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Impact of WHO's Surgical Safety Checklist-Based Program on Cleft-lip and Palate Repair Outcomes in LMICs—The CLEAN CLEFT Program

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Abstract

Background: "Clean Cleft" (CC) is an adaptation of the Lifebox Clean Cut program, designed to reduce surgical site infections (SSIs) in cleft lip and palate repairs. It focuses on 6 key processes: hand and site decontamination, surgical linen integrity, instrument sterility, timely antibiotic use, gauze counting, and WHO Surgical Safety Checklist compliance. The study explores CC's effectiveness in reducing infections, other complications, and enhancing early recovery.

Methods: CC was piloted in 2 Ethiopian hospitals and 1 in Côte d'Ivoire, the primary public cleft care centers in each country. Baseline data were collected through direct observation in the operating room, with patients monitored postoperatively for infections and complications through daily ward visits and follow-up calls or clinic visits at 30 days. Post-intervention data were collected for 5 months. Data was captured in DHIS2 software and analyzed using SPSS version 26.

Results: The program enrolled 275 patients, with 156 during baseline and 119 post-implementation. Complications significantly dropped from 21.7% to 8.7% ($P = .008$), a 60% decrease. SSI rates fell from 18.1% to 8.0% ($P = .03$), while palatal fistulas decreased from 13.0% to 6.1% ($P = .1$) and wound dehiscence from 18.0% to 8.0% ($P = .03$). Adherence to perioperative standards improved, except for hand and skin preparation while pain management remained effective throughout the program.

Conclusion: CC improved perioperative practices, significantly reducing infections, palatal fistulas, and wound dehiscence, supporting the broader program expansion to any subspecialty.

Keywords

surgical site infection, cleft lip & palate, quality improvement, LMIC, infection prevention, outcome

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Background

Cleft lip and palate (CLP) is one of the most prevalent birth anomalies worldwide.[1] An estimated 1 to 2 cases of CLP occur per 1000 live births.[2,3] As a result, CLP repair is one of the most frequently performed reconstructive operations.[4] Palatoplasty, the surgical procedure for correcting CLP, is associated with various complications that cause concern among surgeons.[5] The incidence of these complications ranges from 1.7% to 8.2% and include wound dehiscence, surgical site infection (SSI), stitch granuloma, hypertrophic scarring, and notching on the white roll and vermilion segment of the lip.[6]

Correcting CLP typically involves a "clean-contaminated" surgical procedure, and postoperatively the wound is exposed to saliva and oral flora due to its location. Wound infection is a recognized potential risk of clean-contaminated surgical procedures, with reported rates ranging from 5% to 10%.[7] However, the chance of developing postoperative infection after CLP surgery is relatively low, at approximately 1.5%.[8] However, the majority of studies on SSI after CLP have been performed in high-income countries,[5,6,8] whereas most CLP surgery is performed in low- and middle-income countries, where resources are scarce, hygiene standards are lower, and patient compliance and follow-up care are less reliable.[9] There is also little information in the literature describing wound dehiscence after CLP repair wound infections, however, more generally SSI is a risk factor for wound dehiscence.[6]

There is a paucity of robust data on the prevalence of SSI following CLP surgery in low- and middle-income countries, which includes almost all countries in Sub-Saharan Africa. Therefore, we set out to determine the prevalence of SSI following CLP surgery at 3 hospitals in sub-Saharan Africa and evaluate the effectiveness of quality improvement interventions in reducing this complication.

This study aimed to characterize gaps in perioperative infection prevention practices for CLP surgery in LMIC settings, as well as to determine the impact of the CC program on perioperative practices, SSI, and other cleft surgery-related outcomes.

Patients and Methods

Setting

This study was conducted at 3 cleft care centers: 2 in Addis Ababa (hospitals 1 and 3), Ethiopia, and 1 in Abidjan (hospital 2), Côte d'Ivoire. These 3 centers are public hospitals that provide comprehensive CLP treatment. The hospitals in Ethiopia are affiliated with Addis Ababa University; the Ivorian Hospital is affiliated with Felix Houphouet Boigny University, and all hospitals currently serve as teaching centers for CLP surgery.

Participants

The study population consisted of patients undergoing cleft lip and/or palate surgery during the study period who provided consent, or whose parents/guardians consented for postoperative follow-up by phone or outpatient clinic follow-up visits. Patients who were lost to follow-up were excluded from outcome assessments.

