A multimodal infection control and patient safety intervention to reduce surgical site infections in Africa: a multicentre, before–after, cohort study

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Summary

Background Surgical site infections (SSIs) are the most frequent health-care-associated infections in developing countries. Specific prevention measures are highly effective, but are often poorly implemented. We aimed to establish the effect of a multimodal intervention on SSIs in Africa.

Methods We did a before–after cohort study, between July 1, 2013, and Dec 31, 2015, at five African hospitals. The multimodal intervention consisted of the implementation or strengthening of multiple SSI prevention measures, combined with an adaptive approach aimed at the improvement of teamwork and the safety climate. The primary outcome was the first occurrence of SSI, and the secondary outcome was death within 30 days post surgery. Data on adherence to SSI prevention measures were prospectively collected. The intervention effect on SSI risk and death within 30 days post surgery was assessed in a mixed-effects logistic regression model, after adjustment for key confounders.

Findings Four hospitals completed the baseline and follow-up; three provided suitable (ie, sufficient number and quality) data for the sustainability period. 4322 operations were followed up (1604 at baseline, 1827 at follow-up, and 891 in the sustainability period). SSI cumulative incidence significantly decreased post intervention, from 8·0% (95% CI 6·8–9·5; n=129) to 3·8% (3·0–4·8; n=70; p<0·0001), and this decrease persisted in the sustainability period (3·9%, 2·8–5·4; n=35). A substantial improvement in compliance with prevention measures was consistently observed in the follow-up and sustainability periods. The likelihood of SSI during follow-up was significantly lower than pre-intervention (odds ratio [OR] 0·40, 95% CI 0·29–0·54; p<0·0001), but the likelihood of death was not significantly reduced (0·72, 0·42–1·24; p=0·2360).

Interpretation Implementation of our intervention is feasible in African hospitals. Improvement was observed across all perioperative prevention practices. A significant effect on the overall SSI risk was observed, but with some heterogeneity between sites. Further large-scale experimental studies are needed to confirm these results and to improve the sustainability and long-term effect of such complex programmes.

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Introduction

Health-care-associated infections are one of the most common adverse events during care delivery.[1] Little evidence exists on the morbidity, mortality, and effect of health-care-associated infections in low-income and middle-income countries, but WHO estimates indicate that the overall prevalence in these countries is double the average reported in high-income countries.[2–5] According to WHO, surgical site infection (SSI) is the most surveyed and most frequent health-care-associated infection in countries of low and middle income, and can affect up to one-third of surgical patients. The significantly increased risk of SSI in countries of low and middle income affects all types of procedure, including clean surgery.[2] SSI is also the second most common health-care-associated infection in Europe and the USA.[6,7] Given the increasing recognition of the need for wider access to essential and safe surgical services in countries of low and middle income by organisations such as WHO,[8] a reduction of the risks associated with surgery and health care in general will be key to the achievement of this goal.

SSI prevention is complex, because the risk of SSI results from multiple factors affecting the patient's entire surgical journey, including after hospital discharge. However, similar to other health-care-associated infections, SSIs are largely avoidable. In 2016, WHO published new recommendations for the prevention of SSIs, which span the preoperative, intraoperative, and postoperative periods to tackle the multifactorial nature of these infections.[9–11] Evidence and expert consensus indicate that the effective implementation of recommendations for the prevention and control of infections requires multimodal strategies and multidisciplinary

Research in context

Evidence before this study

Surgical site infections are the most frequent health-care-associated infections in countries of low and middle income. Prevention of surgical site infections is complex because of their multifactorial determinants and surveillance is difficult to do in low-resource settings. The evidence of effective prevention approaches in low-income and middle-income countries is scarce and mostly limited to single interventions focusing on surgical antibiotic prophylaxis improvement. We searched the PubMed, Embase, CINAHL, Cochrane Library, WHO regional databases, and AFROLIB and Africa-Wide Information for articles published from Jan 1, 1990, to Oct 23, 2017. We used search terms related to "surgical wound infection" and "infection control", "checklists", "patient safety", "leadership", "education", or "communication". We restricted our search to publications in English, French, and Spanish. We selected studies describing strategies to reduce surgical site infections and increase compliance with evidence-based infection prevention measures. We identified 270 eligible studies of which only 44 (16%) were done in low-income and middle-income countries. Multifaceted approaches and multidisciplinary teams supported implementation in most studies in high-income countries, but the large majority of interventions in countries of low and middle income aimed at improving the appropriateness of surgical antibiotic prophylaxis only, rather than addressing multiple perioperative prevention measures.

Added value of this study

Our study is the first report based on multicentre surgical site infections surveillance and a multimodal intervention aimed at improving multiple surgical site infection prevention measures at hospitals in sub-Saharan African countries. The risk of surgical site infections during follow-up was significantly lower than pre-intervention and a substantial improvement in compliance with prevention measures was consistently observed.

