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# Scalability and Sustainability of a Surgical Infection Prevention Program in Low-Income Environments

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Supplemental content

**IMPORTANCE** Surgical infections are a major cause of perioperative morbidity and mortality, particularly in low-resource settings. Clean Cut, a 6-month quality improvement program developed by the global nonprofit organization Lifebox, has demonstrated improvements in postoperative infectious complications. However, the pilot program required intense external programmatic and resource support.

**OBJECTIVE** To examine the improvement in adherence to infection prevention and control standards and rates of postoperative infections in hospitals in the Clean Cut program after implementation strategies were updated and program execution was refined.

**DESIGN, SETTING, AND PARTICIPANTS** This cohort study evaluated and refined the Clean Cut implementation strategy to enhance scalability based on a qualitative study of its pilot phase, including formalizing programmatic and educational materials, building an automated data entry and analysis platform, and reorganizing hospital-based team composition. Clean Cut was introduced from January 1, 2019, to February 28, 2022, in 7 Ethiopian hospitals that had not previously participated in the program. Prospective data initiated on arrival in the operating room were collected, and patients were followed up through hospital discharge and with 30-day follow-up telephone calls.

**EXPOSURE** Implementation of the refined Clean Cut program.

**MAIN OUTCOMES AND MEASURES** The primary outcome was surgical site infection (SSI); secondary outcomes were adherence to 6 infection prevention standards, mortality, hospital length of stay, and other infectious complications.

**RESULTS** A total of 3364 patients (mean [SD] age, 26.5 [38.0] years; 2196 [65.3%] female) from 7 Ethiopian hospitals were studied (1575 at baseline and 1789 after intervention). After controlling for confounders, the relative risk of SSIs was reduced by 34.0% after program implementation (relative risk, 0.66; 95% CI, 0.54-0.81; $P < .001$). Appropriate Surgical Safety Checklist use increased from 16.3% to 43.0% ($P < .001$), surgeon hand and patient skin antisepsis improved from 46.0% to 66.0% ($P < .001$), and timely antibiotic administration improved from 17.8% to 39.0% ($P < .001$). Surgical instrument (38.7% vs 10.2%), linen sterility (35.5% vs 12.8%), and gauze counting (89.2% vs 82.5%; $P < .001$ for all comparisons) also improved significantly.

**CONCLUSIONS AND RELEVANCE** A modified implementation strategy for the Clean Cut program focusing on reduced external resource and programmatic input from Lifebox, structured education and training materials, and wider hospital engagement resulted in outcomes that matched our pilot study, with improved adherence to recognized infection prevention standards resulting in a reduction in SSIs. The demonstration of scalability reinforces the value of this SSI prevention program.

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Surgical site infections (SSIs) are an important quality metric. They generally occur at a much higher rate in low- and middle-income countries (LMICs)[1,2] and represent the most common cause of health care–associated infection in Sub-Saharan Africa.[3] A recent study[4] demonstrated that 23% of patients developed SSIs after gastrointestinal surgery in low–human development index (HDI) settings vs 9% in high-HDI settings. Inequalities in accessing health care resources in Ethiopia continue to be high,[5] and estimates of SSI rates in Ethiopia range from 11% to 14%[6-8] but are typically estimated via patient medical record review, a strategy known to underestimate SSIs in LMICs.[9]

Surgical infection prevention and control (IPC) bundles have been shown to reduce SSIs in many settings, from high-resource ventral hernia repair practices[10] to colorectal surgery groups.[11-14] In sub-Saharan Africa, a recent randomized clinical trial of changing gloves and instruments before abdominal wound closure demonstrated a 13% reduction in the risk of SSIs.[15] Surgical IPC standards and recommendations are well established and supported by multiple guidelines,[16-21] but implementation of best practices, especially in resource-limited settings, is difficult to accomplish and measure.[22,23]

Clean Cut is an adaptive, multimodal surgical quality improvement program that aims to reduce SSIs through improved adherence to best practices. The program is implemented in concert with partner hospitals focused on surgical infection prevention in 6 key areas: (1) appropriate surgeon hand scrubbing and patient skin preparation, (2) surgical instrument decontamination and sterilization, (3) antibiotic prophylaxis, (4) reusable gown and drape integrity and sterility, (5) gauze counting, and (6) use of an adapted World Health Organization Surgical Safety Checklist (SSC).

