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Evaluation and Preparation for Introduction of a Low-Cost Bubble Continuous Positive Airway Pressure Kit and Oxygen Blender for Neonates

Midterm Report

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Acronyms and Abbreviations

bCPAP	bubble CPAP (device)
CPAP	continuous positive airway pressure (device)
DfM	design for manufacture
NICU	neonatal intensive care unit
RDS	respiratory distress syndrome
SL@B	Saving Lives at Birth
USAID	United States Agency for International Development

Executive Summary

This report is the midterm deliverable for the two-year Saving Lives at Birth (SL@B) project entitled "Evaluation and Preparation for Introduction of a Low-Cost Bubble Continuous Positive Airway Pressure (bCPAP) Kit and Oxygen Blender for Neonates." PATH's aim is to accomplish three objectives: (1) generate technology awareness and determine potential demand; (2) determine the feasibility of the bubble continuous positive airway pressure (bCPAP) kit for Africa; and (3) finalize design and engineering of the oxygen blender and bCPAP kit. Several activities in this project have been implemented in collaboration with Adara Development; Kiwoko Hospital, Uganda; Seattle Children's; and the University of Washington, Department of Pediatrics.

Inspired by an improvised bCPAP device, initially conceived and employed in clinical practice by Dr. Ashish Jain at Hindu Rao Hospital in New Delhi, India, PATH configured a bCPAP kit that employs inexpensive components commonly found in hospitals—including oxygen tubing, stopcocks, microburettes, and nasal cannulae. Uniquely, our kit also includes a PATH-designed inline, passive air-oxygen blender. Our inexpensive, robust oxygen blender can be used where no source of pressurized air is available and has been designed to provide a stable source of blended gas, regardless of user input. It can be used with any bCPAP system where pressurized oxygen is available. Inclusion of our oxygen blender in the kit ensures a safe blend of gas to the neonate. Our kit does not require electricity or a source of pressurized air for use, making it appropriate for and accessible to a broader range of medical settings than currently available for safely administering continuous positive airway pressure.

With a prior SL@B grant, PATH, with input from Dr. Jain and in collaboration with Rob DiBlasi, a respiratory therapist at Seattle Children's, achieved proof of concept of a functional bCPAP device that could be assembled using a variety of components that could be commonly sourced in low-resource settings. PATH also achieved proof of concept of a blender that provided a 40 percent blend of air and oxygen that could be added to the bCPAP configuration to improve safety. A human factors assembly evaluation with health care workers in a New Delhi hospital revealed that a *prepackaged* bCPAP kit with an oxygen blender would improve performance, assembly time, ease of use, and safety—eliminating potential errors in the assembly of the kit by health care workers—and allow for the optimization of components not necessarily available in the hospital (e.g., larger-bore tubing). This feedback has shifted the focus of our next steps in development from improvised bCPAP assembly instructions for materials sourced at the point of care, to a low-cost, prepackaged kit.

With a new two-year SL@B seed grant, awarded in September 2014, PATH is now focused on determining public-sector need and target market segments in Africa, generating awareness of the technology, and further refining and preparing a prepackaged kit for manufacture, assembly, and scale-up. Following successful completion of the above activities, the bCPAP kit will be poised for programmatic and clinical evaluation, as well as technology transfer.

To date, PATH has worked to refine the components of the preassembled kit; conducted a stakeholder workshop in Uganda to collect user feedback; met with ministry of health officials in Ethiopia, Malawi, Rwanda (under other funding), and Uganda to better understand procurement and policy; visited health care facilities in Ethiopia, Malawi, Rwanda (under other funding), South Africa, and Uganda to share information on the kit and understand best use-cases for early adoption; and compiled a list of potential blender manufacturers and kit distributors located in South Africa, based on publicly available company information and using criteria such as current distribution to hospitals of medical consumables, including tubing, cannulae, and nasal prongs. As a next step, we will be meeting with both manufacturers and distributors.

Project Overview

Background

Respiratory distress syndrome (RDS), a condition resulting from a lack of surfactant and underdeveloped lungs, affects the majority of babies born before 32 weeks of gestational age; it is almost always fatal without effective treatment. A lifesaving procedure commonly used in high-resource facilities to address RDS is continuous positive airway pressure (CPAP). Commercially available CPAP devices are often unaffordable in resource-limited hospitals and clinics, so health care workers have devised improvised solutions such as nasal bubble CPAP (bCPAP) devices assembled using tubing, connectors, nasal prongs, and a water bottle as the bubbler.

These improvised devices provide lifesaving respiratory support; however, they generally rely on a 100 percent source of oxygen and lack the ability to blend air into the gas provided to the infant. High concentrations of oxygen are very dangerous to pre-term infants, frequently resulting in complications such as retinopathy of prematurity, chronic lung disease, and brain damage.

Project inception—first round of SL@B seed funding

On September 30, 2011, with seed funding received from the Savings Lives at Birth (SL@B) program, a project was launched at PATH to develop a low-cost bCPAP kit and oxygen blender for neonates.

This bCPAP kit was born from a concept developed by Dr. Ashish Jain, a leading neonatologist at Hindu Rao Hospital in New Delhi, India. A lack of CPAP equipment at Hindu Rao meant that many neonates who could have benefited from this simple treatment were dying, and Dr. Jain was determined to find a solution. His idea was to use basic and readily available supplies in the hospital to assemble an improvised bCPAP device. Using intravenous tubing, a microburette, two stopcocks, and adult nasal cannula, he was able to fashion single-use, inexpensive bCPAP devices that could provide the necessary lung support to his neonates. The use of adult nasal cannula was intended to ensure that sufficient positive airway pressure could be provided to the neonate.

Under this project, PATH sought to build on and validate Dr. Jain's original concept by subjecting the bCPAP device to testing to identify hazards, determine the optimal selection and configuration of components, and provide clear instructions for assembly and use of the device. In addition, the development of an oxygen blender as a supplement to this kit (or to complement other improvised bCPAP devices) was planned. Three objectives were defined and achieved:

1. Create a bCPAP kit and instructions for use.
2. Demonstrate proof of concept for a simple oxygen blender.
3. Perform a human factors evaluation of the bCPAP kit, oxygen blender, and instructions for use.

The bCPAP kit and oxygen blender designs were configured and validated, achieving proof of concept. A human factors evaluation of the bCPAP kit, oxygen blender, and instruction set was completed in mid-August 2013 at Hindu Rao Hospital. Results from this evaluation indicated that although point-of-care assembly was feasible, the time taken to assemble kits using existing components was lengthy and assembly errors were challenging to avoid. This early work was pivotal in identifying the need for a *preassembled* bCPAP kit that would reduce the burden on health care workers, eliminate errors associated with incorrect assembly, and allow for optimization of components such as the use of larger-bore tubing. On September 30, 2013, this scope of work concluded.

Further development—second round of SL@B seed funding

PATH received a second SL@B seed award in September 2014 to conduct work through September 2016.

For this new scope of work, we proposed to evaluate and ready a prepackaged bCPAP kit for introduction by preparing the blender design for manufacture (DfM), identifying distribution opportunities for the kit, and evaluating the use of the kit in low-resource settings in order to pave the way for scale-up.

The following three objectives have been defined and activities are underway toward their achievement:

1. Generate technology awareness and determine potential demand.
2. Determine the feasibility of the bCPAP kit for Africa.
3. Finalize design and engineering of the oxygen blender and bCPAP kit.

Current status

Table 1 summarizes both scopes of work and the status of project activities as of October 2015.

Table 1. Output indicators and verification status.

SEED AWARD SEPTEMBER 30, 2011-SEPTEMBER 30, 2013			
Objective	**Output indicator**	**Means of verification**	**Status**
1. Create a bCPAP kit and instructions for use.	1A. Survey of available components in India.	Components received.	COMPLETE
	1B. Bench testing of protocols.	Protocols finalized.	COMPLETE
	1C. Bench test.	Validation report drafted.	COMPLETE
	1D. Instructions for use.	Instructions for use drafted.	COMPLETE
	1E. Findings report.	Findings report finalized.	COMPLETE
2. Demonstrate proof of concept for a simple oxygen blender.	2A. Design concept.	N/A.	COMPLETE
	2B. Prototypes.	Final prototype selected.	COMPLETE
	2C. Reference design.	Design finalized.	COMPLETE

SEED AWARD SEPTEMBER 30, 2011-SEPTEMBER 30, 2013			
Objective	**Output indicator**	**Means of verification**	**Status**
3. Perform a human factors evaluation of the bCPAP kit, oxygen blender, and instructions for use.	3A. Preliminary hazard analysis.	Preliminary hazard analysis drafted and reviewed.	COMPLETE
	3B. Human factors (use and error assessment) protocols.	Protocols finalized.	COMPLETE
	3C. Human factors assessment.	Field work completed.	COMPLETE
	3D. Report and dissemination of findings.	Report submitted. Draft manuscript completed.	COMPLETE

SEED AWARD SEPTEMBER 30, 2014-SEPTEMBER 30, 2016			
Objective	**Output indicator**	**Means of verification**	**Status**
1. Generate technology awareness and determine potential demand.	1A. Stakeholder workshop in Uganda.	Workshop conducted.	COMPLETE
	1B. Assessment of target market segments and survey of potential early adopters.	Market assessment.	COMPLETE
	1C. Potential distributors for the bCPAP kit and oxygen blender.	Meetings with distributors.	ONGOING
2. Determine the feasibility of the bCPAP kit for Africa.	2A. Assessment of neonatal intensive care unit/hospital supply distribution chains.	Market assessment.	ONGOING
	2B. Assessment of feasibility of preassembly at the distributor level.	Meetings with distributors.	ONGOING
3. Finalize design and engineering of the oxygen blender and bCPAP kit.	3A. Prepackaged, preassembled bCPAP kit.	Assembled, packaged kit.	ONGOING
	3B. Oxygen blender DfM.	Finished molded devices.	ONGOING
	3C. Technology transfer documentation.	Final documentation for technology transfer.	ONGOING

The first half of this current scope of work was dedicated to understanding where the best early use-case scenarios are for the kit, understanding current distribution chain scenarios in areas where neonates are given treatment for RDS, identifying and engaging early adopters and champions of the kit, and receiving feedback on key design direction decisions.

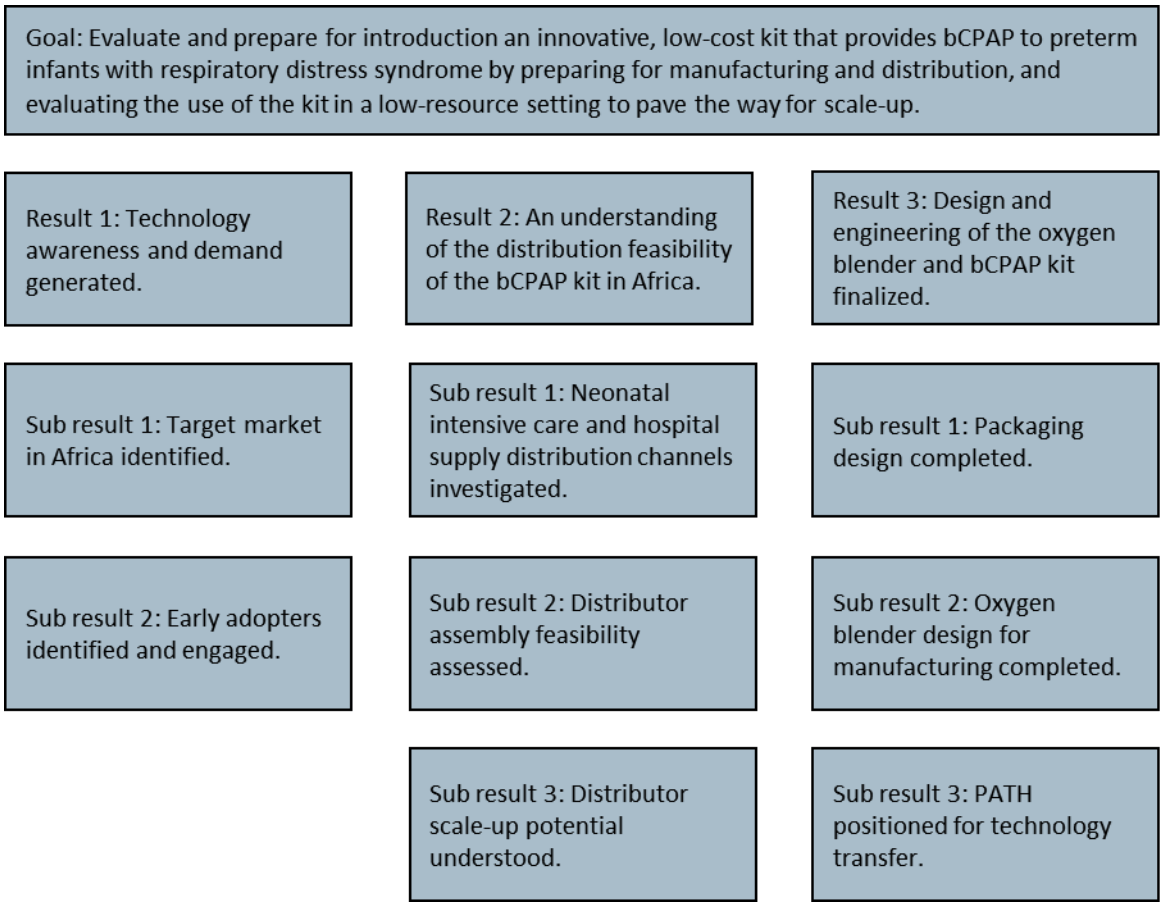
Detailed reports on these findings can be found in the report on the bCPAP workshop in Uganda, and stakeholder meetings in Ethiopia and South Africa in Appendix A and the draft market assessment in Appendix B.

In tandem, PATH's engineering team is working toward finalizing the design and engineering of the kit to ensure consistent, low-cost, high-quality production. A presentation on progress in this area was submitted to USAID in June 2015 and can be found in Appendix C.

Conceptual framework

Figure 1 on the following page outlines the conceptual framework for our project and how we plan to move forward to position the bCPAP kit for scale-up.

Figure 1. Conceptual framework for the second round of SL@B seed funding for bCPAP kit development.



Approach and methodology

With SL@B funding, PATH is focusing on determining public-sector need and target market segments in Africa, generating awareness of the technology, and further refining and preparing the oxygen blender and other components of the kit for manufacture, assembly, and scale-up. Following successful completion of our current activities, the bCPAP kit will be poised for programmatic/clinical evaluation and technology transfer.

During this reporting period, we worked to define the public-sector need, target market segments, and early adopters through desk research and stakeholder input. Activities during this period culminated in a stakeholder workshop in Uganda (September 2015) and visits with stakeholders in Ethiopia (October 2015), Malawi (January 2015), and South Africa (April, May, and October 2015). Our workshop and country visits were intended to generate awareness of PATH's bCPAP kit and blender, solicit end-user feedback to inform future device design, and help us to better understand the programmatic context for future introduction. Methods used to collect information included a survey, discussion guides, in-person interviews and email correspondence, sharing our device, and inviting others to share what they were

using in their facilities. The objectives and activities in the following section outline our approach to advancing the bCPAP kit.

Project Implementation Progress

Overview

Table 2 outlines the project work plan. As of December 2015, we have completed the following milestones:

- Monitoring and evaluation plan and work plan.
- bCPAP kit design presentation.
- Midterm report on project progress that includes a report on the workshop held in Uganda and a draft report on the target market and potential early adopters.

Table 2. Work plan for the second round of SL@B seed funding.

Objective	Activity	Milestone	Y1	Y2
1. Generate technology awareness and determine potential demand.	1A. Conduct a workshop in Uganda.	Workshop report.	x	
	1B. Identify target market segments and potential early adopters.	Market assessment identifying target markets and early adopters.	x	
	1C. Identify and engage potential distributors for the bCPAP kit and oxygen blender.			x
2. Determine the feasibility of the bCPAP kit for Africa.	2A. Conduct an assessment of neonatal intensive care/hospital supply distribution chains.	Market report.	x	
	2B. Determine the feasibility of preassembly at the distributor level.	Feasibility report.		x
3. Finalize design and engineering of the oxygen blender and bCPAP kit.	3A. Create a prepackaged, preassembled bCPAP kit.	Kit assembled.	x	
	3B. Implement the DfM for the oxygen blender.	DfM feasibility report.		x
	3C. Finalize technology transfer documentation.	Complete design history files.		x

Progress by objective and activity

Objective 1. Generate technology awareness and determine potential demand.

Activity 1A. Conduct a workshop in Uganda (complete).

The purpose of this activity was to inform the question of programmatic acceptability for future clinical use. The workshop took place on September 21 and 22, 2015, at Kiwoko Hospital, Uganda. The two key goals of the workshop were to create a community of bCPAP users in which experiences and information could be shared and feedback gathered to inform work on advancing PATH's device. PATH's collaborators—Adara Development; Kiwoko Hospital; Seattle Children's; and the University of

Washington, Department of Pediatrics—co-hosted this event. Our collaborators presented on their experiences in establishing a neonatal intensive care unit (NICU) and implementing an improvised bCPAP program in the unit. We also invited 3rd Stone Design and Thrive Networks to give presentations on their low-cost bCPAP options and unique experiences in implementation. The workshop involved more than 60 invited stakeholders from four African countries (Benin, Nigeria, South Africa, and Uganda). Nearly all of the participants were CPAP users and more than half of those used improvised bCPAP. A few that fell into neither category were either policymakers or were interested in implementing a bCPAP program at their facility. A report on the workshop can be found in Appendix A.

Activity 1B. Identify target market segments and potential early adopters (complete).

We conducted a preliminary market needs assessment to identify target markets. To achieve this, we conducted web-based secondary research, stakeholder and potential user interviews, and projected need and demand modeling. Components of the assessment include an understanding of where the bCPAP kit and oxygen blender are most likely to be used and determination of early adopters interested in using the bCPAP kit. The workshop in Uganda also contributed to the identification of additional early adopters and champions for the device. A report on these findings can be found in Appendix B.

Activity 1C. Identify and engage potential distributors for the bCPAP kit and oxygen blender (ongoing).

We are in the process of conducting an assessment of the medical consumables distribution chain for hospitals with NICUs and other points of neonatal respiratory care in Africa. We are working to identify, and, when feasible, meet with potential distributors from those identified for assembly of the bCPAP kit. We are initiating this work in South Africa in conjunction with a process for identifying potential manufacturers. We are also working on a similar supply distribution overview for Ethiopia, Malawi, Rwanda (under other funding), and Uganda.

Objective 2. Determine the feasibility of the bCPAP kit for Africa.

Activity 2A. Conduct an assessment of NICU/hospital supply distribution chains (complete).

The team has interviewed procurement and medical staff and visited facilities in Ethiopia, Malawi, Rwanda (under other funding), South Africa, and Uganda in order to understand the supply distribution chains and policies in these countries. This information will help us to identify potential distribution partners and appropriate channels to target during scale-up. A report on our findings can be found in Appendix B.

Activity 2B. Determine the feasibility of preassembly at the distributor level (ongoing).

The purpose of this activity is to understand if it will be feasible, less expensive to the consumer, and more attractive to a distribution partner if components of the kit are assembled and packaged before distribution to the consumer. We are also trying to understand if this would enable easier access to the kit while building a sustainable business approach. We are currently finalizing the kit components and

working to determine availability of components in our target geographies. Additionally, we have identified potential distributors in South Africa with in-country and export capabilities.

Objective 3. Finalize design and engineering of the oxygen blender and bCPAP kit.

Activity 3A. Create a prepackaged, preassembled bCPAP kit (ongoing).

Informing this activity are the results of the performance testing of the optimized kit parts, stakeholder feedback from the workshop in Uganda as well as one-on-one stakeholder meetings, and the DfM. We have identified many of the optimal components (as described in Appendix C) and received feedback from stakeholders (as described in the report in Appendix A).

Activity 3B. Implement the DfM for the oxygen blender (ongoing).

In order to ensure that the blender's design is reliably reproducible at the lowest possible cost, PATH is engaging with a local manufacturer to refine and complete a DfM. At present, we have developed and validated several working prototype blender designs using 3D printing techniques. Communication with manufacturers will be necessary to determine overall feasibility of the different designs and materials for larger production volumes, along with a discussion about tradeoffs of cost, functionality, reliability, and durability.

Activity 3C. Finalize technology transfer documentation (ongoing).

A full design history file for the oxygen blender (to include the bCPAP kit configuration) will be generated in preparation for transfer to a potential manufacturer. The design history file is a living document that is continually being updated.

Challenges

Given that it is known that improvised bCPAP devices are currently used in low-resource settings to provide an alternative means of meeting clinical needs for neonatal respiratory support, the need for access to very low-cost equipment is evident. For this reason, we theorized that expert opinion on design and use, as well as early adoption of our bCPAP kit, might likely be found in places where improvised kits are already in use. Some evidence of this was found in the feedback from medical providers in India who participated in the form factors study and expressed a preference for a kit that was preassembled. We also postulated that medical providers who were experienced with improvised bCPAP devices may feel comfortable with the look and feel of PATH's kit, given that it was based on the improvised model. The added benefit of an affordable oxygen blender that could improve safety and outcomes for those using improvised devices also filled an existing gap within that context of care and could make these kits very desirable to improvised bCPAP users. The kit will also be safer for users, as it is intended to be both preconfigured and preassembled.

A challenge for the PATH team was identifying these stakeholders and validating this theory. There is very little existing literature on improvised bCPAP users and no known community of practice or association for this group. In order to identify an adequate number of stakeholders in this field, PATH and our collaborators (Adara Development; Kiwoko Hospital; Seattle Children's; and the University of Washington, Department of Pediatrics) combed literature, and reached out to colleagues and associations to begin to compile a list of global stakeholders who work with and/or advocate for improvised bCPAP devices. PATH was able to use this list to generate invitations to our workshop in Uganda in September 2015. For some of the stakeholders on the list who were unable to come to Uganda, we corresponded via email, or if they were located in Ethiopia or South Africa, we attempted to set up in-person meetings to discuss both their experiences and level of interest in PATH's device. We also created a survey on the context of commercial and improvised bCPAP use and challenges surrounding use and uptake. This survey was distributed to the entire stakeholder list and we requested that these stakeholders share the survey with other users. We will be able to take the findings of these various approaches and incorporate them into our ongoing activities in kit development and manufacturer and distributor engagement.

Key findings to-date

The following is a summary of the key findings based on the results of our workshop (Appendix A) and our draft market assessment (Appendix B).