Implications of all the available evidence

To date, the available evidence on the effectiveness of multimodal surgical site infections prevention interventions is only from high-income countries. Our study shows the feasibility and successful effect of such strategies in low-resource settings in sub-Saharan Africa. Our study proposes an innovative approach on the basis of local adaptation and co-development of a complex surgical site infection prevention intervention, including the use of adaptive tools for the promotion of a wider patient safety culture. However, our results need to be confirmed by an experimental study.

efforts.[12,13] Several approaches have been tested with demonstrable success in reducing SSIs in high-income countries,[14] but little evidence exists from countries of low and middle income, especially in sub-Saharan Africa.[15] Thus, a substantial knowledge gap exists as to the most effective strategies to reduce SSIs in low-resource settings, including whether the approaches used successfully in high-income countries can achieve similar results in low-income and middle-income countries.

Our multisite study, in five hospitals in four African countries, aimed to measure the risk of SSI according to a standardised surveillance method, and to reduce the occurrence of SSIs following the implementation of a multimodal intervention, combining prevention measures and approaches to improve patient safety.

Methods

Study design

We did a before–after intervention cohort study between July 1, 2013, and Dec 31, 2015, in the surgical services of five hospitals in Kenya, Uganda (two hospitals), Zambia, and Zimbabwe. We hypothesised that a multimodal intervention aimed at increasing compliance with infection prevention measures would lead to a reduction in the risk of SSI. Implementation was supported by an adaptive approach aimed at improvement of teamwork and the safety climate in the surgical services by the placement of emphasis on local leadership. We did SSI surveillance throughout the study using an adapted protocol, based on methods described by the US Centers for Disease Control and Prevention National Health Care Safety Network.[16,17] The characteristics of the included hospitals and interventions are described in figure 1.

The project was named the African Surgical Unit-based Safety Programme, and was adapted from a similar study done simultaneously in the USA under the coordination of the Johns Hopkins Armstrong Institute for Patient Safety and Quality (Baltimore, MD, USA).[18]

Our study was approved by the WHO ethics review committee and the institutional ethics committees of all participating hospitals. Because these activities were done as a planned quality improvement programme of normal surgical services, verbal assent to participation in surveillance was sought from all patients, rather than written consent.

Procedures

A step-wise implementation protocol, including five planned periods supported by a range of tools, was used across all sites. The first period was a so-called preparatory period, during which experts from WHO and Johns Hopkins Armstrong Institute for Patient Safety and Quality and senior surgeons (surgical team leads) from the African hospitals adapted or co-developed tools and protocols. During this period, local core teams also identified the key SSI prevention measures to be prioritised, and prepared all necessary conditions for the start of SSI surveillance.

	Hospital type	Setting	Intervention implementation activities common to all sites	Additional activities
Kijabe AIC Hospital, Kenya	Private, mission hospital, 360 beds	Rural	Technical SSI preventive measures*: patient preoperative bathing with plain or antiseptic soap; appropriate hair removal (avoidance of or using clippers); optimise patient skin preparation, including local production of alcohol-based and chlorhexidine-based skin disinfection product; optimise surgical hand preparation, including local production of alcohol-based hand rub product and appropriate rubbing technique; appropriate antibiotic prophylaxis based on locally formulated policy, given within 1-h preoperatively and discontinued postoperatively; improved operating theatre discipline, including limitation of the number of individuals and reduction of intraoperative movement. Adaptive (team-working and safety) elements†: formation of local SUSP perioperative team; engagement of surgical leads and senior executives; patient safety culture survey; patient safety video played by local surgical leaders; use of CUSP adaptive tools, including Staff safety assessment and Learning from defects; morbidity and mortality meetings; participation in monthly multisite SUSP webinars; conduct of local educational meetings; feedback of data on SSI surveillance and compliance with the SSI preventive measures, including SSI rates.	Provision of antiseptic soap to patients for bathing; addition of food dye to alcohol-based skin preparation to aid visualisation of the application area around the incision site; leaflets explaining the intervention
Mulago Hospital, Uganda	Public sector, tertiary referral, 1500 beds	Urban		Better management of students to reduce crowding in operating theatres; work with hospital pharmacy to ensure an antibiotic supply for surgical prophylaxis; patient information card on surveillance in English and local language
Kisiizi Hospital, Uganda	Private, mission hospital, 260 beds	Rural		New locks and lockers in operating theatres to minimise staff movement during operations
Ndola Hospital, Zambia	Public sector, tertiary referral, 851 beds	Urban		Better management of students to reduce crowding in operating theatres

Figure 1: **Characteristics of the four participating hospitals and activities implemented during the intervention**
Due to unforeseen local difficulties, one site (Zimbabwe) was unable to recruit adequate numbers of patients and was not included in the analysis. SSI=surgical site infection. SUSP=Surgical Unit-based Safety Programme. CUSP=Comprehensive Unit-based Safety Programme. *Support materials related to the technical SSI preventive measures are available at http://www·who·int/infection-prevention/countries/surgical/en/ (see appendix). †Materials from the CUSP study used in this project are available at https://www.ahrq.gov/professionals/quality-patient-safety/hais/tools/surgery/index.html.

