Original Article

# Lifebox pulse oximeter implementation in Malawi: evaluation of educational outcomes and impact on oxygen desaturation episodes during anaesthesia

**V. Albert,[1] S. Mndolo,[2] E. M. Harrison,[3] E. O'Sullivan,[4] I. H. Wilson[5] and I. A. Walker[6]**

*1 Foundation Year-two Doctor, Broomfield Hospital, Chelmsford, UK*
*2 Specialist, Department of Anaesthesia, Queen Elizabeth Central Hospital, Blantyre, Malawi*
*3 Senior Lecturer, Clinical Surgery, University of Edinburgh, Royal Infirmary of Edinburgh, UK*
*4 Consultant, Department of Anaesthesia, St James' Hospital, Dublin, Ireland*
*5 Consultant Anaesthetist, Trustee, Lifebox Foundation, London, UK*
*6 Consultant, Department of Anaesthesia, Great Ormond Street Hospital NHS Foundation Trust, UCL Great Ormond Street Institute of Child Health, London, UK*

## Summary

Pulse oximetry is an essential monitor for safe anaesthesia but is often not available in low-income countries. The aim of this study was to determine whether the introduction of pulse oximetry with training was feasible and could reduce the incidence of oxygen desaturation during anaesthesia in a low-income country. Pulse oximeters were donated, with training, to 83 non-physician anaesthetists in Malawi. Knowledge was tested immediately before and after training and at follow-up. Providers were asked to record the lowest peripheral oxygen saturation ($SpO_2$) for the first 100 cases anaesthetised after training. The primary clinical outcome was the proportion of cases with an oxygen desaturation event ($SpO_2 < 90\%$). Seventy-seven of 83 (93%) participants completed all pre- and post-training tests. Pulse oximetry knowledge improved after training from a median (IQR [range]) score of 39 (37–42 [28–48]) to 44 (42–46 [35–50]) and this knowledge was maintained for 8 months ($p < 0.001$). Oxygen saturation data and provider responses were recorded for 4772 cases. The proportion of oxygen desaturation episodes decreased from 17.2% to 6.5%, representing a 36% reduction in the odds of an oxygen desaturation event in the second 50 cases compared with the first 50 (OR 0.64, 95% CI 0.50–0.82, $p < 0.001$). We conclude that donation of pulse oximeters, with training, in Malawi was feasible, improved knowledge and reduced the incidence of oxygen desaturation events.

*Correspondence to: I. Walker*
*Email: isabeau.walker@gosh.nhs.uk*
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## Introduction

Anaesthesia outcomes have improved steadily in high-income countries in recent decades, but the same progress has not been made in poorer parts of the world [1, 2]. There are major disparities in access to surgical care around the globe, highlighted recently by the Lancet Commission on Global Surgery [3]. The 2015 World Health Assembly commitment to increase access to essential and emergency surgery in all member states is an important first step to address this problem [4]. As access to surgery is improved in low- and middle-income countries, it is particularly important to address the safety of the anaesthetic and surgical services provided [5].

Pulse oximetry is a mandatory monitor in all countries that have published standards of anaesthesia care [6], it is included in the World Federation of Societies of Anaesthesiologists (WFSA) 'International Standards for Safe Practice of Anaesthesia 2010' and the WHO Standards for Safe Surgery [7, 8]. However, pulse oximeters are still not available in operating theatres in many low-income countries [6, 9].

The Lifebox Foundation was formed in 2011 to improve the safety of surgery and anaesthesia in low- and middle-income countries through implementation of the World Health Organization Surgical Safety checklist and to improve access to pulse oximeters (www.lifebox.org) [10]. The 'Lifebox' handheld pulse oximeter (AX-MH Acare Technology Ltd., Taiwan) conforms to WHO specifications for a medical-grade oximeter, to the relevant International Electrotechnical Commission (IEC), Conformité Européene (CE) and International Organisation for Standardisation (ISO) standards, and meets FDA requirements for accuracy [11]. A successful large-scale implementation of Lifebox pulse oximeters has previously been reported in Uganda, a low-income country in East Africa, [9] but a change in anaesthetic practice, with a reduction in hypoxic events, has not been previously demonstrated in this region.

