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. We evaluated the impact of a multicomponent safe surgery intervention (Safe Surgery 2020) in Tanzania, hypothesizing it would (1) increase adherence to safety practices, teamwork and communication, and documentation in patient files, and (2) reduce the 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 three-month pre-intervention period in 2018 and three-month post-intervention period in 2019. Safe Surgery 2020 is a multicomponent intervention to support four surgical quality areas: 1) leadership and teamwork, 2) evidence-based surgery, anaesthesia, and equipment sterilization practices, 3) data completeness, and 4) 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 caesarean delivery), postoperative sepsis, and surgical site infections 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% CI, 7.2%-33.7%; *P*=.003) and teamwork and communication conversations by 33.3% (95% CI, 5.7%-60.8%; *P*=.02) in intervention facilities compared to control facilities. Maternal sepsis rates reduced significantly by 1% (95% CI, 0.1%-1.9%; *P*=.02). Documentation completeness improved by 41.8% (95% CI, 27.4%-56.1%; *P*<.001) for sepsis and 22.3% (95% CI, 4.7%-39.8%; *P*=.01) for surgical site infections.

**Conclusion**

Our findings demonstrate the benefit of the Safe Surgery 2020 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 caesarean 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 ten patients develops an infection [1], a rate two to ten 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 caesarean delivery [4], and one in ten 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: 1) leadership, teamwork and communication; 2) evidence-based surgery, anaesthesia, and equipment sterilization practices; 3) quality of documentation in patient files; and 4) 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 1) improve safety practice adherence, teamwork and communication, and completeness of documentation in patient files, and 2) reduce the incidence of maternal sepsis (vaginal or caesarean 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 (anonymized). We obtained verbal informed consent from all participants. We followed the 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 caesarean or vaginal deliveries [17]. We did not follow patients after discharge. We excluded patients under five 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 nine months in three phases. The intervention's target group included the surgical team, defined as healthcare providers in the operating theatre (surgical provider, anaesthesia provider, 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 1).

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, anaesthesia, sterilization, and documentation. Training sessions included simulations demonstrating correct use of the Surgical Safety Checklist (SSC), best practices for perioperative infection prevention, safe anaesthesia, and equipment sterilization practices. Surgical team members also learned about using data for improvement.

Phase 3 focused on facilitating sustainability. Surgical teams received bi-monthly 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 3 process measures: adherence to 1) safety practices, 2) teamwork and communication conversations, and 3) documentation in files of patients diagnosed with maternal sepsis, postoperative sepsis, and SSIs, and 3 outcome measures: rates of 1) maternal sepsis (vaginal or caesarean delivery), 2) postoperative sepsis, and 3) SSIs, up to a 30-day postoperative or postpartum hospitalization period. Our study outcomes are described in Supplementary Table 2.

Procedures

We trained 25 Tanzanian physicians to identify and classify our process measures and pre-specified complications using standardized data collection tools and assigned them to the 20 study facilities during the pre-intervention (February to April 2018) and post-intervention (March to 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: 1) perioperative care, 2) sepsis diagnosis, 3) SSI diagnosis, and 4) 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 1 and Supplementary Table 3).

Multivariable difference-in-differences regression models were implemented for determining intervention effects on patient outcomes using Generalized Estimating Equations (GEE) 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. We performed statistical analyses using R (version 3.5.2, R Foundation for Statistical Computing, Vienna, Austria). Analyses of all outcomes used a two-tailed *a priori* criteria of $P<.05$ to establish statistical significance as described in our study protocol [15]. One deviation from the study protocol was the use of generalized estimating equations (GEE) 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% confidence intervals.