The four periods to follow the preparatory period were: baseline (6 months), including the start of SSI surveillance and monitoring of a range of perioperative indicators related to planned SSI prevention measures and final preparations for the formal rollout of the intervention; intervention (on a defined date), consisting of the rollout of the intervention through local launch activities; follow-up (between 7 and 12 months), representing the first evaluation period of the effect of the intervention (end date of the intervention was fixed for all sites); and sustainability (between 4 and 6 months), representing the long-term follow-up when the intervention had become part of the regular process of care.

The multimodal intervention comprised six technical SSI prevention measures to be implemented or improved, and an adaptive approach based on the Comprehensive Unit-based Safety Programme developed in the USA.[18–21] The surgical team leads identified the SSI prevention measures during the preparatory phase using a perioperative staff safety assessment tool,[22] which is designed to help surgical teams to assess the gaps that most frequently cause SSI in their local context. The prevention measures identified through this process included preoperative patient bathing, avoiding hair removal or doing it with clippers, appropriate surgical hand preparation, appropriate patient skin preparation, optimal antibiotic prophylaxis, and improving operating room discipline. All sites consistently implemented or strengthened these measures based on the use of evidence-based protocols or standard operating procedures. Information about the implementation activities is given in figure 1. A more detailed description, process indicators used, and available implementation support documents are provided in the appendix. Local teams were encouraged to adapt these activities and to develop additional actions according to the local needs and culture (figure 1). An important feature of the intervention was the local production of the WHO-recommended product for surgical skin preparation (ie, a chlorhexidine alcohol-based product) and an alcohol-based hand rub to be used as an alternative to antimicrobial soap for surgical hand preparation (WHO formulations were modified according to Suchomel and colleagues;[23] appendix). External quality control testing of the alcohol-based hand rub was done at Geneva University Hospitals (Geneva, Switzerland).

See Online for appendix

The Comprehensive Unit-based Safety Programme approach aimed at the creation or improvement of the local safety climate, and the motivation of local teams to comply with SSI prevention measures implemented through the intervention. In brief, the Comprehensive Unit-based Safety Programme is a five-step iterative process that includes the education of staff on the science of improving patient safety, identification of defects (defined as anything clinically or operationally that should not recur) by the teams, engagement of local leadership, promotion of accountability of front-line staff and senior leaders, identification of how to learn from defects, and implementation of tools to help to improve teamwork and communication.[19,21]

Implementation of the Surgical Unit-based Safety Programme intervention was done entirely by local teams. Staff from WHO and Johns Hopkins Armstrong Institute for Patient Safety and Quality formed a central coordinating team that provided technical expertise and mentorship on project management and data collection.

This central coordination was delivered at a distance through monthly webinars, e-mails, and telephone discussions, until the end of follow-up. During the study, each site received one support visit from the WHO team, and participated in three inter-site meetings. Between-site exchange of information was encouraged throughout the study. A small budget was provided to each hospital to be used only for costs incurred from data collection extending beyond normal clinical services. Funds were not used for the procurement of equipment or products related to the project or for the remuneration of pre-existing staff.

