SPECIAL ARTICLE

The Capnography Project

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Capnography is an essential tool used in the monitoring of patients during anesthesia and in critical care which, while required in most high-income countries, is unavailable in many low- and middle-income countries. Launched in 2020, the Smile Train-Lifebox Capnography Project aimed to find a "capnography solution" for resource-poor settings. The project was specifically interested in a capnography device that would meet the needs of the Smile Train partner hospitals to help monitor children requiring airway or cleft surgery. Project advisory and technical groups were formed and included representation from anesthesia practitioners from a balanced representation from all level of income countries, technical experts in capnography, and representatives from the Global Capnography Project (GCAP), the University of California at San Francisco Center for Health Equity in Surgery & Anesthesia (CHESA), and the World Federation of Societies of Anaesthesiologists (WFSA). Built upon the WFSA minimum capnometer specifications, a human centered design approach was used to develop a Target Product Profile. Seven manufacturers submitted 13 devices for consideration and 3 devices were selected for the testing phase. Each of these devices was evaluated for build quality, and clinical and usability performance. Based on the findings from the overall testing process, a combined capnography and pulse oximetry device by Zug Medical Systems was chosen. To accompany the new Smile Train-Lifebox capnograph, an international team of experienced anesthesiologists and educators came together to develop the necessary education materials. These materials were piloted in Ethiopia, subsequently modified, and endorsed by the education team. The device is now ready for distribution, with the accompanying education package, to the Smile Train network and beyond. In addition, a study is being planned to measure the impact of capnography introduction into operating rooms in resource-constrained settings. (Anesth Analg 2023;137:922–8)

GLOSSARY

AG = Advisory Group; **CE** = Conformité Européene; **CHESA** = Center for Health Equity in Surgery & Anesthesia; **Etco$_2$** = end-tidal CO_2; **FDA** = Food and Drug Administration; **GCAP** = Global Capnography Project; **ISO** = International Organization for Standardization; **LMIC** = low- and middle-income country; **RFP** = Request for Proposal; **Spo$_2$** = oxygen saturation; **TWG** = Technical Working Group; **UCSF** = University of California at San Francisco; **WHO-WFSA** = World Health Organization-World Federation of Societies of Anaesthesiologists; **WFSA** = World Federation of Societies of Anaesthesiologists

RATIONALE

Capnography is an essential tool used in the monitoring of patients during anesthesia and in critical care. It provides real-time information about the patency of a patient's airway, respiratory function, cardiovascular status, and metabolism.[1–3] Its use as a patient monitor has contributed to the dramatic improvements seen in patient safety in anesthesia over the past 50 years.[4–6] However, these improvements have not been seen globally as there continues to be a high incidence of preventable perioperative morbidity and mortality in low- and middle-income countries (LMICs).[7] The most recent World Health Organization-World Federation of Societies of Anaesthesiologists (WHO-WFSA) International Standards for a Safe Practice of Anesthesia classified capnography as only a "recommended" monitoring device compared to pulse oximetry which was considered "highly recommended" (ie, mandatory).[8] For most high-income countries, a capnograph is a required monitor.[9] The reality for many LMICs is that capnography is not widely available due to the high cost and complexity of existing devices. Increasing capnography accessibility in LMICs has been previously highlighted as a priority for improving safe anesthesia practice globally.[10,11]

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Lifebox (www.lifebox.org) is a nonprofit organization, cofounded by Atul Gawande and leaders in global anesthesia in 2011, that works to improve the safety of surgery and anesthesia globally. Smile Train, with its network of over 1100 partner hospitals around the world, empowers local medical professionals with training, funding, and resources to provide free cleft surgery and comprehensive cleft care to children. Both organizations have a commitment to programmatic and technical innovation to improve safety in anesthesia and surgery. The Smile Train-Lifebox Safe Surgery and Anesthesia Initiative was launched in 2020 as a multiyear program aimed at elevating the quality and safety of cleft and pediatric surgery. Specifically, this initiative sought to strengthen surgical systems within the Smile Train partner network, which represents 70 countries around the world, by jointly working on projects that focus on capacity building, innovation, and research. This article details one of the main programs of this initiative, The Smile Train-Lifebox Capnography Project, which aimed to find a "capnography solution" for resource-poor settings. The project was specifically interested in a capnography device that would meet the needs of the Smile Train partner hospitals to help monitor children requiring airway or cleft surgery. It describes the methodology used to select a suitable capnography device, the development and pilot of an educational package to accompany the device distribution, and future plans for impact assessment.

