





PREFACE

If we are to end the unnecessary deaths of children and newborn babies, then we need strong investments in surgical and anesthetic care for children.

In my region of East Africa, the mortality rate for children undergoing surgery is still high. It is particularly challenging to specialize in the provision of pediatric surgery in this region because of limited infrastructure and human resources. Too often we lose our patients due to a lack of basic resources. The fact that in 2022, children are still dying during surgery due to a lack of simple resources is a terrible injustice: Surgery is a fundamental part of healthcare.

Surgery is a team effort. Each member of the surgical team - from the nurse, to the surgeon, to the anesthesia provider - all play a critical role in making a surgery safe. If my anesthesia colleagues are lacking critical resources, it does not matter how skilled I am as a surgeon, the surgery will not, cannot, be safe.

Many surgical teams across Africa continue to lack access to a pulse oximeter. A pulse oximeter measures the level of oxygen in the blood. It is a critical tool for monitoring patients, before, during, and after surgery. This is why a pulse oximeter is the only piece of equipment on the World Health Organization Surgical Safety Checklist. If you do not have a pulse oximeter, you cannot provide safe surgery for your patient. Yet, this simple device remains out of reach for too many of my anesthesia colleagues – putting millions of lives at risk every year. The risks are particularly high for pediatric patients whose blood oxygen levels fall faster than adults.

This is why, as Global Ambassador of the Smile Train-Lifebox Safe Surgery and Anesthesia Initiative, I am delighted to announce the launch of the Lifebox-Smile Train pulse oximeter to rapidly scale up access to pulse oximetry. The Safe Surgery and Anesthesia Initiative is committed to distributing 11,000 pulse oximeters, designed for use in low-resource settings, to more than 20 countries over the next three years – making surgery safer for 14 million patients.

This report details the impact of pulse oximetry through first hand experiences from anesthesia colleagues across Africa. It also highlights the remaining gaps in the safe provision of anesthesia care.

I am enormously proud to be part of this Initiative, working to address critical gaps in surgical and anesthesia safety. I look forward to updating you on this lifesaving work.

Thank you.

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Professor Miliard Derbew Pediatric Surgeon and Global Ambassador of the Smile Train-Lifebox Initiative

Professor Miliard Derbew, is a pediatric surgeon from Ethiopia. He serves as CEO of King Faisal Hospital, Kigali – Rwanda's largest referral hospital – and Professor of Pediatric Surgery at the College of Health Sciences, Addis Ababa University.

Professor Derbew is Global Ambassador of the Smile Train-Lifebox Safe Surgery and Anesthesia Initiative and a Lifebox Board Member

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INTRODUCTION

"I got interested in patient safety when I realized how here in Africa, we bear an unfair share of perioperative mortality. In my country [Kenya], many hospitals still do not have access to reliable and accessible pulse oximetry."

- Dr. Zipporah Gathuya, pediatric anesthesiologist, Kenya - May 2022

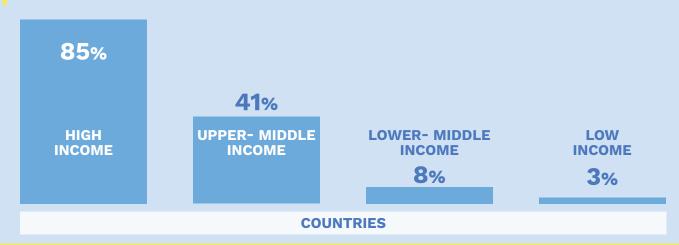
Improving access to timely, quality, and affordable surgical care for all is an essential component of global health. Surgical care can treat a wide variety of conditions, from cancer and injuries to obstructed labor, up to one third of the global burden of the disease. Yet, five billion people cannot access safe, timely and affordable surgical care and anesthesia. In many low- and middle-income countries (LMICs), nine out of ten people cannot access even the most basic surgical services. (1)

This lack of access to surgical care is estimated to lead to 18 million deaths each year, far exceeding deaths from HIV and TB combined. (1) Surgery in resource-limited countries is associated with a far higher number of deaths and disability than in high-income countries (HICs).

Every year more than 4.2 million deaths occur within 30 days of surgery, half of them in LMICs. This accounts for 7.7% of all global deaths, making unsafe surgery the third largest contributor to mortality worldwide, after heart disease and stroke. (2)

There is a particularly high gap in the provision of essential surgical care for children. Safe surgery is vital to treat children born with conditions such as cleft lip and palate and congenital heart disease, as well as for life-threatening injuries and illnesses. Yet, an estimated 1.7 billion children and adolescents do not have access to surgical care – 65% of whom live in LMICs. It is further estimated that 453 million children under five years-old do not have access to basic lifesaving surgical care.⁽³⁾

Pediatric population with access to surgical care (3)



THE WHO SURGICAL **SAFETY CHECKLIST**

The last 20 years have seen increasing recognition of the importance of safe perioperative care (i.e., encompassing preoperative care, surgical intervention, and postoperative care). In 2008, as part of its "Safe Surgery Saves Lives" program, the World Health Organization (WHO) issued a global Surgical Safety Checklist. The Checklist was developed under the leadership of Lifebox co-founder and Immediate Past Chair, Dr. Atul Gawande,

together with nurses, anesthesia providers, and surgeons.

"A wonder drug on a piece of paper" the 19item list provides a communications framework to eliminate error from surgical procedures. The Checklist addresses serious and avoidable surgical complications, by ensuring critical steps are taken in every surgery, every time, everywhere.



The Checklist has been a transformational force in the global movement for safer surgery. When used properly, it has been found to achieve a nearly 50% reduction in mortality and a 36% reduction in postoperative complications, as well as improved teamwork and communication among members of the surgical team. (4)

There is only one piece of equipment on the WHO **Surgical Safety Checklist: The pulse oximeter.**



Perioperative care is multidisciplinary integrated patient-centered care, covering all stages of a surgical process







PERIOPERATIVE CARE





In Focus: The Sustainable Development Goals and Universal Health Coverage

"We don't have a national insurance program or policy yet. We are a low and middle-income country, so we're basically all one illness away from poverty."

