Ensuring oxygen and pulse oximetry access for treatment of children in low-resource settings

Consultation with manufacturers of oxygen concentrators and pulse oximetry

Photo: PATH/ Doune Porter

November 5–6, 2015

Seattle, WA, USA

Notes from Consultation

Contents

Consultation summary

I. **The attendance of nearly 60 individuals at the consultation demonstrates the level of engagement of manufacturers, distributors, and other organizations interested in this space**.

- Manufacturers were eager to share information about their companies and how they could engage in a strategy to increase availability of oxygen therapy, including pulse oximetry, in focus countries (India, Ethiopia, Nigeria, Pakistan, and the Democratic Republic of Congo).
- Participants were solutions oriented, especially technically, and expressed interest in the public health issues discussed, including the burden of pneumonia and need for oxygen therapy devices, existing work being conducted by PATH and others, barriers and challenges working in focus countries, understanding the public-sector procurement process, and the crucial role of partners and in-country connections to help facilitate the process.
- Many expressed interest in participating in moving forward and shared how they could contribute to the oxygen concentrator initiative—from advising on technical specifications, to engaging in actual product development, to selling into markets in the 5 focus countries.

II. **The consultation resulted in a convergence of ideas from industry and the identification of common challenges or barriers to product access**.

- Manufacturers openly discussed their perspectives on current market challenges: the oxygen concentrator market is highly competitive; there is already significant pressure on price reduction; and transaction costs impede entry into focus country markets.
- The complexity of distribution—cost of logistics and time to get into market—is high, and there is a need for enabling environments. A distribution infrastructure is necessary to support the endeavor. In addition, lack of regulations or changing regulations and trade agreements that discourage foreign manufacturers are a concern. However, many participants felt regulatory hurdles are solvable with other systems and incentives in place.
- After-sales support is critical to the successful introduction and utilization of oxygen concentrators. There is a lack of ownership of the burden of maintenance, and inadequate training and high staff turnover prevent local capacity for maintenance. Furthermore, health budget funds and resources dedicated to maintenance support are often limited.

III. Remaining gaps were identified for future work.

- Greater advocacy and demand generation are needed to bolster limited funding and financing prioritization from key stakeholder groups.
- Uptake and improved access to existing devices require increased awareness, knowledge and training among buyers and users; they must know what they need, how to use devices, and how to make informed purchases of good-quality devices.
- Barriers to utilization include lack of electricity and provision for maintenance that create opportunities for future work in product design and development and potential new business models.

IV. Participants were interested in next steps and requested additional information.

- Manufacturers requested more clarity on tangible demand and refined market size estimates. Critical information includes refined market segmentation and a deeper understanding of country-level buyers and user requirements.
- Manufacturers requested more information to better understand the priority of device specifications. This is critical for product development, where tradeoffs between device performance and cost are likely to occur. Manufacturers were interested in both small modifications to existing devices to make them more appropriate for developing-country settings, as well as product development for facilities with unreliable access to power and maintenance.
- Manufacturers requested costs analyses to determine price targets and affordability of devices, taking into consideration financing, transaction costs, and drivers of landed cost.
- Most participants expressed the need for a project road map for each country that is arranged by priority and includes greater clarity on the timeline and next steps for involvement.

Summary of barriers and solutions discussed

	Identified barriers	Proposed actions
Awareness	• Top-down purchasing—user does not make product selection and purchase decisions • Lack of training—costs, availability, or transportation prevent people from receiving training • Relatively small market in comparison to chronic obstructive pulmonary disease—need is there, but historical lack of demand	• Support advocacy and efforts to increase awareness—pertinent here was emphasizing the issues of quality and service, and building an understanding of the total cost of ownership • Increase studies that demonstrate clinical integration of oxygen concentrator and pulse oximetry use in these settings • Set up training programs to increase the number of users and technicians and improve uptake