Clean Cut was piloted at 5 hospitals in Ethiopia[8] by Lifebox, a nonprofit organization focused on improving the safety of surgery and anesthesia worldwide. The 2-year pilot phase (2016-2018) demonstrated significant improvement in adherence to IPC standards and a commensurate 35% relative risk (RR) reduction in SSIs after program implementation.[24] After the pilot phase, clinician feedback on program strengths and weaknesses was gathered in a qualitative study[25] to further refine program implementation.

Recognizing that scalability and affordability were necessary for long-term success and wider implementation, several programmatic changes were made: formalization of programmatic and educational materials, creation of an automated data entry and analysis platform, modifications of hospital-based team composition, and elimination of stipends for program participation. The COVID-19 pandemic necessitated additional reduction of in-person external engagement from 2020 onward. This study examines the improvement of adherence to IPC standards and rates of postoperative infections in 7 additional hospitals after updating implementation strategies and refining Clean Cut program execution.


## Key Points

**Question** Is a quality improvement program to reduce surgical site infections in low-income settings, modified to enhance scalability and sustainability, associated with similar outcomes as a pilot program?

**Findings** This cohort study of the Clean Cut quality improvement initiative included 3364 surgical patients from 7 Ethiopian hospitals; after program implementation, all 6 infection prevention process measures improved significantly, with a 34% relative risk reduction of surgical site infection.

**Meaning** The modified, scalable Clean Cut program was associated with similar improvements in infection prevention practices and reduction in surgical infections as the pilot program, supporting its value for wider implementation.

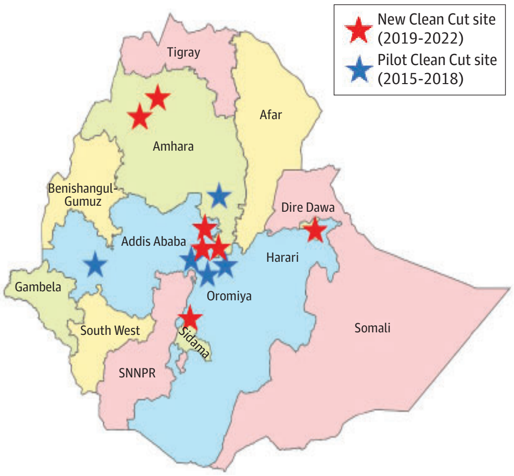

## Methods

### Clean Cut Program and Data Collection

The structure of the Clean Cut program (**Figure 1**) includes phased implementation and team building, collecting data on adherence to IPC standards via direct observation of behaviors in the operating room by surgical staff, coupled with tracking inpatient and 30-day outcomes. All adult patients undergoing major operating room cases at participating hospitals during the study period were included in this cohort study; patients were excluded if they were younger than 18 years. Postoperative data were collected prospectively by daily review of the patient's clinical factors, antibiotic prescriptions, signs of SSI, other complications, and mortality. Surgical site infection was defined according to the 2008 Centers for Disease Control and Prevention criteria.[26] Thirty-day follow-up data were collected for each patient with a telephone call by a trained nurse, who inquired about signs and symptoms of SSI. All data, both before and after program implementation, were collected by the same team at each hospital and were entered into a web-based data collection platform using the DHIS2 software, version 2.38 (DHIS2). Ethical approval was obtained by the Ethiopian Federal Ministry of Health through the Armauer Hansen Research Institute. The requirement for informed consent was waived by the Armauer Hansen Research Institute Institutional Review Board (which functions as the national institutional review board for the Ministry of Health) because this was a quality improvement program with any patient-facing elements of the study being the implementation of best evidence-based infection prevention practices. This study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guideline.