– Dr. Elizabeth Igaga, anesthesiologist, Uganda - May 2022

Improving access to safe surgical care is fundamental to the attainment of the UN Sustainable Development Goals (SDGs)⁽⁵⁾. This is particularly the case for SDG3: Ensure healthy lives and promote well-being for all at all ages and for the specific targets within it.

SDG3.8 is focused on the attainment of universal health coverage (UHC) – the goal that everyone, everywhere can access the quality health services they need without risk of financial hardship.⁽⁶⁾. In 2015, following efforts to embed surgery in the global health agenda, notably through the Lancet Commission on Global Surgery ⁽¹⁾ the WHO and Member States recognized surgical and anesthesia care as being a critical component of UHC. The adoption of World Health Assembly (WHA) Resolution WHA68.15, which commits to: "Strengthening emergency and essential surgical care and anesthesia as a component of universal health

coverage" mandates WHO and Member States' global actions to ensure safer surgical and anesthesia care.

Safe surgical care is also fundamental to numerous other targets embedded within SDG3, including: to reduce the maternal mortality ratio to less than 70 in 100,000; to end preventable deaths in neonates and children under-5 by 2030; and to halve the number of deaths and injuries from road traffic injuries, as well as targets to reduce deaths from noncommunicable diseases and increase the health workforce, amongst others. Beyond the specific health targets of SDG3, safe surgical care is also an important component of several other SDGs. This includes targets aimed at poverty reduction, achieving gender equality, and reducing inequalities and promoting peace.⁽⁷⁾



A provider's perspective: **Democratic Republic of Congo**

William Baraka – May 2022

"I don't like to see people suffer pain. I wanted to help, so I decided to become an anesthesia provider because in my province, anesthesia care is not well developed. My sister passed away at a hospital in Kigali because of anesthesia related complications. Her death really touched me, and I wanted to avoid that happening again.

There have been incidents here. A child died during circumcision because of a lack of equipment and monitoring and the anesthesia team was blamed for this. It really pushed me to focus on the safety of patients. I am very happy to see that from the moment I decided to provide safe anesthesia care, we no longer have many complications, and the mortality rate has reduced. Surgery is now safer in my hospital than it was before.

Pulse oximetry is a standard of safe care for monitoring oxygen during anesthesia. There is one case I still remember vividly. I was in Burundi, working in an operating room in Gitega province. There was a power cut, we had no electricity, but our Lifebox pulse oximeter was fully charged. We used it to monitor the patient and the surgery was safer. That patient was saved and from that day I will not miss having a pulse oximeter in my box.

When I hear a pulse oximeter I don't feel well, it breaks me down, but I just have to check it. The situation here is not good in some hospitals. Some hospitals in town are using

pulse oximeters but many hospitals in the remote areas don't have them. I was in one of the far-off areas in the province recently and they can't afford pulse oximeters. They don't have one, even when they need it. Although the WHO protocol for security and safety requires pulse oximeters, most hospitals in rural areas don't have them because they are working with limited resources. We try but we don't have pulse oximeters.

Having organizations like Lifebox in the Democratic Republic of Congo will help. When I returned from my studies abroad and asked about Lifebox, they said they don't know. Lifebox can support, especially the hospitals in rural areas. They have more needs than the hospitals in town. All of us deserve safe practices. I wish to see all operating rooms having a pulse oximeter to improve the safety of patients. It is a must to respect the WHO protocol and having pulse oximeters is a must."

William Baraka, anesthesia provider at the BIOGLODI Medical Center, Bukavu, South Kivu province, DRC

In 2021, Smile Train renovated a pediatric operating room at its partner hospital CBCA Bethesda Hospital, in North Kivu province in DRC as part of its partnership with Kids OR. Lifebox has distributed more than 400 pulse oximeters in DRC, with half of these to support the COVID-19 response.

PULSE OXIMETRY THE "FIFTH VITAL SIGN"

"One case that always stays with me was a four-year-old boy [having] a skingraft operation. During the surgery, the pulse oximeter alarm sounded...[it] showed that his oxygen saturation and heart rate were plummeting, he had gone into cardiac arrest. The pulse oximeter saved that boy's life, without a doubt."

- Mubarak Mohamed, anesthesia provider, Somaliland - May 2022

Invented by the Japanese engineer, Dr. Takuo Aoyagi, in the 1970s⁽⁸⁾ pulse oximeters are simple, non-invasive tools that measure the percentage of oxygen in red blood cells and pulse rate. Pulse oximeters are also used to monitor patients being given supplemental oxygen.

Pulse oximeters are critical for the detection of hypoxia, a condition caused by too little oxygen in the blood (hypoxemia), in which there is insufficient oxygen in a body's tissues for it to function correctly. This is particularly important in pediatric patients - young children and babies are still developing their lung capacity, meaning they consume oxygen faster than adults; this puts them at high risk of rapid desaturation.

A pulse oximeter is connected to a probe, usually clipped onto a patient's finger. The patient's statistics are then shown on the monitor. Audio is key - a monotone beep indicates that everything is normal, a drop in pitch indicates the patient is desaturating, and an alarm sound indicates the need for lifesaving action. This tonal change allows medical staff to listen for changes in levels of oxygen saturation.

Pulse oximeters, "the fifth vital sign", have been

standard equipment in HICs for more than 40 years. They are credited with playing a key role in the transformation of anesthesia care which saw countries such as the United States experience a dramatic reduction in anesthesia-related deaths in a generation.

"When you hear the alarm of a pulse oximeter go off, it makes the head tick and the heart race. It always makes you stand up and check the patient. To think of not having one is extremely unnerving."

- Dr. Zipporah Gathuya, pediatric anesthesiologist, Kenya – May 2022



CRITICAL GAPS IN ACCESS TO PULSE OXIMETRY

"Some hospitals in town are using pulse oximeters but many hospitals in the remote areas don't have them. I was in one of the far-off areas in the province recently and they can't afford pulse oximeters. They don't have one, even when they need it."