Lifebox, with its experience in technical innovation in low-resource settings, was chosen to lead the Smile Train-Lifebox Initiative capnography project. The organization had experience directing both the Lifebox pulse oximeter[12,13] and headlight projects.[14] The plan was to follow a similar methodology (Figure 1). An Advisory Group (AG) consisting of key stakeholders from Smile Train and Lifebox as well as individuals and core partners with expertise in capnography (eg, Global Capnography Project [GCAP],[15] Center for Health Equity in Surgery & Anesthesia [CHESA] at University of California at San Francisco [UCSF],[10] and World Federation of Societies of Anaesthesiologists [WFSA][16]) was formed to provide strategic guidance for the project. In addition, a Technical Working Group (TWG) was formed to give regular technical and clinical input. This group was composed of anesthesia providers working in low-resource settings, and individuals with clinical and/or technical expertise in capnography.

In 2020, the WFSA developed minimum capnometer specifications.[15] These were based on the International Organization for Standardization (ISO) capnometer specifications but recognized the many factors constraining the use of capnography in resource-poor settings such as cost, durability of devices, availability of consumables, lack of dependable power supply, and maintenance. It was expected that these specifications would be acceptable to industry and stakeholders, and useful in reducing costs and guiding development and investment into resource appropriate capnography devices to help meet the unmet need.

TARGET PRODUCT PROFILE

Using a human centered design approach,[17] the Lifebox team and technical advisory group worked closely with Spark Health Design (https://www.sparkhealthdesign.com) to interview key

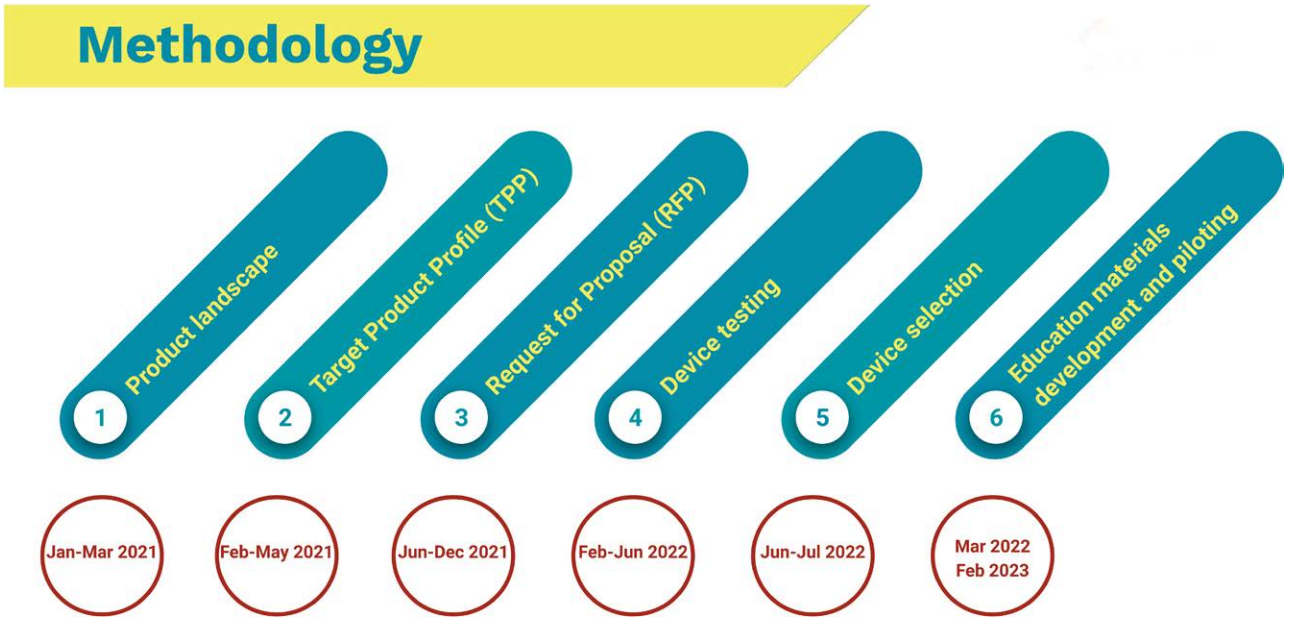

Figure 1. Smile Train-Lifebox Capnography project plan and timeline.

stakeholders to help characterize the "ideal requirements" of an $Etco_2$ monitoring device for pediatric surgical patients requiring airway or cleft surgery in under-resourced settings. Eleven health care professionals (1 oral-maxillofacial surgeon, 1 plastic surgeon, 2 biomedical engineer technicians, 2 nurse anesthetists and 5 anesthesiologists) representing 7 countries (Kenya [2], Ghana [2], India [1], Nigeria [3], Democratic Republic of Congo [1], Ethiopia [1], and Peru [1]), who work in Smile Train partner hospitals, were interviewed. Key findings from the interviews established that:

- A side-stream device would be preferable to a mainstream device as it is less bulky and heavy.
- The device should consist of reusable components where possible.
- The device should be portable.
- An $Etco_2$ device would be satisfactory; a combination device that included both $Etco_2$ and pulse oximetry would be ideal.