- Access to commercially available CPAP machines is limited, primarily due to cost.
- While very little published information is available on its prevalence, we have observed that improvised bCPAP therapy is a common solution in all of the countries that we visited (Ethiopia, Malawi, South Africa, and Uganda) as well as in Nigeria, as evidenced by the number of Nigerian attendees at the workshop in Uganda who shared their improvised bCPAP experiences.
- There is no known community of practice for African improvised bCPAP implementers, but there is a strong desire to organize one to improve how relevant information is disseminated as well as to share information on sourcing medical supplies that can be used as components of a bCPAP circuit.
- If affordable commercial bCPAP devices were available, health care providers would use them.
- The next limiting factors to bCPAP use after cost are related to capacity issues, such as inadequate numbers of staff trained to provide bCPAP therapy and facilities with NICUs that have not been able to implement important first steps to accommodate expanded care for premature infants (e.g., infection control and thermoregulation).
- Improvised bCPAP devices perform inconsistently and do not give reliable results. This is due to a number of reasons, including lack of access to optimal supplies and a lack of understanding of the basic operation of a bCPAP circuit.
- Stakeholders who currently use improvised bCPAP devices would use PATH's bCPAP kit and they felt that the kit would be appropriate in a range of settings (urban and rural; national, regional, district; transport to referral hospitals).

A number of these findings support our assumption that many early adopters will likely be improvised bCPAP users. The findings also highlight the importance of training and communication to improve NICUs as a component of successful introduction of PATH's bCPAP kit.

Environmental monitoring and mitigation report

PATH abides by US laws and recognizes, follows, and/or exceeds World Health Organization regulations on waste management. The activities conducted during this project involve meetings, computer-aided design, bench-based product development, and desk research. These activities do not involve the procurement, storage, management, or disposal of public health commodities or generation and disposal of hazardous waste, nor will they result in any environmental impact.

Key results

Table 3 shows the monitoring and evaluation midterm results for indicators that required annual reporting. Note that indicators that are reported on at project end are omitted at this time.

Table 3. Monitoring and evaluation indicators.

Indicator type	Indicator	Expected output/outcome/ impact	Source of data	Method of data collection	Schedule of data collection	Baseline #, %, other	Target (for each year and/or final)	Midterm results	Narrative
Outcome	Number of innovative prototypes developed.	3–4 prototypes/ iterations.	Design for manufacture.	Review of project records.	Annually	1	3	12	Status at project inception Currently, we have one prototype. Upon completion of the project, we expect to have developed two more iterations, with the goal of improving the product for optimized manufacturability. Annual update To date, we have looked at 8 different bubbler/kit configurations and 4 different 40 percent blender designs. Also, under separate funding, we have examined 5 different blender designs for an expanded range of blends.
Outcome	US$ funds leveraged.	Increased scope and/or accelerated results.	Co-funding, in-kind support, and proposal outcomes.	Review of project records.	Annually	US$50,000	Unknown	US$0	Status at project inception Current funding to conduct the complementary scope of work is US$50,000. Annual update We submitted two proposals for additional funding, neither of which were funded.
Pipeline	Amount of testing of product or service to understand user needs/behaviors.	Feedback and test results incorporated into design to result in a kit that meets the needs of end-users.	• Workshops/ dissemination activities. • Prototypes. • Health care facility visits.	• Stakeholder input. • Bench testing.	Annually	2—Some testing of product has occurred, but more needs to be done to understand user needs/behavior in order to lead to increased adoption.	3—Some testing of product has occurred, leading to changes in design with a resulting DfM.	2—Some testing of product has occurred, but more needs to be done to understand user needs/behavior in order to lead to increased adoption.	Options at project inception 1—No testing of products/services has occurred, and they remain as originally planned without any adaptations. 2—Some testing of product/services has occurred, but more needs to be done to understand user needs/behavior in order to lead to increased adoption. 3—Some testing of products/services has occurred, leading to changes in offerings with resulting slight increase in adoption by users. 4—Significant testing of products/services has occurred, leading to increased adoption by users. More refinement of offerings needs to be done to capture more of the market. 5—Products/services have been thoroughly tested; there is adoption by users and corresponding behavior change. Annual update Several aspects of the bCPAP kit and blender were evaluated at the Kiwoko workshop, including bubbler design, blender design, and scenarios of use. Feedback has been collected, but these changes will be further analyzed and incorporated into later stages of the project.
Communications	Number of papers and/or public awareness, outreach outputs published or otherwise undertaken.	Awareness generated to create champions and early adopters.	Workshops, publications, web postings.	Project records.	Annually	2—Overview documents.	1—New overview document.	2	Status at project inception We currently have two documents describing our work. We plan to create a new one to disseminate the information generated from this current scope of work. Annual update Blog post on Uganda workshop preparation: http://blog.path.org/2015/09/device-to-save-newborn-lives-thinking-big-small/. Workshop held in Uganda September 21–22, 2015, with 60+ participants from 4 African countries.

Next Steps

Our project activities are on track to be completed by the end of September 2016. The focus of the second year of the project is on finalizing the DfM, exploring packaging options, engaging with potential distributors, identifying a manufacturer for the blender, and readying documentation for technology transfer. The next steps for ongoing activities under our three objectives are outlined below.

Objective 1. Generate technology awareness and determine potential demand.

Activity 1C. Identify and engage potential distributors for the bCPAP kit and oxygen blender.

Further discussions with distributors will take place in year two of the project to understand optimal distribution scenarios that may enable broad reach, and the potential for assembly and packaging at the distribution level.

Objective 2. Determine the feasibility of the bCPAP kit for Africa.

Activity 2B. Determine the feasibility of preassembly at the distributor level.

In conjunction with design progress, understand distributors' willingness and the feasibility of assembly and packaging at the distribution level of the supply chain.

Objective 3. Finalize design and engineering of the oxygen blender and bCPAP kit.

Activity 3A. Create a prepackaged, preassembled bCPAP kit.

With stakeholder input gathered from Ethiopia, South Africa, and Uganda in September and October 2015, we will move forward with using suitable recommended component and blender options. We have identified which components and their quantities are appropriate to include in the main kit.

Activity 3B. Implement the DfM for the oxygen blender.

In November 2015, we will begin work with a plastics prototyping firm to evaluate feasible design solutions and make an initial run of blenders. Their performance characteristics will be evaluated in our laboratory and final modifications will be suggested for initial production in the first quarter of 2016.

Activity 3C. Finalize technology transfer documentation.

The design history file will continually be updated as the kit evolves, with the intent of having a complete document ready to share with a manufacturer for technology transfer by the end of September 2016.

Unfunded next steps

We continue to look for funding opportunities that could augment the scope of work that we are funded to complete under SL@B in order to move the kit scale at a faster pace. To date, we have submitted two proposals, but neither has been funded. Additional activities that could complement our work as we move toward a manufacturable design include:

- Creating an online community of practice for improvised bCPAP users that can build on and strengthen the connections that were made during the workshop in Uganda. Keeping this group engaged will help to create champions and consumers of the bCPAP kit.
- Creating pictorial instructions and packaging for the kit.
- Creating an instructional video on the assembly and use of the bCPAP kit.

Appendix A—Stakeholder Workshop in Uganda and Stakeholder Meetings and Health Care Facility Visits in Ethiopia and South Africa

Appendix A—Stakeholder Workshop in Uganda and Stakeholder Meetings and Health Care Facility Visits in Ethiopia and South Africa

Overview

Key activities under this Saving Lives at Birth award included traveling to Africa and meeting with stakeholders to create champions for PATH's bubble continuous airway pressure (bCPAP) kit, identifying potential early adopters of the bCPAP kit, generating awareness of our innovation, and receiving feedback on its acceptability. In September 2015, these activities were carried out in three countries: Ethiopia, South Africa, and Uganda. The most comprehensive of the three visits took place in Uganda, in the form of a workshop to which early adopters and key stakeholders throughout Africa were invited. Visits to Ethiopia and South Africa followed this workshop; team members visited hospitals and ministries of health to share information on the workshop and PATH's innovation, and to better understand use-cases for bCPAP therapy in a range of health care settings.

Workshop in Uganda

Background

PATH and our partners, Adara Development; Kiwoko Hospital, Uganda; Seattle Children's; and the University of Washington, Department of Pediatrics, met in Spring 2015 for a two-day planning session to determine how best to organize a workshop that would be cost effective for the project and appealing for stakeholders to attend, while also serving as a forum for PATH to share information on our innovation and receive feedback on design and use in low-resource settings. It was felt that there was growing fatigue among medical professionals in low-resource settings with regard to committing precious time to user feedback meetings. In order to ensure that we had a well-attended gathering, we determined that the best approach would not be to emphasize user feedback and PATH's device as the focus of the meeting, but instead to create an environment where users of bCPAP devices were given an opportunity to share their experiences as well learn from others. In this way, PATH would not be the sole voice in the room but one of many that could contribute to the conversation. We decided to title the workshop "Expanding Access to Bubble Continuous Positive Airway Pressure Devices: A Workshop for Newborn Care Providers."

Our partners generously offered to help organize and host the workshop at their facility in Kiwoko, Uganda. The use of the facilities in Kiwoko, partner travel, and their labor were offered to the project at minimal to no expense.

Objectives

We identified the following as key objectives for the workshop:

- Foster collaboration among newborn care providers.
- Provide a forum for newborn care providers to share their experiences and lessons learned from the implementation of bCPAP devices in low-resource settings.

- Provide an opportunity for participants to provide input on the development of PATH's bCPAP kit, appropriate level of care for the kit, and the use of the PATH-designed oxygen blender with existing bCPAP devices.

Methodology

The workshop theme—expanding access—made for a logical progression of information: Day 1 presentations by invited stakeholders outlined the current landscape and challenges in that landscape; and on Day 2, PATH and our partners concluded with new ideas and examples of how challenges can be addressed. This approach allowed us to organize the sessions with the hope that the open forum for sharing of ideas and discussion began at the onset of the workshop and would build momentum throughout.

We created a long list of questions that we hoped to have answered during the workshop. The categories of questions are summarized below:

- What are the use-cases at various levels of care in multiple countries?
- How/where does PATH's bCPAP kit fit into health care systems in various countries?
- What aspects of PATH's device are appropriate, what aspects need to be altered, and what considerations need to be taken into account?
- What resource limitations are people facing and at what levels of the health care system?

In order for PATH to maximize the amount of information we could gather, while at the same time not create a tedious environment of endless questions for the attendees, we devised an array of methods for gathering information. Using a variety of methods for collecting information kept the content of the workshop lively, useful, and interesting. Some examples of our approach are listed below:

- A survey on bCPAP use and limitations to use. This was sent globally to all bCPAP users in low-resource settings that the team identified as stakeholders. We asked these stakeholders to share the survey link with their colleagues as well. We promised to share the results of the survey at the workshop, which we believe helped increase incentive among attendees to complete the survey.
- Presentations on improvised bCPAP. Improvised bCPAP users were invited to present on the use of their improvised devices in their facilities. A PowerPoint template was sent to those who volunteered to present. By following the prompts in the template, all presenters would report on the same topic areas, which would allow us to collect the same information from all sources.
- Discussion session that focused on challenges. Challenges would be recorded on a white board and participants would share their experiences regarding various challenges.
- Small group discussion/debate. We planned to have attendees break into small groups to determine design decision priorities for PATH's innovation based on cost, need, and ease of use. These decisions were to be recorded on worksheets by the individual groups, shared with the full workshop, and recorded by PATH on posters for further discussion.
- One-on-one interviews with specific stakeholders (e.g., ministry of health officials, procurement staff). Through opportunistic one-on-one interviews during meals and breaks, we planned to ask targeted questions of individuals with unique expertise.
- Collection of ideas for next steps. At the conclusion of presentations on Day 2, attendees would be asked to offer ideas for next steps in expanding access to bCPAP and these ideas would be captured on a white board.

- Exit survey. The exit survey would be used to collect feedback from attendees on what was useful, successfully presented, and what questions still needed to be answered.

Site selection

Our partners offered the use of their facility, Kiwoko Hospital, in Uganda. There, we could accommodate a gathering of roughly 70 people as well as benefit from our partners' coordination support at very little to no cost to the project. Kiwoko Hospital was an ideal and appropriate setting for our workshop. Not only did we have a facility where we could meet, but the hospital itself served as a use-case and example from which visitors could learn. The hospital staff represented the type of stakeholder with which we want to engage; Kiwoko has a neonatal intensive care unit (NICU) where they employ improvised bCPAP devices; and the hospital faces the types of challenges that we have heard reported from stakeholders throughout low-resource settings, such as unreliable power, limited funding for equipment, and high staff turnover.

Participants

Our workshop was intended for newborn care providers interested in expanding access to the use of the bCPAP devices in Africa. We especially encouraged users of improvised bCPAP devices in Africa to attend.

There were a total of 51 registered participants: 46 represented four African countries (Benin, Nigeria, South Africa, and Uganda), and the additional five were from the United States. These stakeholders came from 32 different organizations: 25 hospitals, three nongovernmental organizations, one university, one product design firm, and three government agencies. We were very pleased that just less than half of all attendees (23) were improvised bCPAP users. The table below gives a detailed breakdown of the make-up of stakeholders at the workshop.

Table 1. Participant characteristics, bCPAP stakeholder workshop, Uganda.

Country	City	Facility/Organization	Type	Title	Improvised bCPAP user
Benin	Cotonou	Centre Hospitalier et Universitaire de la Mère et de l'Enfant	Teaching hospital	Doctor	Y
Nigeria	Kanu	Aminu Kano Teaching Hospital	Tertiary	Doctor	Y
Nigeria	Enugu	Enugu State University Teaching Hospital	Tertiary	Doctor	Y
Nigeria	Katsina	Federal Medical Centre	Tertiary	Doctor	N
Nigeria	Gombre	Federal Teaching Hospital	Tertiary	Doctor	N
Nigeria	Jos	Jos University Teaching Hospital	Tertiary	Doctor	N
Nigeria	Jos	Jos University Teaching Hospital	Tertiary	Doctor	N
Nigeria	Jos	Jos University Teaching Hospital	Tertiary	Doctor	N

Country	City	Facility/Organization	Type	Title	Improvised bCPAP user
Nigeria	Lagos	Lagos University Teaching Hospital	Tertiary	Doctor	Y
Nigeria	Akure	Mother and Child Hospital	Private	Doctor	N
Nigeria	Abuja	National Hospital Abuja	Tertiary	Doctor	Y
Nigeria	Nnewi	Nnamdi Azikiwe University Teaching Hospital	Tertiary	Doctor	Y
Nigeria	Abuja	Save the Children		Doctor	Y
Nigeria	Benin City	University of Benin Teaching Hospital	Tertiary	Doctor	Y
Nigeria	Maiduguri	University of Maiduguri Teaching Hospital	Tertiary	Doctor	Y
Nigeria	Port Harcourt	University of Port Harcourt Teaching Hospital	Tertiary	Doctor	Y
South Africa	Johannesburg	Community Partners International	Nongovernmental organization	Doctor	N
Uganda	Kumi	Atutur Hospital	District	Midwife	N
Uganda	Kumi	Atutur Hospital	District	Nurse	N
Uganda	Jinja	Jinja Regional Referral Hospital	Regional referral hospital	Nurse	N
Uganda	Jinja	Jinja Regional Referral Hospital	Regional referral hospital	Nurse	N
Uganda	Jinja	Jinja Regional Referral Hospital	Regional referral hospital	Doctor	Y
Uganda	Jinja	Jinja Regional Referral Hospital	Regional referral hospital	Head Researcher	Y
Uganda	Jinja	Jinja Regional Referral Hospital	Regional referral hospital	Nurse	Y
Uganda	Jinja	Jinja Regional Referral Hospital	Regional referral hospital	Nurse	Y
Uganda	Kagando	Kagando Hospital	Nongovernment nonprofit hospital	Nurse	N
Uganda	Kagando	Kagando Mission Hospital	Nongovernment nonprofit hospital	Doctor	N
Uganda	Kiwoko	Kiwoko Hospital	Nongovernment nonprofit hospital	Doctor	Y
Uganda	Kiwoko	Kiwoko Hospital	Nongovernment nonprofit hospital	Doctor	Y
Uganda	Kiwoko	Kiwoko Hospital	Nongovernment nonprofit hospital	Nurse	Y
Uganda	Kiwoko	Kiwoko Hospital	Nongovernment nonprofit hospital	Nurse	Y

Country	City	Facility/Organization	Type	Title	Improvised bCPAP user
Uganda	Kiwoko	Kiwoko Hospital	Nongovernment nonprofit hospital	Nurse	Y
Uganda	Kampala	Kumi District Local Government	Government agency	Principal Nursing Officer; Member, National Newborn Steering Committee; National Trainer, Helping Babies Breathe+	Y
Uganda	Kampala	Makerere University School of Public Health	University	Doctor	N
Uganda	Masaka	Masaka Regional Referral Hospital	Regional referral hospital	Doctor	N
Uganda	Kampala	Mengo Hospital	Referral hospital	Doctor	N
Uganda	Kampala	Ministry of Health	Government agency	Assistant Commissioner of Health Services	N
Uganda	Kampala	Mulago National Referral Hospital	National referral hospital	Doctor	Y
Uganda	Nakaseke	Nakaseke Hospital	District	Doctor	N
Uganda	Nakaseke	Nakaseke Hospital	District	Nurse	N
Uganda	Soroti	Soroti Regional Referral Hospital	Regional referral hospital	Nurse	N
Uganda	Nsambya	St. Francis Hospital Nsambya	Nongovernment nonprofit hospital	Midwife	N
Uganda	Kampala	St. Francis Hospital Nsambya	Nongovernment nonprofit hospital	Doctor	Y
Uganda	Kampala	St. Francis Hospital Nsambya	Nongovernment nonprofit hospital	Doctor	Y
Uganda	Kampala	Thrive Networks	Nongovernmental agency	Regional Director	N
Uganda	Kampala	Thrive Networks	Nongovernmental agency	Training Coordinator	N
United States	San Rafael	3rd Stone Design	Product design company	Product Manager	N
United States	Seattle	Seattle Children's Hospital	Regional	Doctor	N
United States	Washington, DC	US Agency for International Development	Government agency	Innovation Advisor	N
United States	Washington, DC	US Agency for International Development	Government agency	Program Assistant	N

We obtained written consent from all participants for use of workshop content, including photographs, presentations, and feedback.

Workshop agenda

The agenda as well as biographies of the presenters are included in Annex 1—Agenda and Biographical Descriptions of the Presenters. Details about each of the programmed sessions as well as several other valuable aspects of the workshop are discussed in the following sections.

The workshop agenda was designed to maximize the amount of "naïve" feedback that could be elicited before presenting PATH's proposed technology solution. This was important, as we were keen to understand existing use-cases and device solutions in a way that did not make participants feel that they were "doing it wrong." Given the nature of improvised CPAP devices, it was anticipated that participants might be hesitant to share their devices and experiences. With this in mind, it was decided that participant presentations would be allocated for the first morning, just after the introductory welcome presentations. Ten presentations were given in total, most of which were accompanied by physical demonstrations by the presenters on their improvised devices. These presentations were followed by a discussion session in the afternoon to learn more about current challenges and the context of use. The day ended with presentations by 3rd Stone Design on their Pumani device and Thrive Networks on their bCPAP device.

Day 2 was focused around PATH's device and what is currently being implemented at Kiwoko Hospital. In the morning, PATH presented on the PATH bCPAP kit and blender, which was followed by small group discussions (groups of about five) designed to elicit feedback on specific design elements. Handouts were given to participants to ensure that feedback was captured by the team. The remainder of the day was focused on the NICU program at Kiwoko, challenges, successes, and lessons learned. The workshop concluded with a quick recap of the content, what was learned, and an open-format discussion to find out what next steps were most desired.

During breaks and lunches, the test lung was set up to allow people to see demonstrations of the PATH device. Participants were also encouraged to try their improvised devices on the test lung to see how they performed. In addition, tours of the NICU were arranged at several times throughout the workshop.

Workshop sessions

bCPAP landscape: Showcasing current solutions

We invited all participants using improvised bCPAP devices to give a brief presentation on their devices. Participants from ten facilities gave presentations and most of these facilities also displayed and demonstrated components or actual devices. Table 2 provides a list of facilities represented in the presentations.

Table 2. Organizations represented in the improvised bCPAP presentations, Day 1.

Medical facility	Country
Aminu Kano Teaching Hospital	Nigeria
Enugu State University Teaching Hospital	Nigeria
Jinja Regional Referral Hospital	Uganda
Kumi District Local Government Hospital	Uganda
Lagos University Teaching Hospital	Nigeria
Mulago National Referral Hospital	Uganda
National Hospital Abuja	Nigeria
Centre Hospitalier et Universitaire de la Mère et de l'Enfant	Benin
St. Francis Hospital Nsambya	Uganda
University of Benin Teaching Hospital	Nigeria

Eight of the ten device designs were based on a modified oxygen cannula similar to Trevor Duke's guidelines, which are currently in draft stages as World Health Organization guidelines. The location of cuts and affixed tubing varied slightly, but the basic principles were the same. These devices sometimes used very small-bore tubing with a potentially long expiratory limb. Small-bore expiratory tubes, especially if lengthy, can result in pressures much higher at the nares than indicated by the bubbler tube. Many of the Nigerian devices used normal saline bottles for the expiratory bubbler.

Two of the ten presenters were not using improvised bCPAP devices. One used commercial CPAP components rather than modified low-flow oxygen equipment to construct an improvised CPAP device with Fisher & Paykel CPAP parts (humidifier and tubing) set up to use either Hudson RCI® prongs or the Neotech RAM Cannula®, and instead of a bubbler, employed a 5 cm H_2O positive end-expiratory pressure valve (therefore not a bCPAP). The other presenter discussed experiences using the commercially available Thrive Networks MTTS bCPAP device.

In general, a mix of oxygen sources was being used at presenters' facilities, such as concentrators, cylinders, or central supply, with some facilities using more than one type. All groups reported providing some sort of humidification, with most using a passive bubble humidifier. Only two facilities were able to provide blended gas or heated-humidified air, and this was listed as a common challenge to CPAP therapy.

During this session, PATH presented on findings from previous work, including facility visits in South Africa (Annex 2—Observations from facility visits in South Africa) and the results of the participant survey (Annex 3— Challenges and needs in the management of newborn respiratory problems: A discussion of survey results). More detailed analysis of the online survey itself can be found in Appendix B.