Study Design

A prospective cohort study was conducted over 1 year from September 2022 to August 2023. The intervention was the implementation of the CC program, a quality improvement program aimed to reduce surgical infections as well as complications relevant to cleft surgery. The program targets 6 key infection prevention and control (IPC) areas: hand and surgical-site skin antisepsis; maintenance of sterile surgical field; appropriate instrument decontamination and sterilization, appropriate timing and selection of prophylactic antibiotics; routine surgical gauze counting; and routine use of the WHO Surgical Safety Checklist.

Trained data collectors using structured data collection tools in the intraoperative, postoperative inpatient, and outpatient phases of the patient surgical course collected baseline and intervention data. Postoperatively patients were followed daily in the hospital until discharge and had a follow-up clinic visit or phone call on or around the 30th postoperative day to assess surgical infections, other postoperative complications, and mortality. After baseline data collection the CC program was implemented, which includes process mapping for identification of gaps in perioperative infection prevention practices, developing corrective action plans with all involved stakeholders, and delivering training to improve compliance with best practices.

Data were collected intraoperatively, including demographics, surgical procedures, compliance with standards, and intraoperative events including intraoperative complications. In the wards following surgery, data were collected daily through the day of discharge, including status of the surgical wound, early postoperative complications such as post-operative bleeding and airway obstruction, pain control, duration and type of postoperative antibiotics, reoperations, and mortality. Follow-up assessment was performed on the 30th postoperative day by outpatient clinic visit or phone call, and the parents were asked about the status of the wound for any sign of surgical complications (wound infection, lip/palatal wound breakdown, palatal flap detachment, palatal fistula), any hospital visit and wound management, the overall status of the patient including mortality. We were using pictures of the wound taken by the relatives or health care giver at nearby health service or at the out patient department to assess the wound.

A surgical resident and surgeons supported the program implementation by organizing team meetings once or twice per month at each of the hospitals, guiding initial modification of the checklist, conducting staff training to ensure accurate data collection, leading process-mapping exercises, and facilitating the review of surveillance and process-mapping information to identify opportunities for improvement. Data was entered and analyzed on DHIS2 (District Health Information Systems 2) software. The data was also extracted from DHIS2 to Excel spreadsheet and further analyzed using SPSS version 26. Patient demographics were analyzed via chi-squared tests for categorical variables and t-tests for continuous variables. Adherence to each of the 6 IPC standards before and after implementation and outcomes including morbidity and mortality were compared. A composite morbidity outcome included postoperative bleeding, post-operative airway obstructions, pneumonia, upper respiratory tract infection (URTI), palatal flap necrosis, wound dehiscence, palatal fistula,

uncontrolled pain, and reoperation. The relative risk (RR) of morbidity and mortality before and after implementation was calculated using logistic regression controlling for age, sex, comorbidities, and wound class. A mean compliance score was calculated using the sum of the total areas of perioperative infection prevention, with perfect adherence being 6 out of 6. Mean adherence scores before and after implementation were compared using 2-tailed, unpaired t-tests.

Results

Demographic and Clinical Characteristics

Two hundred and seventy-five patients were enrolled for surgery throughout the program. One hundred and fifty six patients were enrolled during the baseline period and 119 patients after intervention. Follow-up was completed for 252 patients (91.6%). Patients who underwent surgery were aged between 3 months and 43 years. Adults represented 7% of patients. Demographics and clinical characteristics of the patients in the baseline and post-intervention cohorts are summarized in Table 1.

Before the intervention, all perioperative infection prevention standards had significant gaps in all 3 facilities. Compliance with 4 of the 6 infection prevention standards improved significantly after the quality improvement interventions[1] (Table 2). The presence of internal sterility indicators significantly increased from 5.8% at baseline to 84.9% post-intervention ($P < .001$). Although there was a disparity between compliance in different checklist points, the checklist use increased from 44.2% at baseline to 82.3% post-intervention ($P < .001$). The preoperative gauze count compliance significantly increased from 45.5% at baseline to 96.6% in post-intervention ($P < .001$). The linens sterility compliance statistically slightly increased from 32.6% at baseline to 48.7% post-intervention ($P = .01$).