	Total (n=4322)	Baseline (n=1604)	Follow-up (n=1827)	p value*	Sustainability period (n=891)
Mean age (n=4309)	40·3 (17·3)	40·5 (18·0)	39·9 (17·2)	0·2861	41·1 (16·3%)
Female sex (n=4310)	2813 (65·3%)	988 (61·8%)	1259 (69·1%)	<0·0001	566 (63·6%)
ASA class† (n=4318)	..	..	..	<0·0001	..
1	2380 (55·1%)	1108 (69·2%)	942 (51·6%)	..	330 (37·0%)
2	1512 (35·0%)	392 (24·5%)	694 (38·0%)	..	426 (47·8%)
3	361 (8·4%)	78 (4·9%)	154 (8·4%)	..	129 (14·5%)
4	53 (1·2%)	20 (1·3%)	30 (1·6%)	..	3 (0·3%)
5	12 (0·3%)	3 (0·2%)	6 (0·3%)	..	3 (0·3%)
Surgical wound class (n=4312)	..	..	..	<0·0001	..
Clean	1897 (44·0%)	896 (56·0%)	621 (34·1%)	..	380 (42·7%)
Clean-contaminated	2091 (48·5%)	575 (35·9%)	1064 (58·4%)	..	452 (50·8%)
Contaminated	262 (6·1%)	98 (6·1%)	111 (6·1%)	..	53 (6·0%)
Dirty or infected	62 (1·4%)	32 (2·0%)	26 (1·4%)	..	4 (0·5%)
NNIS Risk Index (n=4251)	..	..	..	<0·0001	..
0	1717 (40·4%)	618 (39·4%)	797 (44·3%)	..	302 (34·2%)
1	2101 (49·4%)	818 (52·1%)	819 (45·5%)	..	464 (52·6%)
2	338 (8·0%)	110 (7·0%)	128 (7·1%)	..	100 (11·3%)
3	95 (2·2%)	23 (1·5%)	56 (3·1%)	..	16 (1·8%)
Type of surgery (n=4221)	..	..	..	<0·0001	..
AAA repair	4 (0·1%)	1 (0·1%)	2 (0·1%)	..	1 (0·1%)
Amputation of limb	92 (2·2%)	35 (2·3%)	39 (2·2%)	..	18 (2·0%)
Appendix surgery	71 (1·7%)	36 (2·3%)	20 (1·1%)	..	15 (1·7%)
Bile duct, liver, or pancreas surgery	24 (0·6%)	9 (0·6%)	8 (0·5%)	..	7 (0·8%)
Breast surgery	250 (5·9%)	97 (6·3%)	79 (4·4%)	..	74 (8·3%)
Cardiac surgery	6 (0·1%)	4 (0·2%)	1 (0·1%)	..	1 (0·1%)
Gallbladder surgery	70 (1·7%)	41 (2·7%)	20 (1·1%)	..	9 (1·0%)
Colon surgery	91 (2·3%)	45 (2·9%)	33 (1·8%)	..	13 (1·5%)
Craniotomy	11 (0·3%)	8 (0·5%)	1 (0·1%)	..	2 (0·2%)
Open reduction of fracture	404 (9·6%)	129 (9·0%)	137 (7·6%)	..	142 (16·0%)
Gastric surgery	237 (5·6%)	76 (4·9%)	99 (5·5%)	..	62 (7·0%)
Herniorrhaphy	335 (7·9%)	169 (11·0%)	110 (6·1%)	..	56 (6·3%)
Neck surgery	27 (0·6%)	10 (0·6%)	9 (0·5%)	..	8 (0·9%)
Kidney surgery	24 (0·6%)	8 (0·5%)	12 (0·7%)	..	4 (0·5%)
Prostate surgery	209 (5·0%)	87 (5·7%)	102 (5·7%)	..	20 (2·2%)
Rectal surgery	20 (0·5%)	13 (0·8%)	6 (0·3%)	..	1 (0·1%)
Small bowel surgery	41 (1·0%)	16 (1·0%)	16 (0·9%)	..	9 (1·0%)
Thoracic surgery	19 (0·5%)	9 (0·6%)	5 (0·3%)	..	5 (0·6%)
Thyroid and parathyroid surgery	312 (7·4%)	103 (6·7%)	137 (7·6%)	..	72 (8·1%)
Abdominal surgery (other)	872 (20·2%)	294 (19·1%)	394 (22·0%)	..	184 (20·7%)
Caesarean section	1087 (25·8%)	340 (21·1%)	564 (31·4%)	..	183 (20·6%)
Operation duration, min (n=4263)	76·1 (59·3)	80·4 (68·0)	73·4 (56·4)	0·00095	74·1 (46·5)

(Table 1 continues on next page)

Outcomes

The primary study outcome was the first occurrence of SSIs diagnosed according to the first study protocol and the outcome measure was the cumulative incidence of SSI per 100 surgical operations within 30 days of the procedure. The secondary outcome was mortality within 30 days. SSI surveillance was done according to a protocol developed specifically for this project and based on methods described by the US Centers for Disease Control and Prevention National Health Care Safety Network.[16,17] This approach involved a 30-day follow-up after all operative procedures, regardless of the use of implanted materials, and used inpatient chart reviews, outpatient clinic attendance, and telephone calls for contact with patients. We aimed to have at least three separate postoperative interactions (of any type) with each patient during the 30-day period. All major elective and emergency operations were eligible for inclusion and there were no other inclusion or exclusion criteria. Sites enrolled an intake reflective of their overall surgical case load. We aimed to include at least 50 operations per month per site into SSI surveillance. Data collection for surveillance was done by staff in operating theatres for perioperative data, and by trained infection control staff postoperatively. One additional member of nursing staff in each hospital was employed to lead surveillance activities.

As process indicators, we collected data on adherence to the six perioperative SSI prevention measures according to the study protocols (appendix). Data were collected on paper forms and entered into an Epi-Info database (version 3.1.4), with a monthly external review of data quality.

Statistical analyses

With an estimated pre-intervention risk of 12%, based on a WHO meta-analysis related to countries of low and middle income,[2] we anticipated that the SSI incidence would be reduced by one-third between the before and after intervention periods. Assuming a 90% statistical power at a 5% level of significance, an expectation of a 1:2 size ratio between time periods, and a 10% drop-out, we aimed to include 3000 operations in surveillance across all study sites. This sample size calculation was done for the total number of operations and with no expectation to assess the effect of the intervention within each individual site. Descriptive data were analysed by study period in a combined dataset and then stratified by

site. Comparisons of mean values were done using Student's *t* tests and χ^2 tests for categorical variables. We estimated the 95% CI for proportions with the Clopper-Pearson exact method.