Photo: PATH/Kelly Ebels

Discussion of challenges and needs in the management of newborn respiratory problems.

These sessions were followed by a discussion on the current challenges and context of use in treating respiratory distress syndrome with improvised bCPAP devices. Participants were split into ten groups of approximately five people each, and each group was provided a list of questions to consider (Annex 4—Discussion of challenges and needs in the management of newborn respiratory problems). Participants were given time to discuss, and then a nominee from each group gave a five-minute summary of their discussion, followed by discussion. Table 3 outlines the challenges and needs identified by participants during the discussion

Table 3. Challenges and needs identified by workshop participants.

In what clinical settings are devices most needed?
• Delivery room • NICU • Emergency room • Pediatric ward • Theater
What methods are used to secure the interface to the neonate's face?
• Face mask • Endotracheal tube • Hats • Tape/bandage • Rubber bands
What issues are encountered in securing the interface to the neonate's face?
• Adhesive to face • Securing/allergic to tape
What are your challenges with nasal prong sizing/availability?
• Knowledge of proper sizing • Availability • Procurement knowledge • Expense

What are the limitations of current bCPAP devices?

- Expensive
- Quality
- Labor intensive
- Measurement of FiO_2
- Acceptable by all physicians
- Affordability
- Maintenance of equipment
- Replacement of parts
- Inadequate training
- Perceptions of efficacy

Are there challenges with lighting where bCPAP for newborns is used?

- Power source
- Power surges
- Poor generator back-up
- Need power to monitor babies/run incubators

What ability do health care workers have to clean and disinfect bCPAP devices?

- Knowledge of parts to be cleaned
- Have the skill and ability to clean
- Washing w/chlorine or water
- Rinsing well
- Decontamination
- Soak—4° to 6° / 10 minutes
- Dry
- Autoclave
- When is it time to discard the device

Does your facility have an adequate number of devices for the number of patients requiring bCPAP therapy?

- No—not enough
- Yes—more than 10
- Yes/No—Improvise, not enough access
- Depends upon flow of patients, length of time on bCPAP device

What are the needs for heat and humidification? If using room air…

- Hot water
- Source of heat
- Storage
- Tubing
- Yes, needed—system for humidification
- Proper system

What are the needs for heat and humidification? If using dry oxygen…

- Heat
- Staffing—Nursing
- Gadgets for heating water
- Provide heat and humidification

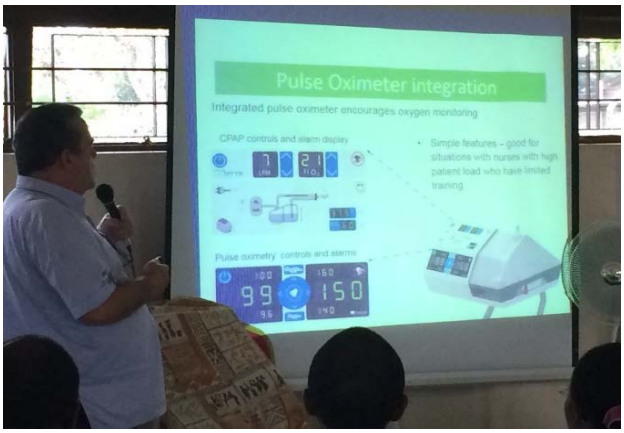
What do you think would be the best way to expand access to bCPAP?

- Training for ALL health care workers
- Teamwork
- Primary care hospitals
- Secondary hospitals
- Protocols—simple device design
- Continuous training
- Mentorship & supervision
- Availability of equipment

- Adequate source of O_2 (blenders, cylinders, concentrators)
- Funding ←Public Private Partnership
- Collaboration
- Increase/improve staffing
- Support/supervision
- Ongoing research
- Policy/government
- Stakeholders—medical, government
- Alternative to power source
- Availability to lower level of health care
- Guidelines/standard training
- Local manufacturers
- Availability should be need-driven
- Institutionalization of CPAP standard
- Disseminate information of efficacy of CPAP

Low-cost, commercially available solutions

We felt that it was important that providers of low-cost, commercial bCPAP solutions have a voice at the workshop. Therefore, in addition to presenting improvised solutions and PATH's proposed low-cost solution, we invited representatives from 3rd Stone Design and Thrive Networks to give presentations on their low-cost bCPAP options and unique experiences in implementation. While many participants felt that these devices were out of reach for their facility, the presenters were able to contribute to learning at the workshop by sharing information on implementation strategies and lessons learned. Additionally, sharing information about these devices gave participants an opportunity to learn about options, and provided a context for the functionality of improvised devices. Furthermore, we felt that it was important to engage proponents of a variety of solutions, spanning a range of costs, with the goal of improving solutions across the spectrum of care to meet the needs of end-users, which ultimately will expand the reach of bCPAP care.



Photos: PATH/Gene Saxon

Introducing PATH's bCPAP solution

Photo: PATH/Kelly Ebels

The main objectives of this presentation (Annex 5—PATH's Continuous positive airway pressure kit and blender) were to share the background of PATH's role in the bCPAP community, discuss the design and testing of our device, and more generally to provide a solid understanding of how bCPAP works. These topics were intended to set the stage for an informed discussion with participants on the requirements, desirable features, and configuration of a suitable pre-assembled bCPAP kit. The presentation included work-to-date, current PATH prototype details, intended use, blender performance, and future work.

A discussion session with three topic areas followed the PATH presentation, allowing us to gain invaluable user feedback about the bCPAP kit. Workshop participants were given a handout (Annex 6—Bubble CPAP Kit Configuration Worksheet) to help channel their thoughts. The first topic area involved discussing the ideal configuration of a pre-assembled bCPAP kit as well as desirable supplemental components (e.g., number of nasal prong sizes or oxygen blenders that should be included, and should users be able to purchase additional units separately). Participants were particularly interested in the possibility of including blending options,* and a major focus of the discussion involved identifying which blends made the most sense to include. The second topic area focused on characteristics of an ideal CPAP bubbler. Material, location, cleaning, and usage were discussed.

Photos: left PATH/Alec Wollen, right PATH/Kelly Ebels

* Under other funding, PATH is designing blenders with a range of blending options, from 30% to 80%, that are compatible with PATH's bCPAP kit as well as a range of other bCPAP devices.

Below is a summary of feedback from these discussion topics:

Kit configuration:

- Participants expressed a wide range of preferences on number and blends of oxygen blenders to include and anywhere from one to five blenders were desired.
- Many expressed interest in a 30% blender if possible (given the current World Health Organization guideline).
- The highest blend that was thought to be useful was a 60% blend. If more than 60% O_2 is required, the baby is very sick and likely requires further intervention (such as intubation). In this situation, the benefits over using 100% oxygen are minimal.
- Preferences for number and sizes of cannulae to include were broad. Most desired a wide range of sizes to be available.
- Replacement cannula should also be made available for purchase separately.
- The kit should be compact, pre-assembled, and ready to use and have pre-cut tubes.
- Tubes should be long enough to reach the oxygen source and bubbler (approximately 2 m total). Alternatively, extra tubing could be purchased separately for faraway sources.
- It could be helpful to include a bubble humidifier, but many were already able to provide their own and saw this adding to the expense of the kit.
- The kit must be able to withstand many re-use cycles.
- Other components such as instructions, cleaning brush, oxygen tubing fittings, and bottle stands should be considered and investigated for inclusion at the trade-off of cost.

Characteristics of an ideal bubbler:

- Square or round bubbler bottles are acceptable.
- Bubbler bottle should not be glass—hard or firm plastic is preferred.
- Bottle must be clear, not translucent or opaque.
- Bottle size does not matter, but it should have a large opening for easy cleaning.
- Bleach was the most common means of disinfection, therefore the bottle must be chemically resistant.

The third topic area was meant to focus on blender properties, but remaining time permitted only a brief discussion. However, the unexpected interest in the multiple blender options allowed us to gather the necessary information we had hoped to collect in this third topic area.

Implementation of bCPAP therapy at Kiwoko Hospital

In the afternoon of Day 2, our partners from Adara Development; Kiwoko Hospital; Seattle Children's; and the University of Washington, Department of Pediatrics presented on their experiences at the Kiwoko Hospital NICU. We hoped that sharing successes and challenges of building and implementing a NICU would give participants tools and examples to take back to their facilities. The following three sessions elaborated on these experiences as they pertain to bCPAP rollout.

1. Setting up a neonatal intensive care unit: Lessons learned.
2. Developing a CPAP Program: How to implement a CPAP program effectively in a high turnover environment.

3. Training approach for improvised bubble CPAP: How to train effectively in a high turnover environment.

The nurse in charge of the Kiwoko Hospital NICU presented on setting up a neonatal intensive care unit and lessons learned. She emphasized that before implementing bCPAP therapy, there needs to be a foundation of care in place, including infection control, thermoregulation, and nutrition management. These treatments were introduced sequentially and deliberately, to ensure a high standard of quality. Another key element was ensuring that staff were properly trained, and monitoring was in place. The team developed a respiratory severity score to rate infants on a scale of 1 to 5 in order to help determine whether bCPAP therapy was warranted. This was seen as a critical piece of the bCPAP program.

Photos: PATH/Gene Saxon

Kiwoko Hospital's Deputy Medical Director's presentation, titled "Developing a CPAP Program: How to implement a CPAP program effectively in a high turnover environment," described the challenges of training staff and the strategies he and his colleagues have employed to ensure high-quality care in the NICU.

Our partners' final presentation was designed to show evidence of the success of improvised bCPAP implementation. The University of Washington, Department of Pediatrics worked with Kiwoko Hospital to set up a data collection system to document the impact of NICU care. The final session, "After Implementation of bCPAP at Kiwoko: Use Characteristics and Outcomes,"[†] presented by a neonatologist from the University of Washington, described some of the evidence gathered to date, which will be published in a peer-reviewed article in 2016. The team explained that Kiwoko Hospital found great value in the data collected; the data serve a greater purpose than just to show the results of a study at a point in time; and the data outputs continue to be used to help the hospital staff make improvements. By performing a monthly check of data outputs,

[†] The title of this session was updated after the agenda (Annex 1) was printed.

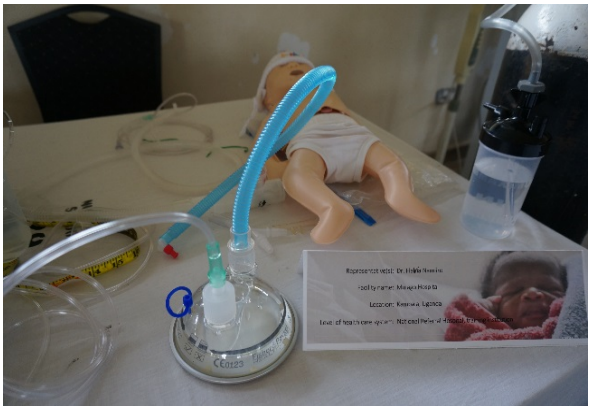
feedback is generated to the staff if adjustments to their care practices need to be made, which in turn continues to improve the quality of care at Kiwoko's NICU.

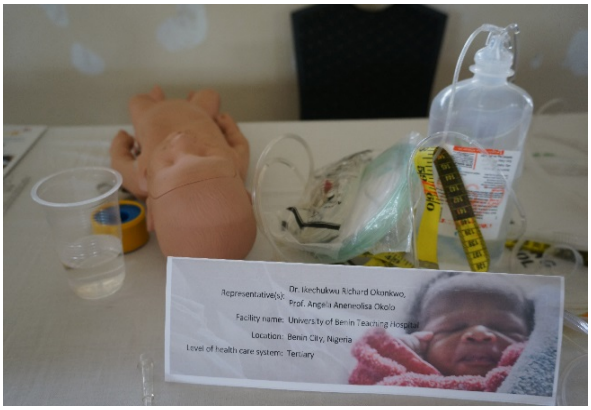
Other key workshop elements

In addition to the sessions, a number of other elements were planned or naturally occurred. These are described below.

Display of devices

Participants were invited to bring their improvised devices for display. In addition to these devices, PATH's bCPAP kit, 3rd Stone Design's Pumani device, and Kiwoko Hospital's KPAP (Kiwoko positive airway pressure) device were available for viewing.





Photos: PATH/Kelly Ebels

Demonstrating devices

All participants who used improvised devices were encouraged to bring and display an example of one of their bCPAP circuits. PATH brought a test lung to the workshop and invited participants to try their circuits on the test lung. While no formal testing was conducted on any of the devices, participants were allowed the opportunity to see what pressures were generated at the nasal cannula over a range of clinically relevant flows. This gave improvised bCPAP users the opportunity to compare their circuit configurations to other configurations in the room, giving insight into which configurations were working effectively.

Photo: PATH/Kelly Ebels

Initial demand to see their device operating on the test lung was so great, the table with the lung was completely surrounded with eager participants. During the course of the workshop, we determined that all of the devices were capable of delivering bCPAP under the right conditions, but some circuits with high-leak, small-bore, or lengthy expiratory tubing required a high degree of flow being

administered to maintain expected pressure. In addition, several circuits provided pressures that were significantly higher than the pressures indicated by the level of the tube in the bubbler. This was attributable primarily to the small-bore, lengthy expiratory limbs and their associated loss of pressure due to resistance, particularly at high flows.

Neonatal intensive care unit tours

Participants were invited to tour Kiwoko Hospital's NICU in small groups. Kiwoko Hospital also presented during the second day on steps for setting up a NICU and how to prioritize various services within the unit when resources are limited. In this way, participants were able to experience the facility and understand how it was established.

Photos: PATH/Gene Saxon

Informal discussions

The location of the workshop was conducive to developing a community of bCPAP users. Because of the rural location of Kiwoko Hospital, nearly all participants and co-hosts arrived the day prior to the workshop and departed the day following the workshop's conclusion. This, as well as limited access to Internet connection, provided ample unprogrammed time for networking, deepening relationships, and informal information gathering.

Photo: PATH/Gene Saxon

Conclusions and next steps

It was clear that there was a great deal of enthusiasm for the gathering and participants were keen to know that the outputs from the workshop would be shared. In addition, there was a desire to create a community of practice around improvised bCPAP use and ensure that participants were able not only to keep in touch, but to expand the community to include others who were not in attendance. Participants felt that it

was important to have a continued dialog around the need for bCPAP therapy and increase awareness and dissemination of information regarding safe practices.

It was also felt that PATH's kit, and the oxygen blender in particular, should be made available as soon as possible. The configuration of the kit was still a question at the end of the conference, but participants generally felt that a kit with a single blender would provide a great deal of value, although additional blends should also be made available as they are developed.

Finally, there was strong interest from representatives of both the Uganda Ministry of Health (MOH) and the Nigerian Society of Neonatal Medicine for members of the workshop team to be included in their respective countries' steering committee meetings regarding neonatal health. Both groups proposed that pilot studies be conducted in their countries and expressed their support for such studies. These are seen as critical.

> *We are here, we are here…. We are going to advocate!* Jesca Nsungwa-Sabiiti, Uganda MOH

Not only were objectives met, relationships and resolve were strengthened. For example, we received a note from a participant and member of the Nigerian Society of Neonatal Medicine following the workshop, sharing that the group took advantage of connections made and lessons learned and is moving forward to expand use of improvised devices across the country:

> *On our part, we are committed to neonatal care and to see how we can improve and expand our reach. With regards to the improvised bCPAP, we have divided responsibilities and have a tentative plan.*

Exit survey

The last activity of Day 2 was the completion of an exit survey, which consisted of six questions:

1. What are your main takeaways from this workshop?
2. What was most beneficial to you?
3. Would you recommend this workshop to your colleagues?
4. Would you attend a similar workshop in the future?
5. What unanswered questions do you have?
6. What other feedback would you like to share?

We received 43 completed exit surveys. Examples of responses to the first two questions include:

1. What are your main takeaways from this workshop?

- *Improvised bCPAP are more prevalent than originally thought.*
- *CPAP can be used even in areas where there is no electricity.*
- *bCPAP is a life saving device with a great impact for the reduction of neonatal mortality.*
- *Training and retraining of health care workers at all levels will go a long way in reducing child mortality and will help to increase access to bCPAP.*
- *Blending oxygen is very important.*
- *Good quality newborn care can be delivered at all levels of the health system by emphasizing consistent use/application of newborn care practices.*
- *Training and dedicated staff are key to implementation of bCPAP.*

- *CPAP can be used even in low resource settings.*
- *Other cadres of the health care workforce can apply CPAP.*
- *My device needs some improvement (needs a blender).*
- *bCPAP is a lifesaving intervention that is relevant and mandatory if one is to reduce newborn morbidity and mortality significantly.*
- *Indications of CPAP, contraindications of CPAP, uses of CPAP.*
- *The need to network to know what people and how people work.*
- *It has been very helpful to understand what types of bCPAP are being devised and used, what user requirements are for bCPAP, and what is currently available on the market for bCPAP.*
- *CPAP is under-utilized in my facility.*
- *That together as a team of committed personnel of stakeholders, we can expand not only the reach of bCPAP but also excel neonatal and maternal health care services.*

2. What was most beneficial to you?

- *Understanding the landscape of both improvised devices and other solutions.*
- *Several experiences from other countries and good facilitation.*
- *Networking with other professionals is very important to enhance quality of care.*
- *Acquiring knowledge on blending oxygen.*
- *People sharing ideas on CPAP (heat/humidification).*
- *Sharing experiences from other practitioners.*
- *Interaction/networking with different stakeholders involved in newborn health.*
- *Sharing of experiences regarding CPAP usage from different areas.*
- *Setting up improvised CPAP correctly.*
- *Gaining more knowledge on the use of CPAP.*
- *The research findings in support of CPAP use benefits.*
- *Assembly of CPAP simplified.*
- *The idea that a simple blender will soon be available.*
- *The presentation by different centers on what is currently available.*
- *The test lung demonstration on the pressure effects of the available options.*
- *The interactive nature of the workshop, I interacted and feely shared ideas w/a diverse group of health care providers.*
- *The management of resources and team work of NICU of Kiwoko Hospital.*
- *I now know what other people are doing in their countries with bCPAP and I can improve on what I am doing in my country.*
- *Practical demonstrations of the various bCPAP devices and exchange of experiences from different countries and centers.*
- *The knowledge that we have a committed personnel with the same common goal—improving newborn care.*

In addition to the information participants gleaned from presentations, it was apparent that they placed high value on the opportunity to gather together to understand what other people were doing in the field, exchange ideas, and build on the community that was created over two days.

All respondents to the exit survey enthusiastically stated that they would recommend a similar workshop to their colleagues and would attend a future workshop themselves.

A the end of the workshop, questions that participants still wanted to have answered primarily centered on the following three topic areas:

1. Will we provide training in the future on bCPAP use?
2. How soon will the PATH bCPAP kit and blender be available and what will it cost?
3. When will the next workshop be offered?

Additional feedback on the workshop included:

> *Much time was spent on devices itself (which was important) but I think addressing the ecosystem and prerequisites for bCPAP could be helpful too.*
>
> *There is a need to integrate CPAP and HBB [Helping Babies Breathe] to manage the newborns holistically.*
>
> *Team should also visit us and see what we are doing and help build up on what is already on the ground.*
>
> *Keep inviting us to more workshops.*
>
> *PATH needs to advocate with ministries of health to make CPAP devices easily accessible to hard to reach health centers.*
>
> *I want to commend the organizers. Communication was good, hospitality was wonderful, housekeeping good, topics etc. generally excellent.*
>
> *I'll appreciate continued communication w/PATH and related companies on how to purchase bCPAP.*
>
> *I loved that this was a comprehensive look at the bCPAP landscape not just a discussion of the PATH tool though I think you all got some wonderful feedback in that regard as well.*
>
> *I liked the interactive sessions best—love when the group can debate and discuss w/each other.*
>
> *There is a need to expand this training to other parts of Africa and developing countries.*
>
> *Really great workshop, very well organized and lots of useful info—please continue to follow up/share contact info with the group.*
>
> *Excellent organizations, highly effective and courteous staff, and clean, serene environment.*
>
> *Let's try and make this workshop an annual learning gathering and also try to take it to other facilities around the countries of our operations.*
>
> *Good organization, great job, a thousand thanks!*

Stakeholder meetings and hospital visits in Ethiopia

We visited NICUs in 11 hospitals in both rural and urban settings in three states in Ethiopia: Addis Ababa, Oromia, and the Southern Nations, Nationalities and Peoples' Region (see Table 4). In addition to these visits, we met with three officials at the MOH, including the Director of Child and Maternal Health; the Director of the Pharmaceutical Fund Supply Agency (PFSA), the procurement and distribution arm of the MOH; the Deputy Director of the Food, Medicine and Health Care Administration and Authority, the agency charged with regulation of medicines and medical devices; the Bill & Melinda Gates Foundation; and the Clinton Health Access Initiative. We had planned to meet with the United Nations Children's Fund and Raechelon, a local manufacturer of medical devices (resuscitators), but these meetings were ultimately not possible due to conflicting schedules.

Table 4. Facilities visited in Ethiopia.

Name	Type	State	NICU
Yekatit 12	Referral	Addis Ababa	Yes
Shashemanne	Referral	Oromia	Yes
Melka Oda	District	Oromia	Yes
Adare	District	Southern Nations, Nationalities and Peoples' Region	Yes
Hawasa	Referral	Southern Nations, Nationalities and Peoples' Region	Yes
Sher	Private	Oromia	No
Batu	District	Oromia	No
Tirunesh Beijing	District	Addis Ababa	Yes
Aklesia Memorial	Private	Oromia	No
Adama	Referral	Oromia	Yes
Ghandi Memorial	Referral	Addis Ababa	Yes

During our meetings, we shared information on the recent bCPAP workshop in Uganda, as well as an overview of PATH's bCPAP kit and oxygen blender. We learned that improvements in maternal and newborn health have been made an immediate priority in Ethiopia, as demonstrated by the five-year Health Sector Transformation Plan. Efforts to improve neonatal health include increasing the number of primary-, secondary-, and tertiary-level hospitals from about 380 to 500 over the next year, and the construction of NICUs. Of particular note was a recent purchase by PFSA of 875 Fanem® CPAP machines intended for use at level 1, 2, and 3 hospitals throughout the country. According to PFSA, approximately 500 of these machines had already been distributed, although the machines were observed in only two hospitals, Yekatit 12 and Tirunesh Beijing. In both instances, the machines were stacked in crates in the corridor and hospital staff seemed unaware of either their presence or procurement. In addition, the MOH indicated that a purchase of several hundred oxygen concentrators was planned by September 2016.