– William Baraka, anesthesia provider, Democratic Republic of Congo (DRC) - May 2022 The benefits pulse oximetry brought to the safety of anesthesia have not been equally distributed across the world. In LMIC settings, pulse oximetry often remains a scarce resource. A 2010 study – part of the WHO's ongoing work on safe surgery – found that more than 77,000 operating theaters in LMICs lacked a pulse oximeter. (9) Further studies suggest that if the gap was measured across all areas of a hospital that would benefit from a pulse oximeter, it could exceed 1 million. (10)



A provider's perspective: Somaliland

Mubarak Mohamed - May, 2022

"We see a lot of children for surgical procedures at my hospital. Children desaturate faster than adults, which means that the rate of oxygen in their blood falls at a faster rate than that of adults. A pulse oximeter is a critical tool that I use for the care of my patients, during and after anesthesia. A pulse oximeter means that we can "see" what is happening to the oxygen levels in a patient's blood and take action if this starts to change.

One case that always stays with me was a four-year-old boy from Mogadishu. He had traveled 1,000km by road for a skin-graft operation.

During the surgery, the pulse oximeter alarm sounded. As an anesthesia provider, I know this change in sound means that I have to immediately go into active response, treating the patient by looking for the cause of the hypoxia. The pulse oximeter showed that his oxygen saturation and heart rate were

plummeting, he had gone into cardiac arrest.

The pulse oximeter saved that boy's life, without a doubt.

There is also a huge need for pulse oximetry after surgery. We have a small area for recovery at my hospital where we monitor patients after surgery, until they are fully awake. I've spent 24 hours in this area with a child after surgery when they were not breathing well after a difficult intubation. The pulse oximeter helped me to know that I was monitoring this patient as well as I could, and that if there were any problems it would let me know. It is truly a lifesaving device."

Mubarak Mohamed, Head of Anesthesia at Edna Adan University Hospital, Hargeisa, a Smile Train partner facility. The hospital supported the distribution of 60 Lifebox-Smile Train pulse oximeters throughout Somaliland in response to COVID-19.

LIFEBOX - FOUNDED TO CLOSE THE "OXIMETRY GAP"

"I was in Burundi [when] there was a power cut, we had no electricity, but our Lifebox pulse oximeter was fully charged. We used it to monitor the patient and the surgery was safer. That patient was saved and from that day I will not miss having a pulse oximeter in my box."

– William Baraka, anesthesia provider, Democratic Republic of Congo - May 2022

In 2011, four of the world's leading medical organizations, The Association of Anaesthetists,¹ Brigham and Women's Hospital, Harvard T.H. Chan School of Public Health, and the World Federation of Societies of Anaesthesiologists (WFSA) joined forces to create Lifebox.

Lifebox's founding aim was to close the "oximetry gap" initially by equipping operating rooms and post-anesthesia care units with pulse oximeters. Lifebox's founders procured a low-cost, hospital-grade pulse oximeter for use in low-resource settings. The devices had rechargeable batteries to ensure patients stayed monitored during frequent power cuts, were intuitive and low maintenance, could withstand extreme heat and cold, and survive falling off an operating table.

It was Smile Train's commitment to purchase and distribute more than 2,000 Lifebox pulse oximeters that helped establish Lifebox as an organization. This purchase guarantee not only made anesthesia safer for thousands of

patients, but also proved that there was a market large enough to make pulse oximeters affordable. With Smile Train's commitment, Lifebox was able to work with manufacturers to drive down the cost of pulse oximeters to just \$250 a unit, a reduction of 80%.

Today, Lifebox is a global nonprofit working to make surgery and anesthesia safer worldwide through tools, training, and partnerships. Lifebox focuses on three core areas – anesthesia safety, surgical teamwork, and reducing surgical infection – to address critical gaps in surgical systems.

As of June 2022, Lifebox has distributed more than 32,400 pulse oximeters in 116 countries, alongside providing training and education for anesthesia providers.

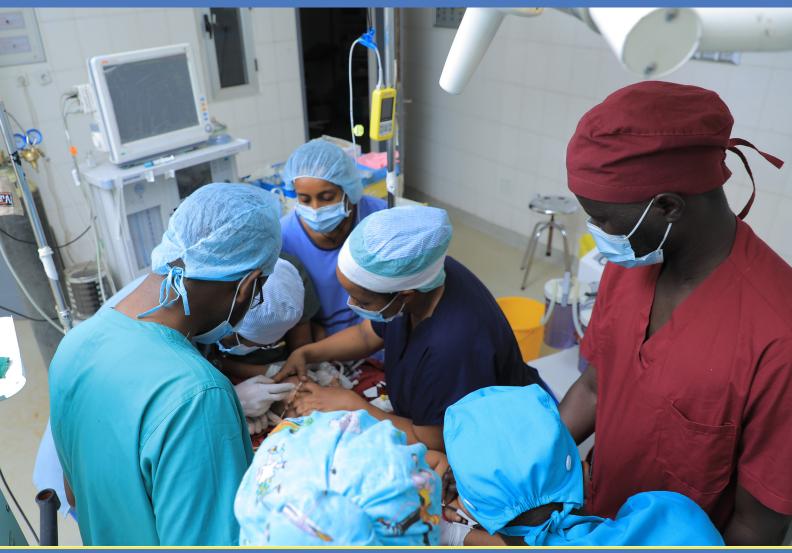
¹Formerly The Association of Anaesthetists of Great Britain and Ireland



An example from Ethiopia illustrates how robust the devices are. In a recent survey of overall monitoring capacity in the country, 140 Lifebox devices were identified, of which 123 were still in use up to seven years later. Of the remainder, nine were reported as missing and eight as malfunctioning. (11)

"Pulse oximetry is indispensable for patient safety; it is also important for care providers. Critical situations have a heavy impact - we do not come out unscathed from such experiences as the death on the table of a patient who initially did not present a major anesthetic risk. We can't wait for pulse oximetry to be available to support the safety of all patients."