As data were clustered at site level, we used a logistic regression model with mixed-effects to assess the effect of the intervention on outcomes. In the first model, SSI was the dependent variable, the site was the random factor, and the intervention phase was the main independent variable. Random effects were introduced on the intercept and the regression coefficient for the intervention phase to take into consideration variability of effects between sites. We applied this model combining all operations across all four sites to estimate the effect during follow-up compared with baseline. One site was unable to provide sufficient data in the sustainability period. Therefore, to estimate the effect during both follow-up and sustainability period, we applied the same model only to data generated by the other three sites. For the purposes of the analysis, we considered only the single anatomically deepest form of SSI (organ or space, followed by deep, and then superficial) in patients with more than one SSI diagnosed during the surveillance period. In this model, we adjusted for key confounders (ie, patient age in categories, <27, 27–36, 37–51, and >51 years) and the US Centers for Disease Control and Prevention National Nosocomial Infection Surveillance (NNIS) Risk Index. The NNIS Risk Index is an internationally accepted method for surgical risk stratification, whereby data related to the Surgical Wound Class, the American Society of Anesthesiologists (ASA) score, and the operation duration are used to assign a score of between 0 and 3. We used the NNIS Risk Index score as follows: the reference category (zero) was assigned if the ASA score was 2 or less, the surgical wound class was clean or clean-contaminated, and the operation duration was less than 60 min. A score of 1 was assigned if any one variable was above the cutoff value, a score of 2 if two variables were above the values, and a score of 3 if all variables were above the values. The NNIS Risk Index variable was included in the multivariable models because it is a potential confounder in the relationship between intervention and outcomes.

We used the same statistical approach in the second model to assess the likelihood of death within 30 days of surgery (dependent variable). We also did post-hoc analyses by site to explore the trends of cumulative SSI incidence per 100 surgical operations on a monthly basis, in two separate comparisons: baseline and follow-up; and between follow-up and sustainability period. For this purpose, we used a linear regression model. Simple autoregressive models, such as AR(1), were used if autocorrelation was suspected. We did statistical analyses using Stata (version IC 14), and interrupted time series analysis using R (version 3.3.3, package nlme). We adhered to ORION guidelines for the reporting of results.[24]

	Total (n=4322)	Baseline (n=1604)	Follow-up (n=1827)	p value*	Sustainability period (n=891)
(Continued from previous page)					
Urgency of operation (n=4313)	..	..	..	0·0155	..
Elective	2268 (52·6%)	830 (51·9%)	949 (52·1%)	..	489 (54·9%)
Semi-elective	575 (13·3%)	207 (12·9%)	214 (11·8%)	..	154 (17·3%)
Urgent	425 (9·9%)	112 (7·0%)	180 (9·9%)	..	133 (14·9%)
Emergency	1045 (24·2%)	451 (28·2%)	479 (26·3%)	..	115 (12·9%)
Grade of lead surgeon (n=4277)	..	..	..	<0·0001	..
Senior	2384 (55·7%)	976 (61·4%)	983 (54·7%)	..	425 (47·8%)
Middle	1237 (28·9%)	407 (25·6%)	424 (23·6%)	..	406 (45·6%)
Junior	656 (15·3%)	207 (13·0%)	390 (21·7%)	..	59 (6·6%)

Data are mean (SD) or n (%). Some percentages do not add up to 100% because of rounding. ASA=American Society of Anesthesiologists. NNIS=National Nosocomial Infection Surveillance System. AAA=abdominal aortic aneurysm. *All statistical tests were performed between baseline and follow-up. †ASA classes: (1) normal healthy, (2) mild systemic disease, (3) severe systemic disease, (4) incapacitating systemic disease, (5) moribund.

Table 1: **Patient and operation characteristics across the four study sites**

	Baseline (n=1604)	Follow-up (n=1827)	p value	Sustainability period (n=891)
Preoperative patient bathing (n=4321, 0·02%)	1238 (77·2)	1544 (84·5)	<0·0001	799 (89·7)
Appropriate hair removal (n=4310, 0·3%)	1169 (73·1)	1702 (93·5)	<0·0001	880 (98·8)
Appropriate skin preparation (n=4307, 0·3%)	330 (20·7)	1644 (90·2)	<0·0001	845 (94·8)
Quality of surgical hand preparation (n=4223, 2·3%)	1213 (78·7)	1694 (94·4)	<0·0001	865 (97·4)
Appropriate use of antibiotic prophylaxis (n=4322, 0%)	205 (12·8)	714 (39·1)	<0·0001	635 (71·3)
Theatre discipline				
Theatre door openings per hour of operation time (n=4031, 6·7%)	14·8 (17·8)	14·2 (16·1)	0·3771	19·0 (21·6)
Number of individuals present at the start of the operation (n=4313, 0·2%)	8·3 (3·4)	7·7 (2·5)	<0·0001	7·4 (2·5)
Number of entries during the operation (n=4236, 2·0%)	5·0 (4·1)	4·8 (4·9)	0·1758	4·2 (2·7)

Data are mean (SD). Data per variable and percentage missing data are also given. SSI=surgical site infection.