The standard that showed the greatest improvement was instrument sterility, which improved 15-fold after intervention (5.8% vs 84.9%, $P < .001$), and was mostly due to the addition of an internal sterility indicator inside the tray to verify the instruments had reached sterile conditions during the autoclave cycle. However, compliance with hand and surgical field preparation (32.6% vs 26.9%, $P = .3$) did not show significant improvement but decreased compliance. The antibiotics administration compliance (82.6% vs 89.9%, $P = .2$) slightly increased but statistically not significant.

Based on the mean compliance score, OR teams were complying with an average of 2.4 of the 6 critical perioperative infection prevention standards at the baseline; after the implementation of process improvement changes, this improved to an average compliance of 4.2 out of 6 ($P < .001$) (Figure 1).

Outcomes

Morbidity

We observed a statistically significant reduction in overall complications after the program implementation from 21.7% to 8.7% ($P = .008$), with the frequency of complications

Table 1. Overall Patient Demographics and Clinical Characteristics Before and After Interventions.

		Baseline N = 156 (**%)	Post intervention N = 119 (**%)	*P*-value
Hospital	Hospital 1	41 (26.3%)	22 (18.5%)	.1*
	Hospital 2	47 (30.1%)	33 (27.7%)	
	Hospital 3	68 (43.6%)	64 (53.8%)	
Age (months)	Mean (SD)	53.2 (77.9)	43.4 (59.2)	.2**
Age group	Median (ITQ)	23 (10-71)	14 (7-59)	.3*
	Range	2-516	3- 251	
	0-12 months	55 (35.3%)	41 (34.5%)	
	1-3 years	43 (27.6%)	42 (35.3%)	
	3-5 years	17 (10.9%)	11 (9.2%)	
	6-12 years	25 (16%)	11 (9.2%)	
	13-18 years	5 (3.2%)	8 (6.7%)	
	> 18 years	11 (7.1%)	6 (5%)	
Sex	Male	92 (59%)	69 (59%)	1*
	Female	64 (41%)	50 (41%)	
Type of Surgery	Cleft lip and palate procedures	155 (99.3)	117 (98.3)	.01**
	Palate repair	70 (46.1)	36 (30.3)	
	Lip repair	73 (48)	61 (51.3)	
	Fistula repair	4 (2.6)	8 (.76)	
	Lip/nose revision	4 (2.6)	10 (8.4)	
	Alveolar bone graft	0	2 (1.7)	
	Other facial left procedure	1 (0.7)	2 (1.7)	

Values in parentheses are percentages unless indicated otherwise.
*χ^2 test; ** *t*-test.

Table 2. Overall Adherence to the 6 Standards at Baseline and After Interventions and Compliance Score in all Sites.

N (%)	Baseline N = 156	Post intervention N = 119	*P*-value
Overall instruments sterility compliance	**9 (5.8)**	**101 (84.9)**	**<.001***
Internal sterility indicator present	9 (5.8)	101 (84.9)	**<.001***
Instrument tray is dry	156 (100)	118 (99.1)	.1*
Overall checklist compliance	**69 (44.2)**	**98 (82.3)**	**<.001***
Sign in performed aloud	94 (60.2)	104 (87.3)	**<.001***
Time out performed aloud	80 (51.2)	88 (73.9)	**<.001***
Sign out performed aloud	104 (66.6)	114 (95.7)	**<.001***
Overall gauze count compliance	**71 (45.5)**	**115 (96.6)**	**<.001***
Preoperative gauze count performed	73 (46.7)	118 (99.1)	**<.001***
Completion gauze count performed	72 (46.1)	115 (96.6)	**<.001***
Overall linen sterility compliance	**51 (32.6)**	**58 (48.7)**	**.01***
Internal sterility indicator present	51 (32.6)	61 (51.2)	**.002***
Linens are dry	156 (100)	99 (83.1)	.06*
Linen are intact without holes	156 (100)	117 (98.3)	.08*
Antibiotics compliance	**129 (82.6)**	**107 (89.9)**	.2*
Prophylactic antibiotics administered	155 (99.3)	119 (100)	.4*
Antibiotics given within 60 min of incision	129 (82.6)	107 (89.9)	.2*
Hand/skin antisepsis compliance	**51 (32.67**	**32 (26.9)**	.3*
Appropriate surgeons hand preparation	51 (32.6)	32 (26.8)	.3*
Skin/mouth preparation performed correctly	192 (100)	139 (100)	-
Mean compliance score Mean (SD)	2.4 (1)	4.2 (0.8)	**<.001****

