MEDICAL DEVICES & HEALTH TECHNOLOGIES

Oxygen blenders and bubble continuous positive airway pressure for neonatal respiratory support

BABE: a low-cost, standalone, preassembled device to help babies with respiratory distress syndrome

Health need

Respiratory distress syndrome (RDS), a condition resulting from a shortage of surfactant in underdeveloped lungs, affects most babies born before 32 weeks of gestational age and is almost always fatal without effective treatment.

Continuous positive airway pressure (CPAP) is a lifesaving procedure commonly used to treat RDS. However, commercially available CPAP devices or ventilators are often unaffordable in resource-limited hospitals and clinics, and to compound the problem, unreliable power limits the practicality of this equipment in many of these settings. To address these challenges, health care workers often improvise solutions such as nasal bubble CPAP (bCPAP), which are assembled using tubing, nasal prongs, and a water bottle as a bubbler. However, these improvised kits rely on a 100% source of oxygen gas, and they cannot reduce the oxygen concentration by blending room air into the gas provided to the newborn. Excessive oxygen is extremely dangerous to preterm newborns, frequently resulting in complications such as retinopathy of prematurity, chronic lung disease, and brain damage.

There is a critical need for a safe, rigorously tested, very low-cost bCPAP method that includes oxygen-blending capabilities for resource-constrained sites. It has been estimated that the effective use of such devices in referral and district hospitals could prevent 178,000 neonatal deaths in Africa each year.[1]

Technology solution

Inspired by these improvised bCPAP kits, PATH, in collaboration with neonatologists and respiratory therapists at University of Washington and Seattle Children's Hospital, developed BABE, a low-cost bCPAP device fitted with two oxygen blenders that provide fixed 37% and 60% blends of oxygen. The two oxygen blenders included with the device work by entraining room air into the flowing oxygen stream to dilute the concentration of oxygen delivered. Designed to be inexpensive, robust, and easy to use, the blenders provide a stable and reliable source of blended gas under all clinically relevant conditions of pressure and flow. This blended gas is much safer for preterm newborns than the 100% oxygen commonly given with improvised bCPAP kits, and reduces the risk of retinopathy of prematurity, chronic lung disease, and brain damage.

BABE does not require assembly at the point of care and is designed to provide bCPAP therapy to preterm newborns with RDS without requiring a power source (i.e., electricity or battery) or medical-grade compressed air.

Figure 1. PATH's bCPAP configuration.

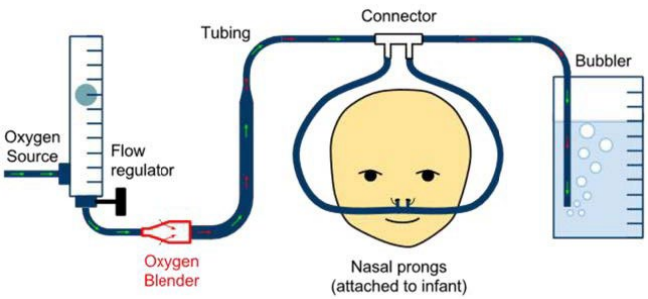


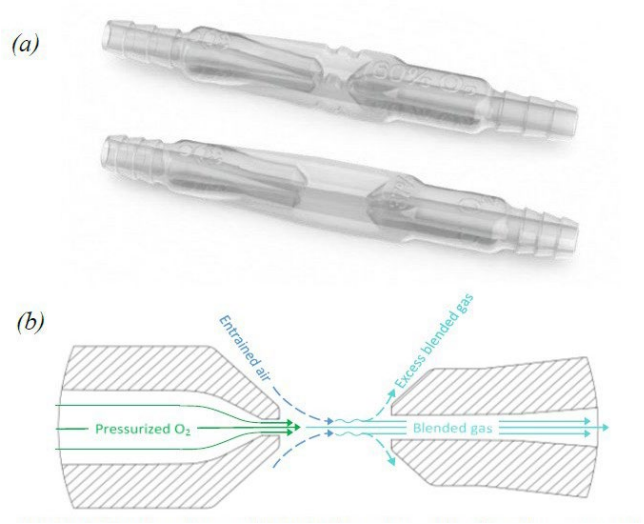
Figure 2. PATH's bCPAP device—BABE.

Finalizing design and engineering

With funding from Saving Lives at Birth, the team conducted bench testing of BABE and collected user-centered design feedback that informed the development of several prototype iterations. Our bench studies demonstrated that the device delivers clinically relevant pressures (up to 8 cmH_2O) and oxygen blends (37% and 60%) at typical bCPAP flow rates (2 liters to 5°liters per minute).

PATH has conducted a design-for-manufacturing process to ensure that the oxygen blenders can be reliably manufactured at a low cost at scale using injection-molding methods. PATH's two oxygen blenders are designed to operate on oxygen cylinders, mid-to-large-sized oxygen concentrators, or central oxygen supplies.

Figure 3. (a) PATH's fixed-rate bCPAP blenders. (b) Blender principle of operation.



Demonstrating operational feasibility

In 2021, PATH and partners from Adara Development, Kiwoko Hospital, and Seattle Children's assessed the **feasibility** of use of the novel BABE device on neonatal patients as well as the **usability** and **acceptability** of the device by health care workers.[2] Over a 4-month period (October 2021–January 2022):

- 14 neonates were enrolled and treated with the bCPAP device.
- 12 of those 14 neonates received treatment with blenders.
- 13 nurses cared for patients using the bCPAP device.
- Median time to set up the device was 15 minutes.
- Median time to change between blenders was 15 seconds (interquartile range calculation: 12–27).
- **Overall nurse satisfaction with the device was 8.5 out of 10.**

Next steps

PATH is now seeking partnerships and funding for conducting a technology transfer to a manufacturing partner, regulatory approvals, device introduction, and scale-up of use in key geographies, primarily in sub-Saharan Africa.

Project contact

To learn more about the BABE project, contact Mike Ruffo, project leader, at mruffo@path.org.

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1. Lawn JE, Kerber K, Enweronu-Laryea C, Cousens S. 3.6 million neonatal deaths--what is progressing and what is not? *Semin Perinatol*. 2010;34(6):371–386. https://doi.org/10.1053/j.semperi.2010.09.011
2. Hedstrom AB, Nyonyintono J, Saxon EA, Nakamura H, Namakula H, Niyonshaba B, et al. Feasibility and usability of a very low-cost bubble continuous positive airway pressure device including oxygen blenders in a Ugandan level two newborn unit. *PLOS Glob Public Health*. 2023;3(3):e0001354. https://doi.org/10.1371/journal.pgph.0001354

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Address
437 N 34th Street
Seattle, WA 98103

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