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 (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 9,381 patients during the pre-intervention period and 9,483 patients after the implementation of SS2020. Pre-intervention, there were no statistically significant differences between patients in the intervention and control facilities except for ASA score and procedure type. Post-intervention, there were no differences except for gender, age, wound class, and ASA score (Supplementary Table 4).
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% to 33.7%; \( P = .003 \)) 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% to 64.8%; \( P < .001 \)) (Supplementary Table 5). After intervention, adherence to safety measures ranged from 43.9% to 99.6% in intervention facilities compared to 0.3% to 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% more (95% CI, 5.7% to 60.8%; \( P = .02 \)) in intervention facilities compared to control facilities. Surgical teams discussed risk of airway difficulty or aspiration (47.4%; 95% CI, 24% to 70.8%; \( P < .001 \)), risk of blood loss (47.2%; 95% CI, 28.2% to 66.2%; \( P < .001 \)), postoperative recovery concerns (39.1%; 95% CI, 14.4% to 63.8%; \( P = .002 \)), equipment problems during surgery (41.5%; 95% CI, 16.8% to 66.2%; \( P < .001 \)), and sterility of equipment (52.8%; 95% CI, 33.9% to 71.8%; \( P < .001 \)) at
significantly higher rates in the intervention facilities than in the control facilities (Supplementary Table 5). After intervention, adherence to teamwork and communication measures ranged from 12.5% to 99.8% in intervention facilities compared to 0% to 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, 27.4% to 56.1%; \( P < .001 \)) and documentation of SSI diagnosis and one or more symptoms of SSI was 22.3% higher (95% CI, 4.7% to 39.8%; \( P = .01 \)) (Table 3).

Maternal Sepsis, Postoperative Sepsis and Surgical Site Infections

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% to 1.9%; \( P = .02 \)) in intervention facilities compared to control facilities (Table 4).

At 10 months, the maternal sepsis rate among caesarean 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 6).
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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, possibly due to training and reinforcement of teamwork practices by mentors. Teamwork in the OR 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 caesarean and vaginal deliveries separately, and it was not the primary objective of our study, a subgroup analysis showed maternal sepsis rate among caesarean deliveries for intervention sites experienced a greater reduction compared to control sites. The clinical training on safe caesarean 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 age 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. Quality improvement 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
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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 1) capacity building in the infection prevention bundle, proper sterilization, and SSC use; 2) capacity building in monitoring processes and outcomes; 3) systems change through equipment support; and 4) 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 with training focusing on leadership, teamwork and communication; technical skills such as safe surgery, anaesthesia and sterilization; and data quality, combined with in-person and virtual 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
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and patient safety resulted in significant improvements in safety processes, teamwork and communication, and 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.
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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.
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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      |         |
| Laparotomy                     | 6            | 8       | 0.66    |
| Open Fracture Repair           | 0            | 0       |         |
| **Patient Sample with SSC Observation Completed** | n=626       | n=611   |         |
| Sex (Female) – no. (%)         | 541 (86)     | 526 (86)| .93     |
| Age – no. (%)                  |              |         |         |
| Less than 18 years             | 46 (7.4)     | 34 (5.6)|         |
| Between 18 and 34 years        | 385 (61.5)   | 387 (63.3)| .93   |
| Greater than 34 years          | 195 (31.2)   | 190 (31.1)|       |

*Statistically significant
### Table 1. Baseline Facility and Patient Characteristics (continued)

|                                | Intervention     | Control        | P Value |
|--------------------------------|------------------|----------------|---------|
| **Urgency of operation – No. (%)** |                  |                |         |
| Emergency                      | 440 (70.3)       | 438 (71.7)     | .63     |
| **Wound classification – no. (%)** |                  |                |         |
| Clean                          | 93 (14.9)        | 73 (11.9)      |         |
| Contaminated                   | 22 (3.5)         | 34 (5.6)       | .07     |
| 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)     |         |
| 2                              | 421 (67.3)       | 442 (72.3)     |         |
| 3                              | 14 (2.2)         | 26 (4.3)       | .004*   |
| 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. (%)**     |                  |                |         |
| 1                              | 4191 (96.5)      | 4881 (96.9)    | .33     |
| **Age categories – no. (%)**   |                  |                |         |
| Less than 18 years             | 242 (5.6)        | 285 (5.7)      | .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. (%)**   |                  |                |         |
| Caesarean delivery             | 1126 (25.9)      | 1117 (22.2)    |         |
| Laparotomy                     | 180 (4.1)        | 219 (4.3)      | <.001*  |
| SVD                            | 2804 (64.6)      | 3498 (69.4)    |         |
| Open reduction internal fixation | 1 (0.0)         | 0 (0)          |         |