Seven of the eleven hospitals were seen to be providing bCPAP to neonates at the time of our visit (CPAP was not seen at Shashemanne, Sher, Batu, or Aklesia), and improvised bCPAP was observed in all seven. Two of the hospitals (Hawasa and Adama) also had commercial brand bubblers (Fisher & Paykel and Babi.Plus™ bubble PAP Valve), although the circuits themselves were improvised. Hawasa was using a Fisher & Paykel heated humidifier. Examples of these bCPAP devices are in the images below.

Photos: PATH/Gene Saxon

The majority of improvised bCPAP bubblers were constructed from blow-fill-seal bottles designed for intravenous administration of normal saline or lactate ringer. We also observed the use of glucose bottles, suction bottles, open containers, and water bottles used for drinking water. The latter are known colloquially as Highland bCPAPs, a reference to the brand name of the water bottles used.

Bubbler tubing typically comprised the distal end of the expiratory limb tubing itself, but in one case the body of a ball point pen was used. Many, but not all, of the bubblers were affixed with a vertical label marked at centimeter intervals to provide an indication of tubing depth. It was not uncommon, however, to see bubblers with water levels up to three centimeters below the datum (zero mark); bubblers made from translucent (i.e., not transparent) materials, making visualization of the bubbler depth very difficult; and bubbler tubing taped at a fixed level (and therefore not adjustable). In the latter case, bubbler depth was commonly set at a nominal depth of 5 cm, although as noted earlier, the water level did not always align with the datum.

Tubing ranged widely from large-bore corrugated ventilator tubing to intravenous tubing and very small-bore nasogastric tubing. Intravenous administration kits were often repurposed (including the drip chamber) to connect the tubing. Gas was administered to the patient through either nasal prongs (often of a single size for all patients) or nasogastric tubes. An abundance of tape was used to fasten, secure, and strengthen component connections, plug leaks in ventilator tubing, and, commonly, to secure the nasal interface to the neonate's face. In many instances, the tape completely covered the infant's nares and nose in an attempt to reduce leakage.

In the majority of cases, gas was provided from free-standing 51 kg oxygen cylinders, always one per neonate. Cylinders were generally connected to a regulator, flow meter, and passive (unheated) bubble humidifier proximal to the bCPAP circuit. Occasionally, oxygen concentrators provided the source of gas, again with the use of passive, bubble humidifiers. Many of the bCPAP circuits observed were constructed of very long lengths of narrow-bore intravenous tubing, at flow rates ranging from 2 to 10 LPM.

Oxygen cylinders were ubiquitous in Ethiopia, all of which we were told were supplied and filled by transportation to and from Addis Ababa. The cost of a cylinder was reported to be between US$400 and US$500 (described as expensive). The cost of filling, however, was not considered particularly expensive, at US$20 to US$25 per 51 kg cylinder, but supply and availability was reported to be a problem due to challenges with predicting patient load and distance to Addis Ababa. Presumably, this challenge is greater still, the more distant the health care facility is from Addis Ababa.

With the exception of Yekatit 12 and Ghandi Memorial Hospitals, each of which had a neonatologist on staff, all of the NICUs were overseen by general practitioners or, less commonly, pediatricians. It appeared that in all instances, the nurses were responsible for construction and monitoring of the improvised bCPAP devices. In every case, whether improvised bCPAP was used or not, neonates were given 100% oxygen, as there was neither a supply of pressurized air nor provision for blending gases. Only two hospitals were actively using pulse oximetry (Tirunesh Beijing and Ghandi Memorial), although a Lifebox® pulse oximeter was seen in the maternity ward of Aklesia Memorial Hospital.

Stakeholder meetings and hospital visits in South Africa

We visited two large health care facilities in Cape Town, Tygerburg Hospital and Mowbery Maternity Hospital.

Table 5. Facilities visited in South Africa.

Name	Type	State	NICU
Tygerburg	Referral	Cape Town	Yes
Mowbery Maternity	Referral	Cape Town	Yes

In the former, the gas supply was a wall source with blended air and oxygen that was humidified using a heated humidifier. Large-bore ventilator tubing was used, and CPAP was generated by using high flows and a relatively long expiratory limb open to the atmosphere (i.e., no bubbler). A purpose-built pressure gauge was connected to a port at the nasal prongs to indicate the pressure generated. Mowbery Maternity Hospital used heated, humidified, high-flow nasal cannula exclusively. The following figures show these arrangements.

Improvised CPAP at Tygerburg Hospital in Cape Town.

Improvised CPAP with heated, humidified, high-flow nasal cannula at Mowbery Maternity Hospital.
Photos: PATH/Gene Saxon

Annex 1—Agenda and biographical description of presenters

Expanding the reach of bubble CPAP devices

A workshop for newborn care providers

Agenda

September 21, 2015

Day 1

7:00am – 9:00am	*Registration Check-In/Breakfast/Set-up of device display*
900am – 10:30am	**Welcome/Introductions** Presenter: Dr. James Nyonyintono
10:30am – 12:30pm	**Session 1: Landscape of bubble CPAP: Showcasing current solutions** Facilitator: Gene Saxon Presenters: Improvised presenters by hospital
12:30pm – 2:00pm	*Lunch*
2:00pm – 3:30pm	**Session 2: Discussion of challenges and needs in the management of newborn respiratory problems** Facilitator: Hlahla Mayimele
3:30pm – 4:00pm	*Tea break*
4:00pm – 4:30pm	**Session 3: Low-cost solutions** **The Pumani CPAP** Presenter: Jocelyn Brown
4:30pm – 5:00pm	**The MTTS Breath of Life CPAP** Presenter: Dr. Dan Fitzpatrick
5:00pm – 5:30pm	**Optional: Tour of Kiwoko Hospital's neonatal intensive care unit**
5:30pm – 6:30pm	*Break*
6:00pm	*Transport back to Diocese Guest House*
6:30pm – 8:00pm	*Dinner*

September 22, 2015

Day 2

7:00am – 8:30am	*Breakfast*
8:30am – 9:00am	**Welcome/Recap** Presenter: Debbie Lester
9:00am – 11:00am	**Session 4: Introducing PATH's bubble CPAP solution** Presenters: Gene Saxon and Alec Wollen
11:00am – 11:30am	*Break*
11:00am – 11:30am	**Optional: Tour of Kiwoko Hospital's neonatal intensive care unit**
11:30am – 12:30pm	**Session 5: Setting up a neonatal intensive care unit/Lessons learned** Presenters: Debbie Lester, Dr. James Nyonyintono, Sr. Christine Otai
12:30pm – 2:00pm	*Lunch*
2:00pm – 3:00pm	**Session 6: Developing a CPAP Program: How to implement a CPAP program effectively in a high turnover environment** Presenters: Dr. Maneesh Batra, Dr. Anna Hedstrom, Debbie Lester, Dr. James Nyonyintono
3:00pm – 4:00pm	**Session 7: Training approach for improvised bubble CPAP: How train effectively in a high turnover environment** Presenters: Dr. Maneesh Batra, Dr. Anna Hedstrom, Dr. James Nyonyintono
4:00pm – 4:30pm	*Tea break*
4:30pm – 5:30pm	**Session 8: Conclusions and next steps** Presenter: Kelly Ebels
5:30pm – 6:30pm	*Break*
6:00pm	*Transport to Diocese Guest House*
6:30pm – 8:00pm	*Dinner*

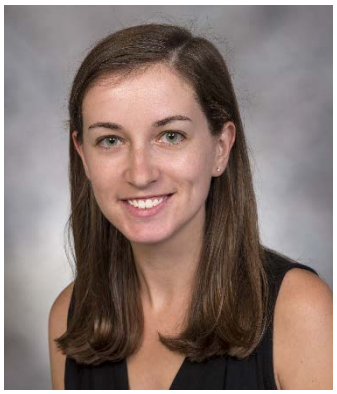
Biographical Descriptions of the Presenters

Dr. Maneesh Batra, University of Washington Department of Pediatrics and Seattle Children's Hospital

Dr. Maneesh Batra is an associate professor in the Department of Pediatrics, Division of Neonatology, with an adjunct appointment within the Department of Global Health. His research interests include epidemiology and newborn outcomes in developed- and developing-country settings. His primary interests revolve around improving newborn care in resource-poor settings. Dr. Batra is also an associate director of the pediatric residency program and co-director of the residency pathways in global health and community pediatrics/advocacy. He is involved with the clinical training of students, residents, and fellows at the University of Washington, and with the training of health workers of all levels in Ethiopia, Kenya, and Uganda.

Dr. Batra received his undergraduate degree in biology from Brown University in Providence, Rhode Island; his MD from Stanford University in Stanford, California; and his MPH from the University of Washington in Seattle, Washington.

Jocelyn Brown, 3rd Stone Design



Jocelyn Brown is a product manager at 3rd Stone Design, where she oversees the production, sales, distribution, and customer support of 3rd Stone's suite of affordable medical devices, including the Pumani bubble continuous positive airway pressure (CPAP) device. She is one of the original inventors of the Pumani bubble CPAP, and she interfaces regularly with Pumani bubble CPAP designers, engineers, manufacturers, and customers to produce a Pumani bubble CPAP that meets the needs of newborns around the world. Prior to joining 3rd Stone, she was a program associate at the Rice 360° Institute for Global Health Technologies, where she provided technical support for the Pumani bubble CPAP clinical study and led the efforts to distribute the Pumani bubble CPAP to all central and district hospitals in Malawi.

Ms. Brown holds a bachelor of science in bioengineering degree from Rice University in Houston, Texas.

Kelly Ebels, PATH

Kelly Ebels is a program associate with PATH's Devices and Tools Global Program. Ms. Ebels' major responsibilities include project management and technical research activities for water, sanitation, and hygiene projects as well as maternal and child health projects. Her work experiences prior to joining PATH include managing a finance and accounting department for an international nonprofit as well as serving as a Civil Engineering Officer in the United States Air Force.

Ms. Ebels has a master's of arts in counseling and psychology from the Seattle School of Theology and psychology and a bachelor of science in civil engineering from the United States Air Force Academy.

Dr. Dan Fitzpatrick, Thrive Networks

Dr. Dan Fitzpatrick is Regional Director, East Africa for the Breath of Life Program, Thrive Networks. Breath of Life is a hospital-based newborn care program that involves the donation of sustainable equipment that is specifically designed for low resource environments, the provision of clinical and technical training and monitoring and evaluation.

Breath of Life is a collaboration between Thrive Networks and MTTS, a social enterprise that manufactures newborn care equipment appropriate to low resource environments where robustness, ease of use and zero consumables are key to achieving reductions in newborn mortality and morbidity.

Dr. Fitzpatrick has a background in business and academia but has been working in development for many years. He has set up and run the Breath of Life program in 4 countries. He studied at several universities and has a PhD from the London School of Economics.

Dr. Anna Hedstrom, University of Washington Department of Pediatrics and Seattle Children's Hospital

Dr. Anna Hedstrom is a neonatologist at Seattle Children's Hospital and an Assistant Professor in the Department of Pediatrics, Division of Neonatology at the University of Washington. Her clinical interest is in global neonatal health. Her research focuses on the implementation of CPAP in neonatal intensive care units in developing countries and on the use of a respiratory severity score to guide treatment with CPAP.

Dr. Hedstrom received her undergraduate degree in biology from Pomona College in Claremont, California, her MD from the University of Washington in Seattle, Washington completed pediatric residency at Northwestern University in Chicago and her neonatal/perinatal medicine fellowship at the University of Washington in Seattle, Washington.

Debbie Lester, Adara Development

Debbie Lester is currently the Clinical Program and Country Director of Adara Development—USA. She has 25 years of experience as a clinician in maternal and child health, specializing in global and public health. Her expertise lies in maternal and child health in an international development context, focusing on diverse and underserved populations in resource limited settings. Ms. Lester spent the first twelve years of her career building maternal and child health programs in Bermuda, working in both the tertiary and public health setting. For the next ten years, Deborah worked at Seattle Children's Hospital in the care of critically ill infants and was hired on the leadership and management team as the Clinical Educator of the Neonatal intensive care unit. In 2008, Ms. Lester joined Adara Development full time to grow their clinical programs and has been managing that work ever since.

Ms. Lester received her diploma in nursing from St. Boniface Hospital School of Nursing; advanced diploma in neonatal health from the British Columbia Institute of Technology; undergraduate degree from California State Dominguez Hills in nursing; and MPH from the University of Washington, in Seattle, Washington.

Hlahla Mayimele, PATH

Hlahla Mayimele is a commercialization officer with the PATH South Africa Country Program. He began his career in sales, marketing, branding, and communication where he worked in senior positions for Frito-Lay International a subsidiary of PepsiCo; Reckitt Benckiser, a global company listed on the London Stock Exchange; and L'Oréal Paris before venturing into investment and entrepreneurship. He was previously the Founder and Managing Director of First Seed, an entrepreneurial consulting agency for start-up companies, entrepreneurs and corporate companies that focuses on capital raising, business development strategies and entrepreneurship policy. His experience in the marketing sector has earned him extensive and abundant skills in strategic planning, strategy development, execution process, and agreement negotiations.

Mr. Mayimele holds a degree in marketing and post graduate diploma in strategic marketing and is completing a master's degree in entrepreneurship, new venture creation specializing in SME and entrepreneurship policy and investment at Wits Business School, the University of the Witwatersrand, Johannesburg, South Africa.

Dr. James Nyonyintono, Kiwoko Hospital

Dr. James Nyonyintono is surgeon and deputy medical director at Kiwoko Hospital in Luwero, Uganda. As junior doctor he worked in Kiwoko's neonatal unit gaining a wealth of experience which lead to his appointment to the unit after completing his advanced training. He is keenly interested in innovation.

He received both his undergraduate degree, bachelor of medicine and bachelor of surgery and master's degree, master of medicine in general surgery, from Makerere University, Uganda.

Sr. Christine Otai

Sister Christine Otai is a registered midwife and nurse. She has worked for Kiwoko hospital for nearly 25 years. Since 2000, she been the nurse in charge of the neonatal intensive care unit, a ward that currently employs 31 staff at Kiwoko. Prior to working on the intensive care unit, she served as the nurse in charge of the maternity unit for seven years.

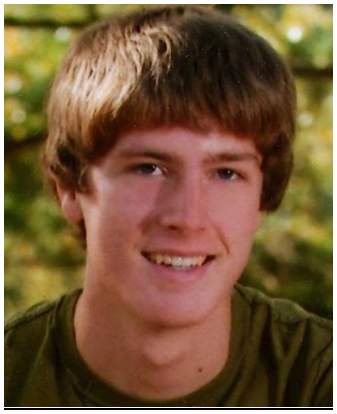
She has training certifications from Helping Babies Breathe, the Neonatal Resuscitation Program, and PRONTO. She has won the Champion Nursing award and the Neonatal award.

Gene Saxon, PATH

Eugene Saxon is a product engineer with the PATH Devices and Tools Global Program. His major responsibilities include managing project activities for vaccine delivery technology and medical device projects, researching and advising teams on technical topics, and collaborating with contract manufacturers and partners to develop manufacturing plans and oversee manufacturing and scale-up processes. Prior to joining PATH, Mr. Saxon was an engineer at Spencer Technologies in Seattle, Washington, where he worked with a team to develop a novel Doppler ultrasound system for measuring intracranial pressure.

Mr. Saxon holds bachelor of engineering and master of engineering degrees in mechanical engineering from the University of Bristol in Bristol, England, and a master of science degree in medical engineering from the University of Washington in Seattle, Washington.

Alec Wollen, PATH



Alec Wollen is a product development shop technician with the PATH Devices and Tools Global program. He is primarily involved in research and development as well as providing technical expertise on various medical device projects at PATH including bubble CPAP, oxygen concentrators, and infusion pumps. Before his employment at PATH, he worked with the Yager Research Laboratory at the University of Washington developing point-of-care diagnostics systems for low-resource-settings.

Mr. Wollen holds a bachelor's degree from the University of Washington in Seattle, in bioengineering with a concentration in diagnostics and therapeutic instruments.

This workshop is presented by the following organizations: PATH, Adara Development, Kiwoko Hospital, Seattle Children's, and The University of Washington's Department of Pediatrics.

The workshop organizers would like to extend a special thank you to Kiwoko Hospital for their generosity in providing this location for us to gather and for being extraordinary hosts.

We would also like to express our deep appreciation of all of the workshop participants who have taken the time from their important work to travel to Kiwoko in order to share their experiences, input, and expertise.

This project is made possible through the generous support of the Saving Lives at Birth partners: the United States Agency for International Development (USAID), the Government of Norway, the Bill & Melinda Gates Foundation, Grand Challenges Canada, and the UK Government. This was prepared by PATH and their partners and does not necessarily reflect the views of the Saving Lives at Birth partners.

Annex 2—Observations from facility visits in South Africa

Expanding the reach of bubble CPAP devices

A workshop for newborn care providers

Observations from facility visits in South Africa

Hlahla Mayimele

Commercialization Officer

September 21, 2015

SAVING LIVES AT BIRTH: A GRAND CHALLENGE FOR DEVELOPMENT

A PARTNERSHIP OF

USAID FROM THE AMERICAN PEOPLE

NORWEGIAN MINISTRY OF FOREIGN AFFAIRS

BILL & MELINDA GATES foundation

Grand Challenges Canada™ Grands Défis Canada℠

UKaid from the British people

Photos: PATH/Amy MacIver

Introduction

Conducted facility visits in Johannesburg and Pretoria, South Africa in April and May 2015.

The goal of the health facility visits was to understand:

- What levels of health facilities treat respiratory distress syndrome (RDS)?
- What types of continuous positive airway pressure (CPAP) devices are in use?
- What challenges are experienced with CPAP device use?

Visited 12 health facilities.

- 2 national tertiary central general.
- 2 provincial tertiary hospitals.
- 2 regional hospitals.
- 4 district hospitals.
- 2 clinics.

Infant mortality rate and the need- 2013/2014

- 978,196 births took place in South African health facilities.
- 29,262 live births were recorded outside of health facilities.
- 17% of infants born out of health facilities suffer from neonatal complications.
- 206,351 cases of RDS were reported in South Africa.
- These RDS cases are 21% of total births.
- 9% of infant deaths are caused by RDS.
- In rural areas the majority of RDS cases are only treated in district and regional hospitals, not in clinics.

Current treatment of RDS using CPAP

- CPAP devices are typically situated in intensive care units (ICUs) and pediatric wards.
- All facilities from Tertiary to District Hospitals have gas sockets in the wards that supply oxygen through a central gas system.
- Health centers use oxygen tanks.
- None of the health facilities visited used oxygen concentrators for CPAP devices.
- All hospitals use the following 3 steps of infant resuscitation to treat RDS:
  1. Use the Neopuff™ Infant T-Piece Resuscitator.
  2. If the problem persists, place the infant on a CPAP device.
  3. If the critical condition persists the infants are moved to ICU.

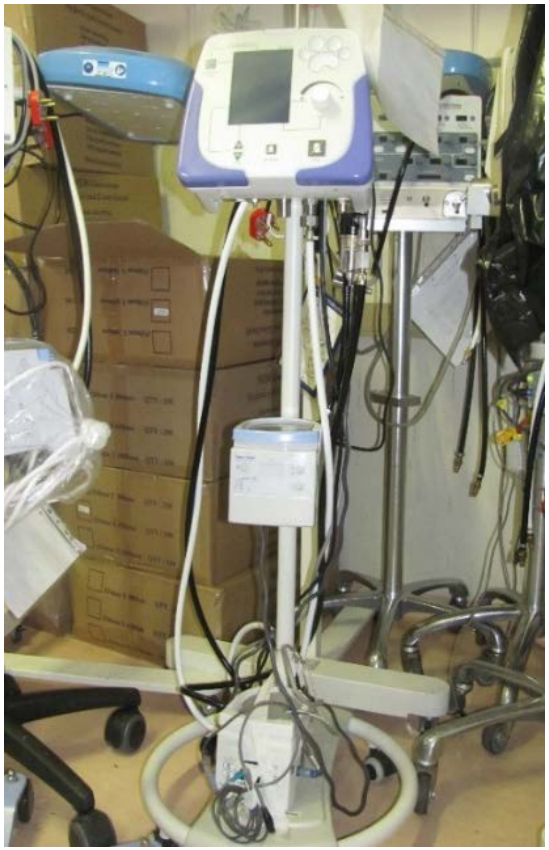
Photos: PATH/Hlahla Mayimele

Landscape of CPAP devices at the facilities visited

CPAP Manufactures	Forms/Type
Fisher & Paykel Healthcare	Bubble CPAP
medin Medical Innovations GmbH	CPAP
CareFusion	Variable Flow CPAP
Phoenix Medical Systems	CPAP
Philips Healthcare	CPAP

CPAP products found during hospital visits

Phoenix Medical Systems



Fisher & Paykel Healthcare

Combination of Brands

Photos: PATH/Hlahla Mayimele

CPAP products found during hospital visits (continued)

medin Medical Innovations GmbH

CareFusion

Photos: PATH/Hlahla Mayimele

Challenges facilities face when using CPAP for RDS

- **Training**: not enough trained staff on the operation of CPAP machines.
- **Maintenance**: lack of skilled staff to maintain the equipment.
- **Wastage**: most hospitals visited are not using their new CPAP machines due of lack of training, these machines, as a result, are in storage.
- **Suitability**: preference for high-tech and expensive machines which are not always suitable for health settings.
- **Replacement parts**: CPAP equipment with consumables require budgets and processes for obtaining new parts.
- **Location at facility**: CPAP devices are often located in a different part of the facility and not easily available for use in treating neonates with RDS.
- **Power supply**: all CPAP devices at the health facilities visited required electricity.

