Lifebox: A Global Patient Safety Initiative

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The safety of anesthesia was dramatically improved by the introduction of pulse oximetry. This technology was rapidly adopted by anesthesiologists and made a standard of practice in many countries. In 2007, during development of the Surgical Safety Checklist, the World Health Organization recommended a pulse oximeter as a monitor for all patients undergoing anesthesia. However, clinicians in low- and middle-income countries lack access to basic anesthesia equipment, including pulse oximeters. The Lifebox Foundation was formed to determine how a suitable oximeter could be made available to anesthesia providers in these countries. Almost 11,000 oximeters have been delivered in 90 countries, with education courses completed in over 50 countries. (A&A Case Reports. 2016;6:366–9.)

Pulse oximetry was introduced into routine clinical monitoring in the mid-1980s. We recall using an oximeter for the first time in clinical practice as a transformational event in anesthesia safety. A simple, noninvasive probe placed on a finger displayed, in real time, the percentage of oxygen saturation of hemoglobin. This was a revolutionary change in patient safety because hypoxia, the silent killer, could be detected much earlier than through changes in the color of the tongue or lips. Accurate and reliable detection of hypoxemia was now possible, and an appropriate intervention could be made in time to avert disaster.

At about the same time, anesthesia mortality was being reported in different countries. One of the first major studies in 1982 in the United Kingdom[1] reported an anesthesia-related mortality of about 1:10,000. By the 1990s, several studies had repeated this work, quoting much improved figures, typically an anesthesia-related mortality of 0.5 to 1:200,000.[2–4] What had made the difference? There were important developments within the specialty during this time, including improvements in training and better drugs, for example, propofol, new volatile agents, and short-acting nondepolarizing neuromuscular blocking drugs. A key event was the adoption of pulse oximetry and capnography into clinical practice. National and international standards of perioperative monitoring followed and included the mandatory use of pulse oximetry.[3,5,6]

Despite excellent progress in reducing mortality in anesthesia in high-income countries (HICs), mortality rates in low- and middle-income countries (LMICs) have remained considerably higher. Anesthesia-related mortality has not shown significant improvement since the 1950s in many LMICs, with figures as high as 1:133 recorded as recently as 2005.[4,7,8]

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In 2007, the World Health Organization (WHO) investigated avoidable deaths in surgery as part of the Second Global Patient Safety Challenge, "Safe Surgery Saves Lives." Professor Atul Gawande, a surgeon, researcher, and writer based at Harvard led this work, the outcome of which was a simple, but effective approach to surgical safety, the WHO Standards for Safe Surgery and the Surgical Safety Checklist (SSCL).[9] The adoption of the WHO Standards, and the straightforward series of checks and communications defined by the SSCL, resulted in an impressive reduction in mortality and major complications in pilot sites in HIC and LMIC settings. The Standards recommended only one piece of equipment, a pulse oximeter, which became a new WHO standard of care.[10] However, there was a challenge, how could hospitals in LMICs access pulse oximeters, technology often donated and treasured while it still worked, but deemed too expensive to be a realistic option in many settings?[6]

The Current State of Anesthesia in LMICs

The recent Lancet Commission on Global Surgery has detailed the huge deficiencies in the provision of surgical and anesthesia care globally.[11] The Commission estimated that 5 billion patients worldwide lack access to safe and affordable surgery when required.[11] In anesthesia, the workforce is scarce, drugs and equipment are frequently in short supply, and hospitals may be barely functional. A study from Uganda in 2007 showed that, in a country of 27 million, there were only 343 anesthesia providers, the vast majority being nonphysician clinical officers.[12] Of this group, all practiced anesthesia with many deficits in the most basic of equipment, 74% did not have a functioning pulse oximeter. Another survey in Southwest Uganda revealed that, of hospitals established to undertake surgery, only 40% were functional.[13] This situation is repeated in LMICs around the globe.[11]

Failure to meet international standards in clinical monitoring is a significant issue in these settings, particularly in dark-skinned patients in poorly lit and equipped theaters. When working in such difficult circumstances, safety is often compromised. Although substandard operating room practice can be improved with training and the use of protocols such as the SSCL, there is little doubt that the environment needs considerable additional investment.

The World Bank defines a low-income country as annual per capita Gross National Income ≤US$1045 and a middle-income

country as per capita Gross National Income >US$1045 <US$12,746.[a] Medical equipment is expensive in economically sound environments, but in LMICs, where health care expenditure is only 5% to 10% of that in wealthier nations, the cost of equipment is a particular barrier. Manufacturers are wary of investing in impoverished markets because it is difficult to develop an effective sales strategy without sufficient local finance. This lack of sustainable markets, and the small number of orders, means that, paradoxically, the cost of basic items for individual hospitals in LMICs is often higher than that for hospitals in wealthier countries.