*a Statistically significant

b The wound class for one patient was missing
Table 1. Baseline Facility and Patient Characteristics (continued)

|                                | Intervention | Control | P Value |
|--------------------------------|--------------|---------|---------|
| Other procedures              | 232 (5.4)    | 204 (4.0) |        |
| **Maternal Characteristics**  |              |         |         |
| Age categories – no. (%)      |              |         |         |
| Less than 18 years            | 201 (5.1)    | 259 (5.6) | .43 |
| Between 18 and 34 years       | 3311 (84.2)  | 3843 (83.3) |        |
| Greater than 34 years         | 418 (10.6)   | 513 (11.1) |        |
| **Procedure – no. (%)**       |              |         | .001*   |
| Cesarean section              | 1126 (28.7)  | 1117 (24.2) | <.001* |
| Spontaneous vaginal delivery (SVD) | 2804 (71.3)  | 3498 (75.8) |        |

*Statistically significant
### Table 2. Adherence to Safety Practices and Teamwork and Communication

|                          | Pre       | Post      | Adjusted Difference<sup>b</sup> | 95% Confidence Interval | P Value |
|--------------------------|-----------|-----------|---------------------------------|--------------------------|---------|
|                          | Intervention (n=626) | Control (n=611) | Intervention (n=683) | Control (n=791) |                |         |
| Overall adherence (full SSC with 35 items) | 12.2% | 15.8% | 56.9% | 24.6% | 29.1% | (9.4%, 48.8%) | .004<sup>a</sup> |
| Safety adherence | 35.0% | 37.1% | 69.4% | 44.4% | 20.5% | (7.2%, 33.7%) | .003<sup>a</sup> |
| Teamwork and communication adherence | 0.9% | 5.0% | 49.0% | 14.6% | 33.3% | (5.7%, 60.8%) | .02<sup>a</sup> |

<sup>a</sup>Statistically significant

<sup>b</sup>Adjusted for age, procedure type, baseline differences and common changes over time
Table 3. Completeness of Files of Patients Diagnosed with Maternal Sepsis, Postoperative Sepsis, or Surgical Site Infection

|                                         | Pre  | Post | Difference (95% Confidence Interval) | P Value |
|-----------------------------------------|------|------|--------------------------------------|---------|
| Total maternal sepsis, postoperative sepsis and SSI cases | n=157 | n=53 |                                     |         |
| Patient files found – No. (%)           | 107 (68) | 44 (81) | .07                                 |         |
| Perioperative documentation,\(^{b,c}\)  | 86.8% | 88.4% | 1.6% (-9.6%, 12.8%)                 | .78     |
| Sepsis documentation\(^{b,a}\)         | 43.2% | 85.0% | 41.8% (27.4%, 56.1%)                | <.001\(^a\) |
| SSI documentation\(^{b,e}\)            | 45.2% | 67.5% | 22.3% (4.7%, 39.8%)                 | .01\(^d\) |
| Clinical progress documentation\(^{b,f}\)| 54.4% | 51.2% | -3.2% (-13.3%, 6.8%)                | .5      |

\(^a\)Statistically significant
\(^b\)Among files found
\(^c\)Perioperative documentation: post-op notes, indication of cesarean section
\(^d\)Sepsis documentation: The clinician's notes include a keyword "sepsis" and two or more of the following criteria: Temperature, Heart rate, Systolic BP, and Respiratory rate.
\(^e\)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, operative findings indicative of infection.
\(^f\)Clinical progress documentation: Patient history included, daily progress notes are written (everyday patient was in the ward), Doctors' order documented (everyday), partogram utilized (among obstetric patients).
Table 4. Outcomes of Surgical Patients and Postpartum Women

|                  | Pre     | Post    | Adjusted Difference<sup>b</sup> | 95% Confidence Interval | P Value |
|------------------|---------|---------|----------------------------------|-------------------------|---------|
|                  | Intervention | Control | Intervention | Control |                    |          |
| Maternal sepsis<sup>c</sup> | 78/3930 (2.0%) | 69/4615 (1.5%) | 12/4458 (0.3%) | 46/4201 (1.1%) | -1.0% (-1.9%, -0.1%) | .02<sup>a</sup> |
| Postoperative sepsis<sup>d</sup> | 25/413 (5.8%) | 29/423 (6.9%) | 6/401 (1.5%) | 12/423 (2.8%) | -0.07% (-0.4%, 0.2%) | .96 |
| SSI<sup>e</sup> | 113/1539 (7.3%) | 129/1540 (8.4%) | 73/1626 (4.5%) | 76/1542 (5%) | 0.04% (-1.5%, 1.6%) | .61 |