Table 2: **Process indicators for SSI prevention intervention measures across study periods in four (baseline and follow-up) and three (sustainability period) hospitals**

Role of the funding source

This study was funded by the US Agency for Healthcare Research and Quality and the WHO Service Delivery and Safety Department. The study was designed by academic investigators from Johns Hopkins Armstrong Institute for Patient Safety and Quality and WHO technical staff. Data were analysed by a statistical team appointed by the study sponsors. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Four study sites collected data according to the study protocol, and implemented the intervention during the

planned timeframe. Due to unforeseen local difficulties, including long-lasting health-care workers' strikes, one site (Zimbabwe) was unable to recruit adequate numbers of patients and was not included in the analysis. 4322 operations were followed up in surveillance between Jan 1, 2014, and Dec 31, 2015. These included 1604 operations at baseline, 1827 at follow-up, and 891 during the sustainability period. Sustainability data from three sites were included in the final analysis, because one site failed to collect sufficient data, and those data that were collected were of poor quality. During the study, 94% (3976/4322) of patients had two or more follow-up interactions (ie, inpatient reviews, outpatient clinic, or telephone interviews) and 80% (3458/4322) had three or more interactions during their 30-day surveillance period. Patient and surgical procedure characteristics across the four study sites are summarised in table 1. Of 4322 operations, the most common procedures were caesarean section (1087; 25·8%), herniorrhaphy (335; 7·9%), and open reduction of fracture (404; 9·6%). According to the surgical wound class, procedures were mainly clean or clean-contaminated wounds (1897 [44·0%] and 2091 [48·5%]). The proportion of clean-contaminated wounds increased significantly over the study periods (p<0·0001; table 1). Overall, most patients were healthy individuals according to the ASA score (ASA 1; 55·1%), or affected only by mild systemic disease (ASA 2; 35·0%). The proportion of patients with ASA scores of 2 and 3 increased significantly over the study (p<0·0001; table 1).

All indicators of compliance with the SSI prevention measures improved significantly between baseline and follow-up (table 1). This effect was also confirmed in the sustainability period in three sites (table 2). The unadjusted cumulative incidence of SSI decreased significantly during a 30-day postoperative period between baseline (8·0%, 95% CI 6·8–9·5) and follow-up (3·9%, 3·0–4·8; p<0·0001; figure 2; table 3). In the sustainability period, the overall pooled SSI incidence was 3·9% (2·7–5·4). Superficial SSI decreased significantly (p<0·0001), as did overall unadjusted SSI cumulative incidence in clean-contaminated, contaminated, and dirty or infected wounds between baseline and follow-up (p<0·0001; table 3).

When all operations across all four sites were combined and adjusted for the NNIS Risk Index and age categories in our multivariable model, the likelihood of SSI during follow-up was significantly lower than before implementation of the intervention (odds ratio [OR] 0·40, 95% CI 0·27–0·61; p<0·0001; table 4). The NNIS Risk Index was independently associated with the likelihood of SSI, and showed a dose–response relationship. For each increase of the Risk Index, the likelihood of SSI was higher than the previous (table 4). When the same model was applied to data generated by the three sites that provided data for the sustainability period, the likelihood of SSI was even smaller during follow-up than before implementation of the intervention (0·35, 0·25–0·49; p<0·0001). This result was confirmed when the sustainability period and baseline were compared (0·32, 0·22–0·49; p<0·0001), but we did not find any difference in the likelihood of SSI when the sustainability and follow-up periods were compared (0·92, 0·59–1·43; p=0·71).

Month-by-month cumulative incidence of SSI per 100 surgical operations over the study periods in the

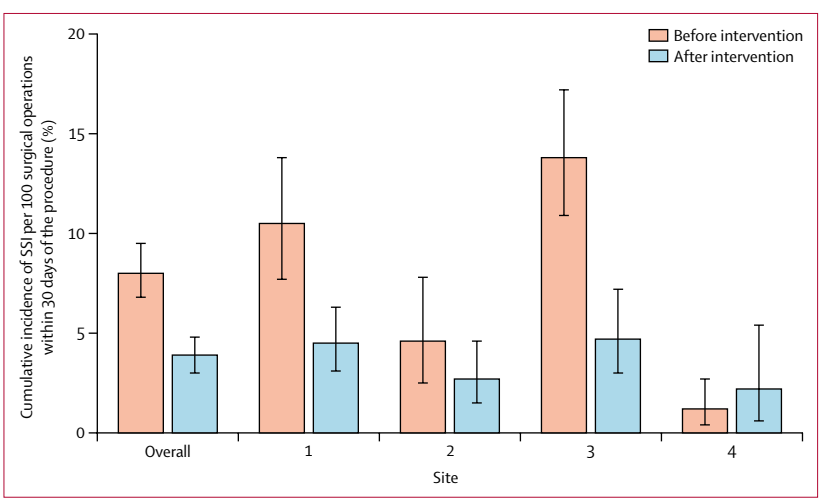

Figure 2: **Unadjusted SSI cumulative incidence overall and by site at baseline and follow-up in four sites**
Error bars show 95% CIs. SSI=surgical site infection.