– Dr. Bertille Ki, anesthesiologist, Burkina Faso - May 2022



Smile Train: Supporting Cleft and Palate Surgery

Globally more than 200,000 babies are born with clefts every year. A cleft occurs when certain body parts and structures do not fuse together during fetal development. Clefts can involve the lip and/or the palate (the roof of the mouth, which is made up of hard and soft palate). Children with untreated clefts face physical difficulties eating, breathing, hearing, and speaking. Cleft treatment alleviates many of these difficulties, and with proper follow up can allow patients to thrive. However, in many LMIC settings, most babies born with cleft may never get treatment, remaining marginalized their whole lives. More than 90% of children

with untreated clefts die before they reach the age of 19. (12)

Smile Train was set up in 1999 to help children across the world gain access to safe cleft care. Today it is the world's largest cleft organization. Smile Train supports local hospitals and medical professionals across a global network of more than 1,000 hospitals in 70 countries. As well as surgery, local partners support cleft patients with speech therapy, psychological support, nutritional services, and orthodontic and other essential care. Over 23 years, Smile Train has helped more than 1.5 million children across the world get the cleft care they need.



Researching Pulse Oximeter Accuracy in Different Skin Tones

Studies dating back to 2005 suggest that pulse oximetry readings may be less accurate in patients with darker skin tones. In some cases, they have noted that clinically significant hypoxia may be missed. (13, 14, 15, 16) This issue was widely reported during the COVID-19 pandemic when health care providers were using thresholds of oxygen saturation from

pulse oximeters to determine the care pathway of COVID-19 patients. Lifebox is working with partners to overcome these knowledge gaps, seeking to conduct independent studies to quantify the performance of pulse oximeters across different skin pigmentations, and to find solutions that ensure pulse oximeters are accurate for all skin tones.





A provider's perspective: Burkina Faso

Dr. Bertille Ki, anesthesiologist - May 2022

"I only practiced anesthesia care for a short time without a pulse oximeter, but that was long enough to experience the kind of emergency that can arise without one. We were giving a four year-old boy a hernia repair. There was no known history of pathology, so at the start we thought there was no particular risk for this child.

I saw the child before his admission into the operating room; he was calm and cooperative. We explained to him how things would go in the operating room. We had a very limited number of anesthesiologists in our hospital, so we all had to do several things at the same time and anesthesia care was mostly provided by nurse anesthetists. And so other members of the team had started the induction before I came into the room.

When I entered the operating room moments later, I found the child struggling to breathe, trying to rip off his face mask. His agitation contrasted with what had been described as happening during the inhalation induction. I thought for a moment that there was probably another reason for such a commotion. Then I looked at the anesthesia machine and saw that the fresh gas flow was at zero. The child was only breathing halogens.

For a long time afterwards, I trembled and wondered about what could have happened if we had not seen this error in time. If we had had a pulse oximeter, we would have observed the desaturation, and everyone would have understood immediately where the problem was.

Pulse oximetry is indispensable for patient safety; it is also important for care providers. Such critical situations have a heavy impact – we do not come out unscathed from such experiences - the death of a patient on the table who did not present a major anesthetic risk. Pulse oximeters also help us to avoid experiencing such stressful and demoralizing situations. We can't wait for pulse oximetry to be available to support the safety of all patients."

Dr. Bertille Ki, anesthesiologist, Charles de Gaulle Children's Hospital, Ouagadougou, Burkina Faso. Dr. Ki has partnered with Lifebox to facilitate pulse oximeter distributions and training in the country. Six hundred pulse oximeters have been distributed in the country to date.

COVID-19 AND SAFE PERIOPERATIVE CARE

"We currently have one Lifebox oximeter that we are sharing between two COVID-19 wards – at times covering more than 60 patients. This really makes the monitoring of patients quite difficult and may have contributed to morbidities and missed hypoxic events."

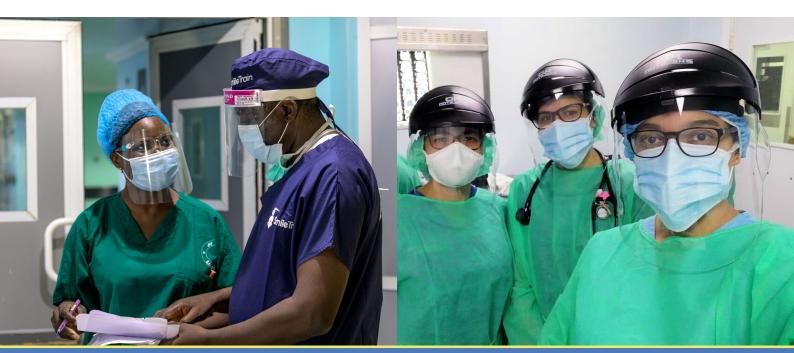
- Dr. James Nonde, emergency medicine consultant, Zambia - July 2021

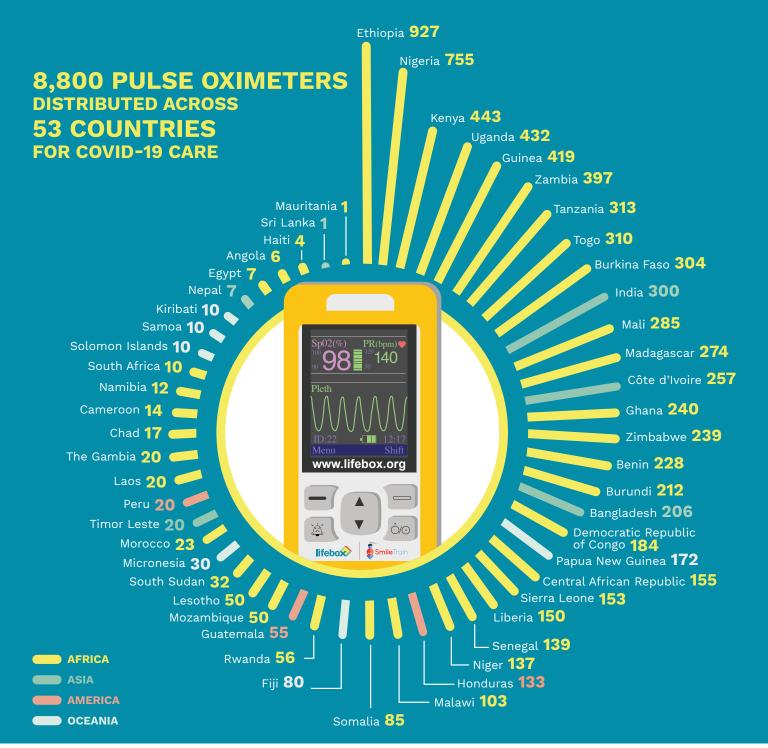
The COVID-19 pandemic has shone a light on the vast disparities between access to health care in LMIC and HIC settings. Across global health care systems, we continue to witness the consequences of inequitable access to vaccines and treatments, lack of personal protective equipment (PPE), and essential supplies - including pulse oximeters and sustainable oxygen supplies.