Availability	• Manufacturers want a better understanding of financing with government budgets • Regulatory and distribution processes and requirements are complex and vary between countries • Service support and maintenance system are needed to maintain reliable operation of devices • Manufacturers concerned about competition and lack of exclusivity agreements for product development for such a small market	• Clarify market demand size and share with manufacturers, including ministry of health commitments and target price point validation • Provide assistance with in-country logistics, and create enabling regulatory and import environments • Help align incentives for maintenance and training—options include building in-house maintenance staff, allocating health budgets for recurring maintenance costs, including service contracts in purchase price, or including replacements for parts that are easily worn in a small compartment on the machine itself
Affordability	• Industry already has high pressure to decrease costs • Manufacturers want a better understanding of price sensitivity in these markets	• Seek local manufacturer of concentrators—taxes and other import fees are higher for exporters, but if you encourage local manufacturing this could reduce the cost • Consider oxygen delivery as a service, not a device (i.e., rental or leasing model) to necessitate servicing of the unit by the renter, and bill over a longer period of time. • Investigate demand aggregation methods, alternative business models, and innovative financing options to support risk sharing
Appropriate design	• Devices operate in tough climates and environmental conditions • End-user feedback at country level is needed to determine prioritization of specifications and realistic lifetime	• Seek funding for product development for a product that could meet both Use Case A and Use Case B (e.g., bigger capacity, disposable) • Develop revised target product profile for oxygen concentrators and pulse oximeters with simple ranking of most important specifications • Perform proof of concept pilot: demonstrate that the model being recommended is viable
Assured quality	• Provision of service and of warranties need to be justified by volume • Issues with quality control arises with local manufacturing if quality assurance measures are not in place	• Create consumer reports, product selection guidance, and list of approved vendors to help inform purchases • Investigate potential of webinar training, technician certification programs, telemedicine, and other innovative models for technical support and maintenance

Appendix I. List of participants

Developers and Manufacturers

Oxygen concentrators

AlviMedtech
- Alok Gupta, Director
- Vivek Gupta, Managing Director

Chart Industries
- Paul Edwards, Director of Engineering
- Sara Farling, Regional Sales Manager

Drive Medical
- Allan Jones, Director of Engineering, Research and Development

Inogen
- Pete Hanson, Research & Development Manager
- Byron Myers, Vice President, Marketing

Invacare
- Bob Messenger, Manager, Clinical Education
- Tim Lis, Director of Global Product Development, Respiratory
- Sam Shelnutt, Director of Engineering

Global Good
- Dan Lieberman, Project Lead
- Celina Schocken, Global Health Advisor

Gradian Health Systems
- Ismael Cordero, Biomedical Services Manager
- Stephen Rudy, Chief Executive Officer

O2 concepts
- Bill Lindsay, Vice President, International

Philips
- Niels Buning, Venture Manager
- Pavan Dadlani, Project Leader

Pulse oximetry

Acare Technology
- Linda Cheng, Chief Executive Officer
- Lisa Hsu, Assistant

Lifebox
- Isabeau Walker, Consultant Anesthesiologist
- Iain Wilson, Anesthesia Consultant

Masimo
- Jon Coleman, President, Worldwide Sales, Professional Services and Medical Affairs
- Anand Sampath, Chief Operating Officer

International Partners

AIT Worldwide Logistics
- Eric Klunder, Account Manager

Clinton Health Access Initiative (CHAI)
- Jeff Grosz, Country Director, Uganda
- Jason Houdek, Senior Technical Advisor
- Frederic Seghers, New Market Opportunities
- Habtamu Seyoum Tolla, Senior Program Manager

IDA Foundation
- Daan Istha, Area Manager

Imres
- Jarno de Lange, International Account Manager
- Erwin van Boven, Account Manager

World Health Organization Collaborating Center (WHO CC) for Priority Medical Devices & Health Technology Policy, National Health System Resource Center (NHSRC), Ministry of Health and Family Welfare, Government of India
- Anjaney, Consultant, Healthcare Technologies (Medical Devices)

Sanrai Med
- Jim Gilkison, Global Director of Sales

United Nations Children's Fund (UNICEF)
- Kristoffer Gandrup-Marino, Chief of Innovation
- Bissie Tarekegn, Pneumonia Program Officer

Consultation Hosts	
The Bill & Melinda Gates Foundation (BMGF) • Becky Frank, Deputy Director, Strategy Planning and Management • Rasa Izadnegahdar, Senior Program Officer, Pneumonia • Tracy Johnson, Senior Program Officer, Integrated Delivery • Steve Kern, Deputy Director Quantitative Sciences, Integrated Development • Katie Maloney, Program Officer, Pneumonia • Susie Nazzaro, Senior Program Officer, Integrated Delivery • Janna Patterson, Senior Program Officer, Maternal, Neonatal, and Child Health • Joel Segre, Independent Consultant, Maternal, Neonatal, and Child Health • Matthew Steele, Senior Program Officer, Integrated Delivery	**PATH** • Glenn Austin, Senior Advisor • Andy Beddoe, Product Development Officer • Ben Creelman, Engineer • Ray Cummings, Director, Market Dynamics • Todd Dickens, Procurement Officer • Jaclyn Delarosa, Senior Program Associate • Mike Eisenstein, Product Development Shop Manager • Jody Garcia, Consultant, Commercialization • Amy Ginsburg, Senior Clinical Research Scientist • Claudia Harner-Jay, Senior Commercialization Officer • Emily Jeffers, Project Administrator • Nick Luter, Market Dynamics Specialist • Michael Ruffo, Commercialization Associate • Gene Saxon, Program Officer • Alec Wollen, Product Development Shop Technician • Grace Wu, Postdoctoral Associate, Biomedical Engineering • Priscilla Yoon, Program Assistant • Darin Zehrung, Program Advisor and Project Lead

Appendix II. Consultation agenda

Day 1: Stimulate manufacturers of oxygen concentrators and pulse oximetry to increase penetration of devices in low- and middle-income country markets.

