of SS2020. Pre-intervention, there were no statistically significant differences between patients in the intervention and control facilities except for American Society of Anesthesiology (ASA) score and procedure type. Post-intervention, there were no differences except for gender, age, wound class and ASA score (Supplementary Table S4).

Adherence to safety practices

Table 2 shows changes in safety practices before and after SS2020. After the intervention, surgical teams in intervention facilities performed, on average, 69.4% of the six-measured safety practices, whereas surgical teams in control facilities performed 44.4% of the practices. Adherence to the composite safety indicator increased by 20.5% more (95% CI, 7.2–33.7%; $P = 0.003$) in intervention facilities compared to control facilities. Surgical teams performed instrument, sponge and needle counts at significantly higher rates in intervention facilities than in control facilities (43.5%; 95% CI, 22.2–64.8%; $P < 0.001$) (Supplementary Table S5). After intervention, adherence to safety measures ranged from 43.9% to 99.6% in intervention facilities compared to 0.3–80.8% in control facilities.

Adherence to teamwork and communication conversations

Table 2 shows changes in teamwork and communication conversations before and after introducing SS2020. After intervention, surgical teams at intervention facilities performed, on average, 49.0% of the eight measured teamwork and communication conversation items, whereas teams at control facilities performed 11.6% of the items. Adherence to the composite teamwork and communication indicator increased by 33.3% (95% CI, 5.7–60.8%; $P = 0.02$) in intervention facilities compared to control facilities. Surgical teams discussed risk of airway difficulty or aspiration (47.4%; 95% CI, 24–70.8%; $P < 0.001$), risk of blood loss (47.2%; 95% CI, 28.2–66.2%; $P < 0.001$), postoperative recovery concerns (39.1%; 95% CI, 14.4–63.8%; $P = 0.002$), equipment problems during surgery (41.5%; 95% CI, 16.8–66.2%; $P < 0.001$) and sterility of equipment (52.8%; 95% CI, 33.9–71.8%; $P < 0.001$) at significantly higher rates in the intervention facilities than in the control facilities (Supplementary Table S5). After intervention, adherence to teamwork and communication measures ranged from 12.5% to 99.8% in intervention facilities compared to 0–36.6% in control facilities.

Completeness of documentation in patient files

We identified 157 and 53 maternal sepsis, postoperative sepsis and SSI cases in the pre-intervention and post-intervention periods, respectively. After intervention, documentation of sepsis diagnosis and two or more vital signs for sepsis was 41.8% higher (95% CI,

Table 1 Baseline facility and patient characteristics

	Intervention	Control	*P*-value
Number of facilities	$n = 10$	$n = 10$	
Type of facility—no. (%)			
Health center	2 (20)	2 (20)	>0.99
District hospital	6 (60)	5 (50)	
Regional referral	2 (20)	3 (30)	
Ownership—no. (%)			
Government	6 (60)	9 (90)	0.30
Faith-based	4 (40)	1 (10)	
No. of beds—no. (%)			
0–100	3 (30)	2 (20)	>0.99
101–300	6 (60)	7 (70)	
300+	1 (10)	1 (10)	
Monthly major surgical volume per facility			
Total	90	75	
Bellwether procedures			
Cesarean delivery	37	38	0.66
Laparotomy	6	8	
Open fracture repair	0	0	
Patient sample with SSC observation completed	$n = 626$	$n = 611$	
Sex (Female)—no. (%)	541 (86)	526 (86)	0.93
Age—no. (%)			
Less than 18 years	46 (7.4)	34 (5.6)	0.93
Between 18 and 34 years	385 (61.5)	387 (63.3)	
Greater than 34 years	195 (31.2)	190 (31.1)	
Urgency of operation—no. (%)			
Emergency	440 (70.3)	438 (71.7)	0.63
Wound classification—no. (%)[a]			
Clean	93 (14.9)	73 (11.9)	0.07
Contaminated	22 (3.5)	34 (5.6)	
Clean-contaminated	494 (78.9)	494 (80.9)	
Dirty	17 (2.7)	9 (1.5)	
ASA score—no. (%)			
1	189 (30.2)	138 (22.6)	0.004[b]
2	421 (67.3)	442 (72.3)	
3	14 (2.2)	26 (4.3)	
4	1 (0.2)	4 (0.7)	
5	1 (0.2)	1 (0.2)	
Patient sample with SSI/sepsis outcomes recorded	$n = 4343$	$n = 5038$	
Sex (Female)—no. (%)	4191 (96.5)	4881 (96.9)	0.33
Age categories—no. (%)			
Less than 18 years	242 (5.6)	285 (5.7)	0.95
Between 18 and 34 years	3455 (79.6)	3995 (79.3)	
Greater than 34 years	646 (14.9)	758 (15.0)	
Procedure type—no. (%)			
Cesarean delivery	1126 (25.9)	1117 (22.2)	<0.001[b]
Laparotomy	180 (4.1)	219 (4.3)	
Spontaneous vaginal delivery (SVD)	2804 (64.6)	3498 (69.4)	
Open reduction internal fixation	1 (0.0)	0 (0)	
Other procedures	232 (5.4)	204 (4.0)	
Maternal characteristics	$n = 3930$	$n = 4615$	
Age categories—no. (%)			
Less than 18 years	201 (5.1)	259 (5.6)	0.43
Between 18 and 34 years	3311 (84.2)	3843 (83.3)	
Greater than 34 years	418 (10.6)	513 (11.1)	
Procedure—no. (%)			
Cesarean section	1126 (28.7)	1117 (24.2)	<0.001[b]
SVD	2804 (71.3)	3498 (75.8)	