The six perioperative infection prevention standards and statistically significant *P*-values are in bold.
Values in parentheses are percentages unless indicated otherwise.
*χ^2 test; ** *t*-test.

decreased by 60% (Table 3). There was one patient who required immediate take back to the operating room for postoperative bleeding control after palate repair. There was no record of uncontrolled pain greater than 5 on the scale of 10 both in baseline and intervention data. The average time of first feeding after the patient completely wakes up from anesthesia was 4 h which is quite a similar trend during baseline and intervention phase. There were unscheduled hospital visits during the baseline and intervention phases, and the reasons for these visits were URTI, severe pneumonia, patient needed anti pain medication (n = 2) during baseline, and patient had pus discharge from wound site (n = 1). There were no cases of airway obstruction. The most encountered complication at the baseline was wound breakdown, which was significantly reduced following program implementation, from 18.1% during the baseline period to 8.0% following the intervention ($P = .03$). The rate of palatal fistula decreased from 13.0% to 6.1% ($P = .1$) and the hanging palate flap rate fell from 10.1% to 0.8% ($P = .002$).

Mortality

There were 2 deaths throughout the program: one patient during the baseline period who underwent cleft lip repair and died of severe malaria 2 weeks after discharge, and the second in the post-intervention phase who underwent cleft lip repair and died 2 weeks postoperatively due to severe pneumonia.

Multivariate analysis showed that the RR of morbidity for patients with good compliance (score 4-6) to critical standards is significantly lower compared to those with poor compliance (score 0-3), with an RR of 0.1 (95% CI: 0.03, 0.70), $P = .017$ (Table 4). This finding underscores the importance of effective intervention training in promoting adherence to established protocols, which in turn leads to better patient outcomes. However, when considering the timing of implementation, there was no statistically significant difference in RR between baseline and post-intervention groups, with an RR of 1.9 (95% CI: 0.5, 7.4), $P = .3$. Additionally, the cleft palate repair procedure than the cleft lip procedure was strongly associated with a high morbidity risk (RR = 6.5, 95% CI: 2.7-15.8, $P < .001$) indicating that even with adherence to protocols, certain procedures may inherently carry higher risks. These results highlight that while professional experience is valuable, structured training and protocol adherence are critical for minimizing morbidity.

Discussion

Adherence to 6 standard perioperative processes showed remarkable improvements after implementation of the Clean Cleft (CC) program. Notably, there were remarkable increases in the confirmation of instrument sterility using internal indicators, surgical linen integrity compliance, surgical gauze count, and prophylactic antibiotic use. The utilization of the checklist

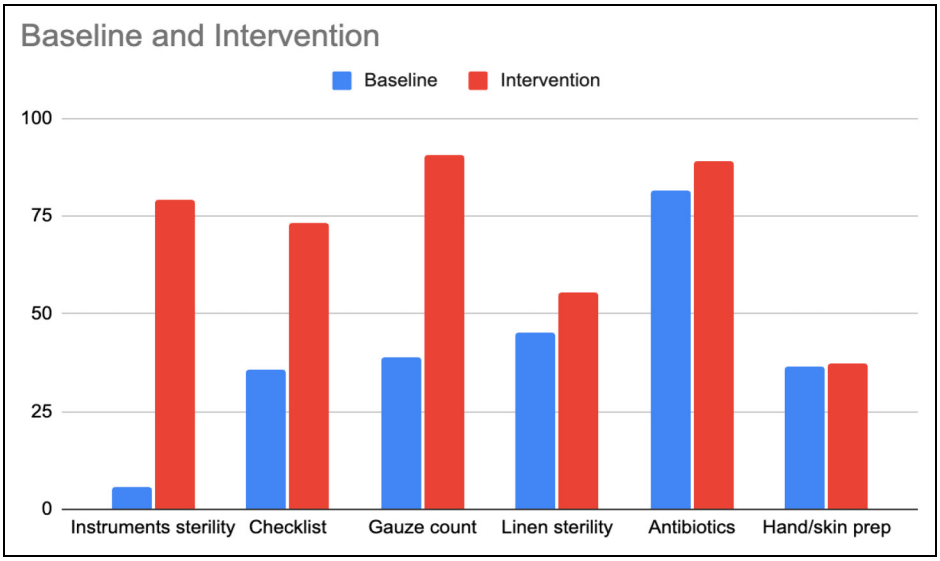

Figure 1. Overall compliance for the 6 process measures.