	Baseline*				Follow-up*				p value	Sustainability period†			
	SSI (n)	Surgical operations (n)	%	95% CI	SSI (n)	Surgical operations (n)	%	95% CI		SSI (n)	Surgical operations (n)	%	95% CI
Overall (n=4322)	129	1604	8·0%	6·8–9·5	70	1827	3·8%	3·0–4·8	<0·0001	35	891	3·9%	2·8–5·4
Cumulative incidence by surgical wound class (n=4312)													
Clean (n=1897)	26	896	2·9%	1·9–4·2	10	621	1·6%	0·8–2·9	0·2677	5	380	1·3%	0·4–3·0
Clean-contaminated (n=2091)	69	575	12·0%	9·5–14·9	46	1064	4·3%	3·2–5·7	<0·0001	25	452	5·5%	3·6–8·1
Contaminated (n=262)	20	98	20·4%	12·9–29·7	11	111	9·9%	5·1–17·0	0·0383	4	53	7·5%	2·1–18·2
Dirty or infected (n=62)	14	32	43·8%	26·4–62·3	3	26	11·5%	2·5–30·2	0·0074	1	4	25·0%	0·63–80·6

SSI=surgical site infection. *All four sites included in the analysis. †Only three sites included in the analysis.

Table 3: **Description of the incidence of SSI within 30 days post surgery across study periods and according to wound class**

individual sites are shown in the appendix. During follow-up, a significant monthly decrease of 2·0% (1·2–2·9; p=0·0010) of the cumulative incidence of SSI in site three was observed (appendix). During the sustainability period, the monthly cumulative incidence trend of SSI in any of the three sites was not significant (appendix). For the 30-day mortality following surgery, we observed a reduction between the baseline (33 [2·1%] of 1604 patients) and the follow-up (29 [1·6%] of 1818 patients). However, this difference was not statistically significant (OR 0·73, 95% CI 0·43–1·22; p=0·22) even after adjustment for the NNIS risk group and age group (0·72, 0·42–1·24; p=0·24).

	Odds ratio	95% CI	p value
Follow-up*	0·40	0·27–0·61	<0·0001
NNIS Risk Index†	..	..	<0·0001
1	1·73	1·14–2·63	0·0094
2	5·00	2·98–8·38	<0·0001
3	7·72	3·81–15·64	<0·0001
Age, years‡	..	..	0·3927
27–36	1·26	0·79–2·00	0·3275
37–51	0·89	0·56–1·42	0·6332
>51	1·17	0·75–1·81	0·4863

N=3357 (of 3426) observations. SD of the random effect estimate on the intercept was 0·61 (95% CI 0·26–1·44) and on the intervention period was 0·12 (0·00–118·65), meaning that the baseline odds of SSI differed between sites. The result of the likelihood ratio χ^2 (df 2) test (comparing the mixed-effects logistic regression with the fixed-effects logistic regression model) was 18·69 (p<0·0001). SSI=surgical site infection. NNIS=National Nosocomial Infection Surveillance System. *Reference: baseline. †Reference: American Society of Anesthesiologists score of 2 or less, surgical wound class clean-contaminated, and operation duration of less than 60 min. ‡Reference: younger than 27 years.

Table 4: **Assessment of the intervention effectiveness on SSI rates: comparison of the baseline to follow-up in four sites**

Discussion

We showed that the implementation of a multimodal SSI prevention strategy is feasible in low-resource settings and can improve preventive measures and reduce the SSI risk. To our knowledge, this is the first report on SSI prevention based on multisite SSI surveillance at hospitals in sub-Saharan African countries. This study is also highly innovative in its description of the adaptation and local co-development of a complex intervention and related tools conceived for use in a high-income country[18] into low-income settings. Participating hospitals were representative of both public and private (faith-based) facilities providing surgical services in east and southern Africa (see figure 1). The intervention combined SSI technical prevention measures identified as a priority for improvement by local leads, together with tools adapted to facilitate the adoption of these measures and the promotion of a wider patient safety culture. SSI surveillance, monitoring of perioperative indicators and the implementation of the intervention were done by trained hospital staff using consistent methods across all sites. We collected detailed process and outcome data on a predefined number of operations in facilities that faced typical challenges for delivering surgical services in this region.

Using an adapted protocol[17] that referred to internationally accepted SSI definitions, we showed that multisite SSI surveillance is feasible in African settings, typically with a single member of the nursing staff able to collect high quality data for around 50 operations per month. In particular, and similar to others,[25–27] by complementing outpatient clinic consultations with telephone calls (including requests to send images to monitor wound status), our 30-day post-surgery patient follow-up involved a high number of patient interactions. However, by limiting surveillance to the 30-day postoperative period, we were unable to detect implant infections, which can occur up to 12 months postoperatively. To limit loss to follow-up, some participating hospitals put in place systems to trace patients included in surveillance, such as inserting coloured signs in their records and links to other clinics in the area. One hospital faced unexpected institutional difficulties that prevented a good-quality collection of a sufficient number of cases in the sustainability period. These difficulties were related to variability in available human resources and increased workload, which reflects the challenges of implementation research in public hospitals in countries of low and middle income. Although local teams considered the overall strategy (particularly the collection of SSI and process indicators) resulted in an increased workload, they also considered that the availability of these data for regular feedback was a crucial lever for changing practices. In our experience, if evaluation and feedback are perceived as crucial for the motivation of improvement and are supported by appropriate training and commitment by the hospital leadership and national public health bodies, this format of surveillance would be practicable and sufficiently low cost for countries of low and middle income to implement into cycles of improvement within routine practice.