Malawi is a small country in sub-Saharan Africa, with a population of 16.4 million and life expectancy of 58 years for males and 61 years for females [12]. It is classified by the World Bank as a 'low-income country' with a Human Development Index (HDI) ranking of 174/187 [13]. There are an estimated 109 anaesthesia providers in Malawi, 104 (95.4%) of whom are non-physician anaesthetic clinical officers (ACOs) [14]. A prospective study of anaesthesia mortality suggested that the anaesthesia 'avoidable mortality rate' (AMR) was 1:504 anaesthetics, 6–100 times higher than the anaesthesia mortality rate in developed countries [15].

In 2014, the College of Anaesthetists of Ireland organised a donation of Lifebox pulse oximeters to anaesthesia and surgery providers in Malawi and funded an oximetry and anaesthesia safety training programme to support this donation. We therefore decided to evaluate the educational impact of the oximetry training programme for anaesthesia providers in Malawi, and to assess whether introduction of pulse oximeters had an impact on the incidence of oxygen desaturation and, by implication, could improve the safety of anaesthesia practice.

## Methods

Exemption from research ethics approval was granted by the National Health Sciences Research Committee (NHSRC). Informed consent was provided by all participants, and all data were anonymised and coded.

Anaesthesia providers working in the central and southern regions of Malawi who had limited, or no, access to a pulse oximeter were identified by the anaesthetic department at the Queen Elizabeth Central Hospital (QECH) and invited to attend a 1-day training course at Blantyre in August 2014. The College of Anaesthetists of Ireland (CAI) ran the course using materials provided by the Lifebox Foundation [10, 16]. Course materials focused on the physiology of oxygen delivery, the use and maintenance of the pulse oximeter, the use of an algorithm in the event of hypoxia, and an introduction to the principles of the WHO surgical safety checklist. At the end of the course, each attendee was given their own Lifebox pulse oximeter, a printed training manual, laminated WHO checklist and hypoxia algorithm, and an educational DVD. Attendees were encouraged to use the educational materials to teach other anaesthesia providers who were unable to attend the training day.

The anaesthesia course participants were asked to complete a hospital questionnaire and an oximeter multiple choice questionnaire at the start and at the end of the course in order to assess their knowledge of pulse oximetry and management of the hypoxic patient [10]. They were provided with a logbook to record information regarding the first 100 anaesthetics in which they used the pulse oximeter. This included: the date; patient age; ASA physical status; operation; anaesthetic administered; lowest $SpO_2$ recorded; the intervention if $SpO_2$ fell below 90%; and the patient outcome [10]. To ensure the logbooks would be completed correctly, each study participant received a 20-minute logbook training session.

Eight months after the delivery of the pulse oximeter and training programme, a single investigator (VA) returned to Malawi and contacted the participants either by telephone or email, and arranged follow-up visits over an 8-week period. Anaesthesia providers were asked to describe how they used the oximeter and to repeat the oximetry multiple choice questionnaire (MCQ). Log books were collected and, where possible, the donated oximeter was seen and checked.