[a]The wound class for one patient was missing.
[b]Statistically significant.

Table 2 Adherence to safety practices and teamwork and communication

	Pre		Post				
	Intervention ($n = 626$)	Control ($n = 611$)	Intervention ($n = 683$)	Control ($n = 791$)	Adjusted difference[a]	95% CI	*P*-value
Overall adherence (full SSC with 35 items)	12.2%	15.8%	56.9%	24.6%	29.1%	(9.4%, 48.8%)	0.004[b]
Safety adherence	35.0%	37.1%	69.4%	44.4%	20.5%	(7.2%, 33.7%)	0.003[b]
Teamwork and communication adherence	0.9%	5.0%	49.0%	11.6%	33.3%	(5.7%, 60.8%)	0.02[b]

[a]Adjusted for age, procedure type, baseline differences and common changes over time.
[b]Statistically significant.

Table 3 Completeness of files of patients diagnosed with maternal sepsis, postoperative sepsis or SSI

	Pre	Post	Difference (95% CI)	*P*-value
Total maternal sepsis, postoperative sepsis and SSI cases	$n = 157$	$n = 53$		
Patient files found—No. (%)	107 (68)	44 (81)		0.07
Perioperative documentation[a,b]	86.8%	88.4%	1.6% (−9.6%, 12.8%)	0.78
Sepsis documentation[a,c]	43.2%	85.0%	41.8% (27.4%, 56.1%)	<0.001[d]
SSI documentation[a,e]	45.2%	67.5%	22.3% (4.7%, 39.8%)	0.01[d]
Clinical progress documentation[a,f]	54.4%	51.2%	−3.2% (−13.3%, 6.8%)	0.5

[a]Among files found.
[b]Perioperative documentation: post-op notes, indication of cesarean section.
[c]Sepsis documentation: The clinician's notes include a keyword 'sepsis' and two or more of the following criteria: temperature, heart rate, systolic blood pressure and respiratory rate.
[d]Statistically significant.
[e]SSI documentation: The clinician's notes include any combination of the following keywords: 'pus draining from the wound,' 'closed wound opened,' 'wound with a foul smell' and 'wound infection' and one or more of the following symptoms: heat, redness, localized tenderness, purulent drainage, spontaneous dehiscence and operative findings indicative of infection.
[f]Clinical progress documentation: patient history included, daily progress notes are written (every day patient was in the ward), doctors' order documented (every day) and partogram utilized (among obstetric patients).

27.4–56.1%; $P < 0.001$) and documentation of SSI diagnosis and one or more symptoms of SSI was 22.3% higher (95% CI, 4.7–39.8%; $P = 0.01$) (Table 3).

Maternal sepsis, postoperative sepsis and SSIs

We found a statistically significant difference between intervention and control facilities' rates of maternal sepsis in the post-intervention period. After intervention, maternal sepsis rates in intervention facilities were, on average, 0.3%; control facilities' rates were 1.1%. Maternal sepsis rates decreased by an additional 1.0% (95% CI, 0.1–1.9%; $P = 0.02$) in intervention facilities compared to control facilities (Table 4).

At 10 months, the maternal sepsis rate among cesarean deliveries for intervention sites experienced a 2.3% greater reduction than control sites (−3.9% vs. −1.6%). For vaginal deliveries where the maternal sepsis rate is extremely low, intervention sites and controls sites had similar rate reductions (−0.76% and −0.5%, respectively) (Supplementary Table S6).