The pandemic underscored the value of pulse oximetry as a crucial device to help determine the level of care patients needed, both in detecting patients with hypoxia and in triaging patients that needed supplemental oxygen.

Lifebox and Smile Train have distributed 8,800 pulse oximeters to frontline providers in 53 countries as part of their COVID-19 response.







Silent hypoxia

A specific risk associated with COVID-19, particularly among patients who are not fully vaccinated, is a form of oxygen deprivation known as "silent" (or "happy") hypoxia. Normally, patients requiring oxygen because of hypoxia are in extreme pain, struggling desperately to breathe, or they are unconscious. With silent hypoxia, a patient is not aware that they are being starved of oxygen. Many patients with COVID-19 pneumonia did not realize anything was wrong as they did not develop the chest pain or shortness of breath that would be expected. By the time these patients felt any symptoms, their oxygen levels were alarmingly low, and they were at risk of acute respiratory failure.





A provider's perspective:

Zambia Dr. James Nonde (email) - July 2021

"My name is Dr. James Nonde. I am an emergency medicine consultant at Ndola Teaching Hospital – a public facility in the Republic of Zambia – where I am Team Lead COVID-19 case manager. Our Hospital is the biggest in the Copperbelt province and hosts the only ICU for the entire province. The third COVID-19 wave hit us hard. At its peak we had more than 120 patients admitted to our different units within the hospital.

We currently have one Lifebox oximeter that we are sharing between two COVID-19 wards – at times covering more than 60 patients. This really makes the monitoring of patients quite difficult and may have contributed to morbidities and missed hypoxic events. The one Lifebox oximeter we have has stood the test of time since it was donated to us by a local equipment supplier. We would love a donation of six more Lifebox oximeters to help us optimize patient monitoring in our COVID-19 units.

The Lifebox oximeters are well suited to our environment in that they handle heavy use very well, are very accurate with a long battery which makes them economical in the long run. The challenge is that they are difficult to access on the market and finances, as well as competing hospital needs, may not permit the purchase of more."

Dr. James Nonde, emergency medicine consultant, Ndola Teaching Hospital - Zambia.

In response to this email, Lifebox and Smile Train donated 390 pulse oximeters to the Zambian Ministry of Health for nationwide distribution by the Society of Anaesthetists of Zambia.

COVID-19: Lifebox and Smile Train Joint Response

In early 2020, as the COVID-19 pandemic took hold, Lifebox and Smile Train began collaborating on a coordinated global COVID-19 response to support hospitals in LMICs with tools and resources for safe surgical, anesthesia, and COVID-19 care. This includes:

- In April 2022 we prepared an article on "COVID-19 preparedness within the surgical, obstetric and anesthetic ecosystem in Sub-Saharan Africa" (published in the Annals of Surgery in June 2020)(17), its wide dissemination included an online event with global experts - the first of an ongoing learning series on COVID-19.(18)
- We distributed 8,800 pulse oximeters across 53 low-resource countries to frontline providers for the detection and management of COVID-19 patients.

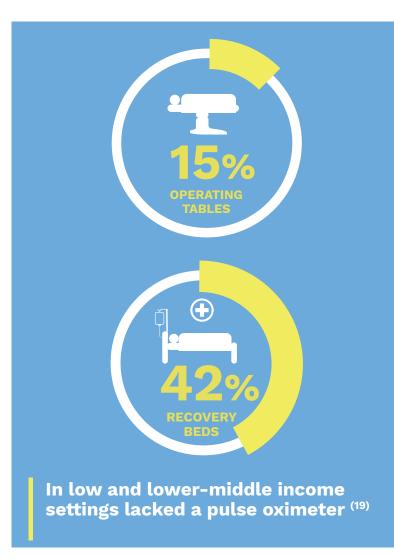
- Together with the WFSA, we developed a communication tool to help keep surgical teams safe from infection, by offering prompts to support key infection prevention measures. More than 130 perioperative providers have been trained as trainers through 23 workshops.
- Published "Perioperative Provider Safety in Low- and Middle-Income Countries During the COVID-19 Pandemic: A Call for Renewed Investments in Resources and Training(19) in the Annals of Surgery. The article assessed gaps in access to PPE and infection prevention protocols, and pulse oximetry. The results informed our distribution plans and to advocate for greater investment and support for essential resources and training in LMICs.

CRITICAL GAPS IN PERIOPERATIVE SAFETY IN LMICS

COVID-19 exposed critical gaps in the availability of pulse oximetry, and other essential resources, such as PPE and oxygen.

In October 2020, a Lifebox, Smile Train, and Jhpiego survey - later published in the Annals of Surgery - found low-resource settings faced significant gaps in access to PPE and other essential resources such as viral filters and pulse oximeters. At the same time there were large gaps in training and implementation of COVID-19-related safety processes. The issues were most pronounced in low and lower-middle income (LIC/L-MIC) settings, as compared to upper-middle income (U-MIC) settings².

In LIC/ L-MIC settings, 15% of operating beds and 42% of recovery beds in postanesthetic care areas, lacked a pulse oximeter. Alongside widespread shortages in PPE, 35.5% of providers in L/L-MIC settings reported feeling unsafe at work during COVID-19, compared with 6.8% of those in U-MIC settings.