At the beginning of the program, a process mapping exercise was conducted to identify practice gaps and improvement opportunities for each of the 6 IPC standards. After this baseline period, which ranged from 1 to 4 months of data collection, hospital staff examined their process mapping and baseline performance data to create action plans for improvement. They gathered monthly for a data review and quality improvement meeting to iteratively improve SSI prevention behaviors. The primary outcome was SSI; secondary outcomes

Figure 1. Clean-Cut Implementation Sites and Program Phases




| | |
|---|---|
| Phase 1: set up the program (week 1) | • Introduce the Clean Cut program<br>• Identify the Clean Cut program team |
| Phase 2: establish a baseline (months 1-2) | • Assess the hospital context and current practices<br>• Perform the process mapping exercise<br>• Establish a surveillance system, begin data collection |
| Phase 3: develop an action plan (month 2) | • Review baseline hospital data<br>• Connect the data with process mapping findings<br>• Develop and implement an action plan |
| Phase 4: improve continuously (months 3-6) | • Perioperative infection prevention refresher courses<br>• Surgical safety checklist strategies workshop<br>• Safer surgical instruments training<br>• Improving teamwork: SAFE OR course |
| Phase 5: beyond the Clean Cut program (month 6 or later) | • Integrate the Clean Cut program with the facility's quality improvement team<br>• Quality improvement beyond Clean Cut |

were adherence to IPC standards, reoperation, length of stay, and mortality.

## Hospital Setting and Ethics

Site selection was guided by the Ethiopian Federal Ministry of Health; 6 of the hospitals were referral-level hospitals, and 1 was a district-level hospital (Figure 1). The program was completed during 6 to 12 months at each site from January 1, 2019, to February 28, 2022.

## Program Modifications

After the pilot phase, a number of program modifications were made to the Clean Cut program aimed at improving program scalability, effectiveness, and integration into the everyday hospital workflow and culture. The first modification involved building a standard set of program and educational materials and creating an online platform for hosting hospital site engagement. An implementation manual was created with accompanying checkpoints for each program phase. These documents were shared with partner hospitals and used to facilitate program delivery.

The second modification involved emphasizing broad engagement of administrative and operating room staff in the program and eliminating hospital-based team stipends for participation. Clean Cut team composition shifted from a compact team of clinical staff to a more hospital-wide model that included all operating rooms and hospital administrators. Quality improvement meetings presented hospital data to a broad audience, including clinicians from surgery, anesthesia, and obstetrics; operating room and ward nurses; staff from the central sterilization room and laundry; environmental services; hospital administration; and finance personnel. Broadening multidisciplinary involvement supported building a community of learning within hospitals to drive lasting changes in culture where best practices are integrated in the hospital workflow. Although remuneration for data collection and entry varied by site, direct financial stipends were no longer provided for staff participation in the quality improvement program.

The third modification involved establishing a platform for data entry, quality checking, and initial analysis. Compared with the pilot program, which used paper forms and manual entry into Excel spreadsheets, we created an open-source DHIS2 software–based platform for data entry. Data were entered using the web-based or mobile telephone–based options for the software and fed into hospital-specific databases that populated real-time dashboards with data on adherence behaviors and outcomes. Data were also accessible for real-time quality checking for accuracy and completeness by program leadership.

The fourth modification involved instituting supplementary education to reinforce infection prevention standards. Supplementary IPC training materials were developed and provided to hospital staff on each of the 6 infection prevention standards. The IPC training was designed using guidelines from the World Health Organization,[16] Jhpiego,[18] and the Centers for Disease Control and Prevention[17] as well as other literature. Pretests and posttests were administered to confirm transfer of knowledge. Workshops on SSC implementation and surgical instrument reprocessing were also conducted with perioperative staff at each hospital, with certain staff selected to complete a training-of-trainers portion to further disseminate the workshop materials to additional staff.