Discussion

Statement of principal findings

We tested a multicomponent intervention to improve surgical quality. After intervention, safety practices in intervention facilities improved significantly by an additional 20.5%, teamwork and communication conversations improved by 33.3%, documentation of sepsis and SSI diagnosis in patient files improved by 41.8% and 22.3% respectively, and maternal sepsis rates were reduced by 1.0%. Our study supports the effectiveness of multicomponent interventions in improving surgical quality in LMICs [10, 11, 24, 25]. To our knowledge, this is one of the largest prospective, longitudinal, multi-site studies focused on safety adherence, teamwork and communication, data quality, sepsis and SSIs in sub-Saharan Africa.

Interpretation within the context of the wider literature

We found significant improvement in adherence to safety practices and teamwork and communication conversations after intervention. Overall adherence was greater with safety practices compared to teamwork and communication conversations, both before and after the intervention, consistent with findings in HICs [26]. Higher adherence to safety practices has been attributed to safety checks being deeply ingrained in surgical practice [26]. In contrast, adherence to teamwork and communication conversations may be hindered by entrenched surgical hierarchies, which may be more pronounced in LMICs [27]. However, the magnitude of change in adherence was greater for teamwork and communication measures,

Table 4 Outcomes of surgical patients and postpartum women

	Pre		Post		Adjusted		
	Intervention	Control	Intervention	Control	Difference[a]	95% CI	*P*-value
Maternal sepsis[b]	78/3930 (2.0%)	69/4615 (1.5%)	12/4458 (0.3%)	46/4201 (1.1%)	−1.0%	(−1.9%, −0.1%)	0.02[c]
Postoperative sepsis[d]	25/413 (5.8%)	29/423 (6.9%)	6/401 (1.5%)	12/423 (2.8%)	−0.07%	(−0.4%, 0.2%)	0.96
SSI[e]	113/1539 (7.3%)	129/1540 (8.4%)	73/1626 (4.5%)	76/1542 (5%)	0.04%	(−1.5%, 1.6%)	0.61

[a]Adjusted for age, procedure type, baseline differences and common changes over time.
[b]Maternal sepsis cases are women who have had a spontaneous vaginal delivery or a cesarean section.
[c]Statistically significant.
[d]Postoperative sepsis cases are surgical patients who have not had a spontaneous vaginal delivery or a cesarean section.
[e]SSI cases are surgical patients who have not had a spontaneous vaginal delivery.

possibly due to training and reinforcement of teamwork practices by mentors. Teamwork in the operating room is essential for surgical excellence [28]. Training surgical providers in LMICs in teamwork and communication is even more important for patient safety because they work in environments with high disease burden, insufficient personnel and inadequate equipment and supplies.

Pre-intervention, maternal sepsis, postoperative sepsis and SSI were poorly documented in patient records [29]. After intervention, documentation of sepsis and SSI diagnosis and care improved. While data strengthening and mentoring efforts may have contributed, our clinical interventions may also have helped increase awareness of SSI and sepsis. Improving documentation in patient files is key to enhancing patient management and continuity of care.

Maternal sepsis rates reduced significantly. While we were not powered to examine maternal sepsis in cesarean and vaginal deliveries separately, and it was not the primary objective of our study, a subgroup analysis showed that maternal sepsis rate among cesarean deliveries for intervention sites experienced a greater reduction compared to control sites. The clinical training on safe cesarean deliveries, sterilization techniques, infection prevention, appropriate antibiotic use and postoperative care may have contributed to these results. Improved teamwork, communication and the inculcation of a strong safety culture may have also contributed to this reduction; in a separate analysis, we saw a significant association between greater teamwork and communication and lower maternal sepsis. Maternal sepsis accounts for a substantial portion of pregnancy-related morbidity and mortality [30]. Importantly, a 1% reduction in the maternal sepsis rates among women aged 15–49 years in Tanzania would correspond to a reduction of 135 736 maternal sepsis cases and 10 451 deaths.

Despite reductions in SSI and postoperative sepsis rates, the changes were not statistically significant. A potential explanation is that control facilities also improved during the same period. We were aware of at least one trained provider who moved from an intervention to a control site. Additionally, study investigators brought the high rates of surgical infections in one control facility to the attention of regional and facility leadership, which may have resulted in improved infection prevention measures. QI interventions need time; our post-intervention assessment may have occurred too soon after intervention to see its full effect. Finally, while SS2020 may have had a catalytic effect on safety practices and teamwork, fixing systemic challenges and resource constraints were beyond the intervention's scope [31]. For example, the lack of adequate staff, sterilization materials, running water or antibiotics could be detrimental to patient outcomes, regardless of adherence to safe practices.