Presentations guidelines

- Break into 10 groups
- Each group will have questions to discuss and present
- The presentations will be guided by themes from survey results
- 20 minutes discussion in groups
- 5 minutes presentation from each group
- Each group to appoint:
  - Chairperson
  - Notetaker
  - Presenter

Annex 3—Challenges and needs in the management of newborn respiratory problems: A discussion of survey results

Session 4

Expanding the reach of bubble CPAP devices

A workshop for newborn care providers

Photos: PATH/Amy MacIver

Challenges and needs in the management of newborn respiratory problems: A discussion of survey results

Kelly Ebels

September 21, 2015

SAVING LIVES AT BIRTH: A GRAND CHALLENGE FOR DEVELOPMENT

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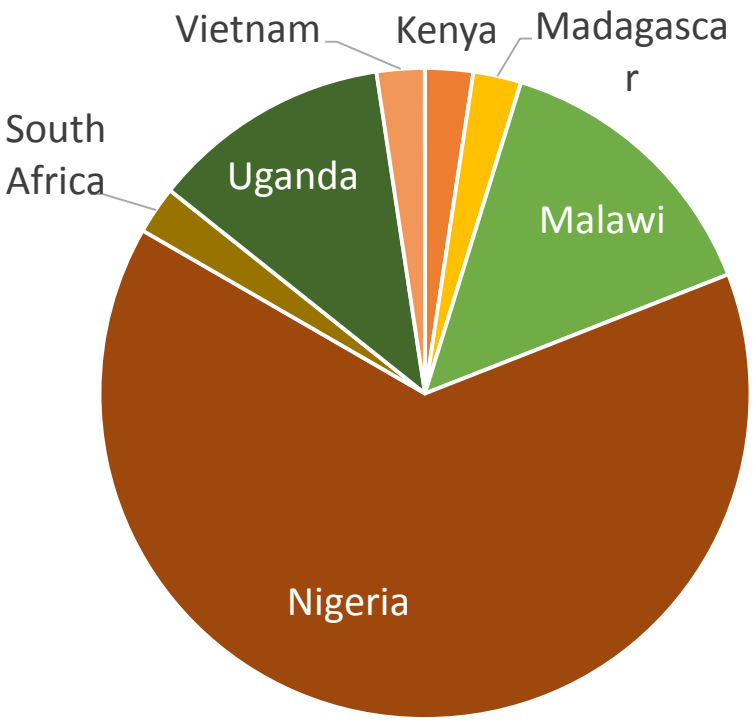
Overview

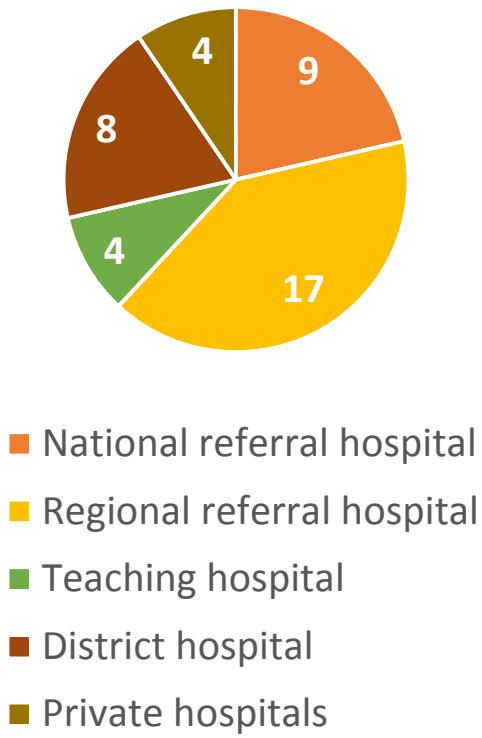
- Survey link sent to 89 stakeholders.
- 42 respondents.
- 34 questions.
- Categories include:
  - Facility
  - Personnel and training
  - Equipment
  - Oxygen
  - Procurement

Background

Respondents by Country



Level of Health Care System



Facilities

Number of births per year

	High volume	Moderate volume	Low volume
National Referral	5	3	
Regional Referral	9	8	
Teaching Hospital	1	3	
District Hospital	5	2	
Private Hospital		2	2

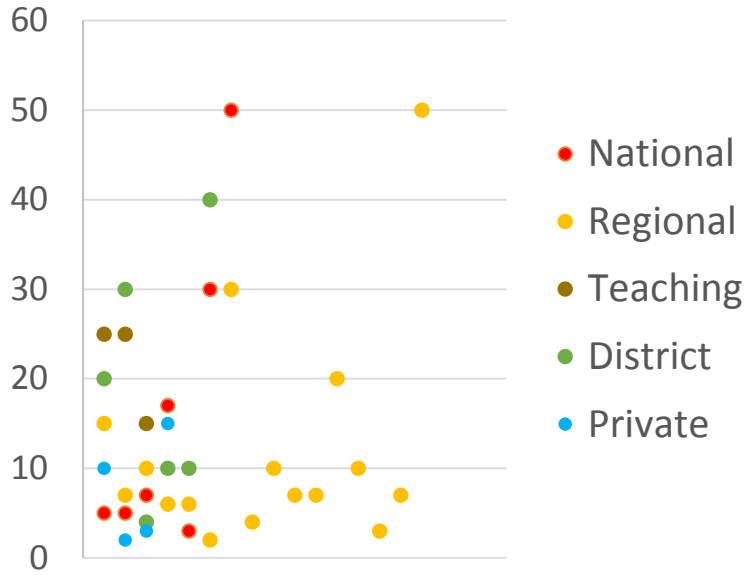
High = >2,000 births/year

Moderate = 100-2,000 births/year

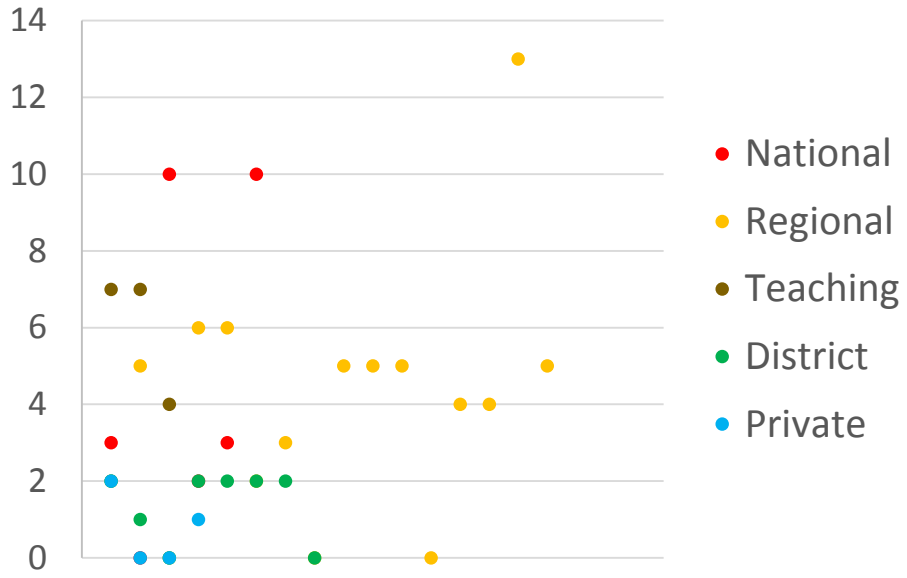
Low = <100 births/year

Facilities (continued)

Number of newborns treated monthly for RDS

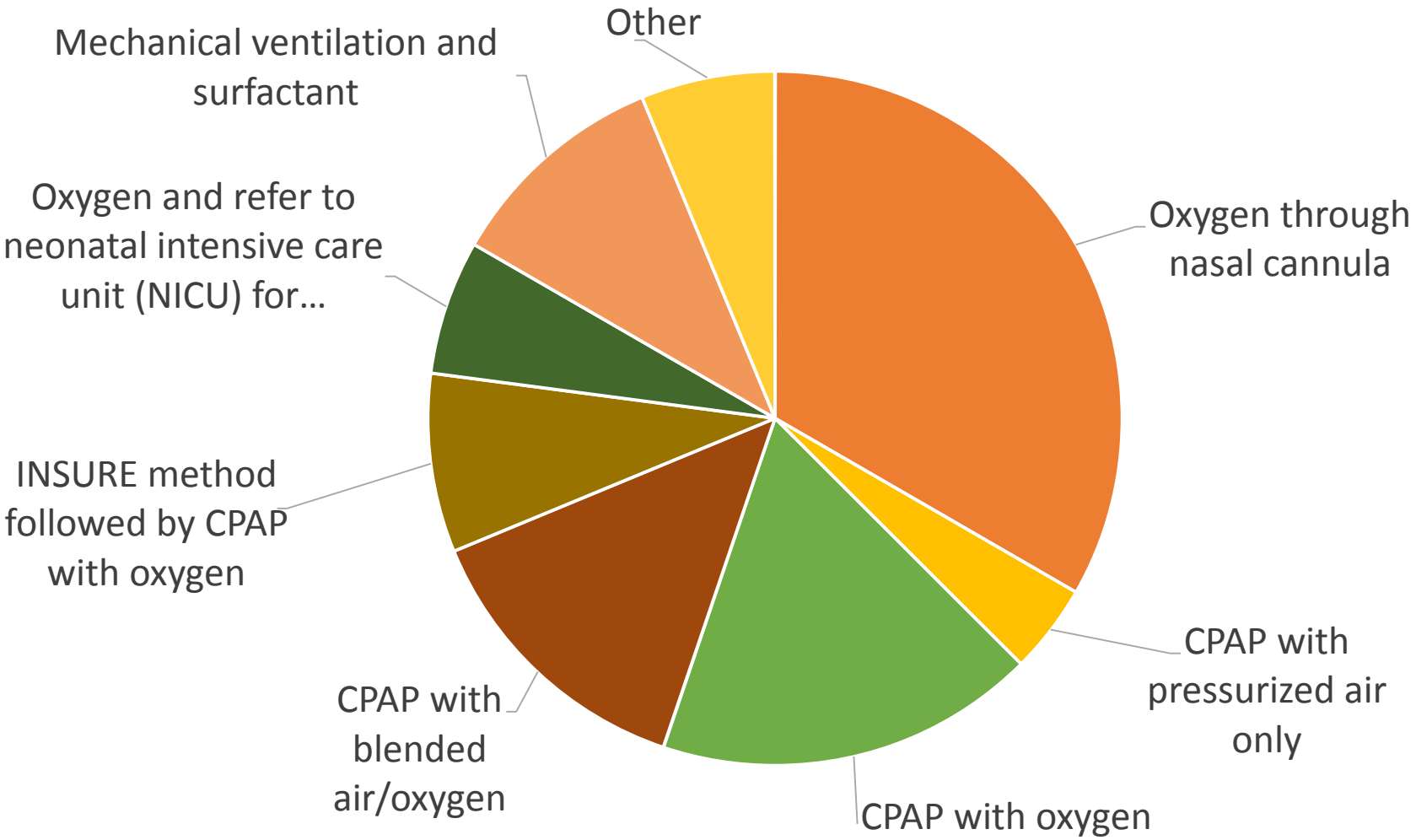


Number of newborns facility can support on CPAP at the same time



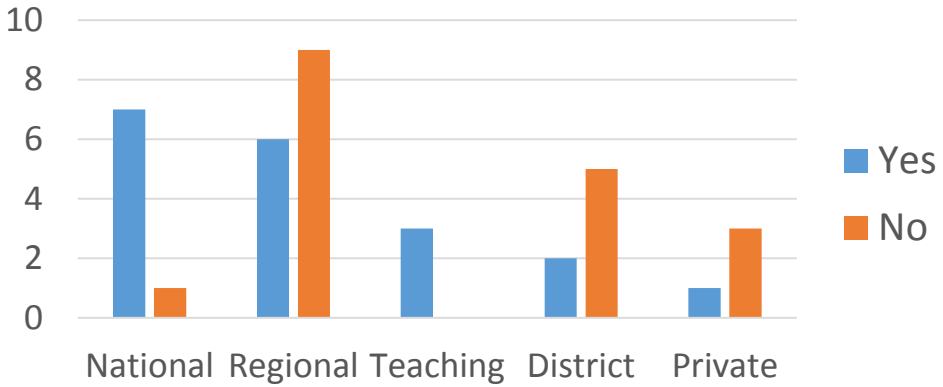
"We get many babies who would require CPAP but we only have one machine and can't afford to buy others." –District Hospital respondent

Personnel and training: Treatment methods for newborns with RDS



Personnel and training (continued)

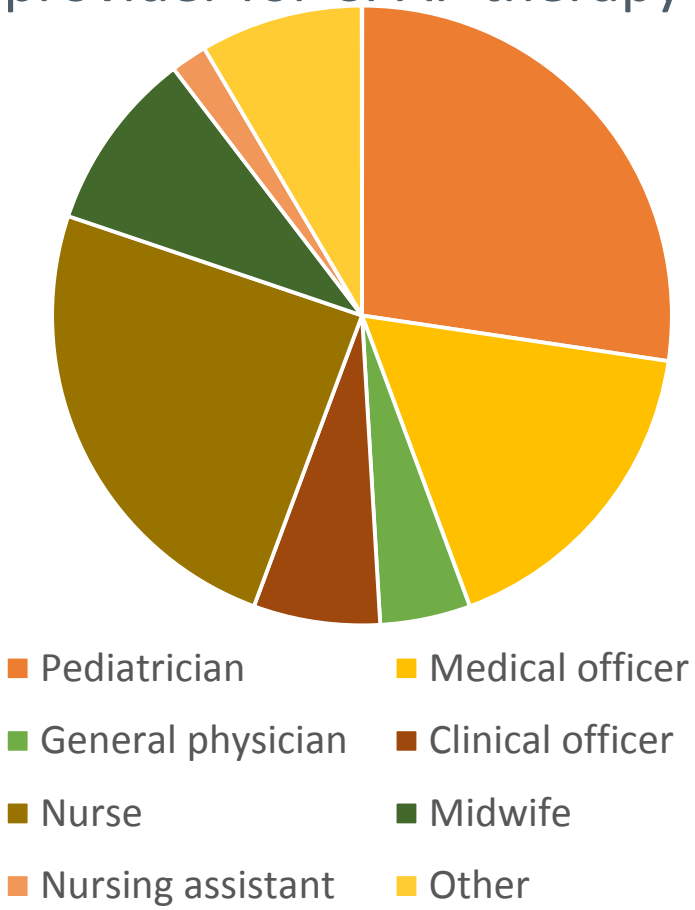
Is training in the management of newborn RDS and use of CPAP provided at your facility?



"Trainings are limited and sparse to come by…both locally and internationally."

–National referral hospital respondent

Cadres of health workers skilled/allowed to act as the provider for CPAP therapy



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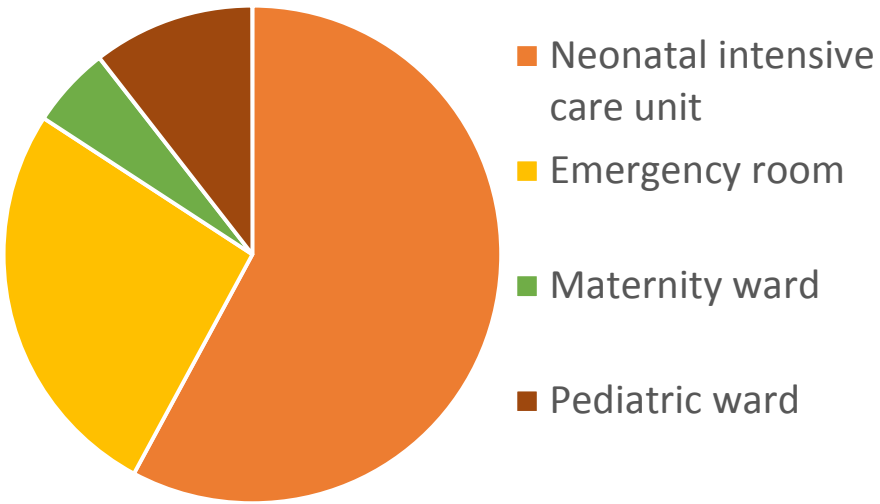
Equipment

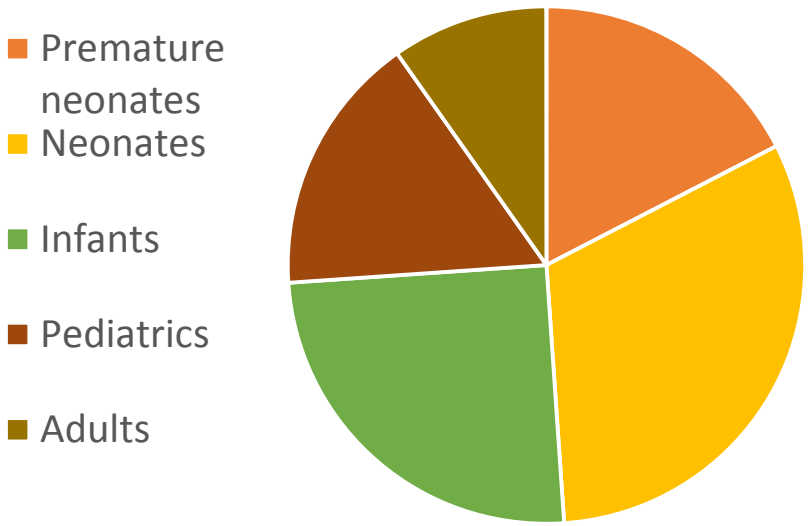
- Several higher level facilities are using multiple improvised devices. Very few CPAP devices are available at secondary-level facilities.
- 74% of respondents indicated they use bubble CPAP devices to treat conditions other than RDS – mainly pneumonia.



"We don't have already made bCPAP devices on standby. Rather, we prepare them instantly once the need arises." –tertiary teaching/referral hospital respondent

Equipment (continued)

Age ranges of patients for which appropriately sized cannulae are available

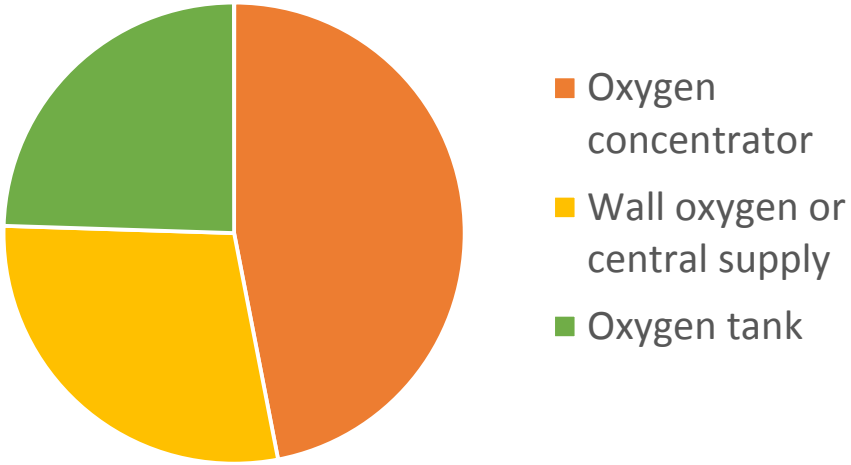


- 90% of respondents indicate pulse oximeters are available in rooms/wards.
- Some respondents indicated frequent or scheduled power outages, though outages are mostly brief.

Oxygen

- 74% of respondents indicated oxygen is always available for use with bubble CPAP devices.
- 76% of respondents do not have oxygen blenders at their facilities

Sources of oxygen supply used for bubble CPAP devices



"We need oxygen separate for paediatric ward and maternity other than being shared." –district hospital respondent

"We do not have sufficient air oxygen blenders for all babies on oxygen." –national referral hospital respondent

Procurement

- Who makes decisions about which medical devices and supplies to purchase for facilities:
  - Many respondents indicated hospital directors
  - Several respondents also indicated heads of departments, the hospital procurement office, and the ministry of health
- Respondents indicated that input from users is important and may or may not be valued

"Input from user department is either not sought before purchase or not respected"

–National referral hospital respondent

Annex 4—Discussion of challenges and needs in the management of newborn respiratory problems

Annex 4

Session 2: Discussion of challenges and needs in the management of newborn respiratory problems

Group 1

1. In what clinical settings are bCPAP devices most needed?

2. What methods are used to secure the interface to the neonates face?

3. What do you think would be the best way to expand access to bubble CPAP?

Session 2: Discussion of challenges and needs in the management of newborn respiratory problems

Group 2

1. In what clinical settings are bCPAP devices most needed?

2. What methods are used to secure the interface to the neonates face?

3. What do you think would be the best way to expand access to bubble CPAP?

Session 2: Discussion of challenges and needs in the management of newborn respiratory problems

Group 3

1. What issues are encountered in securing the interface to the neonates face?

2. What are your challenges with nasal prong sizing/availability?

3. What do you think would be the best way to expand access to bubble CPAP?

Session 2: Discussion of challenges and needs in the management of newborn respiratory problems

Group 4

1. What issues are encountered in securing the interface to the neonates face?

2. What are your challenges with nasal prong sizing/availability?

3. What do you think would be the best way to expand access to bubble CPAP?

Session 2: Discussion of challenges and needs in the management of newborn respiratory problems

Group 5

1. What are the limitations of current bubble CPAP devices?

2. Are there challenges with lighting where bubble CPAP for newborn respiratory problems is used?

3. What do you think would be the best way to expand access to bubble CPAP?

Session 2: Discussion of challenges and needs in the management of newborn respiratory problems

Group 6

1. What are the limitations of current bubble CPAP devices?

2. Are there challenges with lighting where bubble CPAP for newborn respiratory problems is used?

3. What do you think would be the best way to expand access to bubble CPAP?

Session 2: Discussion of challenges and needs in the management of newborn respiratory problems

Group 7

1. What ability do health care workers have to clean and disinfect bubble CPAP devices?

2. Do you feel that your facility has an adequate number of bubble CPAP devices for the number of patients requiring CPAP therapy?

3. What do you think would be the best way to expand access to bubble CPAP?

Session 2: Discussion of challenges and needs in the management of newborn respiratory problems

Group 8

1. What ability do health care workers have to clean and disinfect bubble CPAP devices?

2. Do you feel that your facility has an adequate number of bubble CPAP devices for the number of patients requiring CPAP therapy?