## Statistical Analysis

Patient demographics were analyzed via $\chi^2$ tests for categorical variables and 2-tailed, unpaired *t* tests for continuous variables. Adherence to each of the 6 IPC standards before and after implementation was analyzed using $\chi^2$ tests. Multiple behaviors are required for full adherence with each standard as previously described in our pilot work, and adherence to each was defined as all criteria in

Table 1. Patient Demographics and Outcomes Before and After Implementation of the Clean Cut Program[a]

| Factor | Preintervention (n = 1575) | Postintervention (n = 1789) | *P* value |
|---|---|---|---|
| Sex | | | |
| Female | 1069 (67.9) | 1127 (63.0) | .003 |
| Male | 506 (32.1) | 662 (37.0) | |
| Age, mean (SD), y | 27.1 (16.7) | 26.0 (49.7) | .40 |
| Diabetes | 35 (2.2) | 31 (1.7) | .01 |
| Hypertension | 89 (5.7) | 70 (3.9) | .31 |
| ASA classification | | | |
| I | 1154 (73.3) | 1272 (71.1) | <.001 |
| II | 280 (17.8) | 415 (23.2) | |
| III | 39 (2.5) | 25 (1.4) | |
| IV | 4 (0.3) | 1 (0.1) | |
| Unknown | 98 (6.2% | 76 (4.2) | |
| Procedure | | | |
| General surgery | 538 (34.2) | 638 (35.7) | <.001 |
| Obstetrics/gynecology | 701 (44.5) | 683 (38.2) | |
| Subspecialty surgery | 274 (17.4) | 362 (20.2) | |
| Unknown | 62 (3.9) | 106 (5.9) | |
| Case urgency | | | |
| Elective | 592 (37.6) | 652 (36.4) | .72 |
| Emergency | 877 (55.7) | 1021 (57.1) | |
| Unknown urgency | 106 (6.7) | 116 (6.5) | |
| Wound class | | | |
| Wound class I or II | 969 (61.5) | 961 (53.7) | <.001 |
| Wound class III or IV | 138 (8.8) | 242 (13.5) | |
| Unknown | 468 (29.7) | 586 (32.8) | |
| Outcomes | | | |
| Surgical site infection | 152 (23.2) | 144 (17.4) | .006 |
| Urinary tract infection | 5 (0.4) | 1 (0.1) | .06 |
| Pneumonia | 19 (1.7) | 13 (0.9) | .10 |
| Other complications | 12 (1.1) | 9 (0.7) | .27 |
| Reoperation | 33 (2.9) | 14 (1.0) | <.001 |
| Length of stay, d | 5.6 (4.3-6.9) | 5.1 (4.6-5.5) | .35[b] |
| 30-d mortality | 36 (5.5) | 37 (4.4) | .34 |

Abbreviation: ASA, American Society of Anesthesiologists.

[a] Data are presented as number (percentage) of patients unless otherwise indicated.

[b] Using 2-tailed, unpaired *t* test.

that category being met during intraoperative observation. To aggregate performance in all areas, a mean adherence score was calculated using the sum of the total areas of perioperative infection prevention, with perfect adherence being 6 of 6. Mean adherence scores before and after implementation were compared using 2-tailed, unpaired *t* tests. The RR of SSI before and after implementation was calculated using modified robust Poisson regressions controlling for age, comorbidities, case urgency, American Society of Anesthesiologists classification, type of procedure, and wound class. Because of loss to follow-up at 30 days postoperatively, we conducted sensitivity analyses using best- and worst-case scenarios in which all patients missing follow-up SSI data were recorded as having an SSI or not having an SSI, again using modified robust Poisson regressions controlling for the same factors. The mean adherence score was also plotted over time across all 7 hospitals from 100 days before Clean Cut implementation to 200 days after implementation. Best-fit lines in the before and after implementation were calculated using univariate linear regressions. All analyses were performed using Stata/SE, version 16.1 (StataCorp LLC).