<sup>a</sup>Statistically significant
<sup>b</sup>Adjusted for age, procedure type, baseline differences and common changes over time
<sup>c</sup>Maternal sepsis cases are women who have had a spontaneous vaginal delivery or a Cesarean Section
<sup>d</sup>Postoperative sepsis cases are surgical patients who have not had a spontaneous vaginal delivery or a Cesarean Section
<sup>e</sup>SSI cases are surgical patients who have not had a spontaneous vaginal delivery.
FIGURES

Figure 1 Safe Surgery 2020 Tanzania Evaluation

SUPPLEMENTARY APPENDICES

Supplementary Appendix 1: Safe Surgery 2020 Intervention

| Intervention                     | Aim                                                                 | Target group                               | Description                                                                                                                                                                                                 |
|---------------------------------|----------------------------------------------------------------------|---------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Leadership course               | To develop leadership, teamwork and communication and problem solving skills to improve surgical safety | One surgical team from each facility was invited to the training. Each team typically consisted of six service providers who were not specialists: a surgeon, assistant surgeon, theatre nurse, anaesthetist, circulating nurse, and a nurse for newborn care. | A five-day training workshop covering: 1) leadership skills, 2) conflict management, 3) communication skills, 4) negotiation and problem-solving, and 5) patient safety. Surgical teams identify their priorities for improving surgical quality, identify root causes to the problems and develop a quality improvement plan to implement over nine months. |
| Clinical skills course          | To strengthen knowledge, clinical skills, and teamwork and communication to improve safe cesarean birth practices | One surgical team from each facility was invited to the training. Each team typically consisted of six service providers who were not specialists: a surgeon, assistant surgeon, theatre nurse, anaesthetist, circulating nurse, and a nurse for newborn care. | A three-day workshop followed by two days of on-site training. Topics include a) safe cesarean birth practices b) surgical safety checklist, c) post-operative care and monitoring for surgical site infections, sepsis and maternal sepsis and d) data management tools to collect, visualize and analyze key indicators. |
| Safe obstetric anaesthesia course | To provide training on anaesthesia for obstetric                     | 3 to 4 anaesthesia providers from each      | A three-day course on core and extended anaesthetist roles in obstetric emergencies. Scenarios focus on conditions                                                                                                                                              |
| **Emergencies** | Facility were invited to the training | Causing 80% of maternal deaths: haemorrhage, sepsis, eclampsia, obstructed labour, complications of abortion, complications of anaesthesia, and early newborn care including resuscitation. A SAFE fellow visits trainees 3-6 months later for mentorship and assessment of change in clinical behaviors. |
|---|---|---|
| **Touch Surgery app** | To improve knowledge and confidence of surgical providers on bellweather procedures | Surgical providers (specialists and non-specialists) and surgical residents (students) | Common surgical procedures are filmed and animated. Providers at designated Safe Surgery 2020 hospitals receive clinical training on surgeries covered in the app in addition to training in using the app. Surgery videos are downloaded on tablets and provided to target hospitals. Videos can also be downloaded on a tablet or be available as an app on a phone. Mentors follow up with clinicians monthly to answer questions and troubleshoot. |
| **Mentorship** | A process through which an experienced and empathetic person, proficient in her/his content area, teaches and coaches another individual/group in-person and/or virtually to ensure competent workplace performance and provide ongoing professional development | Surgical provider, anaesthesia provider, theatre nurses, nurses in postsurgical and postnatal wards | Mentoring teams from Bugando Medical Center comprised of 4 members (surgeon, obstetrician/gynecologist, or experienced senior registrar, OR Nurse, ward nurse and anaesthetist) visits their assigned surgical team bi-monthly to follow up and mentor them in their implementation of safe surgery practices and to facilitate an enabling environment for surgical change. Illustrative activities include: review of perioperative best practices; discuss challenging and successful cases that month; review of progress on quality improvement project; performing surgeries alongside mentees for hands-on skill development; running an emergency clinical drill/simulation; and data analysis, reflection and use of data for quality improvement. |
| **Project Echo** | To share best practices and clinical knowledge with surgical teams virtually | Specialist and other experts at Bugando Medical Center (hub) and surgical team members at intervention facilities (spokes) Participants included surgical providers, anaesthesia providers, nurses, sterilization teams, and BMET teams | Tele-ECHO clinics with a didactic lecture followed by a video demonstration of the skills/techniques or case studies. Experts at the hub provide advice and mentorship on these challenges. |
| **Stuff** | To support facilities to overcome financial barriers hindering patient care and health outcome improvement | Surgical teams and facility leadership | Facility accelerator fund awards of up to $10,000 per facility. Proposals are evaluated on relevance, innovation, feasibility and potential. |
| **Facility Accelerator Fund** | To support facilities with their equipment needs to provide high-quality, safe patient care. | Surgical teams | Each facility was provided with one anaesthesia machine, and two pre-op patient monitors, one anesthesia patient monitor, and two post-op patient monitors for a total of 5 patient monitors. |
| **Peri-operative equipment package** | To support facilities to provide high-quality, safe patient care. | Surgical teams | Surgical providers on bellweather procedures |
| **Space** | To provide education, training and mentoring on reprocessing of surgical devices | 3 day training session on sterilize processing standards including (1) transfer of instruments from the operating room(OR) to the decontamination area, (2) cleaning and decontamination processes, (3) inspection and packaging of instruments, sterilization, instrument storage, and (4) instrument transport back to the OR. The training is followed by one day of on-site mentoring. |
| **SPECT course** | Surgical team members in OR and wards (surgical provider, anaesthesia provider, theatre nurses, nurses on postop and postnattal wards) and hospital leadership (Medical Officer in Charge, hospital matron and hospital secretary) | Surgical teams are trained on how to detect/diagnose, properly manage and properly document SSIs, sepsis and maternal sepsis. Training is provided through didactical presentations, practical training (e.g. ward rounds where you can see patients with SSIs and sepsis) and ongoing mentoring on the importance of data quality. |
| **Data strengthening training** | To improve the quality of surgical data collection | Surgical team members in OR and wards (surgical provider, anaesthesia provider, theatre nurses, nurses on postop and postnattal wards) and hospital leadership (Medical Officer in Charge, hospital matron and hospital secretary) | Surgical teams are trained on how to detect/diagnose, properly manage and properly document SSIs, sepsis and maternal sepsis. Training is provided through didactical presentations, practical training (e.g. ward rounds where you can see patients with SSIs and sepsis) and ongoing mentoring on the importance of data quality. |
## Supplementary Table 2. Study Outcomes