3. What do you think would be the best way to expand access to bubble CPAP?

Session 2: Discussion of challenges and needs in the management of newborn respiratory problems

Group 9

1. What are the needs for heat and humidification if using room air?

2. What are the needs for heat and humidification if using a blend of dry oxygen and room air?

3. What do you think would be the best way to expand access to bubble CPAP equipment?

Group 10

1. What are the needs for heat and humidification if using room air?

2. What are the needs for heat and humidification if using a blend of dry oxygen and room air?

3. What do you think would be the best way to expand access to bubble CPAP

Annex 5—PATH's bubble continuous positive airway pressure kit and oxygen blender

Expanding the reach of bubble CPAP devices

A workshop for newborn care providers

PATH's Bubble Continuous Positive Airway Pressure Kit and Blender

Gene Saxon

Alec Wollen

September 22, 2015

SAVING LIVES AT BIRTH: A GRAND CHALLENGE FOR DEVELOPMENT

A PARTNERSHIP OF

USAID FROM THE AMERICAN PEOPLE

NORWEGIAN MINISTRY OF FOREIGN AFFAIRS

BILL & MELINDA GATES foundation

Grand Challenges Canada Grands Défis Canada

UKaid from the British people

Photos: PATH/Amy MacIver

Outline

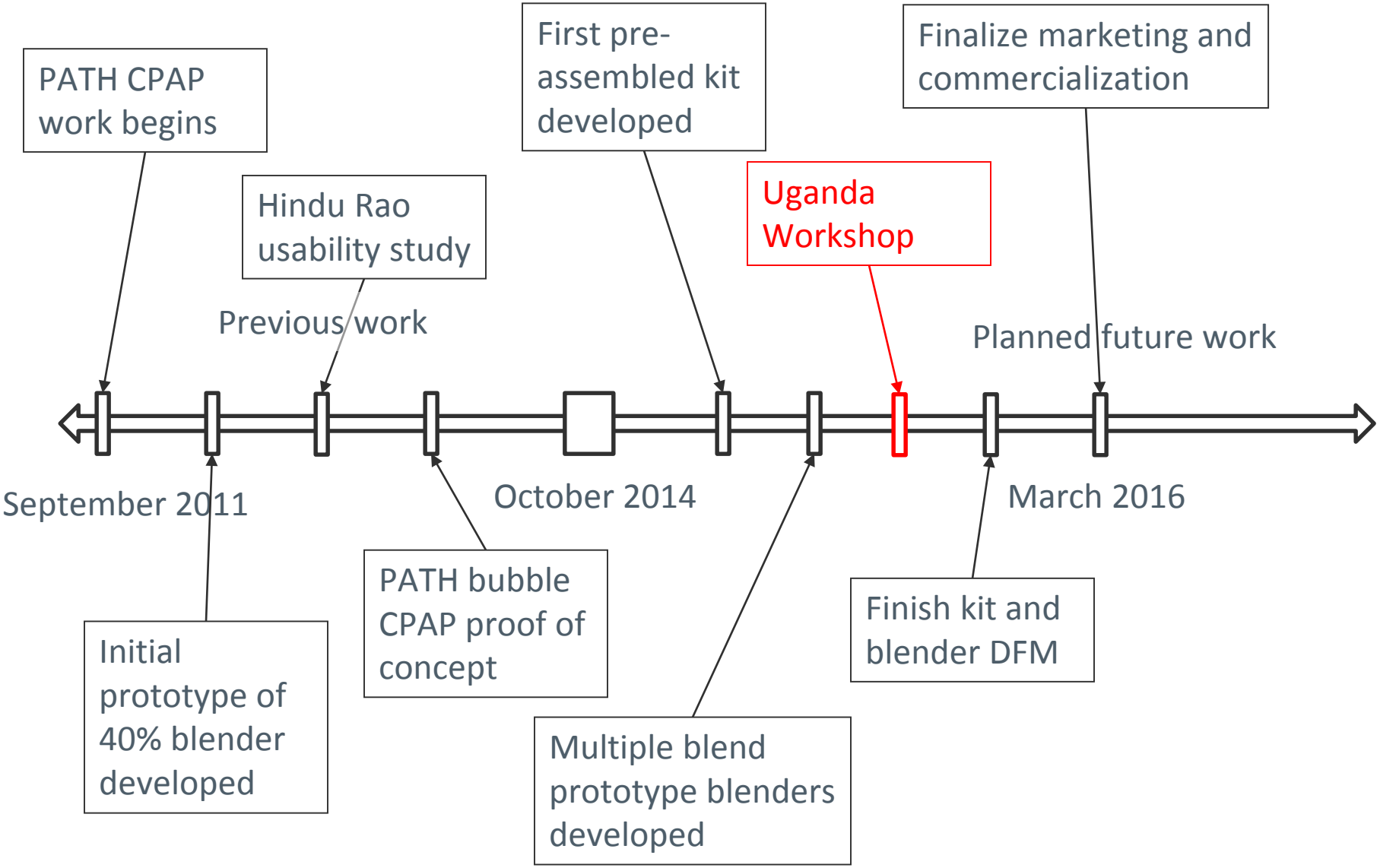
- Background
- Our solution
  - Goal / vision
  - Design parts run-through
  - Stage of development
- Performance
  - Inputs [requirements] / outputs
  - Areas to validate
- Break out into groups to discuss the questions we really need answers to:
  - What components should be included in the bubble continuous positive airway pressure (CPAP) kit?
  - What would the ideal bubbler look like?
  - What are ideal specifications for the oxygen blenders?
- Impact—next steps and future work

Problem Statement

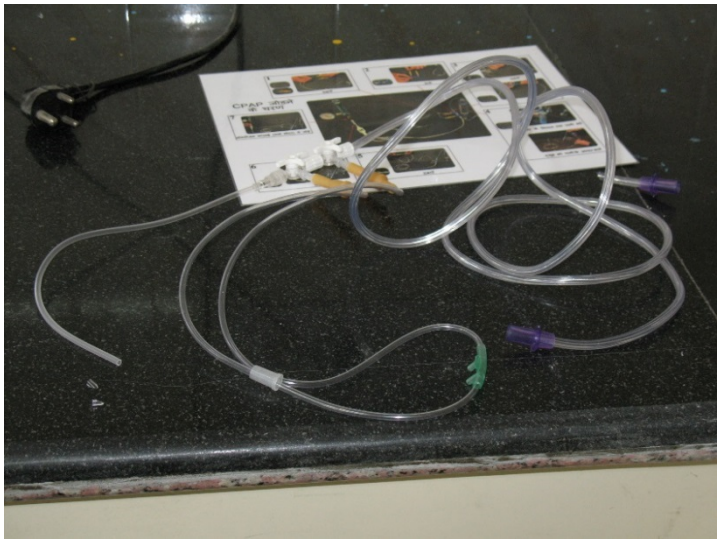
Complications arising from respiratory distress syndrome (RDS) are responsible for the deaths of approximately 1 million babies per year. RDS is also associated with a high rate of morbidity.

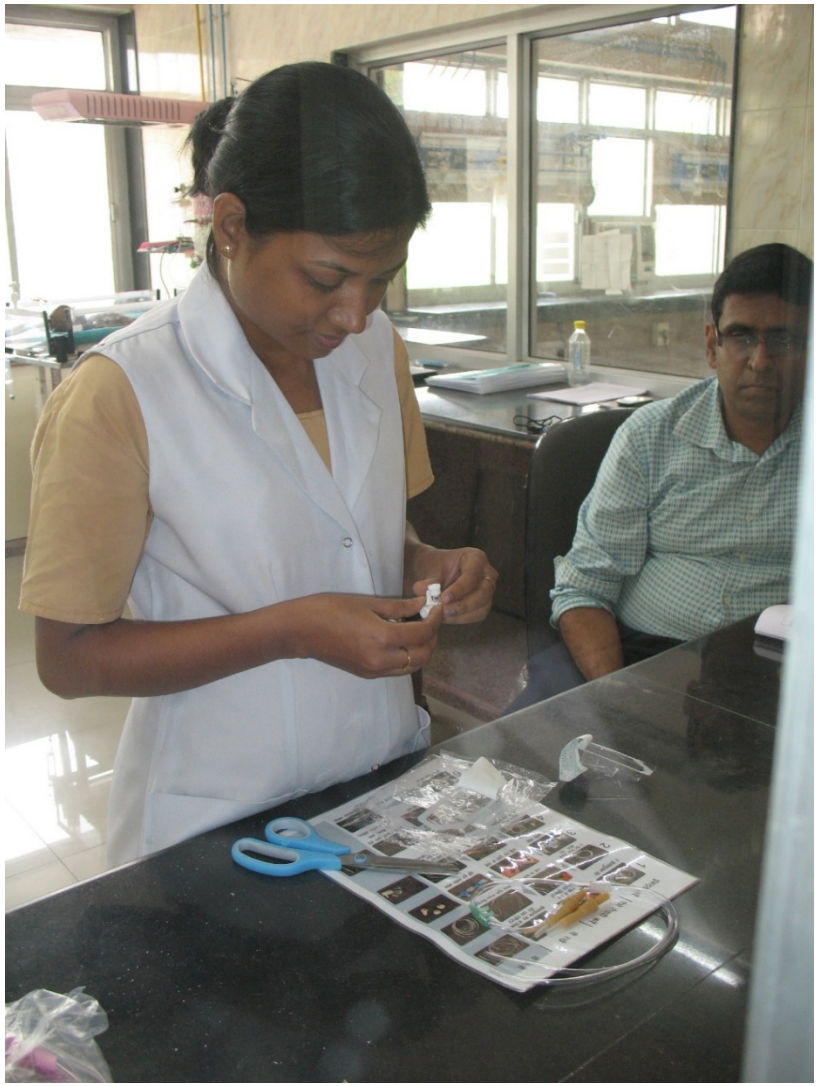
CPAP therapy is an effective therapy option that has the potential to greatly improve health outcomes of premature babies with RDS.

Project Timeline



India Study





Photos: Jennifer Foster

Our Solution

Photo: Gabe Bienczycki

PATH

Goals

Create a bubble CPAP kit that:

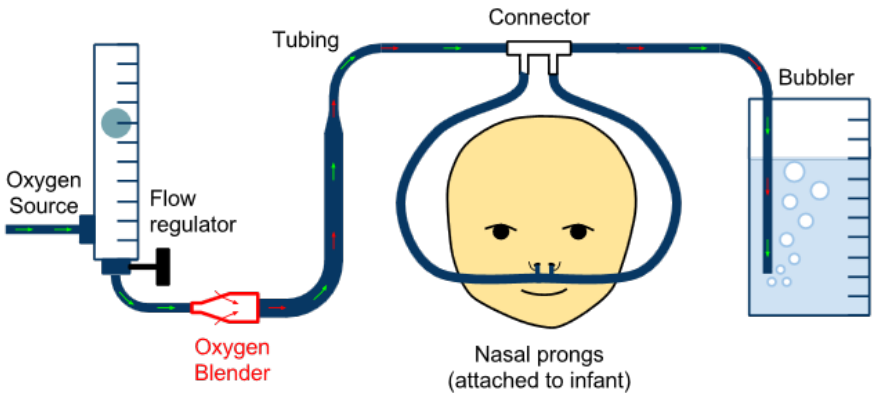
- Is safe and effective
- Does not require electricity or maintenance
- Is easy to use and clean
- Requires minimal time to set up and use
- Is robust and inexpensive

Include an oxygen blender(s) that:

- Does not require a source of compressed air
- Maintains steady oxygen % regardless of:
  - Oxygen flow rate
  - Oxygen source (concentrator, cylinder, or piped)
  - Pressure delivered to infant
- Achieves a range of blends between 40% and 80% oxygen

Optimization of the Bubble CPAP Kit

- Identify suitable components to maximize performance and minimize costs
- Ensure simple and durable design
- Ensure compatibility with commonly available nasal prongs
- Reduce number and complexity of components
  - Combine if possible
- Optimize existing components, especially the bubbler
- Assess hazards associated with reuse



Design Considerations for the Bubble CPAP Kit

Bubbler

- Opacity, size/shape of bottle
- Lid/opening style, potential modifications to off-the-shelf components
- Ability to hang, stand, attach to wall
- Potential to re-purpose existing bubble humidifier or spray bottle
- Evaluate the benefits of a customized bubbler (thermoformed) to incorporate features such as the wye (Y) fitting and water level indicator

Tubing

- Material, flexibility, connection to other components

Connections

- Fitting selection, bore diameter, barb type, wye fitting

General

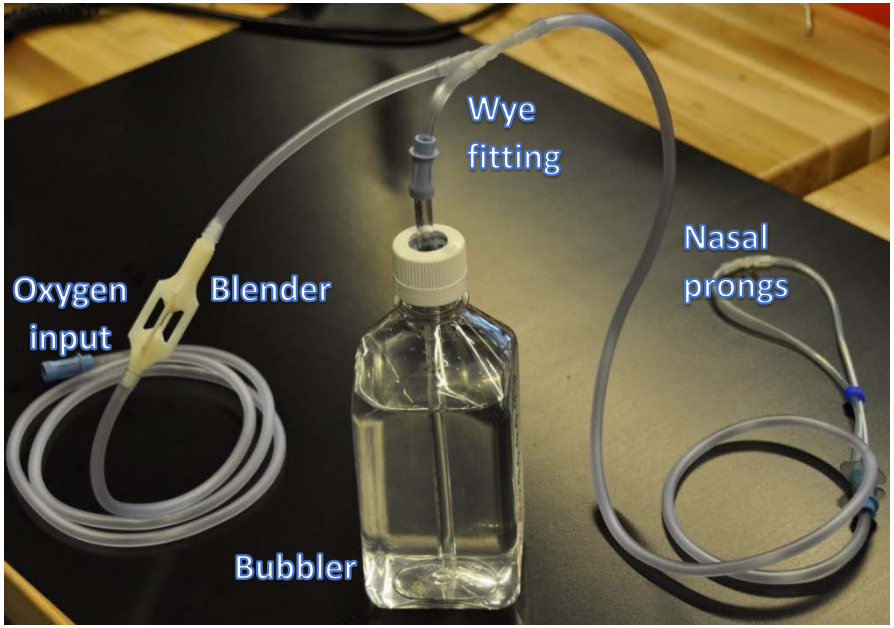
- Cleanability, reusability/durability, size, cost

Examples of Bubbler Design Options Explored

Photos: PATH/Alec Wollen

Current Configuration

- Nalgene bottle
- Vacuum suction tubing with barb fittings
- Wye fitting
- Neotech RAM Cannula®
- Fisher and Paykel Water Manometer
- 3D printed 40% oxygen blender



Photos: PATH/Alec Wollen

Scenarios of Use

Photo: Gabe Bienczycki

Level of care

- Health center
- Neonatal intensive care unit (NICU)

Location of bubble CPAP kit components

- Hanging, on wall, on table, etc.
- Close to patient, far away

Oxygen source

- Availability, proximity to patient or CPAP components
- Cylinders, concentrators, central supply

Health care provider

- Nurse, doctor, midwife

Availability / feasibility of other CPAP devices

Oxygen Blender Specifications (to date)

Blender (nominal FiO2)	Output flow* (LPM)	FiO2 Range (%)	Minimum input oxygen flow (LPM)
40%	3.0–8.0**	35–45	1.0
51%	5.5–11.0	46–54	2.0
61%	3.0–9.0	57–66	2.0
72%	4.0–11.0	70–76	3.0
81%	3.0–9.5	80–86	2.5

Notes:

- Blenders specified for 0–10 cmH_2O of backpressure
- All blenders can be run at higher input flows than rated with no performance drop. Operating lower than the minimum specified input pressure (or flow) or with higher backpressure can cause increased FiO2 variation
- With additional testing, blenders can be further optimized

* Output flow expected from a mid-size O_2 concentrator. Higher flows possible from cylinder

** Max flow 6.5 LPM w/ 10 cm backpressure

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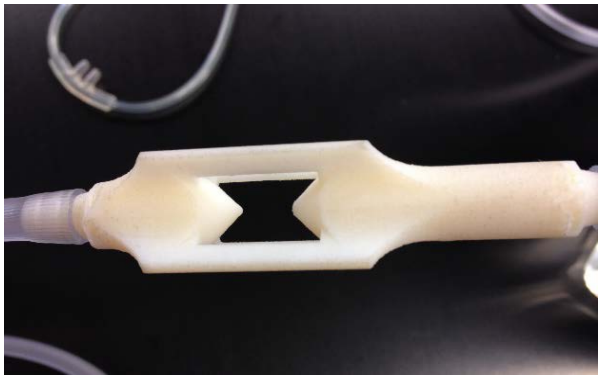
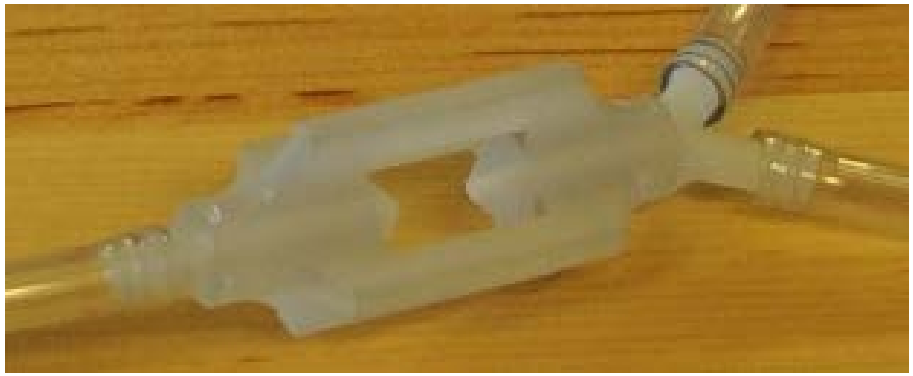
Abbreviation: FiO2 - Fraction of Inspired Oxygen

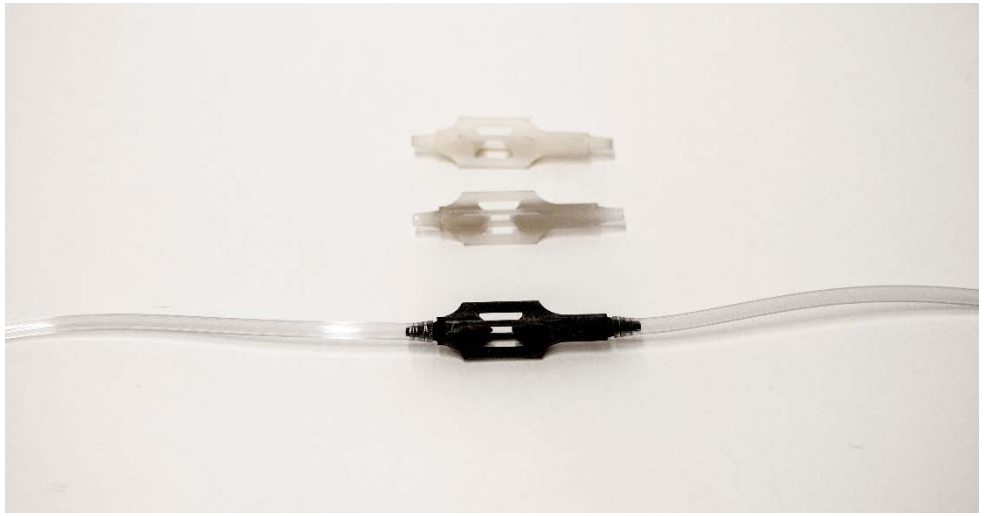
Examples of Blender Design and Iterations



Original 40% FiO2 blender design



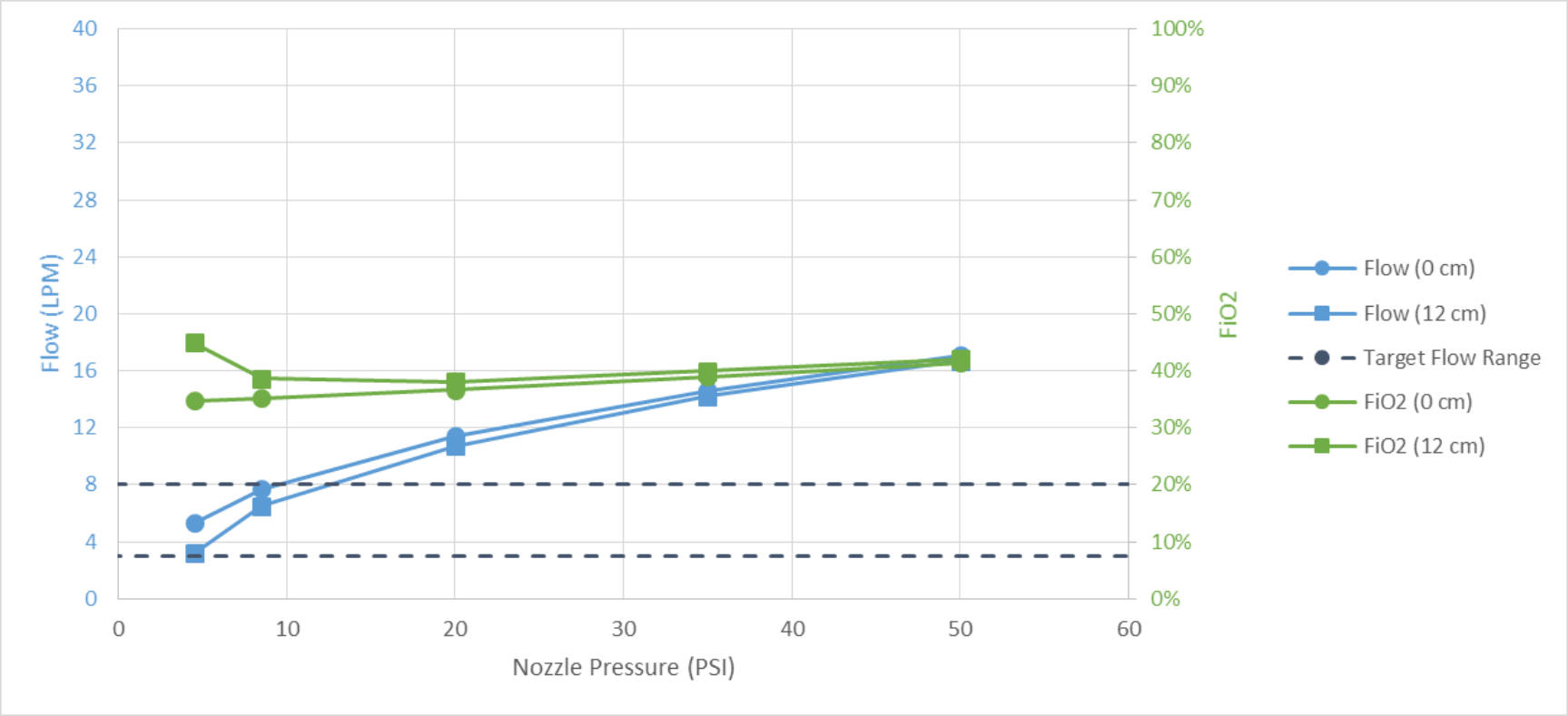
Bunny ears with incorporation of wye fitting



Three discrete blenders for different FiO2 levels

Photos: PATH/Alec Wollen

41% FiO2 Blender



Discussion

Kit Configuration

What should be the target level of reusability?

What parts should be included in a CPAP kit?

- Blender
  - 40% only or multiple blends?
- Tubing
  - What lengths?
- Cannula
  - None, one size, or many sizes?
- Any extra parts?