- Demonstrate the market outlook for oxygen concentrators and pulse oximeters in focus markets.
- Understand potential barriers and challenges to product access and identify strategies to overcome them.

Day 1: Thursday, November 5, 2015

Location: The Bill & Melinda Gates Foundation Headquarters
500 Fifth Avenue North | Lake Washington Conference Room | Seattle, WA 98109

TIME	AGENDA ITEM	CONTENT
8:00 – 8:30 a.m.	*Registration check-in / Breakfast*	
8:45 – 9:25 a.m.	Welcome	**Introductions and consultation objectives** Speakers: Rasa Izadnegahdar (BMGF) and Darin Zehrung (PATH)
9:25 – 9:50 a.m.	Session 1: The Bill & Melinda Gates Foundation oxygen strategy	**The role of oxygen and pulse oximetry: addressing the global burden of childhood pneumonia** Speakers: Rasa Izadnegahdar and Susie Nazzaro (BMGF)
9:50 – 10:15 a.m.	Session 2: Ensuring access to oxygen therapy in low-resource settings	**An introduction to PATH's work on oxygen delivery technologies for treatment of children around the world** Speakers: Gene Saxon and Grace Wu (PATH)
10:15 – 11:00 a.m.	Session 3: Market and opportunity	**Current demand and market outlook for oxygen concentrators and pulse oximetry in focus countries** Speakers: Jody Garcia and Michael Ruffo (PATH)
11:00 – 11:15 a.m.	*Break*	
11:15 a.m. – 12:00 p.m.	Session 4: Commitments to strengthening availability, access, and quality of affordable health solutions	**Bridging the gap: visions of success and priorities for oxygen concentrators and pulse oximetry in low-resource settings** Speakers: CHAI, UNICEF, WHO CC
12:00 – 1:30 p.m.	*Lunch and presentations on training, maintenance, and distribution* *Speakers: Gradian Health Systems, IDA Foundation, Imres, and Sanrai Med*	
1:30 – 2:30 p.m.	Session 5: Discussion on potential barriers and challenges to product access in low- and middle-income countries	**Common challenges or barriers that prevent access to oxygen concentrators and pulse oximetry in low- and middle-income countries from the perspectives of product developers and international partners** Facilitator: Glenn Austin (PATH)
2:30 – 3:30 p.m.	Session 6: Discussion on potential approaches to enhance access to oxygen concentrators and pulse oximetry for children in low-resource settings	**Sustainable products and potential health impact: strategies and opportunities for collaboration to overcome major challenges or barriers to access** Facilitators: Glenn Austin and Claudia Harner-Jay (PATH)
3:30 – 3:45 p.m.	*Break*	
3:45 – 4:45 p.m.	Session 6: Continued	
4:45 – 5:00 p.m.	Closing remarks and next steps	**Remaining questions and continuing engagement** Speakers: Rasa Izadnegahdar (BMGF) and Darin Zehrung (PATH)

Day 2: Individual meetings with consultation hosts to define potential partnership models and expectations for collaboration.

- Identify partnership opportunities to increase uptake of oxygen concentrators and pulse oximetry in focus countries.
- Identify technical and business scopes required to fulfill desired product specifications to reach target markets.

Day 2: Friday, November 6, 2015

Location: PATH Headquarters | 2201 Westlake Avenue, Suite 200 | Conference Room 226 | Seattle, WA 98121

<table>
<tr><th>TIME</th><th colspan="3">AGENDA ITEM</th></tr>
<tr><td>7:30 a.m. and 8:30 a.m.</td><td colspan="3">The Maxwell Hotel to PATH departures (2201 Westlake Avenue, Suite 200, Seattle, WA 98121)</td></tr>
<tr><td>8:00 – 9:00 a.m.</td><td colspan="3">Breakfast</td></tr>
<tr><td>8:30 a.m.</td><td colspan="3">(Optional) PATH Product Development Guided Tour</td></tr>
<tr><td colspan="2">DAY 2: PATH INDIVIDUAL MEETINGS</td><td colspan="2">Day 2: (Optional) WORKING MEETINGS</td></tr>
<tr><td>9:00 a.m. – 12:30 p.m.</td><td>PATH will be requesting individual meetings with participants. Priscilla Yoon will provide the meeting time and details. For additional questions, please contact Priscilla Yoon (pyoon@path.org).</td><td>9:00 – 10:00 a.m.</td><td>Oxygen concentrators and pulse oximetry: designing appropriate technologies for use in infants and children in low-resource settings