| Description | Surgical Quality Processes |
|-------------|-----------------------------|
| Safety adherence rate | Composite rate of adherence to six safety practice measures: |
| | 1. Use of pulse oximetry at the time of initiation of anesthesia |
| | 2. Administration of prophylactic antibiotics within 60 minutes before incision |
| | 3. Oral confirmation, immediately before incision, of the identity of the patient, operative site, and procedure to be performed |
| | 4. Completion of an instrument, sponge and needle count at the end of the procedure |
| | 5. Appropriate operative site cleansing (skin preparation with Chlorhexidine-alcohol or iodine-based solution) |
| | 6. Vaginal preparation with povidone-iodine |
| Teamwork and communication adherence rate | Composite rate of adherence to eight teamwork and communication conversation measures: |
| | 1. Risk for airway difficulty/aspiration |
| | 2. Risk of blood loss |
| | 3. Surgical provider’s discussion on patient-specific concerns |
| | 4. Anesthetist’s discussion on patient-specific concerns |
| | 5. Sterility of instruments and equipment |
| | 6. Anticipated procedure level of difficulty and duration |
| | 7. Equipment/instrument problems that arose during surgery |
| | 8. Patient’s postoperative recovery |
Data quality completion rate | Rate of completion of items in files of patients diagnosed with SSI/sepsis in four domains:
--- | ---
| 1. Perioperative documentation
| 2. Sepsis documentation
| 3. SSI documentation
| 4. Clinical progress documentation