Monitoring gaps in Ethiopia

A survey Lifebox conducted across 60 hospitals in Ethiopia published in The Lancet Global Health, showed that although most operating rooms had good availability of pulse oximetry monitoring, four referral and two general hospitals had at least one operating room without a pulse oximeter. In post-anesthesia care units and critical care units, we found an

average of 1–3 unmonitored beds per unit. The worst affected areas were emergency rooms, with around 75% of critical beds unmonitored in referral and general hospitals, and virtually no pulse oximetry available at all in primary hospital settings. (11)

² Countries are classified according to World Bank data sets, stratified lists are available at: https://data.worldbank.org



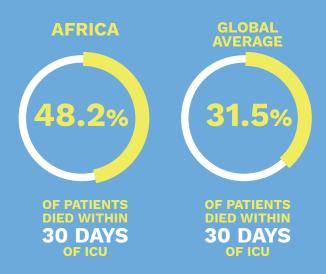


Higher mortality rates among COVID-19 critical care patients in African hospitals

A separate Lancet study across 10 African countries found hospitals with a higher mortality rate from COVID-19 than comparable studies in Asia, Europe, and the Americas. Increased mortality was associated with shortages of essential equipment and resources – only 86% of participating hospitals could provide pulse oximetry to all patients in critical care, and only 50% of patients referred to critical care could be admitted. (20)

The authors estimated an excess mortality of 11–23 deaths per 100 patients, noting that this is likely to be an underestimate when matched for age and severity of comorbidities. Of particular concern is that the majority of the data (70%) came from tertiary hospitals – in most cases providing the highest level of care available in the country. This suggests that lower-level hospitals are likely to have had fewer resources and worse outcomes. (20)

Nearly half (48.2%) of 3077 patients died in the 30 days after high-care or intensive care unit admission, against a global average of 31.5% 20



Oxygen - a vital resource to treat childhood pneumonia

One area that demonstrates the transformative potential of oxygen is childhood pneumonia. Pneumonia is the single largest infectious cause of death in children worldwide, responsible for more than 750,000 deaths in children under-five in 2019, around 15% of the global total – the majority in LMICs.

Hypoxemia is a major cause of death from pneumonia, quadrupling the risk of a child dying

from the infection. In LMIC settings nearly a third of children under-five admitted to hospital with pneumonia are estimated to be hypoxemic.

A 2021 study estimates that strengthening oxygen systems could cut hospital-based pneumonia deaths by nearly half and reduce overall hospital-based deaths of pediatric patients by 25% (24).

In Focus: The Oxygen Ecosystem

"The COVID-19 pandemic unmasked an important gap in our health system. We had a full-blown oxygen crisis and a dire need to scale up oxygen production in the country. Pulse oximetry was useful in ensuring that the patients got just as much oxygen as they needed. This significantly prevented wastage of this precious resource."

- Dr. Elizabeth Igaga, anesthesiologist, Uganda - May 2022

Oxygen is an essential medicine. It is a crucial resource across all levels of a health system, vital for surgeries and in emergencies, and for the treatment of several respiratory and cardiovascular diseases.

However, the provision of oxygen is highly complex and expensive. It takes an entire system of integrated technologies to get oxygen from a source to patients, and to sustain supplies. Managing this requires significant resources and expertise, including trained staff, reliable power, access to a supply chain, maintenance services, and spare parts.

Approximately 24% of hospitals in LMIC settings are estimated to lack an oxygen supply.(1) A

recent review of data from four African countries. estimates that just 13% of healthcare facilities had any form of oxygen, and only 4% of these had an uninterrupted supply of electricity, able to keep systems running at all times. (21)

COVID-19 underscored the lack of robust oxygen ecosystems, with numerous countries facing severe crises. In February 2021, with multiple countries facing devastating waves of COVID-19, the WHO estimated that more than half a million people in LMICs needed oxygen treatment every day, with 25 countries - mostly in Africa, reporting surges in demand. (22)



Lifebox, with support from the Bill & Melinda Gates Foundation, has developed a pediatric probe, and made the design available open access, to improve use of pulse oximeters in children. (25) Lifebox and Smile Train will, together, continuously seek ways to develop and improve our pulse oximeter technology to meet the needs of all patients.



A provider's perspective: Uganda

Dr. Elizabeth Igaga – May 2022

"During the second wave of COVID-19 [June 2021] almost everyone in this country knew someone who was severely ill or had died. We lost colleagues and had colleagues and friends who lost their parents and other loved ones. It was catastrophic.

I lived in constant fear, thinking if my parents or loved ones were ill enough to require intensive care, I wouldn't be able to provide the care they needed. We don't have a national insurance program or policy yet. We are a low and middle-income country, so we're basically all one illness away from poverty.

There are only six emergency medicine physicians in Uganda, so as anesthesiologists, we also had to play an emergency medicine role to some extent. Our phones were ringing incessantly with callers asking, "Do you know a hospital that has an intensive care unit (ICU) bed that's available? Do you know a place where I can take my parents, they are not doing well, I've been told they need an ICU."

I think that the pulse oximeter was one of the most lifesaving pieces of equipment during the pandemic. Dr. Alenyo, an emergency medicine physician, told me, "The pulse oximeter saved us." They used it as a screening tool. Some patients were sicker than they appeared to be,

and the pulse oximeter was crucial in teasing that out.

As was the case in other LMIC settings, the COVID-19 pandemic unmasked an important gap in our health system. We had a full-blown oxygen crisis and a dire need to scale up oxygen production in the country. Pulse oximetry was useful in ensuring that the patients got just as much oxygen as they needed. This significantly prevented wastage of this precious resource.

Oxygen saturation was one of the parameters considered when making appropriate referrals; to decide who stayed at home, who went to hospital and where they should be taken when they finally got to hospital. The pulse oximeter was also helpful in monitoring the progress of resuscitation and assessing the outcomes of resuscitation attempts. Before the pandemic there was not much monitoring in ambulances, but once there was a lot of infection in the community, pulse oximetry was used to monitor patients during transportation to hospitals from home, within the hospitals, and to higher care centers.