Table 3. Outcomes at Baseline and After Process Improvement Interventions in all Sites.

	Baseline n = 138 n (%)	Post intervention n = 114 n (%)	*P*-value
Morbidity	30 (21.7)	10 (8.7)	**.008***
Post-operative bleeding	1 (0.6)	0 (0)	-
URTI	2 (1.2)	2 (1.6)	-
Pneumonia	1 (0.7)	1 (0.8)	-
Uncontrolled pain	2 (1.4)	0	.5**
Wound dehiscence	25 (18.1)	9 (7.9)	**.03***
Hanging palatal flap	14 (10.1)	1 (0.8)	**.002****
Palatal flap necrosis	1 (0.7)	1 (0,8)	-
Palatal fistula	18 (13)	7 (6.1)	0.1*
Mortality^	1 (0.7)	1 (0.8)	**-**

The six perioperative infection prevention standards and statistically significant *P*-values are in bold.
Values in parentheses are percentages unless indicated otherwise.
*χ^2 test.
** Fisher test.
^Complications obtained only on in inpatient data, denominator is 156 at baseline 119 post intervention.

Table 4. The Relative Risk of Morbidity Based on Compliance to 6 Critical Standards Timing Controlling for Timing of Implementation, Sex, Age Group, and Type of Procedure.

	RR (95% CI)	*P*-value
Compliance	**0.1 (0.03, 0.70)**	**.017**
Poor (score 0-3) (reference)		
Good (score 4-6)		
Timing of implementation	1.9 (0.5, 7.4)	.3
Baseline (reference)		
Post intervention		
Sex	0.82 (0.38, 1.7)	0.3
Male (reference)		
Female		
Age group	0.4 (0.21, 1)	.05
Less than 2 years (reference)		
More than 2 years		
Type of procedure	6.5 (2.7, 15.8)	**<.001**
Palatal repair (reference)		
Other		

The six perioperative infection prevention standards and statistically significant *P*-values are in bold.
Values in parentheses are percentages unless indicated otherwise.

also increased significantly, indicating a positive shift in adherence to standardized safety protocols. Similar to previous Clean Cut programs, the current study has demonstrated significantly improved compliance with critical infection prevention standards and reduced postoperative infections without requiring major investments in new infrastructure or resources.[10] However, this study notes only a slight reduction in compliance with hand and surgical site preparation, attributed to a shortage of essential materials such as alcohols, povidone-iodine, chlorhexidine, and running water. This emphasizes the importance of addressing logistical challenges and ensuring the availability of necessary resources by engaging hospital administrators and leaders to maintain consistent adherence to safety protocols.[11]

Comparing the compliance findings in this study to the pilot study findings, which was implemented in general surgery, obstetric and other subspecialty procedures, we noted that both results exhibit distinct differences in adherence to IPC protocols before and after process improvement interventions. The pilot study was characterized by larger sample sizes at baseline and after implementation, and demonstrated higher baseline compliance rates across all metrics, indicative of potentially differing initial adherence levels between the 2 cohorts. Furthermore, the pilot study reported compliance improvement in all of 6 points of the program, and consistently higher compliance rates post-implementation, particularly evident in sterile

field compliance, instrument sterility compliance, and gauze count compliance.[12] The differences in baseline compliance levels and the magnitude of improvement between the 2 studies highlight the importance of contextual factors and intervention strategies in influencing adherence to surgical protocols.

A study from Guwahati Comprehensive Cleft Care Center, Assam, India identified different postoperative complications including, wound dehiscence, hanging palate, and total or partial flap necrosis, which is quite similar to the results we found in this research. However, the rate of postoperative bleeding and immediate take back to operation theater is really low in our research compared to studies from India with a 2.4% rate, while the rate of palatal fistula which was 13% and 6.1% in baseline and intervention phase respectively in our study is quite high compared to this same Indian study which is 3.9%.[13] Incidence of palatal fistula in literatures ranges from 0 to 35%[14,15,16] with an overall incidence of 8.6% reported by a meta-analysis of studies in Europe, America, Asia, and Africa.[17] Hence, the rate of palatal fistula in the current study in both baseline and intervention is in line with most studies across the globe. Although complication rates differ among various studies, the observed reduction in complications and morbidity following the intervention clearly demonstrates the positive impact of the clean cut for cleft program.