A comparison of means between MCQ test results at different time points was performed using the Friedman test. Pairwise comparisons were performed using the Wilcoxon signed-rank test with a Bonferroni correction. An oxygen desaturation event was deemed to have occurred when the lowest recorded $SpO_2$ was less than 90%. Univariate analyses were performed using chi-squared or Fisher's exact test for categorical variables and Wilcoxon signed-rank tests for continuous variables. Univariate logistic regression was performed to allow comparison of multivariable models. Given the structure of the data with patients nested within hospitals and consecutive through time, a hierarchical multivariable Bayesian logistic regression model was used. The hospital identifier was specified as a random effect (random intercepts with gradients constrained). Non-informative priors were used with priors for fixed-effect coefficients normal (0, 10) and random-effect coefficients normal (0, sigma), with sigma ~ uniform (0, 100). Sensitivity analyses were performed on alternative priors with no significant change in direction or magnitude of effects. Markov chain Monte Carlo specification was 10,000 iterations across four chains (40,000 total) with 5000 burn-in steps. Different chain initiation points and chain lengths were tested. Convergence was achieved within 10,000 iterations and models were not sensitive to different starting points. Model diagnostic plots included traceplots to ensure good mixing of chains, Gelman–Rubin–Brooks plots to show the Gelman–Rubin convergence (Rhat or shrink factor), auto-correlation plots and posterior density plots for each chain. The widely applicable information criterion (WAIC) was used in final model selection. Data from the MCQ tests were analysed with SPSS™ (Statistical Package for Social Sciences Version 20.0. IBM Corp, Armonk, NY, USA) and Microsoft® Excel software (Microsoft, Redmond, WA, USA). Multivariable analyses used R (R Foundation for Statistical Computing, Vienna, Austria) and Stan (Stan: A C++ Library for Probability and Sampling, Version 2.10.0. URL http://mc-stan.org/) software. Results are presented as odds ratios and 95% credible intervals (analogous to confidence intervals in frequentist statistics, but philosophically distinct).

## Results

Ninety-seven anaesthesia providers were invited to the oximetry training in Blantyre, and 83 attended from 27 hospitals in the south and central region (approximately 76% of the anaesthesia providers in Malawi). Nine out of 27 hospitals (33%) had a pulse oximeter in every theatre before the training course. During follow-up, 68/83 (82%) anaesthetic officers who had attended the course were contacted. This was 2–3 months after the country had been affected by severe flooding, which meant that it was not possible to communicate with all study participants due to a lack of internet or working telephone connections.

The MCQ assessment was completed by 77 out of 83 (93%) study participants before and after the course and by all 68 anaesthetic officers who were followed up (Fig. 1). Compared with the pre-training assessment, where the median (IQR [range]) score out of 52 was 39 (37–42 [28–48]), pulse oximetry knowledge was higher immediately after training, 44 (42–46 [35–50]), and maintained at follow-up, 43 (41–45 [35–52]); $p < 0.001$. Pairwise tests were significant between pre- and post-training groups ($Z = -7.127$, $p < 0.001$) and pre-training and follow-up training groups ($Z = -5.902$, $p < 0.001$). However, there was no difference between the postcourse and follow-up MCQs ($Z = -2.202$, $p = 0.028$).

Sixty-eight of the 83 pulse oximeters donated to the anaesthesia providers were successfully located at 8-month follow-up. Two pulse oximeters had developed a fault within 3 months of donation and had been reported to the local Lifebox representative. A third oximeter had a broken probe that had been overstretched by an agitated patient, but the oximeter was still in use with a locally sourced probe as a replacement. Therefore, 66 out of 68 (97.1%, (95%CI

 

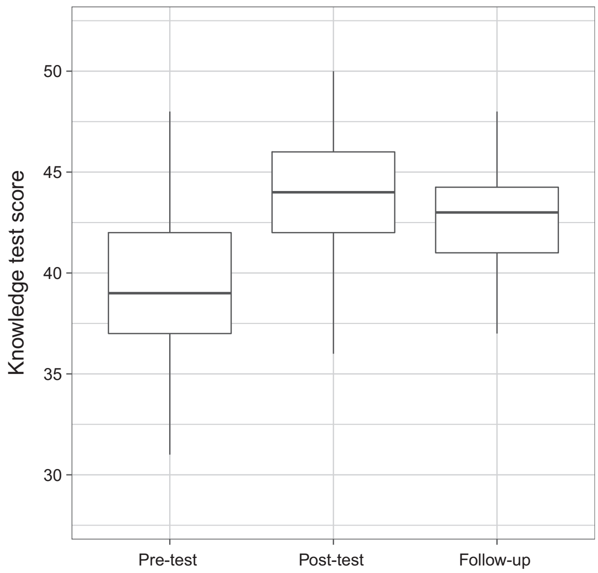


**Figure 1** Box-plot showing multiple choice questionnaire results; pre-, post- and follow-up tests. Horizontal lines are median, boxes are IQR and whiskers are range.

