



# Factors associated with successful implementation of Clean Cut: a perioperative surgical site infection prevention quality improvement programme – a cohort study of low-resource hospitals

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## ABSTRACT

**Introduction** “Clean Cut” is an adaptive, multimodal surgical quality improvement (QI) programme that has been associated with significant reductions in surgical site infections. Following implementation in multiple hospitals and countries, we noted variability in impact. We aimed to understand the attributes of hospitals that contribute to the success of a perioperative QI programme in resource-limited settings. We hypothesised that factors related to hospital context before implementation influenced programme success.

**Methods** Hospital context assessments were undertaken in 18 hospitals in low-income countries prior to the implementation of Clean Cut, which focuses on improving perioperative infection prevention and control (IPC) standards. We assessed staffing, training, infrastructure and prior QI experience. Hospitals also self-assessed compliance with six standards embedded in the IPC programme and compared reported compliance to the baseline compliance observed by trained data collectors. We defined high-improvement hospitals as those who improved three or more of the six standards by either doubling compliance while also achieving a minimum final compliance >50% or reaching a final compliance >90%. We compared context assessments of high- and low-improvement hospitals.

**Results** Infrastructure, trainings and QI experience were not associated with larger improvements. However, high-improvement hospitals had fewer operating room staff ( $p=0.046$ ) and overestimated their baseline compliance with IPC standards ( $p=0.032$ ).

**Conclusion** Clean Cut implementation was more successful with smaller staff numbers, reflecting challenges with engaging large numbers of stakeholders. High-improvement hospitals overestimated baseline IPC practices, suggesting that this programme is most beneficial when it identifies gaps that hospitals were previously unaware of. Reassuringly, improvements were not dependent on specific resources, indicating that the approach can be implemented in many environments.

## WHAT IS ALREADY KNOWN ON THIS TOPIC

- ⇒ Clean Cut is an adaptive, multimodal quality improvement programme shown to reduce surgical site infections through strengthening of infection prevention practices.
- ⇒ However, there is variability in programme success.

## WHAT THIS STUDY ADDS

- ⇒ We assessed the effect of hospital context on changes in compliance with infection prevention practices.
- ⇒ Compliance improvements did not rely on specific resource availability but instead were associated with smaller staff size and an overestimation of baseline infection prevention practices.

## HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

- ⇒ Resource availability and infrastructure are often cited as challenges to implementing best practices for surgical infection prevention, but in this study, improvements were possible despite resource variability.

## BACKGROUND

5 billion people worldwide lack access to safe and affordable surgical care, the majority of whom live in low- and middle-income countries (LMICs).<sup>1</sup> Patients undergoing surgery in Africa are two times as likely to die after surgery and have significantly higher rates of preventable complications, such as surgical site infections (SSIs).<sup>2</sup> As access to surgery improves, renewed focus on the quality of surgical care is critical.<sup>3</sup> The WHO has advocated for implementation of the WHO Surgical Safety Checklist and Programmes to reduce the risk of perioperative infections

as high-value targets for improving surgical safety and quality.<sup>4</sup> However, implementation of these initiatives is particularly challenging in settings where resources are limited.<sup>5 6</sup>

Quality improvement (QI) programmes are one mechanism for translating best evidence into practice. They rely on an understanding of local system organisation and the barriers and resources available.<sup>7</sup> However, hospital context has frequently been identified as critical to successful QI programmes, both in high- and low-income settings.<sup>8–10</sup> While a number of frameworks exist to inform the development of context assessments intended to identify hospitals where QI programmes are most likely to succeed, the ability for such assessments to predict success is limited.<sup>11 12</sup>

In 2016, Lifebox, a global non-profit focused on improving surgical safety,<sup>13</sup> developed Clean Cut, an adaptive, multimodal QI programme to reduce the risk of SSI by strengthening six perioperative infection prevention and control (IPC) standards: (1) the use the WHO Surgical Safety Checklist, (2) hand and skin antisepsis, (3) instrument sterility, (4) sterile field maintenance, (5) antibiotic administration and (6) gauze counting. The programme was successful in reducing SSI by 35%, with additional reductions when compliance with standards was high.<sup>14 15</sup> Clean Cut has since been expanded to a variety of public hospital settings across several countries. A better understanding of the attributes of hospitals and teams that allow for successful QI implementation is needed. We hypothesised that factors related to hospital context would influence the success of the Clean Cut programme.