Speakers: Lifebox, Global Good
Facilitator: Andy Beddoe (PATH)</td></tr>
<tr><td></td><td></td><td>10:00 – 11:00 a.m.</td><td>Panel discussion on training and maintenance: important considerations for oxygen concentrators and pulse oximeters and potential solutions for impact

Speakers: Gradian Health Systems
Facilitators: Ben Creelman, Mike Eisenstein, and Alec Wollen (PATH)</td></tr>
<tr><td>11:00 – 11:15 a.m.</td><td>Break</td><td>11:00 – 11:15 a.m.</td><td>Break</td></tr>
<tr><td></td><td></td><td>11:15 a.m. – 12:15 p.m.</td><td>Panel discussion on distribution of affordable, quality, and appropriate oxygen concentrators and pulse oximeters to focus countries

Speakers: AIT Worldwide Logistics, IDA Foundation, Imres, Sanrai Med
Facilitator: Todd Dickens (PATH)</td></tr>
<tr><td>12:15 – 1:15 p.m.</td><td colspan="3">Lunch</td></tr>
<tr><td colspan="4">DAY 2: PATH INDIVIDUAL MEETINGS</td></tr>
<tr><td>1:15 – 3:15 p.m.</td><td colspan="3">PATH will be requesting individual meetings with participants. Priscilla Yoon will provide the meeting time and details. For additional questions, please contact Priscilla Yoon (pyoon@path.org).</td></tr>
<tr><td>3:15 – 3:30 p.m.</td><td colspan="3">Break</td></tr>
<tr><td>3:30 – 4:30 p.m.</td><td colspan="3">Individual meetings with participants continued.</td></tr>
</table>

Appendix III. Participant survey responses

I. What are the main takeaways from this consultation?

- Education and infrastructure are the biggest hurdles to solve the problem.
- The need is great but the process is complicated to get medical devices into low-resource settings (LRS).
- The main takeaways from this consultation: a) manufacturers' barriers in terms of supply, installation, and maintenance work, and b) this is important and needs to be highlighted on priority in developing countries and low resource setting.
- The complete supply chain of providing medical equipment to the LRS [low-resource settings] is plagued with many barriers.
- Possible to link supplies and end users on oxygen and pulse oximetry; the oxygen concentrator and pulse oximetry market needs huge work especially for RLS [resource-limited settings].
- Both oxygen concentration and pulse oximetry are interesting areas to explore further.
- This is a need and opportunity for oxygen concentrators in SSA [Sub-Saharan Africa]. The challenges are significant and potentially represent barriers to market entry without the support and collaboration with established NFP [not-for-profit] partners.

II. What was most beneficial to you?

- Establishing a better understanding of the challenges and overall landscape of problem and plan.
- Networking and market insight.
- Detailed discussions on barriers needs to be [rectified], we would certainly work on this area for better services.
- Awareness is another way to improve the scenario of mortality due to pneumonia. NGOs [nongovernmental organizations] or nonprofit organizations will come forward for this.
- Hearing the presentations on the first day and the discussions on the first day.
- Sessions 1–4.
- An opportunity to sell into the LRS is possible.
- Manufacturer challenges is getting in-country and work to be done by [me]. Next focus and priority to invest on concentrators and pulse oximeters. Low cost, high quality technology in pipeline.

III. Would you attend a similar consultation in the future?

- All said YES.
- Could be a bit less repetitive and reduced to a single day
- As we are currently working on many projects hopefully we will help out in capturing the details in terms of availability and services etc.

IV. What unanswered questions do you have?

- They have all been communicated.
- Real market potential, demand remains vague.
- What are the innovations we are [bringing] in the presently available technology, as well as would it be cost effective in context of low resource setting?
- What is the direction the agencies want to take? How can the agencies help solve the infrastructure problems in the countries?
- What is the vision for "integrating" pulse oximetry with O2 concentrators?
- Market availability vs. putting the devices in right place and time. Financial funding issues.
- None. Thank you for the opportunity.

V. What other feedback would you like to share?

- It was a great experience to meet the expert from BMGF, PATH and industry. Discussing barriers and solutions, session was [interactive] and informative as well [to] understand the scenarios in the other developing countries. It was [organized] perfectly [wishing] the whole team of BMGF [and] PATH for a great [effort].
- The technology exists to solve the problem. The biggest issue is the infrastructure of the countries.
- Great start! Look forward to continued collaboration!
- This is a superb work and initiative (bringing manufacturers and stakeholders like program [people]). Needs to be continued!