89.8–99.6%)) of the located oximeters were still in regular use. Qualitative free-text comments by anaesthesia providers indicated a positive impact of the pulse oximeter on anaesthesia practice (Appendix 1).

Sixty of the 83 (72%) logbooks were collected and analysed. These logbooks included data on oxygen desaturation events from 4911 surgical cases, with 4772 complete sets of data for all variables assessed. Anaesthesia providers recorded 2500 major cases and 2392 intermediate/minor cases using both general and spinal anaesthesia techniques.

Multivariable analysis accounting for the clustering of patients within hospital operating rooms was used to explore predictors for oxygen desaturation events (Table 1). Oxygen desaturation was more common in sicker patients (ASA physical status 2–5), those undergoing intermediate or major surgery, and patients having a general anaesthetic rather than a spinal anaesthetic. Age was not a predictor for oxygen desaturation.

Oxygen desaturation events were analysed over time, and there was a significant reduction in events when comparing the first 50 with the last 50 cases (OR 0.64, 95%CI 0.50–0.82, p < 0.001) (Table 2). The reduction in oxygen desaturation events after pulse oximeter introduction was linear and consistent over time (Fig. 2). The proportion of oxygen desaturation episodes during the first 10 cases compared with the last 10 cases decreased from 17.2% to 6.5%, and over the total 100 cases resulted in a relative reduction in the odds of oxygen desaturation of 8% per 10 cases performed after pulse oximetry introduction (OR 0.92, 95%CI 0.88–0.96, p < 0.001).

A sensitivity analysis was performed excluding logbooks in which no oxygen desaturation events were recorded, on the assumption that data quality may be poorer. No difference in size or direction of effects was seen (OR 0.64, 95%CI 0.50–0.83, p < 0.001).

**Table 1** Characteristics of patients, operations and anaesthetic methods detailed in logbooks for the first 50 and second 50 cases. Values are mean (SD) or number (proportion).

| | First 50 cases | Second 50 cases | p value |
|---|---|---|---|
| Age; years | 26 (13.5) | 24.8 (14.5) | 0.001 |
| ASA physical status | | | |
| 1 | 2201 (79.6%) | 1773 (84.3%) | < 0.001 |
| 2 | 395 (14.3%) | 255 (12.1%) | |
| > = 3 | 168 (6.1%) | 75 (3.6%) | |
| Missing | 39 (1.4%) | 13 (0.6%) | |
| Operative complexity | | | |
| Minor | 998 (36.1%) | 948 (45.1%) | < 0.001 |
| Intermediate | 241 (8.7%) | 187 (8.9%) | |
| Major | 1521 (55.0%) | 954 (45.4%) | |
| Missing | 4 (0.1%) | 14 (0.7%) | |
| Anaesthetic | | | |
| General | 980 (35.5%) | 863 (41.0%) | < 0.001 |
| Ketamine only | 434 (15.7%) | 405 (19.3%) | |
| Spinal | 1350 (48.8%) | 835 (39.7%) | |
| Oxygen | | | |
| No | 2232 (80.8%) | 1574 (74.8%) | < 0.001 |
| Yes | 532 (19.2%) | 529 (25.2%) | |
| Thiopentone | | | |
| No | 2441 (88.3%) | 1822 (86.6%) | 0.079 |
| Yes | 323 (11.7%) | 281 (13.4%) | |
| Pethidine | | | |
| No | 2654 (96.0%) | 1954 (92.9%) | < 0.001 |
| Yes | 110 (4.0%) | 149 (7.1%) | |
| Ketamine | | | |
| No | 2196 (79.5%) | 1590 (75.6%) | 0.001 |
| Yes | 568 (20.5%) | 513 (24.4%) | |
| Suxamethonium | | | |
| No | 2469 (89.3%) | 1888 (89.8%) | 0.612 |
| Yes | 295 (10.7%) | 215 (10.2%) | |
| Tracheal tube | | | |
| No | 2429 (87.9%) | 1862 (88.5%) | 0.480 |
| Yes | 335 (12.1%) | 241 (11.5%) | |
| Halothane | | | |
| No | 2181 (78.9%) | 1534 (72.9%) | < 0.001 |
| Yes | 583 (21.1%) | 569 (27.1%) | |