**METHODS**

**Study design**

This is a retrospective study of 18 hospitals that underwent Clean Cut implementation in Ethiopia, Madagascar, Liberia, Bolivia and Cote d’Ivoire. Clean Cut is a QI programme that is implemented in five phases

over approximately 6 months–1 year: (1) Programme introduction and creation of a multidisciplinary team, (2) Establishing a baseline and assessing context, (3) Development of an initial action plan, (4) Continuous improvement with targeted training of staff in the primary language of healthcare for each setting, (5) Sustainability planning (table 1). The programme was initially designed and piloted in Ethiopia,<sup>14</sup> then was adapted and streamlined based on the feedback from local staff.<sup>15 16</sup>

An implementation manual was created for participating hospital teams and translated into several languages; local facilitators were trained in the delivery of educational workshops and aspects of programme delivery. It was then implemented in a variety of low-resource settings in different countries in the primary medical language of the region where it was being implemented.

We used context assessments administered via a structured questionnaire during the second phase of Clean Cut to assess the surgical environment at each hospital. All hospitals that completed context assessments were included. The level of improvement was assessed by comparing compliance with perioperative infection prevention standards in the baseline period, defined as the period prior to starting the interventional components of Clean Cut (phases 1–2), and the intervention period, defined as the period after implementation began (phases 3–5).

**Patient and public involvement**

Patients and the public were not involved in the design, conduct, reporting or dissemination plans for this research. This study primarily involved healthcare workers and hospital staff at low-income hospitals, and results from this study will be disseminated back to study participants and hospital leadership.

**Inclusion criteria and data collection**

All hospitals that had completed context assessments and finished Clean Cut implementation between 2019 and 2024 were included. Context assessments were

**Table 1** Phases of Clean Cut

	Time period:	Activities:
Phase 1: programme introduction and creation of a multidisciplinary team	Week 1	<ul style="list-style-type: none"> <li>▶ Introduce the Clean Cut programme</li> <li>▶ Identify the team</li> </ul>
Phase 2: assess context and establish a baseline	Months 1–2	<ul style="list-style-type: none"> <li>▶ Begin by assessing hospital context</li> <li>▶ Perform process mapping</li> <li>▶ Finally, design a surveillance system and begin data collection</li> </ul>
Phase 3: develop an initial action plan	Month 2	<ul style="list-style-type: none"> <li>▶ Begin by reviewing baseline data</li> <li>▶ Connect the data with process mapping findings</li> <li>▶ Finally, develop and implement an initial action plan</li> </ul>
Phase 4: improve continuously	Months 3–6	<ul style="list-style-type: none"> <li>▶ Delivery of trainings</li> <li>▶ Create new action plans monthly</li> </ul>
Phase 5: sustainability planning	Month 6+	<ul style="list-style-type: none"> <li>▶ Integrate Clean Cut with the hospital’s QI team</li> <li>▶ Create a sustainability plan</li> </ul>
QI, quality improvement.		

completed by hospital staff leading QI implementation. During Clean Cut implementation, compliance with perioperative infection prevention standards was assessed intraoperatively by trained data collectors, who observed and recorded specific behaviours of operating room staff related to the six standards of perioperative infection prevention. Hospitals selected a subset of operating rooms in which all operations were observed, regardless of time of day or day of the week, and could include all surgical specialties. All hospitals observed both emergency and elective cases. All cases that were observed were included in the study, as IPC standards were universal to all types of cases, with the additional need for vaginal prep in obstetric and gynaecological surgery. Teams were only considered compliant with each standard if they correctly carried out all behaviours related to that standard. In this study, we assessed aggregated compliance data from each hospital.

### Determining improvement level

Hospitals were divided into two groups, a higher and lower improvement group. Hospital context was compared between these two groups. 'High improvement' was defined a priori by consensus among several study investigators. A hospital was considered to be high improvement if the hospital team made substantial improvements in compliance with at least three standards from the baseline period to the intervention period. Substantial improvements in compliance were defined as meeting either of two criteria: (1) doubling compliance with a minimum final compliance of  $>50\%$  or (2) reaching a final compliance of  $>90\%$ . If compliance in any standard was greater than  $90\%$  at baseline, this standard was excluded from consideration. Hospitals that did meet these criteria were categorised as low improvement.