**Postsurgical/postpartum Outcomes**

| Maternal sepsis rate | Rate of maternal sepsis among all current or returning obstetric inpatients diagnosed before discharge or in-hospital within 30 days of delivery (vaginal or cesarean delivery). |
|----------------------|------------------------------------------------------------------------------------------------------------------|
| Postoperative sepsis rate | Rate of postoperative sepsis among all current or returning postoperative inpatients diagnosed before discharge or in-hospital within 30 days of surgery. |
| SSI rate | Rate of SSIs (superficial, deep or organ/space) among all current or returning postoperative inpatients diagnosed before discharge or in-hospital within 30 days of surgery. |

Supplementary Figure 1. Pre-intervention Trend Graphs

**Overall Adherence**

This graph shows the average for 3-month overall adherence to the full SSC (35 items) pre and post-intervention for the intervention facilities (shown in blue) and the control facilities (shown in red) with a 9-month intervention period between the two periods (bold vertical line).
Adherence to Safety Practices

This graph shows the average for 3-month safety practice adherence pre and post-intervention for the intervention facilities (shown in blue) and the control facilities (shown in red) with a 9-month intervention period between the two periods (bold vertical line).

Adherence to Teamwork and Communication Conversations

This graph shows the average for 3-month adherence to teamwork and communication conversations pre and post-intervention for the intervention facilities (shown in blue) and the control facilities (shown in red) with a 9-month intervention period between the two periods (bold vertical line).
Maternal sepsis rates

This graph shows the average for 3-month maternal sepsis rates pre and post-intervention for the intervention facilities (shown in blue) and the control facilities (shown in red) with a 9-month intervention period between the two periods (bold vertical line).

Postoperative Sepsis Rates

This graph shows the average for postoperative sepsis rates 3-month safety adherence pre and post-intervention for the intervention facilities (shown in blue) and the control facilities (shown in red) with a 9-month intervention period between the two periods (bold vertical line).
SSI Rates

This graph shows the average for 3-month SSI rates pre and post-intervention for the intervention facilities (shown in blue) and the control facilities (shown in red) with a 9-month intervention period between the two periods (bold vertical line).

Supplementary Table 3. Test for Difference in Pre-intervention Trends

|                   | Regression Estimate | Standard Error | Test-Statistic | P Value |
|-------------------|---------------------|----------------|---------------|---------|
| Overall adherence | -0.04               | 0.032          | 1.62          | 0.20    |
| Adherence to safety practices | -0.038         | 0.049          | 0.59          | 0.44    |
| Adherence to Teamwork and communication conversations | -0.039        | 0.032          | 1.52          | 0.22    |
| Maternal sepsis   | 0.002               | 0.007          | 0.23          | 0.63    |
| Post-operative sepsis | 0.0006         | 0.002          | 0.07          | 0.79    |
| SSI               | 0.013               | 0.006          | 4.61          | 0.03*   |

*aStatistically significant
Supplementary Table 4. Pre- and Post-Intervention Facility and Patient Characteristics

| Characteristic                        | Pre-intervention       | Post-intervention      | P Value | P Value |
|---------------------------------------|------------------------|------------------------|---------|---------|
|                                       | Intervention n=10      | Control n=10           |         |         |
| Number of Facilities                  |                        |                        |         |         |
| Type of Facility – no. (%)            |                        |                        |         |         |
| Health Center                        | 2 (20)                 | 2 (20)                 | >.99    | >.99    |
| District Hospital                     | 6 (60)                 | 5 (50)                 |         |         |
| Regional Referral                    | 2 (20)                 | 3 (30)                 |         |         |
| Ownership – no. (%)                   |                        |                        |         |         |
| Government                            | 6 (60)                 | 9 (90)                 | .30     | .30     |
| Faith-Based                           | 4 (40)                 | 1 (10)                 |         |         |
| No. of Beds – no. (%)                 |                        |                        |         |         |
| 0-100                                 | 3 (30)                 | 2 (20)                 | >.99    | >.99    |
| 101-300                               | 6 (60)                 | 7 (70)                 |         |         |
| 300+                                  | 1 (10)                 | 1 (10)                 |         |         |
| Monthly Major Surgical Surgeries per Facility |                        |                        |         |         |
| Total                                 | 90                     | 75                     |         |         |
| Bellwether procedures                 |                        |                        |         |         |
| Caesarean delivery                    | 37                     | 38                     | .66     | .42     |
### Supplementary Table 4. Continued