 

**Table 2** Oxygen desaturation events occurring in the first 50 and second 50 cases recorded in the 60 logbooks. Values are number (proportion) or mean (SD).

| | Oxygen desaturation event | | | |
|---|---|---|---|---|
| | No | Yes | Univariate logistic regression OR, (95%CI, p value) | Hierarchical logistic regression OR, (95%CI, p value) |
| Case numbers | | | | |
| First 50 | 2450 (55.4%) | 314 (64.6%) | | |
| Second 50 | 1932 (43.7%) | 171 (35.2%) | 0.69 (0.57–0.84, p < 0.001) | 0.64 (0.50–0.82, p < 0.001) |
| Age; years | 25.5 (13.5) | 25.4 (17.5) | 1.00 (0.99–1.01, p = 0.924) | 0.98 (0.87–1.10, p = 0.718) |
| ASA physical status | | | | |
| 1 | 3736 (84.4%) | 275 (56.6%) | | |
| 2 | 529 (12.0%) | 126 (25.9%) | 3.24 (2.57–4.06, p < 0.001) | 2.16 (1.52–3.03, p < 0.001) |
| > = 3 | 160 (3.6%) | 85 (17.5%) | 7.22 (5.38–9.63, p < 0.001) | 4.74 (2.98–7.46, p < 0.001) |
| Operation complexity | | | | |
| Minor | 1791 (40.5%) | 173 (35.6%) | | |
| Intermediate | 370 (8.4%) | 59 (12.1%) | 1.65 (1.20–2.25, p = 0.002) | 1.90 (1.22–2.95, p = 0.005) |
| Major | 2250 (50.8%) | 250 (51.4%) | 1.15 (0.94–1.41, p = 0.178) | 2.37 (1.68–3.36, p < 0.001) |
| Anaesthetic | | | | |
| General | 1561 (35.3%) | 293 (60.3%) | | |
| Ketamine only | 751 (17.0%) | 97 (20.0%) | 0.69 (0.54–0.88, p = 0.003) | 0.74 (0.50–1.10, p = 0.138) |
| Spinal | 2113 (47.8%) | 96 (19.8%) | 0.24 (0.19–0.31, p < 0.001) | 0.12 (0.08–0.18, p < 0.001) |
| Oxygen | | | | |
| No | 3514 (79.4%) | 331 (68.1%) | | |
| Yes | 911 (20.6%) | 155 (31.9%) | 1.81 (1.47–2.21, p < 0.001) | 0.79 (0.53–1.18, p = 0.250) |