As an anesthesiologist, training in pulse oximetry and the execution of the hypoxia action plan has been lifesaving. One of the most satisfying things to hear, is the change in

tone of the pulse oximeter when a previously desaturating patient has their oxygen levels going back up after a seemingly simple intervention. The Lifebox-Smile Train pulse oximeter is a particularly robust, versatile and reliable device that was a crucial part of the emergency service team's arsenal. It is portable, has an excellent battery life, and has different options for charging it. These features were particularly helpful when transferring patients from hard-to-reach areas into the city, where the critical care services are.

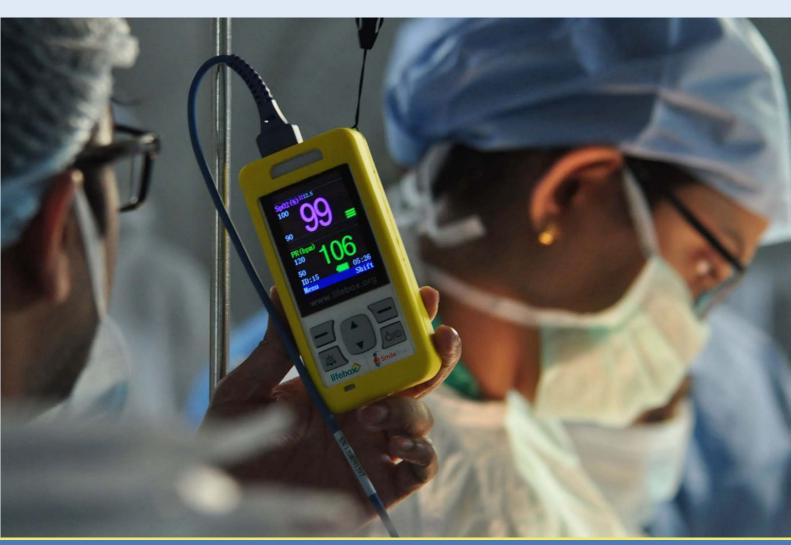
A few years back, it was not uncommon to have elective surgery canceled because of a lack of basic monitoring such as pulse oximetry. Over time that has significantly changed. The hospitals, especially the tertiary ones that are better resourced have heavily invested in standard monitoring equipment, and that includes pulse oximetry. So, in these settings,

cancellation of surgery due to the lack of monitoring has significantly reduced.

This is significant progress, but I am of the opinion that most anesthesia care units need more staffing, especially in the rural areas. The post anesthesia care units, wards, and emergency rooms also need more monitoring equipment installed and health workers need to be trained on their use. This needs to be considered as a matter of urgency."

Dr. Elizabeth Igaga, anesthesiologist, Uganda Heart Institute, and lecturer, Makerere University, Uganda.

Dr. Igaga's account draws on her personal experience, as well as that of her anesthesiologist colleagues Dr. Peter Kaahwa Agaba and Dr. Mary Theresa Nabukenya, and that of emergency medicine physician and Ministry of Health technical advisor, Dr. Annet Alenyo Ngabirano.



ONGOING IMPACTS

"For the first time in a century we are seeing a reduction in life expectancy.

During the pandemic, elective surgeries stopped. People were harmed because they couldn't access safe surgical care."

 Dr. Atul Gawande,
 Assistant Administrator, USAID, and Lifebox Co-Founder and Immediate Past Chair – May 2022

Although the COVID-19 situation has improved in many parts of the world, especially in countries with high vaccine coverage, COVID-19 is far from over. The virus continues to evolve and spread, as seen with the recent major outbreak in North Korea.

In the week starting 27 June, more than 50 countries around the world had COVID-19 infection rates of at least 20% of the population, including countries in Africa, Asia, and the Americas. (26) To stop more dangerous and transmissible variants of COVID-19 developing, we need globally coordinated public health measures, including equitable access to vaccines and treatments. Yet, as of 27 June 2022, just 17.8% of people in low-income countries had received at least one dose of a COVID-19 vaccination. (27)

LMICs also bear a heavy burden of indirect "knock-on" impacts, including breakdowns of social structures and economic pressures, leading to increased poverty and food insecurity in many areas. Access to essential health services has also been interrupted - a third of global surgeries are estimated to have been canceled as a result of COVID-19, at a time when demand for surgical care worldwide is rapidly increasing. (28)

Perioperative providers and hospitals continue to need significant support to manage the impacts of COVID-19. Continued efforts need to be made to support training and ensure continued access to, and best practice procedures, with PPE alongside scale up of pulse oximetry and investment in the wider oxygen ecosystem.

Investing in these measures will not only reduce unnecessary deaths from COVID-19 but will be crucial for the strengthening of health systems, including for future pandemic preparedness.

Provider safety (19)









OF PROVIDERS
FELT UNSAFE AT
WORK DURING
COVID-19





Smile Train and Lifebox are united in their work to improve the safety of surgery and anesthesia globally. Smile Train is Lifebox's longest partner, part of the Lifebox story since its inception in 2011. We recently strengthened our longstanding partnership with the launch of the Smile Train-Lifebox Safe Surgery and Anesthesia Initiative. A critical component of this work is helping to close the pulse oximetry gap, with a planned distribution of 11,000 Lifebox-Smile Train pulse oximeters over the next three years.



As this report is released, we are launching the Lifebox-Smile Train pulse oximeter, a low-cost, high-quality device which aims to rapidly increase access to pulse oximetry for anesthesia and critical care. Together, we will invest in pulse oximetry for safer anesthesia

distributing 11,000 Lifebox-Smile Train pulse oximeters to facilities in more than 20 LMICs over the next three years – making 14 million surgeries safer. Distributions will be accompanied by oximetry and anesthesia safety training.





THE SMILE TRAIN-LIFEBOX SAFE SURGERY AND ANESTHESIA INITIATIVE

In December 2020, we launched the Smile Train-Lifebox Safe Surgery and Anesthesia Initiative. The multiyear program will elevate the quality and safety of cleft and pediatric surgery in more than 70 countries, by strengthening the surgical systems of more than 1,000 Smile Train partner hospitals around the world.

Through training and technological innovation, the Initiative is addressing gaps in cleft and pediatric surgical and anesthetic care. We estimate that our efforts will directly improve the outcomes of 120,000 cleft surgeries, with

benefits spread across the wider surgical system through improved access to monitoring equipment and training. Overall, the Initiative aims to improve the safety of perioperative care for more than 2.6 million patients worldwide.