### Endpoints

Hospitals were scored in each of the five domains evaluated in the hospital context assessments: staffing and size, infrastructure, prior QI experience, training and protocols and overestimation of baseline compliance.

Staffing and size were evaluated based on the total number of operating rooms and number of staff, including surgeons, anaesthesia providers (both physician and non-physicians), operating room nurses and residents. All operating rooms and number of staff were counted if they were included within the departments engaged in the Clean Cut programme. The number of functional operating rooms and operating room staff were compared between high- and low-improvement hospitals. The presence of residents was also assessed.

Infrastructure important to IPC processes—such as an autoclave for surgical instrument reprocessing, a washer and dryer for linens needed for sterile field maintenance and running water for hand washing—was compared between groups. Each hospital was given one point for each of the following pieces of infrastructure: a working autoclave; access to running water with fewer than five

interruptions per month; the presence of a backup generator for power outages; a water distiller, which is needed for autoclave use; a washer and a dryer.

Prior QI experience was assessed by each hospital team. The presence of training and protocols focused on each of the six IPC standards were also assessed at each hospital. Hospitals were given one point per standard if they had topic-related training or protocols related to that standard prior to beginning Clean Cut implementation.

Finally, the overestimation of baseline compliance was assessed by comparing intraoperative compliance data, as collected by trained data collectors, and self-assessment of compliance, as measured on the context assessments. For each standard, self-assessment was reported as 'always', 'sometimes' or 'never'. Measured compliance was divided into  $\geq 80\%$ ,  $<80\%$  to  $\geq 10\%$  or  $<10\%$ . If a hospital overreported compliance compared with its measured compliance, this was considered an overestimation. For example, if a hospital self-reported always using the Surgical Safety Checklist but only had a checklist compliance of  $50\%$  as measured by intraoperative data collectors, it was determined that they overestimated checklist compliance. The total number of standards where overestimation occurred was calculated at each hospital.

### Data analysis

Location and hospital level (district vs referral) were assessed at high- and low-improvement hospitals. To understand differences in compliance with IPC standards between groups, mean compliance scores were calculated for each hospital in the baseline and intervention periods by averaging the total number of standards, out of six, where teams were compliant. Baseline and intervention compliance scores were compared between groups using two-sided t-tests, as was the change in compliance.

Because our criteria defined significant improvement in a standard as meeting a minimum compliance of  $>90\%$ , a number of hospitals started the programme with one or more standards where significant improvements were not possible, due to a compliance rate of  $\geq 90\%$ . For each group, we identified the standards with compliance less than  $90\%$  and designated these the standards that were available for improvement. In both the baseline and intervention periods, we compared the mean number of standards available for improvement among high- and low-improvement hospitals using two-sided t-tests. Finally, in each of the five contextual domains, two-sided t-tests were used to measure differences among high- and low-improvement hospitals. In one domain where some hospitals did not have data in one area of the hospital context assessment, those hospitals were not included in the analysis.

## RESULTS

A total of 18 hospitals were included in the study, the majority of which were from Ethiopia. Bolivia, Madagascar, Liberia, Malawi and Cote d'Ivoire each contributed

**Table 2** Characteristics of included hospitals

	All hospitals	High-improvement hospitals, n=8	Low-improvement hospitals, n=10
Country			
Ethiopia	13	5	8
Bolivia	1	0	1
Madagascar	1	0	1
Liberia	1	1	0
Malawi	1	1	0
Côte d'Ivoire	1	1	0
Hospital characteristics			
Urban	12	6	6
Referral	13	6	7
District	5	2	3

one hospital. There were similar numbers of urban and referral hospitals among the high- and low-improvement groups (table 2).

At baseline, the high-improvement group had a lower compliance score than the lower improvement group (2.35 vs 3.50, out of 6), although the difference was not significant ( $p=0.076$ ). Both groups were compliant with between four and five standards in the intervention period (table 3). Additionally, the high-improvement hospitals started with significantly more standards available for improvement (4.88 vs 3.60;  $p=0.014$ ). However, in the intervention period, high-improvement hospitals had less than one standard remaining available for improvement, compared with 2.40 standards available for improvement in the low-improvement hospitals ( $p=0.013$ ) (table 3).