While the WFSA minimum capnometer specifications were very useful in developing a target product profile (TPP), they were intended to be basic and did not specifically provide requirements when addressing the unique challenges of monitoring a small child requiring airway or cleft surgery. Guided by the findings from the interviews conducted with end-users, the project's TWG finalized the TPP. It included essential requirements in 5 categories: device, display, durability, sample line, and power. It also included some requirements around casing and alarms that the TWG felt would be helpful although not essential. This key document was then used as the basis for the technical discussions with industry partners.

PRODUCT LANDSCAPE

At the same time as the interviews were being conducted, Spark Health Design conducted market research to identify existing capnography devices available for purchase. A total of 84 devices were identified from 43 companies mainly located in the United States and China (70% of all devices). The majority of these companies also offered a dual parameter ($Etco_2$ + oxygen saturation [Spo_2]) configuration with prices ranging from USD 400 to USD 2920. The high cost of capnography had been one of the major barriers to its use in low-income countries. The existence of lower cost devices seemed promising.

REQUEST FOR PROPOSAL

In October 2021, the Smile Train-Lifebox project team released a Request for Proposal (RFP) inviting all manufacturers to submit their proposals for a high-quality, low-cost capnography device that would meet the requirements as set out in the TPP. Seven manufacturers offered proposals for a total of 13 devices. Members of the TWG evaluated the proposals, and 3 devices were selected for the testing phase.

TESTING

To evaluate the overall performance of the selected devices, a multiphase approach that included build quality checks, and clinical and usability evaluations, was developed by the TWG.

Build Quality Checks

An experienced Chartered Engineer from Diamedica (not involved in RFP) (https://www.diamedica.co.uk), who was also a member of the TWG, performed the build quality checks in March 2022 and presented his findings to the rest of the group. While all the devices performed well during the evaluation, 1 device stopped working shortly thereafter.

Clinical Evaluation

The clinical evaluation was performed at the Hypoxia Lab (UCSF) in April 2022. Using a protocol designed by members of the TWG, the CO_2 function of each device was assessed. The evaluation report revealed satisfactory performances by 2 devices while the third device stopped working after being used on 6 subjects. The Spo_2 function was tested according to an existing protocol. Reports revealed satisfactory results from 2 devices, both meeting Food and Drug Administration (FDA) and Conformité Européene (CE) Mark requirements while one failed to comply with both of these international standards.

Usability Evaluation

Two commercially available CE Marked combination capnography/pulse oximetry devices were selected for evaluation based on the results of the first 2 phases of testing. The usability evaluation was performed by 7 anesthesiologists representing different geographical regions (Burkina Faso, Honduras, Kenya, Mongolia, Papua New Guinea, and the Philippines) who all had experience in the use of capnography. Each participant was asked to use both devices to monitor 6 patients (children and adults) and complete a logbook detailing their experiences. At the completion of the trial, evaluators completed a worksheet comparing the 2 devices and were asked to recommend one. The devices were evaluated for their display, alarms, quality of $Etco_2$ waveform, battery quality, durability, ease of storage, portability, and ease of cleaning. Feedback received was mixed, with advantages and constraints for both devices; however, one device seemed more suitable for use in resource limited settings. Summary of device testing is displayed in the Table.

Table. Summary of Multiphase Device Testing

Criteria	Devices		
	A	B	C
Build quality	Pass	Pass	Fail
Clinical	Pass	Pass	Fail
Usability	Pass	Pass	Did not test

The recommended device by Zug Medical Systems (Figure 2), chosen based on the findings of the overall testing process, was presented to Smile Train in the second half of June 2022. Lifebox informed the 3 manufacturers of the decision and engaged in discussions with the chosen manufacturer to finalize an initial order to be distributed to selected Smile Train partner hospitals.

CAPNOGRAPHY EDUCATION

While anesthesiologists in many parts of the world have been using continuous capnography since the 1980s, this has not been the case for many anesthesia providers in less well-resourced areas. Regardless of setting, when introducing a new piece of equipment into daily practice, it is important to ensure that users receive appropriate training in its use. Not only should they become familiar with the technical aspects of how to use the new device, but they also need to understand the physiology underpinning it and be able to correctly interpret and act on the information it provides.

An international team of experienced anesthesiologists and educators in anesthesia came together to develop the necessary education materials to accompany the new Smile Train-Lifebox capnograph. Members of the team came from Australia, Canada, Honduras, Ireland, Kenya, Nepal, Papua New Guinea, Rwanda, United Kingdom, United States, and Zambia. An iterative process was undertaken, and agreement was reached on 5 basic areas to be included in the teaching: (1) Why we should use capnography; (2) Physiology of carbon dioxide; (3) Using the capnograph; (4) Clinical Cases; and (5) Taking care of the Smile Train-Lifebox capnograph.