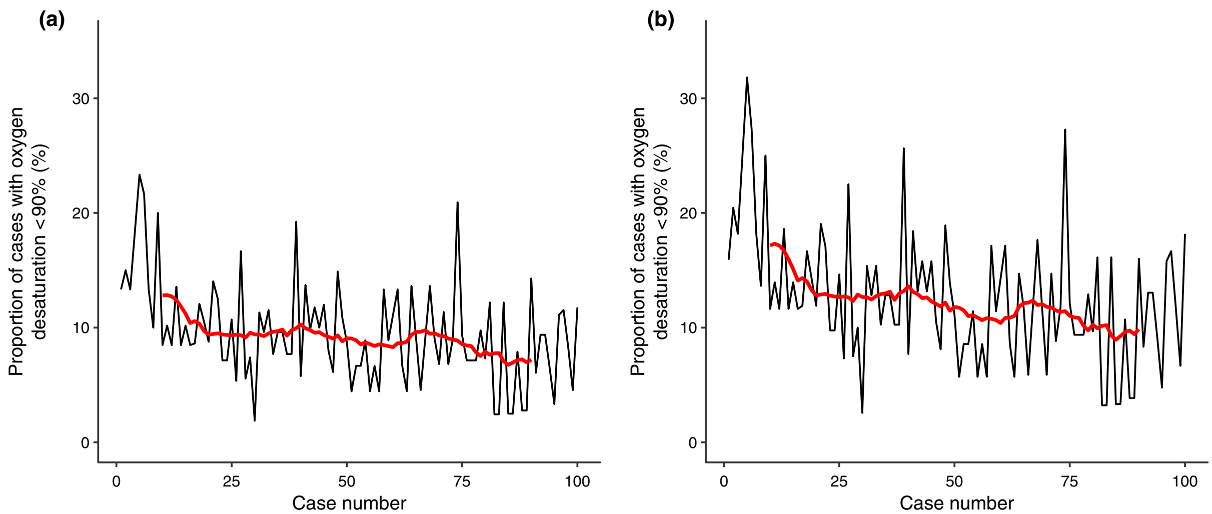


**Figure 2** Total oxygen desaturation events by case number; (a) shows oxygen desaturation events recorded in all logbooks. (b) shows oxygen desaturation events, excluding those logbooks in which no oxygen desaturations were recorded. Red line is mean.

When completing the logbooks, the anaesthesia providers were asked to comment on the oxygen desaturation events and to document the intervention they provided to correct the situation. The responses to oxygen desaturation were appropriate in all cases; clinical examples and comments are described in Appendix 2.

## Discussion

We have evaluated the impact of a large-scale donation of pulse oximeters and standardised oximetry training programme for non-physician anaesthesia providers in the central and southern region of Malawi. Training resulted in a significant improvement in knowledge regarding pulse oximetry and the management of hypoxia, with improvements in knowledge retained over time. Sixty-eight out of the 83 (82%) pulse oximeters were located at follow-up, 97% were in routine use, and the feedback from the anaesthesia providers was uniformly positive. Analysis of logbooks showed that introduction of routine pulse oximetry resulted in an 8% relative reduction in the odds of an oxygen desaturation event for every 10 cases, with practice improving over time. Interventions recorded in the logbooks were clinically appropriate. This study supports the introduction of pulse oximetry to improve the safety of anaesthetic practice in this setting.

Many low-income countries lack the basic medical equipment required to provide safe patient care, but simple donation of equipment does not always result in a beneficial impact. Lack of training, hospital infrastructure and adequate knowledge of equipment management are some of the main causes for this [17]. The WHO published guidelines for equipment donation to developing countries in 2000 [18, 19]. By matching need with donation, and including training and follow-up of equipment, large-scale donations can have a significant impact on the healthcare systems in countries such as Malawi [9, 16]. The Lifebox pulse oximeter is a high-quality, low-cost, handheld pulse oximeter specifically designed for use in operating theatres in low- and middle-income countries. The Lifebox pulse oximeter has been shown to be reliable when used in Uganda [9] and our results have confirmed this finding in Malawi.

It is very difficult to detect hypoxia clinically, particularly in dark skinned patients. Use of a pulse oximeter improves the detection of hypoxia and allows the anaesthesia provider to respond quickly to adverse events. The Lifebox oximeter has an audible tone and allows all personnel to appreciate beat-to-beat changes in heart rate and oxygen saturation. Anaesthesia providers in low- and middle-income countries work with limited access to essential drugs and equipment, including pulse oximeters. Access to surgery is poor, so patients tend to have advanced illness when they present [1–3, 14]. It is not surprising therefore that the anaesthesia mortality rates are higher than in high-income settings [1–3, 5].

This study demonstrates that when anaesthetists are able to measure and record oxygen saturation on a routine basis, they change their practice, and the incidence of hypoxic episodes is reduced over time. Qualitative free-text comments from anaesthesia providers in the follow-up questionnaires support the benefits of pulse oximeters on anaesthesia safety. The introduction of pulse oximeters has been shown to reduce the incidence of peri-operative hypoxia in Moldova using data-recording oximeters; we have demonstrated that the same outcome can be achieved in a low-income setting using logbooks to record oxygen saturation data [20].