Overall, high-improvement hospitals had fewer perioperative clinicians and operating rooms and were significantly more likely to overestimate their baseline compliance. High-improvement hospitals had half the staff size compared with low-improvement hospitals (34.9 vs 76.7,  $p=0.046$ ) and half the number of operating rooms (3.1 vs 6.2), although differences in the number

of operating rooms did not reach statistical significance ( $p=0.077$ ) (table 4). Low-improvement hospitals had more staff members in all professions, including surgery, nursing and anaesthesia, and larger numbers of trainees (figure 1). The presence of anaesthesia or surgical residents was not associated with performance status (table 4). 12 hospitals, 5 in the high-improvement and 7 in the low-improvement groups, reported data estimating their baseline compliance with IPC standards. High-improvement hospitals also overestimated their baseline compliance with IPC standards two times as often. High-improvement hospitals on average overestimated their compliance with 3.2 standards, whereas low-improvement hospitals overestimated their compliance with an average of 1.6 standards ( $p=0.032$ ). These differences were most apparent for instrument reprocessing and sterile maintenance; more than half of high-improvement hospitals overestimated compliance with instrument reprocessing and sterile field maintenance, whereas no low-improvement hospitals overestimated compliance in these areas (figure 1).

Infrastructure scores were similar between high- and low-improvement hospitals, with scores of 4.1 and 4.3, respectively ( $p=0.810$ ) (table 4). For the most part, both groups had similar infrastructure available at their hospitals, with most pieces of equipment available at the majority of hospitals (figure 1). There were no statistical differences among prior QI experience, training and protocols among hospital groups (table 4), although QI experience, training and protocols in all of the six areas except for gauze counting were more common among lower improvement hospitals (figure 1).

## DISCUSSION

This perioperative QI programme was more successful in hospitals with smaller staff and where hospital teams overestimated baseline compliance with perioperative standards on self-assessment. Additionally, high-improvement hospitals started with lower compliance in the baseline period, although differences were not significant. Both groups finished the programme with similar compliance

**Table 3** Compliance scores and number of standards available for improvement

		All hospitals	High-improvement hospitals (8)	Low-improvement hospitals (10)	P value
Compliance scores	Baseline, mean (95% CI)	2.99 (2.31 to 3.67)	2.35 (1.88 to 2.82)	3.50 (2.34 to 4.66)	0.076
	Intervention, mean (95% CI)	4.30 (3.72 to 4.88)	4.55 (4.07 to 5.04)	4.10 (3.03 to 5.15)	0.425
	Change from baseline to intervention	1.31 (0.82 to 1.80)	2.20 (1.66 to 2.75)	0.60 (0.27 to 0.92)	<0.001
Number of IPC standards available for improvement	Baseline, mean (95% CI)	4.17 (3.59 to 4.74)	4.88 (4.34 to 5.41)	3.60 (2.76 to 4.44)	0.014
	Intervention, mean (95% CI)	1.72 (1.04 to 2.40)	0.88 (0.18 to 1.57)	2.40 (1.43 to 3.37)	0.013
	Change in number of IPC standards	2.44 (1.60 to 3.28)	4.00 (3.23 to 4.77)	1.20 (0.54 to 1.86)	<0.001

IPC, infection prevention and control.