Strengths and limitations

The key strengths of our study include its multicenter, longitudinal, quasi-experimental study design to provide high-quality evidence about the effectiveness of the SS2020 intervention and the prospective data collection by trained Tanzanian medical data collectors with weekly data quality checks to collect high-quality primary data. Our study has several limitations. Our findings need to be confirmed in more diverse contexts, with longer follow-up periods. Despite selecting intervention and control sites with similar characteristics, the analyses rely on the parallel trend assumption, which is untestable. Thus, we cannot exclude the possibility of selection bias in our results. While cluster randomization could have reduced bias and confounding, we prioritized geographic separation in selecting control and intervention facilities to minimize cross-contamination. Due to resource and logistical constraints, our study captured inpatient cases of maternal sepsis, postoperative sepsis and SSIs only. Improvements could be a result of surgical teams being observed—the Hawthorne Effect. Lastly, we were unable to control for ASA, wound class or underlying patient conditions such as diabetes and HIV, which might have predisposed them to infections because a smaller subsample of patients had the information.

Implications for policy and practice

Our results have important implications for policy makers, intervention designers and practitioners. The predominant approach to surgical infection prevention in LMICs is on appropriate antibiotic prophylaxis; however, the causes of postsurgical infections are multifactorial and require a multimodal approach [10, 25]. Our approach combined (i) capacity building in the infection prevention bundle, proper sterilization and SSC use; (ii) capacity building in monitoring processes and outcomes; (iii) systems change through equipment support and (iv) promoting a culture of teamwork and patient safety.

Although our results suggest that SS2020 is transforming practice and culture, it is not a turnkey effort. Many of our facilities did not have a quality infrastructure such as the use of teams, data and internal training for improvement at the start [32]. Our results suggest that training surgical providers in technical and non-technical skills combined with follow-up mentorship can help surgical teams to improve practice and culture. A shift in health policy to include elements of such training is key to building this quality infrastructure.

Conclusion

Postsurgical infection rates in LMICs are unacceptably high. Implementation of SS2020, including strategies such as the SSC, infection prevention bundle and proper sterilization, combined with data use and infrastructural improvements, embedded in a culture of teamwork and patient safety, resulted in significant improvements in safety processes, teamwork and communication; completion of patient records; and a reduction in maternal sepsis rates in Tanzania. A multicomponent intervention is a promising approach for facilitating the practice and cultural changes necessary to improving surgical quality.

Supplementary material

Supplementary material is available at *International Journal for Quality in Health Care* online.

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Data availability

All requests for data must be approved by the Tanzania Ministry of Health, Community Development, Gender, Elderly and Children, in accordance with the data sharing agreement.

Contributorship

Study concept and design: W.L., S.A., G.M., I.C., S.S., E.B., A.H., J.G.M., S.K., C.P.R., D.Z., S.M., N.K., S.A.K., D.J., E.M., A.T. and J.V. Acquisition, analysis and interpretation of data: S.A., G.M., L.K., S.S., A.M., C.S., M.S., T.W., D.Z., S.S.A., A.D., D.J., S.K., T.L., W.L. and I.N.. Drafting of the manuscript: S.A., G.M., L.K., S.S., I.N. and D.Z. with input from T.W., S.A., D.B., E.B., A.H., S.K., F.M., A.M., J.G.M., C.P.R., C.S., M.S., F.T., M.U., N.K., S.M., M.C., I.C., A.D., E.E., L.F., H.G., M.G., D.J., A.K., S.A.K., T.W., E.M., S.M., C.R., H.S., D.S., V.S., L.T., A.T., J.V. and N.Z. Critical revision of the manuscript for important intellectual content and approval of the final version to be published: S.A., G.M., S.S., T.W., L.K., S.A., D.B., E.B., A.H., S.K., F.M., A.M., J.G.M., I.N., C.P.R., C.S., M.S., F.T., M.U., D.Z., N.K., S.M., M.C., I.C., A.D., E.E., L.F., H.G., M.G., D.J., A.K., S.A.K., T.W., E.M., S.M., C.R., H.S., D.S., V.S., L.T., A.T., J.V. and N.Z. Statistical analysis: I.N., S.S., T.W., L.K., S.S.A. and D.Z. Obtained funding: J.G.M., E.B., C.P.R. and J.V. Study supervision: S.A., G.M., D.Z. and J.G.M.

Ethics and other permissions

We obtained ethical approval from both Harvard Medical School and Tanzania's National Institute for Medical Research. We obtained verbal informed consent in Swahili from all participants and parental consent for patients under the age of 18 years.

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