Small groups of 2 or 3 separately developed each module. A team of 3 edited all of the submissions and standardized language and approach. All of the materials were reviewed by the team as a whole and any modifications were made. Work with a professional illustrator was then undertaken to develop and standardize all the illustrations. Following completion of this part of the project, the materials were endorsed by the whole education team and approved for testing.

Two experienced educator-anesthesiologists from the team took the materials to Ethiopia for onsite testing. Three 1 day workshops were held, 2 of which were for nonphysician anesthesia providers and 1 for anesthesiologists and residents in training. A Participant Handbook was developed and given to each attendee.

Figure 2. Recommended dual parameter device by Zug Medical Systems.

Only 1 or 2 participants had previously used capnography. The workshops were highly interactive, using a variety of teaching techniques including PowerPoint presentations, videos, quizzes, games, and hands-on exposure to the new capnographs. All the participants were very engaged in the process. Feedback was excellent. Some changes were made to the materials and subsequently presented to the whole education team which approved them. Future plans include training of local teachers on the use on the new device, in all areas where Smile Train-Lifebox capnographs will be delivered.

IMPACT STUDY

In addition to the general distribution of the capnography device and training on its use to the Smile Train network, a study is being planned to measure the impact of capnography introduction into operating rooms in resource-constrained settings. The study will be a prospective mixed-method interventional study to understand the impact of introducing capnography, along with an education program, into 6 hospitals in 2 countries (Ethiopia and Somaliland). Specifically, it will include an assessment of the current monitoring practices in study facilities, effect of the intervention on knowledge, monitoring practices and change in provider practice and confidence with the introduction of capnography. The durability of the introduced capnography device over the time period of the study will also be assessed. Previous work done in Malawi by members of the AG has laid the foundation for this study[16] that is anticipated to start in the summer of 2023.

CHALLENGES

There were many hurdles to overcome to bring this project to fruition.

- Identifying lack of capnography as a problem and determining its extent.
- Gathering a coalition of interested parties and agreeing on a solution.
- Securing funding for the proposal.
- Project management through all phases—standards required, TPP, RFPs, build quality check, clinical and usability testing, and development of education materials.
- Dealing with regulatory and importation issues such as customs regulations, import taxes, device approval, local delivery options.[18]

Now that the device is available, further challenges lie ahead. These include:

- Marketing the Smile Train-Lifebox capnograph to anesthesia providers, departments of health in LMICs, anesthesia societies, and possible funders and donors.
- Managing country specific delivery requirements and language issues.
- Organizing capnography educational activities, in-person and/or virtual, with anesthesia societies, departments of anesthesia and anesthesia providers.
- Assessment of the impact of capnography on anesthesia practice and outcomes in selected countries.

SUMMARY

In this article, we introduce the Smile Train-Lifebox capnograph. We briefly discuss the methodology used in its selection, the development and pilot of an educational package to accompany device distribution, and future plans for impact assessment. It has been a collaborative process involving many individuals and organizations committed to improving perioperative patient safety. It is hoped that this article will not only reiterate to the global community the need for capnography in many areas of the world, but also provide a plausible solution. ■

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DISCLOSURES

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Conflicts of Interest: F. M. Evans Chaired the Smile Train-Lifebox Capnography Project Advisory group; member of both the Technical Advisory group and Education Working group. F. M. Evans is a Lifebox Global Governance Council member. F. M. Evans is a member of the Smile Train Medical Advisory Board.
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Contribution: This author helped with manuscript design, writing of the manuscript, and approval of the final version of the manuscript.
Conflicts of Interest: R. Turc coordinated the Smile Train-Lifebox Capnography Project, member of the Advisory group, the Technical Advisory group. R. Turc is employed by Lifebox.
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Contribution: This author helped in the usability testing, manuscript design, writing of the manuscript, and approval of the final version of the manuscript.
Conflicts of Interest: Maria A. Echeto-Cerrato was a member of the Education Working group.
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Contribution: This author helped in the usability testing, manuscript design, writing of the manuscript, and approval of the final version of the manuscript.
Conflicts of Interest: Z. N. Gathuya was a member of the Smile Train-Lifebox Capnography Project Advisory group, Technical Advisory group, and Education Working group. Z. N. Gathuya is a member of the Smile Train Medical Advisory Board.
Name: Angela Enright, MB, FRCPC.
Contribution: This author helped with manuscript design, writing of the manuscript, and approval of the final version of the manuscript.
Conflicts of Interest: A. Enright was a member of the Advisory group, led the Education Working group. A. Enright is a Lifebox Global Governance Council emeritus member.
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