**Table 4** Contextual factors associated with low- and high-improvement hospitals

	High-improvement hospitals, mean (95% CI) n=8	Low-improvement hospitals, mean (95% CI) n=10	P value
Staff and sizing			
Number of operating rooms	3.1 (1.61 to 4.64)	6.2 (3.13 to 9.27)	0.077
Total number of operating room staff (surgeons, anaesthesiologists, nurses and trainees)	34.9 (22.8 to 47.0)	76.7 (38.83 to 114.57)	0.046
Proportion of hospitals with residents	0.75 (0.36 to 1.14)	0.70 (0.35 to 1.05)	0.827
Infrastructure score (of 6)	4.1 (3.08 to 5.17)	4.3 (3.17 to 5.42)	0.801
Including:			
▶ Working autoclave (1pt)			
▶ Running water with <5 interruptions per month (1pt)			
▶ Automatic generator for power outages (1pt)			
▶ Water distiller (1pt)			
▶ Washing machine (1pt)			
▶ Dryer (1pt)			
Proportion of hospitals with prior experience with QI	0.25 (0 to 0.64)	0.5 (0.12 to 0.88)	0.308
Number of standards (of 6) where perioperative staff had training or protocols.	2 (0 to 4.14)	3.3 (1.68 to 4.92)	0.270
Standards include:			
▶ Hand and skin antisepsis (1pt)			
▶ Antibiotic administration (1pt)			
▶ Instrument reprocessing (1pt)			
▶ Sterile field maintenance (1pt)			
▶ Gauze counting (1pt)			
▶ Use of the WHO surgical safety checklist (1pt)			
Number of standards (of 6) where hospital team overestimated their baseline compliance (n=12)	3.2 (1.16 to 5.24) (n=5)	1.6 (1.08 to 2.07) (n=7)	0.032
Standards include:			
▶ Hand and skin antisepsis (1pt)			
▶ Antibiotic administration (1pt)			
▶ Instrument reprocessing (1pt)			
▶ Sterile field maintenance (1pt)			
▶ Gauze counting (1pt)			
▶ Use of the WHO surgical safety checklist (1pt)			
QI, quality improvement.			

rates. While this might suggest that high-improvement hospitals simply had more room for improvement, high-improvement hospitals improved in nearly all standards where they did not have a baseline compliance of >90%, whereas low-improvement hospitals did not. This suggests that there are differences in how these hospitals function and interact with this QI programme beyond their baseline compliance, which may have impacted their success.

The association between higher improvement and smaller staff size may reflect challenges in engaging a broad range of stakeholders. Engaging stakeholders is a critical step in achieving the political buy-in needed to successfully implement QI.<sup>16,17</sup> Clean Cut relies on multidisciplinary teams to help identify solutions to compliance gaps that are often cross cutting across multiple departments and professions; achieving engagement across large groups of people poses a challenge. In our team's experience, larger hospitals also often had many competing priorities and additional bureaucracy,

presenting further challenges in engaging hospital leadership who oversee supply-chain management and allocation of human resources.

High-improvement hospitals also often overestimated their baseline compliance. This suggests that Clean Cut may be effective, in part, by imparting knowledge of best practices and in identifying gaps in IPC standards that were not previously known. Hospital staff who are not well acquainted with best practices will not be able to differentiate between processes that are not in compliance with standards. In many LMIC hospitals, surveillance systems to track perioperative processes and SSI rates are not well established, so gaps in processes are not always known prior to Clean Cut initiation.<sup>18</sup> Less successful hospitals were more accurately able to self-assess areas where they failed to comply with IPC standards. Knowledge of these gaps without the initiative to address them may reflect underlying characteristics of hospitals and teams that are less ready to engage in behaviour change, whereas



**Figure 1** Association of contextual factors and hospital improvement. — — — — — low-improvement hospitals; — — — — — high-improvement hospitals; ▲ denotes a statistically significant difference in evaluated factor and ◇ denotes a statistically significant difference in contextual domain.

in high-improvement hospitals, identifying areas of improvement that hospitals were not previously aware of may have acted as a catalyst for change.

Importantly, specific infrastructure was not needed for high performance. The infrastructure assessed here is equipment important for surgical instrument reprocessing, linen reprocessing for sterile field maintenance and for hand washing. Prior qualitative assessments of safe surgery initiatives have identified poor underlying infrastructure and variability in resources as barriers to improving the safety of surgery.<sup>19 20</sup> Similarly, on the qualitative assessments of Clean Cut, poor infrastructure has been perceived as a limitation to improving compliance.<sup>17</sup> However, this study suggests that improvements can still be made, even within constraints of poor infrastructure. The presence of trainings and protocols or prior experience with QI were also not associated with higher performance. For the most part, low-improvement hospitals had more exposure to QI, training and protocols, although differences were not significant (table 4, figure 1). Clean Cut incorporates training in several areas as a part of its implementation strategy, including workshops on the WHO Surgical Safety Checklist and instrument reprocessing, which have been associated with decreases in knowledge gaps and improved compliance

in these areas and may negate some of the benefits of pre-existing training or experience.<sup>21 22</sup>