The overall risk of SSI in the hospitals before the introduction of the intervention was high (baseline overall SSI cumulative incidence of 8·0%), similar to other reports in sub-Saharan African countries.[2–4] However, the baseline SSI risk varied markedly between individual institutions, which could be explained, in part, by the different surgical procedures and compliance with some of the key measures for the prevention of SSI. To take this variability into consideration, we used a multivariable model adjusting for different risks in surgery, and variations between sites at baseline and follow-up. Overall, we found an approximate 60% reduction in SSI risk across all sites, as a result of the intervention. Furthermore, in this model, all three components of the NNIS Risk Index were associated with an increase in SSI risk. An appropriate risk stratification approach is essential for any reliable SSI surveillance system, and our study provides some evidence that the NNIS Risk Index could be suitable for

multisite SSI surveillance programmes in countries of low and middle income; however, previous single institution studies in African hospitals have not supported this finding.[28] Although data collection in the sustainability period was only done in three sites, the SSI risk remained significantly reduced when compared with baseline, and without a significant difference when compared with follow-up.

Baseline data showed significant gaps in several key SSI preventive measures before the intervention. As reported in other studies of SSI occurrence done in countries of low and middle income, compliance with appropriate surgical antibiotic prophylaxis and surgical site skin preparation were particularly poor, including the inadequate use of an appropriate skin disinfection product and inappropriate methods of hair removal.[15,29,30] SSI risk reduction following the intervention was mirrored by a significant performance improvement in all indicators. Importantly, our findings linking sustained compliance with prevention measures with SSI risk reduction indicated that the intervention had progressively become part of routine patient care, because hospitals continued to collect data independent of study conditions. Additionally, the local production or procurement of specific products has now become part of the regular hospital budget.

We believe that the success in the improvement of clinical practice and outcomes was mainly attributable to the motivation of site staff to improve their practices, and the status of local project leaders as influential members of their respective departments. Infection prevention and control best practices are most successfully implemented when embedded within a culture of safety and teamwork that is facilitated by an adaptive approach. Although the study was coordinated by a WHO central team with experience in SSI surveillance and infection control interventions, we believe that the level of support was modest, and the intervention could be reproduced in other settings by a small local team with a short period of appropriate training.

Our study has limitations. First, our study had an observational design and we were unable to include control wards due to local decisions. These decisions were linked to feasibility and a risk of contamination between intervention and control wards, given that the intervention had an institutional climate change component. We could not exclude some regression to the mean effect or contamination by external strategies, although we verified that no national or local campaigns that could have interfered with our intervention were implemented in the same period. A stepped-wedge, cluster-randomised controlled trial could be a superior study design to confirm our findings. Second, although, to our knowledge, this study represents the largest report of multisite SSI surveillance in sub-Saharan African countries, it is still small when compared with SSI surveillance datasets in high-income settings, where nationwide or even international activities are well established. Third, our study was not powered to detect the effects of the intervention at individual sites. We observed some remarkable variations between sites, which probably reflect differences in pre-existing institutional infection control expertise coupled with an element of random fluctuations, especially as the numbers of surgical procedures under surveillance periods were relatively modest. Despite this limitation, we did a post-hoc analysis to further explore the effect of the intervention on a monthly basis in each site and found heterogeneous results, with only one site showing a monthly decrease of the cumulative incidence of SSI during follow-up. We cannot be certain to what extent the reduction in SSI risk we observed could be reproduced in other hospitals in the region. Finally, we were unable to collect information that could quantify changes in the organisational safety culture in these hospitals.

Our findings show that the implementation of a multimodal SSI prevention intervention successfully tested in high-income countries is feasible in low-resource settings. The intervention was associated with an improvement in infection prevention and control practices in participating hospitals, particularly when fully embedded in routine hospital practice. Our multimodal strategy was also associated with a significant reduction of SSI risk following the implementation of the programme, but this finding needs to be confirmed by large-scale experimental studies (ideally, pragmatic clinical trials with randomised stepped-wedge design). Efforts will be needed to improve and measure the long-term sustainability and effect of such complex programmes.

Contributors

BA and SMB designed the study and supervised study implementation. BA and AMA led the writing of the paper and contributed to data interpretation. BA, AMA, and NZK coordinated study implementation. AG-A led the data analysis and contributed to the writing of the paper. PN, JB, GO, RM, AE, JJ, MM, and JM led local project implementation and data collection. All authors contributed to the interpretation of data and subsequent writing, reviewing, and revision of the manuscript.

Declaration of interests

SB has a contract agreement with the Agency for Healthcare Research and Quality. All other authors declare no competing interests.

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