## Results

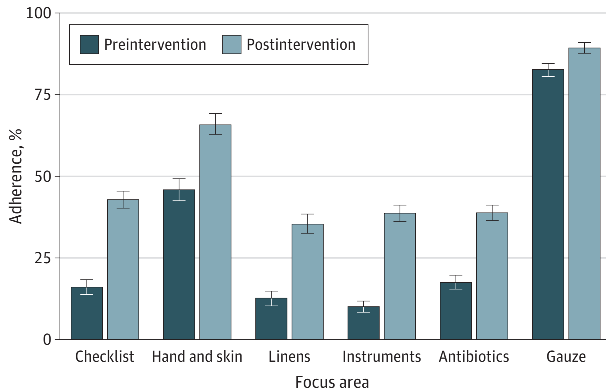
A total of 3364 patients (mean [SD] age, 26.5 [38.0] years; 2196 [65.3%] female and 1168 [34.7%] male) were included in the study: 1575 in the preintervention period and 1789 in the postintervention period (**Table 1**). The 2 groups were demographically comparable, and the case mix of emergency vs elective cases was not statistically different.

Adherence significantly improved in all 6 focus areas after Clean Cut implementation (**Figure 2**), including SSC use (43.0% vs 16.3%), surgeon hand and patient skin antisepsis (66.0% vs 46.0%), timely antibiotic administration (39.0% vs 17.8%), surgical instrument (38.7% vs 10.2%), linen sterility (35.5% vs 12.8%), and gauze counting (89.2% vs 82.5%, $P < .001$ for all comparisons). Mean (SD) adherence scores, calculated as a composite score of perfect adherence to each of the 6 IPC measures, improved from 1.53 (0.48) before Clean Cut to 2.59 (1.22) after the program ($P < .001$). Mean adherence scores improved over time across the intervention (**Figure 3**), with a significant increase in the rate of improvement in the postintervention period (β = 0.026; 95% CI, 0.022-0.023) compared with the preintervention period (β = 0.0135; 95% CI, 0.0131-0.0140; $P < .001$).

A total of 2508 patients (74.6%) were admitted to the ward postoperatively and had complete SSI data, whereas 1481 (44.0%) had complete 30-day SSI data (eTable in Supplement 1). The unadjusted incidence of SSI decreased significantly after Clean Cut implementation (17.4% from 23.2% before implementation, $P = .006$) (Table 1). In multivariate analysis controlling for age, comorbidities, case urgency, American Society of Anesthesiologists classification, type of procedure, and wound class, patients in the postimplementation period had a 34% reduced risk of developing SSI (RR, 0.66; 95% CI, 0.54-0.81; $P < .001$) (**Table 2**). There was also a significant decrease in the need for subsequent operations (1.0% from 2.9%, $P < .001$) (Table 1). Reduction in length of stay (5.1 vs 5.6 days, $P = .35$) and overall mortality (4.4% from 5.5%, $P = .34$) did not reach statistical significance.

More patients were lost to follow-up at 30 days postoperatively in the preintervention period than in the postintervention period (58.4% vs 53.8%) (eTable in Supplement 1). Because of this high loss to follow-up, we conducted sensitivity analyses using best- and worst-case scenarios in which all patients missing follow-up SSI data were imputed as having or not having an SSI, again using modified robust Poisson regressions that controlled for the same factors. The reduction in SSI after program implementation remained significant in best-case (RR, 0.75; 95% CI, 0.61-0.94; $P = .01$) and worst-case (RR, 0.91; 95% CI, 0.86-0.95; $P < .001$) scenarios (Table 2).

Figure 2. Improvements in Infection Prevention Behaviors




$P < .05$ for all comparisons. Error bars indicate 95% CIs.