If not included in the standard kit, what parts should be made available separately (e.g., blender set, cannula set, long tubing)?

Ideal Bubbler

What would an ideal bubbler look like?

- Location
  - Standing on table, hanging, attached to wall?
- Color
  - Clear, translucent?
- Size
  - 500 mL, 1 L?
- Pressure reading
  - On bubbler tube or side of bubbler container?

Desired Blender Requirements

Oxygen blend

- For multiple blends what level of FiO2 control is desirable (e.g., 10% intervals, 20% intervals, or continuously variable)?
- What level of stability (e.g., ± 5%) is necessary over the clinical range of flows and pressures?

Clinical requirements

- What is the minimum output flow used to generate CPAP?
- What is the maximum airway pressure needed?

Trade-off: Would it be better to have a blender that runs with a small concentrator or with lower flow capabilities and from a tank/central supply?

Next Steps / Future Work

Incorporate suggestions from workshop

Continued development of blender and kit

- Finalize design parameters
- Verify and validate performance *in vitro*

Collaborate with local manufacturers for assembly

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Appendix

Scenarios of Use

In what clinical setting would the bubble CPAP kit be most useful?

- Health center
- Neonatal intensive care unit (NICU)

What is the ideal location of bubble CPAP kit components?

- Hanging, on wall, on table, etc.
- Close to patient, far away

Most likely oxygen source?

- Cylinders, concentrators, central supply?
  - What is the availability?

Who administers and monitors bubble CPAP?

- Nurse, doctor, midwife

Availability / feasibility of other CPAP devices

Annex 6—Bubble CPAP Kit Configuration

Name (optional):_____

Bubble CPAP Kit Configuration

All bubble CPAP kits will come with appropriate bubbler, straw, and fittings. Please circle the most desirable option for each given category or enter your own. Also, cross out any options that your group finds unacceptable, and describe why if possible. This symbol ($) indicates approximate relative cost of components.

CATEGORY	OPTION 1	OPTION 2	OPTION 3	NOTES (OR ENTER YOUR OWN IDEA)
BLENDER	One 40% blender $	5 blenders (in 10% intervals from 40-80%) $$	One blender at a blend other than 40% $	
CANNULA	None (use your own cannula, please specify style)	One (at a median or average size) $	Several (one at every size) $$	
TUBING	1m total length (pre-cut) $	2m total length (pre-cut) $	---	
HEAT/HUMIDIFICATION	Neither (use your own)	Bubble humidifier $$	---	
OVERALL REUSABILITY	Can be used a few times before wearing $	Can be reused many times $$	---	

Circle all of the following that would be useful to purchase separately from the whole kit:

Blender set: 5 blenders (in 10% intervals from 40-80%) Cost	Cannula set: one at every size Cost	Extra tubing length (for far away oxygen sources) Cost	Bubble humidifier Cost	Other (write in):

Other questions to consider:

Should common components for replacements be encouraged or avoided? (Potential user error problems for common connectors). Common components refer to standard barbed fittings, for example. If components wear out, there is a risk that other parts may be used as a replacement, with unverified performance. However, the kit may be worthless if there are unique connectors and something breaks.

Would kits remain complete or would they be scavenged (in different levels of care)?

What is the real/practical size needed for nasal prongs? A WHO collaborating center lists five different sizes (birth weight dependent)

What is the advantage of this kit?

What facilities would most benefit from this?

Is there anything else that should be included such as a cleaning brush, an oxygen adapter barb, or a bubbler stand?

The Ideal Bubbler

What would the ideal bubbler look like to you? Please circle desirable options for each given category or enter your own. If neither option is more desirable, state so. Also, cross out any options your group finds unacceptable, and describe why if possible.

CATEGORY	OPTION 1	OPTION 2	OPTION 3	OPTION 4	NOTES (OR ENTER YOUR OWN IDEA)
LOCATION	Standing on bedside table	Hanging (like an IV bag)	Attached to oxygen source (wall, tank, or concentrator)	Standing on floor	
SHAPE / FORM	Square bottle	Round bottle	Bag / bladder	---	
RIGIDITY	Hard plastic	Firm	Soft	---	
COLOR	Clear	Translucent	---	---	
SIZE	≤ 500 mL (small opening)	500 – 1000 mL (small opening)	500 – 1000 mL (large opening)	≥ 1000 mL (large opening)	
PRESSURE SETTING / READING	Marked on bottle wall	Marked on straw (in water)	Marked on straw (above lid) [This assumes the bottle has a fill line]	---	
OPENING / LID	Screw-top lid with straw opening	Press-fit lid (e.g. a stopper)	No lid (straw is attached with something else)	---	
CLEANING	Steam autoclave	Vinegar (acetic acid)	Bleach (sodium hypochlorite)	Detergent	

Other questions to consider:

Are there any other attributes you would find desirable in a bubbler? Anything that you would recommend against?

The Ideal Blender

In general larger ranges and tighter accuracy are harder to achieve, and can lead to trade-offs with other parameters. Discuss with your group the tradeoffs and ideal performance you would expect to use if you were administering bubble CPAP.

SPEC	EXAMPLES (FEEL FREE TO CHOOSE OTHER VALUES)	TRADE-OFFS	MINIMUM REQUIREMENT	DESIRED CHARACTERISTICS
CLINICAL RANGE OF FIO_2	40% – 60%, 35% – 80%	High FiO2 has increased heat + humidity requirements. Lower FiO2 has greater blend variability		
BLEND INTERVALS	10%, 20%, continuous adjustability	Smaller interval increases cost (more parts). Continuous variability cannot be run on oxygen concentrators.		
BLEND ACCURACY / STABILITY	± 2%, ±5%, ±10%	Narrow range limits ability to use oxygen concentrators at higher airway pressures, especially for low blends/flows.		
MAXIMUM DELIVERED AIRWAY PRESSURE	8 cmH_2O, 10 cmH_2O	Higher airway pressure has higher blend variability, especially for low blends/flows with oxygen concentrators		
CLINICAL RANGE OF BLENDED FLOWS	3 – 8 LPM, 4 – 10 LPM	Higher flows are difficult with concentrators at high blends. Lower flows usually have lower blend stability		

Other questions to consider:

Is CPAP without heat or humidification acceptable at low blends since the majority of flow is warm and humid room air (75% room air at 40% FiO2)? At what point does heat and humidification become necessary, and how is it best achieved?

What is the need for/usefulness of different concentrations potentially achievable by set of blenders?

With no pulse oximeter, how safe would it be to have a set of blenders with different FiO2 (higher than 40%) available? Please consider the possibility of high concentration blenders being separated and the skills of health workers in different levels of care. What about an adjustable FiO2 blender?

Appendix B—Draft Market Assessment

Draft Market Assessment

Overview

The focus of this phase of our commercialization work was to better understand the potential customer of PATH's bubble continuous airway pressure (bCPAP) kit, including identifying and characterizing potential early adopters. In order to determine the potential users and resulting market for bCPAP in Africa, project staff interviewed relevant policymakers, clinicians, program managers, and procurement staff during onsite visits in Ethiopia, Malawi, South Africa, and Uganda. Under other funding, we also conducted similar interviews in Rwanda. In addition, key learnings and insights were obtained through an online survey and discussions with participants (including more than 20 clinicians from Nigeria) at a workshop for newborn care providers in Africa on increasing access to bCPAP devices, held in Uganda in September 2015.

The mix of countries selected represents a diversity of environments in Africa, as reflected in Table 1.

Table 1. Countries examined in this market assessment.

Country	World Bank income level	Population	Pre-term birth rate (per 100 live births)	Improvised bCPAP users identified
Ethiopia	Low	90,076,000	10.1%	Yes
Malawi	Low	16,307,000	18.1%	Yes
Nigeria	Low-Middle	184,264,000	12.2%	Yes
Rwanda	Low	11,340,000	9.5%	Yes
South Africa	Upper-Middle	54,844,000	8%	Yes
Uganda	Low	35,760,000	13.6%	Yes

In addition to those listed above, Kenya and Madagascar were identified as African countries where some providers are using improvised bCPAP devices (from in-country visits and stakeholder research, as well as a literature search).

In the following sections, each country of focus is further discussed in terms of health system structure, current respiratory distress syndrome (RDS) treatment practices, availability of electricity, current sources of oxygen, and stated opinions regarding the proposed PATH bCPAP kit. All of these conditions could influence the relevance of the PATH bCPAP kit in those settings as well as its potential adoption.

Visits and interviews in Ethiopia

PATH visited a mixture of teaching, referral, district, and private hospitals in three regions of Ethiopia: Addis Ababa, Oromia, and the Southern Nations, Nationalities, and Peoples' Region. Improvised bCPAP

devices made by nurses (sometimes in conjunction with a neonatologist) were being used in the majority of hospitals with neonatal intensive care units (NICUs). We noted diverse constructions of improvised bCPAP devices, using different kinds of bottles and assorted techniques of tubing. For example, one hospital used a sealed bottle connected to intravenous (IV) tubing and a nasal-gastro tube connected straight to an oxygen tank with a humidifier; another used a water bottle; and a third used an IV fluid bottle with IV, oxygen, and ventilator tubing. We witnessed a lack of consistency in oxygen flow from these improvised bCPAP devices; some produced a low flow and some a high flow of gas to the infants. A variety of technical issues affecting efficacy were observed with the improvised devices. All of the facilities experienced blackouts a few times a week, but the larger hospitals were able to provide back-up power using generators, although at a high cost.

The Ethiopian Ministry of Health was aware of the great need for CPAP equipment and stated that they had recently purchased 875 CPAP devices from FANEM, a Brazilian company. They reported that 500 had already been distributed to facilities, with highest priority given to those facilities with admission capabilities. While these CPAP machines may be appropriate for the higher-level facilities (if reliable power can be provided), given the lack of reliable power and the expense incurred to operate a generator, lower-level facilities (of which there are approximately 3,500) are likely to benefit from the use of the PATH bCPAP kit. For additional information on our trip to Ethiopia, please see Appendix A.

Visits and interviews in Malawi

In the spring of 2015, PATH's team was able to meet with health care providers and a ministry of health official during a visit to Malawi to discuss bCPAP use and related challenges. The table below illustrates the sites visited and the staff we met.

Organization	Title
Malawi Ministry of Health	• Director Reproductive Health
Blantyre District Health Office	• District Health Officer-Head of District Health Office • Principal Administrator • Deputy District Nursing Officer • Zone Assistant • Zone Head of Department
Chirandzulu District Hospital	• District Medical Officer, Head Of Maternity
Chileka Health Centre	• Head of Health Centre
Queen Elizabeth Hospital	• Medical Nursing Officer • Hospital Executive Director • Matron, Labour Ward and Maternity • Hospital Matron • Chief Nursing Officer • Head of Pediatrics Ward • Head of Labor Ward
Mdeka Health Centre	• Head of Health Centre

Organization	Title
Mlambe Hospital	• Hospital Administrator
Mwaiwathu Hospital	• Medical Director
Ndirande Health Centre	• Clinical Officer
Shifa Private Hospital	• Administrator
Zingwangwa Health Centre	• Clinical Officer

The health care system in Malawi is comprised of referral hospitals (tertiary care), district hospitals (secondary care), and health centers and clinics (primary care). All the health centers and hospitals experience electricity and water shortages at least three times a week. Although the referral hospital visited had a generator to use during those times, it was reported as normally consuming an expensive 6,000 liters of petrol an hour and taking between five and eight minutes to kick in.

Newborns suffering from respiratory issues at the health centers visited were either referred to a higher-level facility or treated using a Dräger Rescuscitair® machine, bagging mask, Ambu-bag, or oxygen concentrator. The Pumani bCPAP device* was in use at the hospitals visited; however, during power outages, the newborns would be disconnected. All of the clinicians PATH interviewed at all levels of the health care system showed interest in the PATH bCPAP kit because it does not require electricity; however, they had concerns about how best to use it with an oxygen source, as concentrators require electricity and oxygen tanks are not always available. Maintenance of concentrators was noted as a major issue due to lack of skilled technical workers at most of the hospitals visited. For example, at the time of our visit, Queen Elizabeth Central Hospital had 55 non-functioning oxygen concentrators in need of service.

Left: Nurses at Chirandzulu District Hospital in Malawi examining the PATH bCPAP kit.

Right: bCPAP team meeting with a Director at the Malawi Ministry of Health.

Photos: PATH/Hlahla Mayimele

Visits and interviews in Rwanda

Under other funding, PATH interviewed five doctors from both rural and urban district hospitals and a referral hospital in Rwanda, as well as the Ministry of Health's Director of Maternal and Child Health and

* Over the last two years, the Pumani bCPAP device has been introduced into 28 public hospitals and will soon be in eight nonprofit hospitals.

the Director of the Rwanda Health Development Initiative on challenges and processes in the areas of training, equipment procurement, and equipment repair in the country. While bCPAP equipment was not the specific focus of this activity, the informants cited some of the same challenges reported in interviews in other countries.

The interviewees reported that the key barrier to hospitals having an adequate supply of many types of medical equipment is cost—not only initial purchase cost but also the cost of keeping the equipment in working order. It was reported that at the district hospital level, usually a single person is responsible for keeping all the hospital's equipment and other infrastructure (including plumbing, wiring, etc.) operational. Lack of funds for personnel, replacement parts, and a slow procurement process, results in a large backlog of devices that require repair and parts.

Informants were asked about reliable power at their facilities. Most reported experiencing power outages an average of three times per day.

Given these barriers and challenges, the interviewees were asked to provide desirable attributes for medical devices and listed the following:

- Low cost.
- Durable.
- Easy to use.
- No electricity required.

Visits and interviews in South Africa

The health care system in South Africa is comprised of national central hospitals, provincial tertiary hospitals, regional hospitals, district hospitals, and clinics. PATH visited 11 health facilities in the Johannesburg and Pretoria areas in April 2015 and two health facilities in Cape Town in September 2015 (for additional information on the Cape Town visits, see Appendix A).

Facility	City
Alexandra Clinic	Wynburg
Carletonville District Hospital	Carletonville
Dr.Yusuf Daddoo District Hospital	Johannesburg
Edenvale Regional	Johannesburg
Johannesburg General Hospital	Johannesburg
Leratong Regional Hospital	Krugersdorp
Mowbery Maternity Hospital	Cape Town
Tembisa Clinic	Johannesburg
Tembisa Provincial Tertiary Hospital	Johannesburg
Thswane District Hospital	Pretoria
Tygerburg Hospital	Cape Town
Rahima Moosa Mother & Child Regional Hospital	Johannesburg

Facility	City
Steve Biko National Central Hospital	Pretoria

Staff at Leratong Regional Hospital discussing PATH's bCPAP kit.

Photo: PATH/Hlahla Mayimele

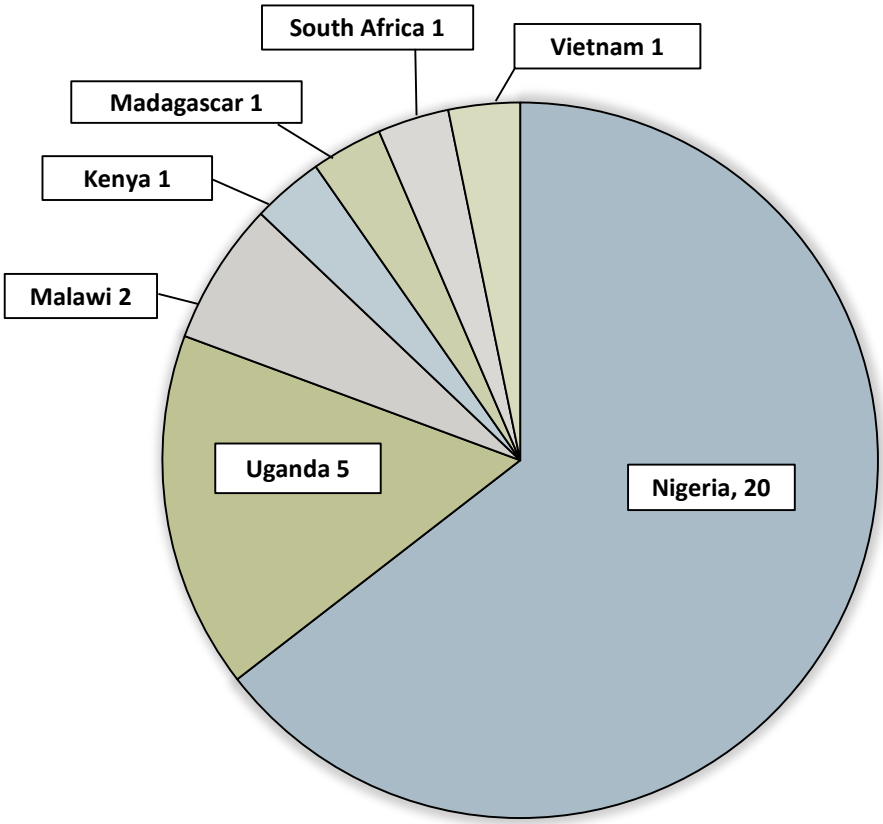
bCPAP machines were found at the national central, provincial tertiary, and regional levels, where the devices were connected directly to oxygen sockets and electrical outlets; back-up generators began working immediately if there was an issue with the electricity.

The district hospitals and clinics visited did not have bCPAP devices or machines in their facilities, citing cost as the main barrier. Clinicians instead used suction canisters, humidifiers, various manual resuscitation devices, Fisher & Paykel Neopuff™ Infant T-Piece Resuscitators, and infant resuscitation masks. District hospital staff visited expressed great interest in the PATH bCPAP kit given its features and anticipated pricing.

Insights from the online survey

In August 2015, PATH conducted a survey to better understand the current landscape and use-cases for bCPAP therapy in low-resource settings. The survey was administered online in English through SurveyMonkey®, and consisted of 34 questions. Responses to the survey were collected between August 23, 2015 and September 9, 2015, with a median response time in the survey of 21 minutes. The survey link was sent to a list of 87 global stakeholders that PATH and our partners had identified. Of the 44 unique respondents, 31 completed the survey in full (see Figure 1 on the following page).

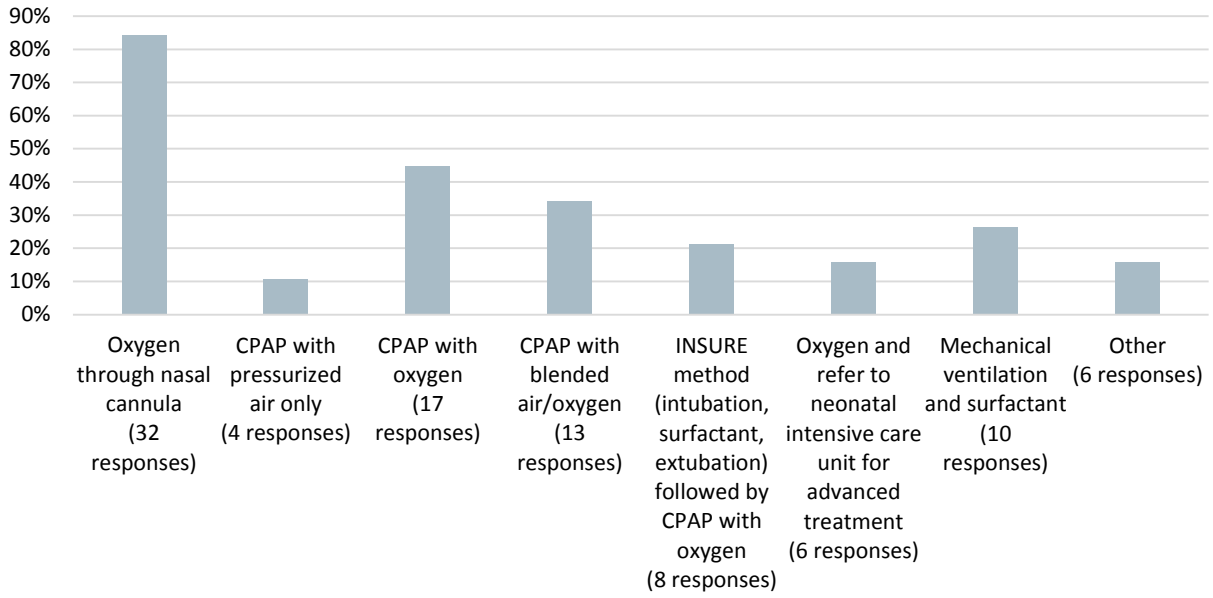
Figure 1. Number of survey respondents who fully completed the survey by country.



In addition to known contacts of PATH and our partners, survey respondents were identified through online and literature searches to discover where improvised bCPAP devices had been used in a facility setting. The respondents represented secondary- and tertiary-level facilities, with the largest group of respondents (45%) from regional referral hospitals.

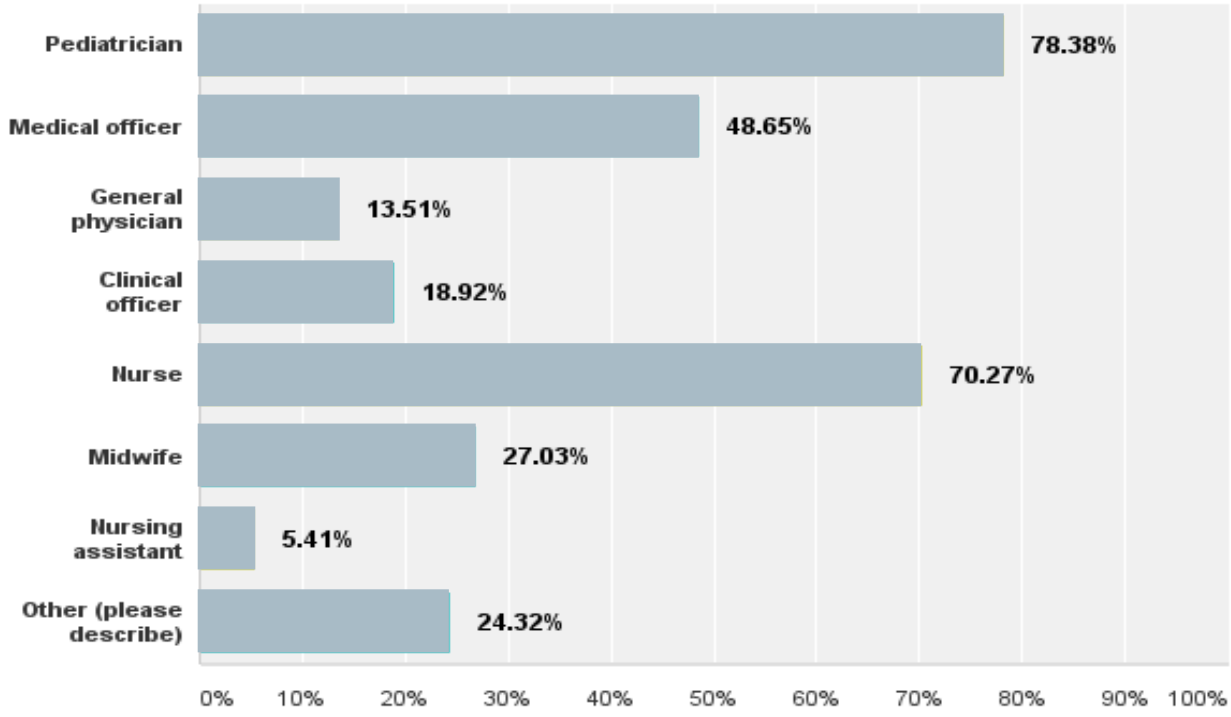
When asked about the treatments available at their facility for newborns suffering from RDS, the most widely available treatment was “oxygen through nasal cannula” (83%), followed by “CPAP with oxygen” (45%), and “CPAP with blended oxygen” (35%) (see Figure 2).