| Characteristic                          | Pre-intervention | Post-intervention | P Value | P Value |
|-----------------------------------------|------------------|-------------------|---------|---------|
| **Patient Sample with SSI/Sepsis Outcomes Recorded** |                  |                   |         |         |
| n=4343                                  | n=5038           |                   |         |         |
| Sex (Female) – no. (%)                  | 4191 (96.5)      | 4881 (96.9)       | .33     | 4704 (96.8) | 4433 (95.9) | .02^   |
| Age categories – no. (%)                |                   |                   |         |         |
| Less than 18 years                      | 242 (5.6)        | 285 (5.7)         |         | 226 (4.7) | 243 (5.3) | .01^   |
| Between 18 and 34 years                 | 3455 (79.6)      | 3995 (79.3)       | .95     | 3942 (81.1) | 3627 (78.4) |         |
| Greater than 34 years                   | 646 (14.9)       | 758 (15.0)        |         | 685 (14.1) | 750 (16.2) |         |
| Procedure type – no. (%)                |                  |                   |         |         |
| Caesarean delivery                      | 1126 (25.9)      | 1117 (22.2)       | <.001^  | 1225 (25.2) | 1117 (24.2) | .23    |
| Laparotomy                              | 180 (4.1)        | 219 (4.3)         |         | 184 (3.8)  | 201 (4.3)  |         |
| SVD                                     | 2804 (64.6)      | 3498 (69.4)       |         | 3233 (66.5) | 3083 (66.7) |         |
| Procedure                                | n=3930 | n=4615 | n=4200 | n=4458 |
|-----------------------------------------|--------|--------|--------|--------|
| Open reduction internal fixation        | 1 (0.0)| 0 (0)  | 0 (0.0)| 0 (0.0)|
| Other procedures                        | 232 (5.4)| 204 (4.0)| 215 (4.4)| 223 (4.8)|
| Maternal Characteristics                | n=3930 | n=4615 | n=4200 | n=4458 |
| Age categories – no. (%)                |        |        |        |        |
| Less than 18 years                      | 201 (5.1)| 259 (5.6)| 175 (3.9)| 220 (5.2)|
| Between 18 and 34 years                 | 3311 (84.2)| 3843 (83.3)| 3790 (85.0)| 3476 (82.8)|
| Greater than 34 years                   | 418 (10.6)| 513 (11.1)| 500 (11.9)| 487 (10.9)|
| Procedure – no. (%)                     |        |        |        |        |
| Cesarean section                        | 1126 (28.7)| 1117 (24.2)| 1117 (26.6)| 1225 (27.5)|
| SVD                                     | 2804 (71.3)| 3498 (75.8)| 3083 (73.4)| 3233 (72.5)|

*Statistically significant
Supplementary Table 5. Pre- and Post-intervention Adherence to Safety Practices and Teamwork and Communication Conversations