Dr. Atul Gawande served as Global Ambassador for the Initiative in its first year, before handing over to Professor Miliard Derbew in December 2021. In addition to our joint response to COVID-19, we have reached many milestones over the past 18-months.



In Focus: The Smile Train-Lifebox Capnography Device

Capnography monitors the concentration of carbon dioxide in a patient's breath, mostly used during anesthesia and in intensive care. Capnography devices are the most reliable indicator that an endotracheal tube - the flexible plastic tube used to help a patient breath - has been placed in the trachea (windpipe) correctly after intubation. This is particularly important for children and babies.

Capnography is universally accepted as an essential patient safety monitor in HICs. Yet, as with pulse oximetry, there is a scarcity of this monitoring tool in low-resource settings. This is despite capnography devices being listed as 'essential' for safety monitoring by the WHO-WFSA International Standards for a Safe Practice of Anesthesia.

Although the size of the capnograph gap in LMICs is not quantified, it is expected to be higher even than the pulse oximetry gap. A 2017 study in Malawi found the country had only one capnograph available nationally, shared among 31 operating rooms - a 97% gap; and that there was no capnograph at all for intensive care units - a 100% gap.(29) The study piloted capnographs with 32 anesthesia providers across the country, estimating that, over the sixmonth study period, at least 57 lives were saved as a result of the intervention.

There has not yet been a robust affordable capnography device developed that is suitable for LMIC settings. Our "Capnography for Cleft" program aims to help overcome this. Building on the work of the WFSA's Minimum Capnometer Specifications 2021 we are developing a device to meet the needs of Smile Train's partner hospitals in carrying out safe surgical care for children with cleft.

A provider's perspective: Kenya

Dr. Zipporah Gathuya - May 2022



"I am a pediatric anesthesiologist and a public health specialist. I have a keen focus on patient safety as a critical part of strengthened health systems. I got into anesthesia by accident. When I was a medical intern my best friend and colleague had a severe asthmatic attack. We were unable to secure the airway and had to wait for a non-physician anesthesia provider to come help us. The waiting seemed like an eternity. And even though everything turned out okay, I was determined that in future I would be able to secure an airway. That was when I realized that I had to do anesthesia.

A pulse oximeter is a lifesaver. It allows you to determine how the patient is doing, how oxygenation and circulation is happening in the patient continuously. When you hear the alarm of a pulse oximeter go off, it makes the head tick and the heart race. It always makes you stand up and check the patient. To think of not having one is extremely unnerving.

I once had a three-year-old patient who we had taken to the post-anesthesia care unit (PACU), following a hernia repair operation. She was awake, and we did not have monitors on the transport from the operating room. When we got to the PACU the pulse oximeter revealed

that her oxygen levels had dropped to 85%, when a normal reading is 95% or above. If we did not have a pulse oximeter, we would have left her there only to discover a problem later - maybe too late. What struck me most was that she had previously been well but got bronchospasms on the way to the PACU. But there was no sign that anything was wrong until we fitted the pulse oximeter.

I got interested in patient safety when I realized how here in Africa, we bear an unfair share of perioperative mortality. In my country, many hospitals still do not have access to reliable and accessible pulse oximetry. While a lot has happened to improve oximetry in the operating rooms, too many PACUs and postoperative wards still lack these important gadgets. I wish I could see complete adherence to the WHO Surgical Safety Checklist everywhere. For this we need to see access to pulse oximetry in all perioperative spaces."

Dr. Zipporah Gathuya, pediatric anesthesiologist, The Nairobi Hospital, Kenya and Smile Train Medical Advisory Board Member.



LOOKING AHEAD

Access to affordable, quality, and safe surgical care underpins the primary aim of health interventions – to enable people to live long and healthy lives. (30)

COVID-19 has exposed the fragility of health systems around the world. This has brought into sharp relief many of the critical gaps surgical and anesthesia providers face, particularly in low-resource settings. More than 40 years since surgical care was described as "the most serious manifestation of social inequity in health care..." the level of this inequity is staggering. (30) Today, five billion people – more than 60% of the world's population – lack access to affordable, quality lifesaving surgical care. (1)

One area of focus is the monitoring gap. The scarcity of pulse oximeters, a basic but vital piece of equipment, is indicative of decades of neglect and underinvestment in the perioperative health system. Closing this gap, as part of efforts to strengthen the wider oxygen ecosystem, is critical.

Achieving this means ensuring pulse oximetry is available across the health care system, well beyond the operating room, and high-level hospitals – and in rural as well as urban centers. Health care workers and patients in LMIC settings need to be at the forefront of decision-making processes to improve and expand their perioperative care systems. Alongside fundamental investment in surgical equipment and infrastructure, there needs to be a significant scale up of funding and resources for education and training.

There are encouraging signs. The political mandate provided by the recognition of safe surgery as a critical component of UHC is an essential first step. Building on this, is the development of national surgical, obstetric and anesthesia plans (NSOAPs), as part of UHC implementation strategies in many LMICs. It is also heartening to see commitments from global donors, such as the United States Agency for International Development (USAID), to fund efforts to strengthen surgical care in LMICs. And to see the appointment of Lifebox co-founder and Immediate Past Chair, the surgeon Dr. Atul Gawande, as USAID's Assistant Administrator for Global Health.

These developments represent real progress for global surgery, the once "neglected stepchild of global health". (31) With increased attention, coordination, and funding there is real potential to increase access to safe surgical and anesthesia care, and to better embed it across national health systems.

Lifebox and Smile Train share a vision of universal access to safe, affordable surgical and anesthesia care for everyone. Together with our partners, we are steadfast in our commitment to doing all we can to achieve this. We look forward to playing our part, including through the distribution of more than 11,000 pulse oximeters over the next three years. To meet the SDGs, and truly attain 'health and well-being for all' a mass mobilization is needed to finance the global transformation of access to safe surgery and anesthesia care worldwide.

Billions of people's lives and well-being depend upon it.

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A Critical Gap: Pulse Oximetry in Low-and Middle-Income Countries

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