Figure 2. Treatment used for respiratory distress syndrome.



Pediatricians (79%), followed by nurses (70%) and medical officers (48%), were noted as health care workers skilled to provide CPAP therapy for RDS (see Figure 3).

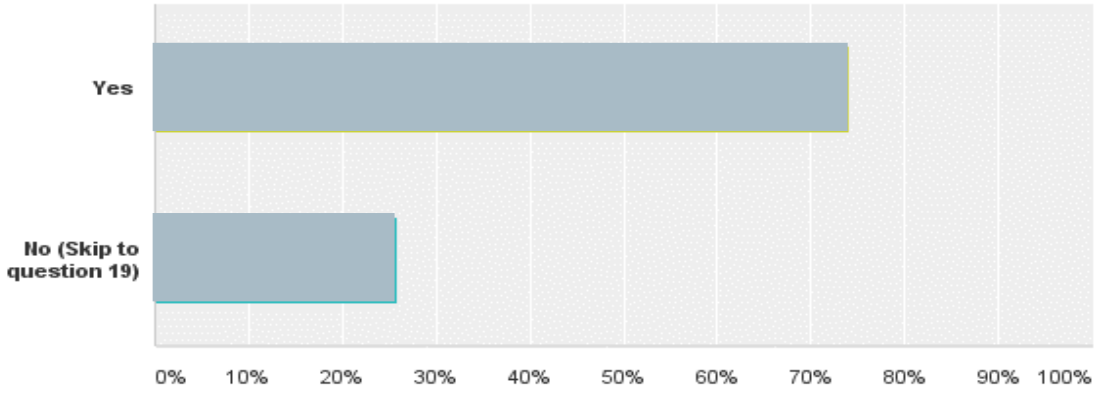
Figure 3. Health care workers skilled in provision of CPAP therapy.



However, of the 39 clinicians who responded to the question, half stated that training for the management of newborn RDS and use of CPAP therapy was not provided at their facility.

As shown in Figure 4, survey results also confirmed that bCPAP therapy is used to treat conditions other than RDS, such as pneumonia (87%) and weaning from mechanical ventilation (30%). This is useful in understanding the potential applications and market opportunities for the PATH bCPAP kit.

Figure 4. Percentage of facilities that treat conditions other than RDS with bCPAP therapy.



Insights from PATH's workshop on expanding access to bCPAP devices

PATH and our partners—Adara Development; Kiwoko Hospital; Seattle Children's; and the University of Washington, Department of Pediatrics—held a workshop at Kiwoko Hospital in Uganda in September 2015, titled "Expanding Access to Bubble Continuous Airway Pressure Devices: A Workshop for Newborn Care Providers." In attendance were more than 50 health care providers representing four African countries. See Appendix A for a detailed description of this workshop.

The following limitations of current improvised bCPAP devices were listed by attendees:

- Affordability/availability of oxygen (especially for high flows without blending).
- Understaffing and high labor burden (assembly, monitoring, cleaning).
- Inadequate training and high staff turnover.
- Need for other basic NICU services (thermoregulation, fluids, nutrition, and infection control) to be in place first.
- Lack of blending or heated humidification.
- Maintenance of equipment (operations budget, trained staff, spare parts availability).
- Misunderstanding of the theory of bCPAP operation.
- Perceptions of quality/efficacy (especially at high-level hospitals with expensive equipment).
- Acceptability for some physicians.

During their own presentations at the workshop, attendees identified many challenges associated with the use of their improvised devices, including lack of oxygen blending; scarcity of all necessary supplies;

unavailability of appropriately sized nasal prongs; inability to maintain a constant temperature of humidified air; lack of trained staff due to high turnover rates; and understaffing, which impacts the number of bCPAP devices that can be used in the NICU.

In addition, potential problems were identified with low-cost, commercially available bCPAP units. Mainly, the costs of these devices are too high for many facilities: for example, ~US$2,600 for the Breath of Life, and ~US$600 for the Pumani. In addition, these devices do not function during power outages and require training, maintenance, and spare parts. However, noted were marked advantages that some commercially available bCPAP devices can have over improvised kits, including blending (which also reduces oxygen consumption), heated humidification, proven efficacy, and greater trust in a commercial device versus an improvised device.

It seemed that the biggest role of the PATH bCPAP kit would be filling the gap between improvised bCPAP configurations and low-cost, commercial bCPAP options. The PATH bCPAP kit combines many of the features and advantages of existing commercial options with a price point that is affordable compared to facilities' current level of spending on improvised devices. Participants mentioned that even facilities with existing bCPAP machines would benefit from having the PATH bCPAP kit with blender on hand during peak periods of treatment and/or in times of power outages. Also noted was the simplicity and familiarity of design, which participants felt would be easier to train new staff to learn how to use, which is important in high-turnover situations.

For these reasons, the PATH kit has potential for use at all levels of health care facilities capable of administering CPAP. Participant responses about appropriate facilities included:

- All facilities.
- Every level lacking equipment.
- All facilities with newborns.
- Facilities with high turnover rates.

Target market segments and early-adopter countries

Initial use-case scenarios identified:

- Facilities currently using improvised bCPAP devices but experiencing barriers to consistent and effective use.
- Facilities not currently using bCPAP/CPAP devices in any format.
- Facilities using bCPAP, CPAP, or ventilator devices but experiencing issues with inconsistent use due to lack of electricity at times or lack of enough machines to treat all patients during peak periods.

The market segment of highest priority based on stated interest as well as need would be facilities below the tertiary level with labor wards. Notwithstanding, developing relationships with teaching hospitals would help to promote bCPAP adoption in lower-level facilities.

Countries in which we anticipate early interest and adoption are those in which we have formed a relationship with key supporters and champions of improvised bCPAP devices. Many of these key clinicians have also expressed interest in being a part of efforts to increase the use of bCPAP therapy within their own countries and across other developing countries, requesting to be part of any upcoming pilots to demonstrate the PATH bCPAP kit being used in a clinical setting as well as connecting with others through communities of practice and other communication channels. We are building on those relationships for next steps with clinicians in Benin, Ethiopia, Malawi, Nigeria, South Africa, and Uganda. There may also be traction in Kenya, Madagascar, and Rwanda, as the project has engaged in initial written correspondence with users of improvised bCPAP devices in those countries.

In-country procurement and distribution

Our in-country visits in Ethiopia, Rwanda (under other funding), South Africa, and Uganda allowed for initial discussions regarding the above; however, further conversations about classification of the PATH bCPAP kit and relevant policies are warranted once specifics of the kit have been determined.

A facility may have more than one way in which to procure an item. As an example, the following highlights the stated process in Rwanda:

> *Devices can be listed on the national Essential Medicines and Devices List through a Ministry-level request made to the Ministry of Health Pharmacy desk. The Pharmacy Desk would then submit a proposal to the Minister of Health for approval. When approved, the list is reviewed by a quantification workshop in each department to produce a procurement plan for each year. This plan is executed by the Central Pharmacy Service, known as the Medical Procurement and Production Division (MPDD). Tenders for specific supplies, devices, or equipment are issued by MPDD on a case-by-case basis. Devices are purchased from distributors, who are usually based in Nairobi or Dubai, or may, in special cases, be provided directly by donors. The central pharmacy then distributes items to the district pharmacy, which in turn distributes items to the district hospitals and health centers, about once a month.*
>
> *An alternate procurement pathway exists in which a district hospital may obtain funding directly from a private donor. With these funds, the hospital may submit a purchase request for direct authorization from the Ministry of Health. When approved, the hospital can then purchase the item directly from a manufacturer's representative and receive customs clearance to import the item duty free.*

During the next phase of our project, we will investigate the supply side of the strategy, such as identifying and engaging potential distributors (including assessing their capabilities and current activities around in-country distribution and export to neighboring countries), as well as determining the feasibility of pre-assembly at the distributor level. Complementing this information is the understanding of country-specific procurement, registration, and distribution processes, which is of critical importance for developing the market strategy and identifying potential early-adopter countries for PATH bCPAP kits.

Appendix C—Evaluation and Preparation for Introduction of a Low-Cost, Bubble Continuous Positive Airway Pressure (bCPAP) Kit and Oxygen Blender for Neonates

Evaluation and Preparation for Introduction of a Low-Cost, Bubble Continuous Positive Airway Pressure (bCPAP) Kit and Oxygen Blender for Neonates

SAVING LIVES AT BIRTH: A GRAND CHALLENGE FOR DEVELOPMENT

A PARTNERSHIP OF

USAID FROM THE AMERICAN PEOPLE

NORWEGIAN MINISTRY OF FOREIGN AFFAIRS

BILL & MELINDA GATES foundation

Grand Challenges Canada Grands Défis Canada

UKaid from the British people

Design Update

June 30, 2015

PATH

Photo: PATH/Alec Wollen

This project is made possible through the generous support of the Saving Lives at Birth partners: the United States Agency for International Development (USAID), the Government of Norway, the Bill & Melinda Gates Foundation, Grand Challenges Canada, and the UK Government. It was prepared by PATH and does not necessarily reflect the views of the Saving Lives at Birth partners.

Definitions

bCPAP	Bubble continuous, positive airway pressure
cmH_2O	Centimeters of water column [pressure]
DfM	Design for manufacture
FiO_2	Volume fraction of inspired oxygen [%]
LPM	Liters per minute [volumetric flow under ambient conditions]
LRS	Low-resource settings
psi	Pounds per square inch [pressure]

Status of bCPAP kit development as of September 2014

Findings

- PATH achieved proof of concept of a functional bCPAP device assembled using a variety of components that could be commonly sourced in LRS.
- User feedback overwhelming supported a pre-assembled bCPAP option over instructions for assembly.
- Not all improvised bCPAP circuits performed equally. Variables in sourced components did impact reliable performance.
- PATH achieved proof of concept of a blender that provided a 40% blend of air and oxygen that could be added to the bCPAP configuration to improve safety.

Conclusions

- Kit took too long to assemble and confidence in correct assembly was not universal.
- Different blends of oxygen would be desirable.

Current and planned activities that will inform further optimization of PATH's bCPAP design

Scope under Saving Lives at Birth funding

- Develop a pre-assembled bCPAP kit.
- Collect stakeholder feedback on design refinements from our project partners and through a series of three workshops in Africa.
- Conduct a DfM.
- Conduct additional bench testing on optimized components.

Related scope under other funding (indicated in blue throughout slide deck)

- Develop blenders with FiO_2 up to 80%.
- Optimize blenders to run on oxygen concentrators.

Summary of technical development as of June 2015

Technical scope

- Refine bCPAP kit and conduct design for manufacturing for the blender.

Status

- A landscape of potential off-the-shelf bubbler candidates has been conducted and several candidates have been identified.
- Concepts for a customized (thermoformed) blender are being generated.
- Exploring the feasibility of combining features into blender or bubbler to reduce overall number of components (e.g., wye fitting).
- Extending blender functionality to work with oxygen concentrators and higher FiO_2 (up to 80%).

Upcoming

- bCPAP kits and blenders will be brought to South Africa, Uganda, and either Ethiopia or Ghana (TBD) in order to elicit feedback and ensure design addresses existing needs and challenges.
- Initiate DfM with a US-based molding house in order to ensure final design is moldable and produced consistently.

Goals for optimizing the bCPAP kit

- Identify suitable components to maximize performance and minimize costs.
- Ensure simple and durable design.
- Compatible with commonly available nasal prongs.
- Reduce number and complexity of components.
  - Combine if possible.
- Optimize existing components, especially the bubbler.
- Assess hazards associated with reuse.

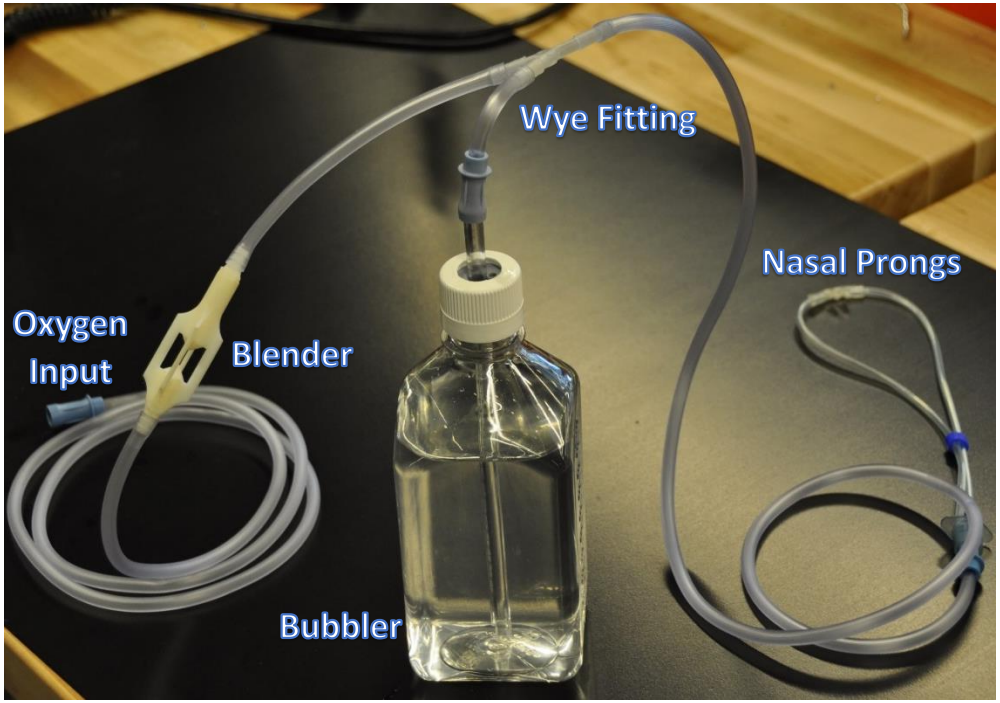


Photo: PATH/Alec Wollen

Design considerations for the bCPAP kit

A landscape* of off-the-shelf bubbler bottle options was conducted and the following components were taken into consideration when choosing the top candidates for further evaluation:

Bubbler

- Opacity, size/shape of bottle.
- Lid/opening style, potential modifications to off-the-shelf components.
- Ability to hang, stand, attach to wall.
- Potential to re-purpose existing bubble humidifier or spray bottle.
- Evaluate the benefits of a customized bubbler (thermoformed) to incorporate features such as the wye fitting and water level indicator.

Tubing

- Material, flexibility, connection to other components.

Connections

- Fitting selection, bore diameter, barb type, wye fitting.

General

- Cleanability, reusability/durability, size, cost.

*The landscape of bubbler research will be included with the midterm report.

Examples of bubbler design options explored

Photos: PATH/Alec Wollen

Oxygen blender design

Current activities that will inform further optimization of the blender

- DfM of the 40% FiO_2 blender.
- Incorporate wye functionality into blender design.
- Development of additional blenders that can provide higher flow.
- Development of additional blenders that can provide higher FiO_2.
- Optimize blender for use with oxygen concentrators in addition to other sources of oxygen.

Oxygen blender goals and specifications

As the design of the oxygen blender is being refined, the following goals and specifications are kept in mind:

Performance Requirements

- FiO_2: 40% to 80%. Stable to ± 5% across clinical ranges of pressures and blended flows.
- Clinical range of pressure: 2 cmH_2O to 10 cmH_2O (accurate to ± 1 cmH_2O).
- Clinical range of blended flow: 3 LPM to 8 LPM.

Oxygen Source

- 50 psi cylinder or wall source.
- Oxygen concentrator will be capable of producing 8.5 psi (typical for a 5 LPM unit).

DfM

- Optimize design to minimize cost and maximize production yield for injection molding.
- Explore the feasibility of “bunny ear” design, incorporating a split barb on the blender to eliminate the need for a wye fitting.

Examples of blender design and iterations

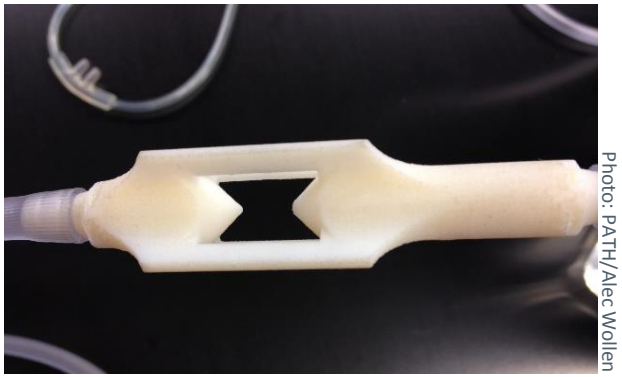


Photo: PATH/Alec Wollen

Original 40% FiO_2 blender design

Photo: PATH/Alec Wollen

Bunny ears with incorporation of wye fitting

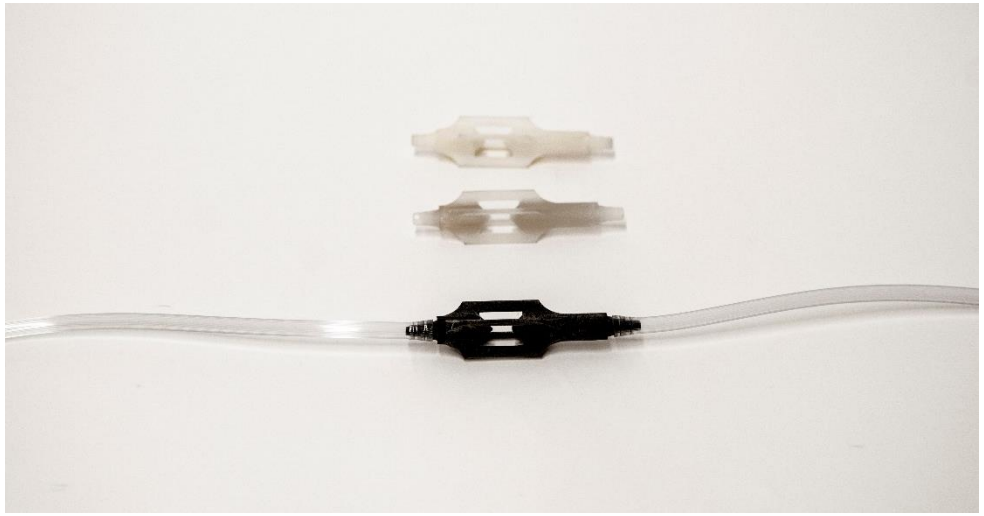


Photo: PATH/Scott Brown

Three discrete blenders for different FiO_2 levels

Gathering stakeholder feedback

In April 2015, PATH and our partners met for two days to plan for a workshop in Uganda and two ancillary workshops in South Africa and a second TBD country (Ethiopia or Ghana). Our partners are stakeholders who comprise a group of respiratory therapists, neonatologists, and clinicians who are implementers of an improvised bCPAP program in Uganda. During this planning meeting, we were able to gain valuable insights with regard to our bCPAP kit and blender designs and the context for use in LRS.

Photo: PATH/Tom Furtwangler

Gathering stakeholder feedback (continued)

During the two-day meeting, the following topics were discussed with regard bCPAP device development. These topics will also be explored during the workshops.

- Key questions to ask workshop attendees regarding context and use cases as design input that would be helpful for development.
- Validate key bubbler requirements.
- Insight on existing improvised bCPAP use.
- Cost vs. re-usability trade-off.
- Basic facility needs that should be implemented before starting a bCPAP program (e.g., infection control).
- Challenges of turnover—training new staff and how that relates to the need for simplicity of design.
- Likely use cases for PATH bCPAP and what the potential market overlap with the Pumani device might be.
- Typical oxygen and power availability situations as well as oxygen concentrator vs cylinder use.

Gathering stakeholder feedback: Workshop activities that inform design

Much of the focus of the workshops in Africa will be on information sharing and stakeholder input, all of which are intended to inform design.

Sharing improvised bCPAP kits

- PATH will share several example bCPAP kit configurations and ask for feedback.
- Attendees who use improvised bCPAP devices will be encouraged to bring their improvised solutions for presentation and discussion.
- PATH plans to bring a test lung to allow users of local solutions to see how they perform.

Stakeholder survey

- A stakeholder survey will be sent before conference to obtain information about the participants and the context in which they work. The results of the survey will be shared with the participants during the workshop.

Gathering stakeholder feedback: Workshop activities that inform design (continued)

Case study of Kiwoko Hospital improvised bCPAP rollout

- Kiwoko will present their implementation and training processes.
- The University of Washington/Seattle Children's Hospital will present results of the implementation to date.
- Adara Development will discuss challenges related to scale up.

Brainstorming session

- Validate assumptions about respiratory therapy practices in LRS.
- Share challenges and needs of neonatal intensive care unit and related newborn care settings.
- Understand what alternatives to CPAP are currently being employed.

Requirements validation

- Validate requirements and assumptions for PATH's bCPAP and oxygen blender.

Post workshop: next steps

- Document and incorporate feedback into design as appropriate.
- Revise kit design based on updated requirements including:
  - Necessary clinical range of flow, pressure and FiO_2.
  - Bubbler features (including need for a hanger or stand).
  - Appropriate length of tubing (distance of oxygen source from infant, bubbler placement).
  - Types of nasal cannula used.
- Finalize kit configuration based on suggestions and technical feasibility.
- Design for manufacturing
  - Maximize production yield
  - Minimize part cost