The Lifebox Project

At the 2004 World Federation of Societies of Anaesthesiologists (WFSA) World Congress, a suggestion was made during a Quality and Safety Committee workshop that access to oximetry in LMICs was often inadequate and needed to be improved before high mortality rates from anesthesia in LMICs could be addressed. These anecdotal discussions were subsequently quantified in the study by Funk et al.[6] The WFSA formed a project team with the Association of Anaesthetists of Great Britain and Ireland (AAGBI) and GE Healthcare, the Global Oximetry (GO) Project, to investigate the feasibility of oximetry in LMICs. Sustained use of pulse oximetry was demonstrated in a 4-country study, and the simplicity and long life of suitable oximeters were particularly important findings.[14]

After the development of the SSCL, a WHO working group defined the specifications for a low-cost pulse oximeter for use in the operating theaters in LMICs. A robust, accurate device was required, which met international performance criteria (ISO 80601). In addition, the oximeter needed a long-life, rechargeable battery (>10 hours), necessary because of the frequency of lengthy power cuts, a screen with a waveform visible from a distance, an audible pulse signal indicating changes in Spo_2, and robust enough to withstand a fall on to concrete from 1 m. These requirements eliminated fingertip models that are often ideal for spot check use but not for continuous monitoring. Price was an important consideration for the oximeter, replacement probes, and batteries. A good warranty was a necessity.

The WFSA put out a tender for an oximeter to match these specifications and, in 2010, an oximeter from Acare Technology Ltd of Taiwan was selected. Currently, the Lifebox pulse oximeter (including 2 probes) costs US$250 delivered by courier anywhere in the world; replacement probes cost $25 and a battery $10. The device is CE (Conformité Européenne) marked, indicating compliance with mandatory European Union safety legislation. There is a 2-year warranty for the oximeter and a 1-year warranty for the probes.

Until 2011, there was no single organization with a focus on the use of the SSCL and ensuring that pulse oximetry is included in the monitoring of every anesthetized patient. At that time, the WFSA and the AAGBI joined with Professor Atul Gawande of the Harvard School of Public Health and Brigham and Women's Hospital, Boston, to form the Lifebox Foundation, registered as a charity in the UK 2011 and then in the United States in 2015 (www.lifebox.org).

[a]Available at: http://data.worldbank.org/news/2015-country-classifications. Accessed February 8, 2016.

The team at Lifebox knew that donations would be a major part of increasing the numbers of oximeters in clinical use but also recognized that equipment donation is fraught with problems in hospitals in LMICs. All too often, well-intended equipment donations lie unused because of a poor match between design and the needs of local clinicians or unaffordable spare parts for maintenance or repair. Also, a monitor on its own is of little use without the expertise to interpret the information it provides and the resources (oxygen, for example) to respond appropriately.

This led to the principles that underpin the vision of the Lifebox Foundation. First, any equipment distributed must be suited to the environment and be of a quality that the Lifebox team would be willing to use themselves. Second, the equipment must be supported by appropriate education. Third, the Lifebox Foundation has a responsibility to advocate for the provision of safe anesthesia and surgery for all patients. An early piece of advocacy was the revision of the International Standards for a Safe Practice of Anesthesia, which embedded pulse oximetry as one of a few "mandatory" monitors.[5]

The focus on pulse oximetry at the heart of the work of Lifebox has been strongly symbolic. The emphasis on monitoring encapsulates the idea that anesthesia is a high-risk specialty that warrants the use of sophisticated technology, requires the expertise to interpret the information technology provides, and needs the skills and resources necessary to respond appropriately. Pulse oximeters are highly valued by all anesthesia providers, irrespective of the situation in which they work, and are a tangible symbol of safe anesthesia.

The Lifebox Education Program

In accordance with the Lifebox vision, each oximeter is accompanied by an education program, at its simplest using the DVD "in the box," but, where possible, provided in person to the end-user. Anesthesiologists with experience in teaching and working in LMICs have led the development of the Lifebox educational materials. There is a manual on pulse oximetry, an algorithm for managing hypoxia and a set of clinical cases for practice, and PowerPoint® presentations on the use and maintenance of the Lifebox oximeter itself.

For anesthesiologists, the materials serve as a refresher course and an introduction specifically to the Lifebox pulse oximeter. For those less familiar with oximetry, the educational materials provide a basis for understanding pulse oximetry and a systematic approach to the management of the hypoxic patient. All are available, free of charge, in 6 languages: English, French, Spanish, Russian, Mandarin, and Arabic, via the WHO (www.who.int/patientsafety/safesurgery/pulse_oximetry/en/) and Lifebox Web sites (www.lifebox.org/education/po-training). A DVD containing all the educational materials is distributed with each Lifebox oximeter.

