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Global scaling of a surgical infection prevention program for low-resource settings: a prospective cohort study in five countries

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Introduction

The burden of surgical site infections (SSI) remains high in low- and middle-income countries (LMICs)(Allegranzi et al., 2011).

Clean Cut (CC), a Lifebox quality Improvement program, first piloted in Ethiopia in 2015, focuses on 6 Infection Prevention Control (IPC) processes:

1. WHO Surgical Safety Checklist use 2. Hand and skin antisepsis, 3. Instrument sterility,	4. Sterile field maintenance, 5. Antibiotic administration, 6. Gauze counting(Feinmann, 2016)

This study evaluates the effectiveness of Clean Cut's scaling up in five hospitals in five countries: Liberia, Madagascar, India, Bolivia, and Malawi

Methods

- Clean Cut is a six-month program sequenced in **phases** with a pre and post program evaluation (baseline vs intervention).
- **Data collection**: all patients/surgical operations performed in selected operating theaters
- **Scaling up organized as follows**:
  - Local lead identification,
  - Implementation manual creation
  - Physical or virtual clinical and programmatic support,
  - Mentoring environment between LMICs staff
  - Materials translations (Bolivia and Madagascar)
  - Adaptations encouraged under mentor's supervision.
- **Scaling up period**: 2021 - 2024
- **Primary outcome**: 30 postoperative days SSI rate (CDC)

Results

- 1856 patients enrolled with a lost to follow up rate of 30% (Table 1).

Table 1: Compliance by Standard

Standards	Baseline*	Intervention*	p-value
Use of the WHO SSC	51 (11·2%)	818 (60·6%)	<0·001
Hand and skin antisepsis	288 (61·3%)	1274 (92·9%)	<0·001
Antibiotic administration	408 (89·5%)	1309 (98·3%)	<0·001
Instrument reprocessing	184 (41·1%)	685 (51·9%)	<0·001
Sterile field maintenance	63 (16·3%)	350 (40·8%)	<0·001
Gauze counting	407 (86·8%)	1316 (95·9%)	<0·001
Compliance score (out of 6)	2·93 (2·84-3·02)	4·15 (4·09-4·21)	<0·001

*Results are N (%) unless otherwise stated **Mean, score of 6

- SSI incidence reduced, with a 49% risk reduction after adjustment. (Table 2)

Table 2: Clinical Outcomes by program phase and compliance rate

Clinical Outcomes by baseline versus intervention status

	Baseline	Intervention	RR	95% CI	p-value
SSI	28·43%	12·12%	0·51	(0·381 - 0·674)	< 0·001
Mortality	1·34%	1·08%	1·11	(0·376 - 3·250)	0·855
Reoperation	10·40%	3·26%	0·81	(0·533 - 1·227)	0·319
Length of stay, d	6·27	4·05	1·08*	(0·998 - 1·179)	0·055

Clinical Outcomes by Compliance Rate (<3 versus ≥3)

	Low compliance	High compliance	RR	95% CI	p-value
SSI	30·10%	18·37%	0·50	(0·382 - 0·648)	< 0·001
Death	1·36%	1·11%	0·57	(0·179 - 1·805)	0·338
Reoperation	8·33%	5·06%	0·80	(0·482 - 1·329)	0·561
Length of stay, d	4·92	4·63	0·96*	(0·382 - 0·648)	0·480

*RR of prolonged LOS defined as LOS ≥ the median LOS of the cohort (4·7 days) versus a reference of non-prolonged LOS (<4·7 days) equal to 1

Discussion

As in the pilot country, compliance with standards has improved and the risk of infection reduced(Forrester et al., 2020).

Challenges	Solutions
• All experts concentrated in Ethiopia • Context variability among countries[0] • Covid -19 pandemy	→ Using virtual resources as much as possible → Fostering the local champions → Local context adaptation

Examples of adaptation:

- **Malawi:** long bone fracture Clean Cut format
- **Madagascar:** team structure adapted to the existing one
- **India:** almost totally independent, relying on the manual

Our study limitations were the loss to follow-up, the high rate of dirty wounds in the "before" group. Both were analyzed with sensitivity tests. Additionally the practice may change when observed(Vervölgyi et al., 2011).

It also revealed a **small-scale scaling-up model** based primarily on **peer-to-peer learning between staff working in LMICs**(Bartels et al., 2022).

Conclusions

Clean Cut reduced the rate of surgical site infections by improving adherence to practices even in different contexts. These scaling up results encourage more implementations in LMICs with lessons learned for more improvement.

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