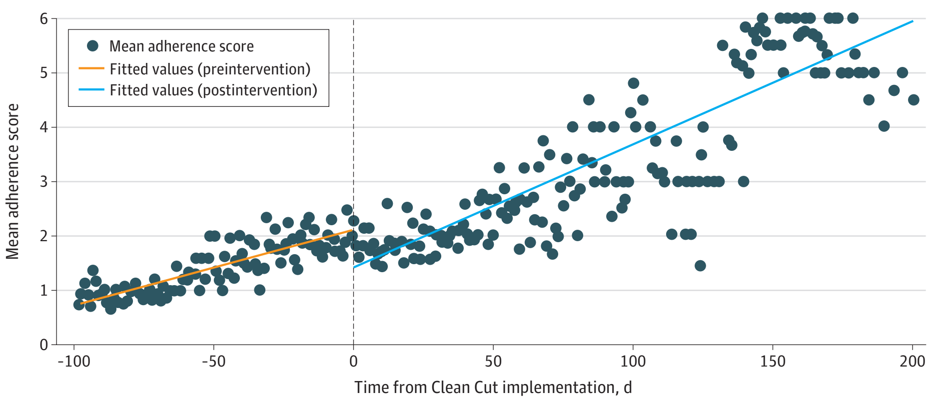
## Discussion

Following initial success of the Clean Cut program, this study found that improvements to standardize program materials and trainings and expand program delivery to entire hospital surgical teams while reducing direct support from Lifebox were associated with improvements in behaviors and reductions in SSI rates on par with the original pilot study. The initial Clean Cut pilot program was resource intensive and required sustained engagement by the Lifebox team at each site. It also lacked standardized materials for program-related education and training or an automated system for data recording. To scale the program, we needed to simplify implementation and facilitate uptake. These findings confirm that the program produced equivalent behavior change and improved patient outcomes using a more scalable delivery model with fewer resource requirements from Lifebox.

### Process Changes

Multiple studies[27,28] have described the impact of quality improvement programs on SSI reduction in low-HDI settings. The choice of intervention is important, as those undertaken in high-income environments may not have the same cost-benefit ratio in low-income settings. As demonstrated by the FALCON trial (Pragmatic Multicentre Factorial Randomised Controlled Trial Testing Measures to Reduce Surgical Site Infection in Low and Middle Income Countries), changes to more expensive products, such as chlorhexidine skin preparation and triclosan-coated sutures, did not reduce SSI in LMICs, despite higher costs.[29] Another multimodal SSI reduction program in sub-Saharan Africa that focused on improving process indicators—including preoperative bathing, hair removal, antibiotic administration, and in-theater traffic—showed significant improvement in each indicator and subsequent reduction in SSI from 8.0% to 3.8%.[30] This intervention focused on local practitioners implementing evidence-based guidelines; however, it lacked attention to instrument cleaning, linen reprocessing, reducing retained surgical items, and team communication through use of the SSC—all areas we found to have major gaps in our setting.[31,32] Furthermore, the Clean Cut program fits within the framework proposed by the International Society for Infectious Diseases (identifying IPC champions, prioritizing IPC training in LMICs, using multimodal improvement measures, and using telecommunication for follow-up)[33] and recapitulates the findings of other multimodal quality improvement programs to reduce SSI in low-income environments.[30,34] Compared with the pilot study, adherence to some standards (antibiotics administration, SSC completion, and skin antisepsis) was lower both before and after program intervention. More stringent criteria were used in the current study to measure adherence to these standards, partially as a result of

Figure 3. Adherence to Infection Prevention Over Time




improved data collection mechanisms using the DHIS2 platform, but the degree of improvement after Clean Cut implementation was similar or better in each area.

## Impact of Specific Program Modifications

For the first modification, which involved building standard program materials and creating an online platform for hosting hospital site engagement, the implementation manual and standard program materials provide a consistent experience for each hospital, enhancing the scalability of the program. During the COVID-19 pandemic, we necessarily transitioned to online delivery of some training and team meetings and noted that these were possible to deliver in a lighter-touch format.