We did not attempt to assess the direct impact of the pulse oximeter donation and training on mortality after surgery. A Cochrane review on pulse oximetry for peri-operative monitoring failed to show an impact of pulse oximetry on outcome for patients, despite this being an essential monitor in every country where there are published anaesthesia standards [6, 21]. The authors of the Cochrane review noted that pulse oximetry may have a greater impact on outcomes in low-income settings where there is less comprehensive provision of healthcare and where mortality rates are higher [21]. Pulse oximeters were present in every theatre in only 33% of hospitals at the start of this study, and our data show that providers in Malawi are routinely undertaking major surgery with a minimum of resources and in the absence of essential monitoring [14]. Expert opinion overwhelmingly supports the use of pulse oximetry as a standard of care in modern anaesthesia practice and we did not feel that it was ethical to attempt to prove that pulse oximetry improves outcomes [22].

There were several limitations to this study. Firstly, the study participants worked in 27 different hospitals across the central and southern regions of Malawi. It was not possible to contact every course participant at follow-up due to severe flooding in the previous months, although it was possible to assess 82% of the donated oximeters, and 66 of the 68 were still being used for routine patient care. Secondly, logbooks can be a valuable aid in training and encourage reflective learning if used appropriately [23]. The logbook we used had been trialled previously and the anaesthesia providers were trained in how to complete it [16]. However, some providers did not record any oxygen desaturation episodes in their logbooks, and none would be rare in normal clinical practice. We are not sure of the reason for this, but it suggests that some clinicians preferred not to admit to any oxygen desaturation. In the other logbooks, the pattern of hypoxia was as to be expected in clinical practice, that is, more oxygen desaturation episodes in sicker patients, having major surgery and undergoing general anaesthesia rather than spinal anaesthesia, supporting the notion that data had been recorded accurately. The responses to hypoxia described in the logbooks were appropriate. The logbooks we examined give an insight into the actions taken by anaesthesia providers to change their practice and to improve anaesthesia safety.

In conclusion, this study describes a large-scale donation of pulse oximeters in Malawi, delivered alongside a standardised training programme. Training improved knowledge regarding pulse oximetry, which was maintained over time. The pulse oximeters were in routine use 8 months after donation. Logbook data suggest that the use of pulse oximetry reduces the incidence of peri-operative hypoxic episodes and has the potential to improve the safety of anaesthesia in this setting.

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## Appendix 1. Examples of provider feedback on the Lifebox Pulse Oximeter

"The pulse oximeter is very useful and important, especially when we are dealing with paediatrics, children are sometimes very scared of the big machines and love the small brightly coloured oximeter" (Participant 4)
"It is very useful, portable and easy to use" (Participant 27)
"It is good as it is simple and easy to use and we know how to care for it to make it last a long time" (Participant 62)
"It has been a very helpful device especially in a district set up where resources are always a constraint" (Participant 69)

## Appendix 2. Representative recorded responses to oxygen desaturation episodes

| Clinical scenario | Lowest SpO2 | Response to oxygen desaturation episode |
|---|---|---|
| 45 years old, ASA 1, Thyroidectomy | 75% | Difficult intubation due to tracheal deviation. Saturations improved once intubated successfully. |
| 16 years old, ASA 1, Caesarean section | 67% | Machine disconnected. Machine reconnected and $O_2$ given. Saturations improved. |
| 28 years old, ASA 3, Emergency laparotomy | 34% then arrested | Massive haemorrhage and shock. Blood, oxygen, adrenaline and fluid given. Good outcome. |
| 28 years old, ASA 1, Lower limb amputation | 58% | Hypovolemic, septic and hypotension blood pressure 80/45. Increased fluids (central line). Epinephrine and mechanical ventilation. |
| 4 years old, ASA 1, Debridement | 90% | Obstruction, inserted Guedel airway and saturations improved. |
| 3 years old, ASA 1, Foreign body removal | 86% | Delay in removing foreign body, oxygen increased. Saturations improved once foreign body removed. |
| 16 years old, ASA 1, Total abdominal hysterectomy | 59% | Tube blocked (kinked). Tube straightened and oxygen given. Saturations improved. |