The rate of wound dehiscence in our study is quite similar to a Ugandan study; however, postoperative infection, which requires prolonged antibiotics, palatal fistula rates, and airway complications is quite low compared to this same Ugandan study.[18]

The irregularities in recording the time of postoperative feeding initiation, averaging at 4 h after complete wakefulness from anesthesia, suggest a need for standardized protocols and meticulous documentation practices in this aspect of postoperative care.[19,20,21] Integrating Enhanced Recovery After Surgery (ERAS) protocols could address these inconsistencies by promoting standardized guidelines for postoperative feeding and documentation. Furthermore, the absence of significant records indicating uncontrolled pain greater than 5 on a scale of 10 in both baseline and intervention data highlights the effective pain management strategies implemented during the surgical procedures. This is crucial for patient comfort and recovery and aligns well with ERAS principles that emphasize multimodal analgesia and patient-centered care.[22]

The unscheduled hospital visits during both baseline and intervention phases, with varied reasons such as respiratory infections (URTI), severe pneumonia, severe malaria with severe anemia, and the need for pain medication, underscore the multifactorial nature of postoperative complications and some like pain control visit are avoidable visits by employing effective pain control methods and feeding practices.

The overall mortality rate remained low and stable throughout the study, preventing a meaningful multivariate analysis of the RR of death after the implementation of the program. The stability in mortality rates may be indicative of the program's success in preventing life-threatening complications, as mortality rates are often influenced by a multitude of factors beyond perioperative care.[23]

Limitations

Although the study findings provide valuable insights into the RR of morbidity based on compliance with critical standards, several limitations should be acknowledged. The observational nature of the study limits the ability to establish causality between compliance with critical standards and outcomes. While the analysis identifies associations, it cannot definitively determine whether improvements in compliance directly lead to reductions in morbidity risk or if other factors are at play. In addition, a Hawthorne effect rather than the program itself might also explain improvements in both compliance and outcomes. Furthermore, the accuracy and consistency of measuring compliance with standards might be subject to bias, because data collectors were OR nurses from each facility.

While the analysis attempts to control for potential confounding variables such as sex, age group, and type of procedure, there may still be unaccounted-for confounders that could influence the observed associations, those that can affect the rate of complications: comorbidities, severity of cleft gap, surgical technique, surgeon experience, and post surgical care at home.

Short-term changes in compliance or outcomes may not accurately reflect the effectiveness of interventions over time. A relatively small number of cleft patients enrolled for the program in some of the centers was also a challenge.

Conclusions and Recommendations

In conclusion, this study demonstrates that the implementation of a comprehensive CC program through effective intervention training in promoting adherence to established protocols with special focus on perioperative standards and infection prevention, is associated with a substantial reduction in complications following CLP surgery. While specific compliance factors may not independently predict complications, the overall impact of improved adherence to perioperative standards is evident in the significant reduction in RR of morbidity. While perioperative standards are key to reduce SSIs, effective implementation of such programs also reduces other relevant surgery and anesthesia-related complications in CLP surgery. These findings underscore the importance of ongoing quality improvement initiatives in enhancing patient safety and surgical outcomes in cleft care.

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Author Contributions

Drs Alamnie, Timo and Mammo had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Dr Mammo is the senior author. Concept and design: Alamnie, Timo, Eshete, Gebreegziabher, Mehendale, Bankole and Mammo. Acquisition, analysis, or interpretation of data: Alamnie, Timo, Arimino, Starr and Mammo. Statistical analysis: Alamnie, Timo, Arimino, Starr and Mammo. Drafting of the manuscript: Drs Alamnie and Timo. Critical review of the manuscript for important intellectual content: All authors.

Data availability

De-identified data is available with GA, MT and TNM and can be made available upon reasonable request to the authors.

Declaration of Conflicting Interests

The authors declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: GA and MT were Safe Surgery Fellows for Cleft at Lifebox. SA and NS advisors at Lifebox. ME and FM advisory board members at Smile Train, HK staff at Lifebox, TNM is the Clinical Director at Lifebox.

Ethical Statement

The study was conducted in accordance with the Declaration of Helsinki and had received ethical approval from the Addis Ababa University, College of Health Sciences IRB (approval #012/22/surg) on March 23, 2022, with verbal informed consent to be taken from the patients or guardian.

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