|                                      | Pre                        | Post                        | Adjusted Difference | 95% Confidence Interval | P Value |
|--------------------------------------|----------------------------|-----------------------------|----------------------|-------------------------|---------|
|                                      | Intervention (n=626)       | Control (n=611)             | Intervention (n=683) | Control (n=791)         |         |
| Overall adherence (full SSC with 35 items) | 12.2%                     | 15.8%                       | 56.9%                | 24.6%                   | 29.1%   | (9.4%, 48.8%) | .004* |
| Adherence to safety practices        | 35.0%                     | 37.1%                       | 69.4%                | 44.4%                   | 20.5%   | (7.2%, 33.7%) | .003* |
| Pulse oximeter used                  | 76.4%                     | 80.9%                       | 93.6%                | 90.9%                   | 9.9%    | (-21.8%, 37.6%) | .48 |
| Prophylactic antibiotic administration within 60 minutes before incision | 55%                       | 43.9%                       | 84.0%                | 25.4%                   | 13.9%   | (-21.1%, 30.0%) | .09 |
| Confirmation by team of patient's identity, site, and procedure | 1.6%                      | 8.8%                        | 46.6%                | 28.4%                   | 7.6%    | (-39.4%, 54.6%) | .75 |
| Instrument, sponge, and needle count completed | 4.2%                      | 6.7%                        | 51.0%                | 20.5%                   | 33.5%   | (22.2%, 64.8%) | <.001* |
| Operative site cleaned               | 48.2%                     | 66.1%                       | 87.7%                | 81.7%                   | 34.3%   | (-2.5%, 51.2%) | .08 |
| Appropriate vaginal cleansing (C/S)  | 19.9%                     | 3.2%                        | 46.0%                | 2.7%                    | 19.7%   | (-5.5%, 44.8%) | .13 |
| Adherence to teamwork and communication conversations | 0.9%                      | 5%                          | 49.0%                | 11.8%                   | 33.3%   | (5.7%, 60.8%) | .02* |
| Discussion of risk of airway difficulty or aspiration | 0.2%                      | 0.7%                        | 54.2%                | 0.9%                    | 47.4%   | (24%, 70.8%) | <.001* |
| Discussion of blood loss             | 1.4%                      | 2.5%                        | 58.9%                | 4.3%                    | 47.2%   | (28.2%, 66.2%) | <.001* |
| Discussion of patient specific concerns - anesthesia provider | 1.8%                      | 0.3%                        | 46.9%                | 22.3%                   | 13.4%   | (-42.8%, 69.6%) | .64 |
| Discussion of patient specific concerns - surgical provider | 1.0%                      | 2.6%                        | 44.9%                | 15.9%                   | 4.2%    | (-62.4%, 70.7%) | .90 |
| Discussion of sterility of instruments and equipment | 0.6%                      | 7.0%                        | 59.3%                | 22.3%                   | 52.8%   | (33.9%, 71.8%) | <.001* |
| Discussion of equipment problems during surgery | 0.2%                      | 4.0%                        | 40.4%                | 1.1%                    | 41.5%   | (16.8%, 66.2%) | <.001* |
| Discussion of post-operative recovery concerns | 0.6%                      | 9.3%                        | 39.2%                | 14.4%                   | 39.1%   | (14.4%, 63.8%) | .002* |
| Discussion of duration and difficulty of procedure | 1.4%                      | 2.9%                        | 58.9%                | 4.3%                    | 21.8%   | (-17.5%, 61.1%) | .28 |

*aStatistically significant
bAdjusted for age, procedure type, baseline differences and common changes over time
### Supplementary Table 6. Outcomes of Surgical Patients and Postpartum Women by Cesarean and Vaginal Delivery

|                      | Pre-intervention | Post-intervention | Adjusted Difference | 95% Confidence Interval | P Value |
|----------------------|------------------|-------------------|---------------------|-------------------------|---------|
|                      | Intervention     | Control           | Intervention        | Control                 |         |
| **Caesarean deliveries** |                  |                   |                     |                         |         |
| Maternal sepsis      | 53/1120 (4.7%)   | 57/1113 (5.1%)    | 8/980 (0.8%)        | 15/427 (3.5%)           | -2.5%   |
|                      |                  |                   |                     |                         | (-6.6%, 1.7%) | 0.243  |
| SSI                  | 73/1120 (6.5%)   | 90/1113 (8.1%)    | 23/980 (2.3%)       | 11/427 (2.6%)           | 0.3%    |
|                      |                  |                   |                     |                         | (-5.4%, 6%)  | 0.91   |
| Postoperative sepsis | NA               | NA                | NA                  | NA                      | NA      |
| **Vaginal deliveries** |                  |                   |                     |                         |         |
| Maternal sepsis      | 22/2798 (0.8%)   | 21/3495 (0.6%)    | 1/2304 (0.04%)      | 2/1506 (0.1%)           | -0.5%   |
|                      |                  |                   |                     |                         | (-0.2%, 1.1%) | 0.141  |
| SSI                  | NA               | NA                | NA                  | NA                      | NA      |
| Postoperative sepsis | NA               | NA                | NA                  | NA                      | NA      |

*Adjusted for age, procedure type, baseline differences and common changes over time

bSSI cases are surgical patients who have not had a spontaneous vaginal delivery

NA- not applicable