For the second modification, which involved hospital-wide implementation, community building, and eliminating financial incentives, the inclusion of more operating rooms in the program enabled more hospital-wide engagement of staff, creating a cultural shift that appears to persist after formal conclusion of the Clean Cut program, as seen in a separate study[35] of program sustainability. In an effort to adapt Clean Cut structure to maximize sustainability and scalability, Lifebox stopped providing stipends to hospital staff for participation in the program. When the hospital rather than an external organization takes on responsibility for aligning staff incentives or modes of compensation for additional responsibilities associated with the program, there is greater potential for uptake and long-term impact.[36-39]

For the third modification, which involved establishing a platform for data entry, quality checking, and initial analysis, the addition of an automated data management system with the ability to synthesize and report real-time adherence and outcome information to program leaders was a major upgrade to the Clean Cut program. The DHIS2 platform was chosen because of its open-source nature[40] and ability to potentially integrate with the existing Ethiopian Federal Ministry of Health reporting system. The ability to audit data for quality and completeness and to view and react to trends in real time without the need for an intermediary to clean and analyze data each month reduced the burden on program staff and allowed for more hospital team autonomy. We anticipate this platform will continue to allow for scalability of the program.

For the fourth modification, which involved instituting supplementary education to reinforce infection prevention standards, supplementary training on infection prevention standards was a critical part of improving practice in Ethiopia, where many IPC processes are nursing driven and fit with recommendations for other LMIC's IPC programs.[20] The available workshops on IPC standards, SSC adaptation and uptake, and surgical instrument reprocessing can now be delivered in a standardized fashion to all Clean Cut sites to close these knowledge and training gaps.[41,42]

## Limitations

This study has some limitations. As with many quality improvement programs in the global health sphere, our work was significantly affected by COVID-19 and shifting geopolitics. Several hospitals had just completed delivery of Clean Cut workshops in March 2020 and then had a long interruption in program delivery because of the pandemic before implementation resumed 6 to 8 months later. Additionally, the political upheaval and ethnic conflicts in Ethiopia over the past several years intermittently interrupted communications and made travel unsafe, which in turn affected the ease of the Clean Cut program implementation. These delays also prolonged the baseline period for some hospitals, which continued to collect data even though the program had formally not been implemented, and resulted in our baseline and follow-up groups being nearly equal in size; our original 6-month program design includes a baseline cohort representing only 1 to 2 months of data.

The loss to follow-up was high in our cohort: up to one-quarter of patients did not have inpatient data, although many likely had outpatient operations (our data format did not distinguish between inpatient and outpatient surgery), and half did not have 30-day outpatient follow-up. The higher loss to follow-up in the preintervention phase mirrors our experience in the pilot study because data collectors get better at following up patients over time. Because our sensitivity analyses assumed that all patients missing data were either positive