The most important educational achievements have been accomplished through the national anesthesia societies and contacts established via the WFSA. To date, training courses have been held in 50 countries, and local teachers have been trained to deliver the education. Oximetry courses have been delivered "stand-alone"

Table 1. Lifebox Oximeter Distribution by WHO Region

Regions	2010	2011	2012	2013	2014	2015	2016	Grand total
AFRO	47	484	1410	1534	867	1166	25	5533
EMRO	3	9	103	44	12	19	30	220
EURO	2	68	97	129	160	279	15	750
PAHO	1	49	354	365	115	342	7	1233
SEARO	4	258	73	180	74	68	53	710
WPRO	7	662	757	349	223	370		2368
Grand total	64	1530	2794	2601	1451	2244	130	10,814

AFRO = African; EMRO = Eastern Mediterranean; EURO = European; PAHO = Pan American; SEARO = Southeast Asian; WPRO = Western Pacific.

or combined with other educational efforts, such as the AAGBI/WFSA "Safer Anaesthesia from Education" courses (https://www.aagbi.org/international/safer-anaesthesia-education-safe/reports). Feedback from teachers and participants is uniformly positive. Further language translations have been necessary, for example, Vietnamese and Portuguese.

The Lifebox educational materials were updated in 2015, based on feedback from participants, from teachers, and from the experience of the Lifebox team in teaching the courses. The course is now modular and can be used by, and for, anesthesia providers at any level of training.

Outcomes

At the time of writing, the Lifebox Foundation has distributed almost 11,000 oximeters to hospitals in >90 LMICs (Table 1). There have been special large-scale distributions in 27 countries, with sufficient oximeters delivered to meet the requirements to safely monitor all patients undergoing anesthesia and during recovery. Oximeter distributions have been followed up, knowledge about oximetry retained by clinicians, and patient care transformed. In Uganda, follow-up at 3 to 5 months after Lifebox delivery and teaching showed a high rate (95%) of oximeter usage in clinical practice and a retention of knowledge similar to immediate postcourse testing.[15] The Lifebox team has estimated that over 10 million more patients are now monitored each year during anesthesia, enabling thousands of clinicians to move from simple monitoring using a finger on the pulse and a stethoscope on the chest, to beat-to-beat measurement of oxygen saturation.

There are many strengths to the Lifebox oximetry program. The process of pooled procurement makes it possible for small remote hospitals to access a high-quality product at low cost.[16,17] By working closely with the national societies and the manufacturer, Lifebox cuts out the "middle man" and is able to reduce costs associated with distribution. Lifebox links the manufacturer to their market, even when the customer is in the most remote hospital in an LMIC. All oximeters are followed up immediately after distribution and again at 1 year to identify any problems. Breakages and failures compare well with industry standards.[15]

The weakness of the program is the reliance on donations to fund oximeters because the market systems required to purchase are not yet well developed. The Lifebox Foundation is planning to work more closely with National Ministries of Health, and National Procurement Agencies, to support an increase in direct purchase of oximeters in the future.

Next Steps for the Lifebox Foundation

The Lifebox Foundation was formed to improve the safety of anesthesia and surgery and to address the problem of access to pulse oximetry in LMICs. The pulse oximetry work has progressed well, but the uptake of the WHO SSCL, although mandated in many countries worldwide, has been slow in LMICs, arguably the regions where it has the potential to be of greatest benefit. Weak surgical systems and a lack of essential resources provide a challenge to successful introduction of the checklist in LMICs, and it is clear that these problems need to be addressed before the checklist can become an effective tool for patient safety.[18]

The Lifebox Foundation is currently embarking on several new ventures. The first is to consider individual elements of the WHO checklist to improve patient safety. The Foundation is working with one of our partners, the GE Foundation, to investigate and strengthen systems to prevent surgical site infection in LMICs, with a pilot project starting in Ethiopia. A second checklist implementation project, funded by Lifebox, will be piloted in Cambodia.

A third project involves childhood pneumonia, which is a leading cause of death in children younger than 5 years old worldwide, with most deaths occurring in children in sub-Saharan Africa and Southeast Asia.[19] The routine use of pulse oximetry and targeted treatment (antibiotics and oxygen) for at-risk children have been shown to improve outcomes.[20] However, as in surgery, many clinicians in LMICs are unable to access this technology.[20] Lifebox is currently leading an international partnership funded by the Bill and Melinda Gates Foundation involving organizations in the UK (University College London, Great Ormond Street Hospital), United States (Johns Hopkins Hospital), and end users in Bangladesh and Malawi to improve access to accurate, low-cost, high-quality pulse oximeters for children in LMICs.

CONCLUSIONS

Every day patients around the world undergo essential surgery at a risk hundreds of times greater than those faced in HICs. Many succumb to preventable complications as a result of inadequate resources. The work of Lifebox is starting to make a substantial difference to the safety of anesthesia for many patients, but the global oximetry need is still large. And the gap between the safety of anesthesia in many LMICs and most HICs is still unacceptable. The efforts of many international colleagues to improve outcomes for their patients are truly humbling, and it is clear that the work of Lifebox, in partnership with many other organizations, is in improving patient safety globally.

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