Clean Cut, like many QI programmes, is intended to be adaptive, relying on local, context-appropriate solutions to make improvements. These results are reassuring that such programmes may be successful in a range of environments and not dependent on specific infrastructure, prior experience or knowledge. To implement this or similar QI programmes, efforts might go towards including smaller hospitals and, at larger hospitals, adapting our approach to engage smaller teams initially prior to hospital-wide scaling, for example, starting programme implementation in a single department within a larger hospital prior to expanding hospital wide. Given our findings that many hospitals overestimated baseline compliance, self-reported compliance with IPC standards should be used with caution when identifying hospitals that would benefit from SSI-prevention programmes, particularly in settings where surveillance systems are poor or non-existent.

**Limitations**

This study includes a limited number of hospitals. While this sample size was large enough to identify differences in staff size and self-assessments of compliance, it may

have failed to capture statistical differences in other areas. A larger sample size is needed to assess if differences demonstrated here hold true across a broader range of hospitals and to identify other differences between high- and low-improvement hospitals that may have been overlooked here. Many of our conclusions here align with our team's lived experiences in implementing Clean Cut, but a larger study or further research paired with qualitative research or root cause analysis would be warranted in the future. In particular, high-improvement hospitals had less exposure to QI, training and protocols, but differences did not reach statistical significance. This study also did not assess differences in operative volume, despite identifying smaller staff size among high-improvement hospitals. While smaller staff size may limit the number of stakeholders engaged, this may only be possible when caseload is also proportionately smaller. Six hospitals did not have data on self-assessment of compliance. These context assessments were used as a part of the delivery of these programmes and were not specifically intended for research purposes. As a result, the assessments evolved over time and the section focused on self-assessment of compliance was added later, after several hospitals had already begun implementation. As such, hospitals that did not participate in self-assessment of compliance were excluded from this analysis, resulting in a smaller sample size for this domain.

Another limitation is that all hospitals included in this study completed the Clean Cut programme, and even low-improvement hospitals made improvements. This study is unable to distinguish the characteristics of hospitals that were unable to complete the programme at all, which has occurred on rare occasions. Since Clean Cut was developed, a handful of hospitals that started the programme were unable to progress due to challenges with team formation or organising data collection and ended the programme early; these hospitals were not included in this analysis, but warrant further investigation into qualities of hospitals unable to complete the programme. Finally, Clean Cut has been primarily implemented in public hospitals, and the majority of hospitals included were in Ethiopia and were in urban settings, which may limit the generalisability of these findings.

Further research is needed to expand on this work. This study was limited to a set of questions administered early in Clean Cut to understand barriers to successful implementation. A more in-depth assessment is needed, particularly in areas where contextual differences relevant to performance were identified. In particular, there is interest in understanding how staff turnover may affect programme success. This study was also limited as it only studied compliance improvements by the end of the programme but did not extend beyond the completion of the programme; while prior research has shown compliance improvements to be sustainable,<sup>23</sup> contextual factors associated with long-term sustainability would provide further insight.

## CONCLUSIONS

QI programmes are a promising strategy for improving the safety and quality of surgical care, but success may depend on hospital context. Challenges in achieving recommended perioperative infection prevention practices are often perceived to be due to a lack of material resources and poor hospital infrastructure as well as a lack of staff training.<sup>20 24</sup> In this study, we found that improvements were still possible where there were limitations in infrastructure, staff training or prior QI experience; instead, working with smaller teams, engaging stakeholders and drawing attention to gaps in IPC processes not previously identified appear to be more important.

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**Contributors** MRN designed the study, NG, AT and NS designed the data collection tools, NG, AT, SA, ST and TNM oversaw data collection and programme implementation, MRN and TGW carried out data analysis, MRN, AT, SA, NS and TGW participated in interpreting the data, MRN drafted in the initial manuscript, all authors provided critical feedback and contributed to revisions of the manuscript and TNM and TGW were responsible for study supervision. MRN and TGW acted as guarantors.

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**Competing interests** MN was a fellow at Lifebox. NG, NS, AT, SA and ST are staff at Lifebox. TNM is the Global Clinical Director and TW is on the global governance counsel of Lifebox.

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