Table 2. Adjusted and Unadjusted Risk Factors for Surgical Site Infection

| Risk factor | Unadjusted RR (95% CI) | Unadjusted P value | Adjusted RR (95% CI) | Adjusted P value |
|---|---|---|---|---|
| Intervention status | | | | |
| Preintervention | 1 [Reference] | NA | 1 [Reference] | NA |
| Postintervention | 0.75 (0.61-0.92) | .006 | 0.66 (0.54-0.81) | <.001 |
| Age, y | | | | |
| <10 | 1 [Reference] | NA | 1 [Reference] | NA |
| 10-19 | 0.75 (0.45-1.26) | .28 | 0.65 (0.40-1.08) | .10 |
| 20-29 | 1.07 (0.81-1.43) | .62 | 1.01 (0.76-1.34) | .94 |
| 30-39 | 1.12 (0.82-1.52) | .48 | 1.08 (0.80-1.47) | .60 |
| 40-49 | 1.07 (0.68-0.1.70) | .76 | 0.99 (0.63-1.57) | .98 |
| ≥50 | 1.05 (0.73-1.50) | .79 | 1.01 (0.70-1.46) | .96 |
| Diabetes | 0.96 (0.43-2.13) | .92 | 1.05 (0.45-2.45) | .91 |
| Hypertension | 1.15 (0.68-1.96) | .61 | 1.29 (0.74-2.25) | .36 |
| Case urgency | | | | |
| Elective | 1 [Reference] | | 1 [Reference] | |
| Emergency | 1.74 (1.38-2.20) | <.001 | 2.01 (1.56-2.60) | <.001 |
| Unknown urgency | 2.14 (1.52-3.01) | <.001 | 1.81 (1.23-2.65) | .002 |
| ASA classification | | | | |
| I | 1 [Reference] | NA | 1 [Reference] | NA |
| II | 0.95 (0.76-1.20) | .69 | 1.04 (0.81-1.34) | .76 |
| III | 1.26 (0.69-2.31) | .46 | 1.12 (0.60-2.06) | .73 |
| IV | 2.36 (0.59-9.50) | .23 | 1.7 (1.02-2.82) | .04 |
| Unknown | 0.39 (0.21-0.71) | .002 | 0.38 (0.21-0.70) | .002 |
| Procedure | | | | |
| General surgery | 1 [Reference] | NA | 1 [Reference] | NA |
| Obstetrics/gynecology | 0.66 (0.51-0.87) | .002 | 0.62 (0.47-0.82) | .001 |
| Other subspecialty | 0.98 (0.76-1.26) | .85 | 1.31 (1.01-1.69) | .04 |
| Unknown | 1.14 (0.78-1.66) | .499 | 0.93 (0.61-1.42) | .73 |
| Wound class | | | | |
| I or II | 1 [Reference] | NA | 1 [Reference] | NA |
| III or IV | 2.18 (1.55-2.89) | <.001 | 1.61 (1.15-2.26) | .006 |
| Unknown | 0.14 (0.12-0.17) | <.001 | 1.66 (1.31-2.12) | <.001 |
| Sensitivity analyses (n = 3364) | | | | |
| Worst case (assumes SSI is present if SSI is missing) | NA | NA | 0.91 (0.86-0.95) | <.001 |
| Best case (assumes SSI is not present if SSI is missing) | NA | NA | 0.75 (0.61-0.94) | .01 |

Abbreviations: ASA, American Society of Anesthesiologists; NA, not applicable; RR, relative risk; SSI, surgical site infection.

or negative for SSIs, this approach biases our work for or against our intervention having an effect, respectively. Because both analyses demonstrated a strong effect of our intervention, we are confident that our findings represent true improvements in outcomes. Although patient follow-up is a pervasive challenge in many environments, the fact that this degree of follow-up was accomplished is a testament to the commitment of the hospital team, who have multiple competing priorities.

Furthermore, the Lifebox Clean Cut program has a relatively narrow focus on 6 infection prevention areas and excluded some standards that are common in bundled quality improvement programs, such as hair clipping, glycemic control, normothermia, and preoperative bathing. The 6 areas were chosen in part because of the clear gaps seen in each during program development[8] and the difficulty in monitoring more complex measures, such as intraoperative temperature or glycemic control in settings with limited patient monitoring and laboratory testing capacity. Other interventions, such as changing gloves and instruments for abdominal wound closure after gastrointestinal surgery, can impact SSI risk in low-income environments as well[15] and could be considered for future iterations of this program.

## Conclusions

This cohort study's findings confirm that the Lifebox Clean Cut program is an effective and scalable surgical quality improvement program with a demonstrable association with improved adherence to infection prevention standards in Ethiopian operating rooms and with a reduction in SSIs. The modifications made to program implementation as a result of shared learning allow for wider implementation with more standardized and automated program features and produced results that were similar to the original pilot program, including comparable reductions in SSI. Because the Clean Cut program is scaled to a wider global audience, further study of the strategies of successful program implementation will be needed.

## ARTICLE INFORMATION

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