Accelerating Access to Oxygen Convening Summary

Contents

ABBREVIATIONS

CHAI	Clinton Health Access Initiative
EML	Essential Medicines List
EMLc	Essential Medicines List for Children
GFF	global financing facility
LMIC	low- and middle-income countries
LPM	liters per minute
MNCH	maternal, neonatal, and child health
MOH	Ministry of Health
NCD	noncommunicable disease
NHSRC	National Health Systems Resource Center
PPP	public-private partnership
UNICEF	United Nations Children's Fund
WHO	World Health Organization

EXECUTIVE SUMMARY

The A2O2: Accelerating Access to Oxygen convening was a three-day meeting held in Dubai November 7–9, 2017. The purpose of the meeting was to foster information sharing and active dialogue between key stakeholders. To achieve this, the agenda included plenary and panel presentations, small-group breakouts, and roundtable working-group sessions (full agenda included in Appendix A). The convening included 102 participants representing four stakeholder groups: country decision-makers, global health partners, financiers, and manufacturers (full attendee list included in Appendix B).

Image 1. A2O2 convening attendees. Photo: PATH/Spike Nowak

The meeting opened with welcome remarks by a consortium of global partners in the oxygen space. These presentations helped establish a baseline understanding for why access to safe oxygen remains unreliable. Presenters described how oxygen is a systems issue that requires coordination across disease areas and health services. It is often overlooked or assumed to be available; however, there is limited awareness of functional availability.

Once the scene was set, leaders from five of the nine country delegations in attendance at the convening walked through their safe oxygen delivery need and direct experiences with scaling access. While the approaches vary from country to country, each country delegation gained a sense for the activities that contribute to improved access to safe oxygen. Delegations and industry were also able to agree that quantification of need remains underutilized. Closing remarks in the first session outlined several quantification approaches that could aid countries in planning and inform business cases for industry.

The afternoon of the first day was structured as small-group discussions focused on the components required to accelerate product selection and industry engagement. The core components included effective planning for implementation, enabling policies, appropriate regulations, and specifications to guide device

selection. Planning approaches stood out during this session as a key takeaway. Needs assessments are essential to first understanding and then beginning to address gaps in access.

The focus shifted to industry perspectives on current device use and innovation potential on the morning of the second day. Industry's vital role in helping to increase access to safe oxygen was discussed with ten of the twenty companies in attendance. Industry members expressed a desire for commitments from the country delegations to finance safe oxygen delivery. Countries highlighted the role industry can play in trialing innovative partnership models and suggested practical device improvements like increasing the compatibility of probes or cables across brands and models.

The afternoon of the second day was spent in small-group discussions where the aspects of supportive systems for safe oxygen delivery in LMIC were considered. This session highlighted methods to ensure sustained operation of medical devices. Topics included streamlined procurement through coordinated ordering, asset management, maintenance strategies to ensure continued device functionality, and budgeting practices that account for costs over time. Improvements in budgeting and tender process for oxygen are needed to support procurement of more appropriate devices. Further, innovation in financing and payment processes is needed improve the efficiency of payment and reduce oxygen service interruptions.

On the final day of the convening, country delegations dedicated time to create or refine work plans that increase access to oxygen in their countries. The goal of this country-led planning session was to identify next steps and (depending on the countries' progress to date) revise, or begin to develop, oxygen and pulse oximetry scale-up strategies. Delegations agreed that it is essential to coordinate scale-up activities across health directorates, partners, financiers, etc. In addition, while this meeting did not focus on strategies for improved clinical practice, a key takeaway for delegations was that health care workers require improved training for when and how to delivery oxygen safely. The group briefly reviewed key takeaways from the three days of concentrated discussion and ended the meeting with actionable next steps and optimism about what is possible. The meeting concluded with a reminder that a continued focus on the patients, particularly the children, we seek to serve will help keep this issue a priority.

DAY ONE—TUESDAY, 7 November 2017

The morning began with a brief welcome and introduction from PATH, the Bill & Melinda Gates Foundation, United Nations Children's Fund (UNICEF), and the World Health Organization (WHO). The remainder of the morning session focused on country experiences with scaling access to safe oxygen delivery. The afternoon included small-group discussions focused on how to create an enabling local market and components required to accelerate product selection and industry engagement.

WELCOME REMARKS

PATH opened the meeting with an overview of the meeting attendees and goals. This session was also used to level-set attendees around what is known about oxygen access. PATH reviewed the portfolio of work that led to the convening, the Gates Foundation reviewed their oxygen investment strategy to date, and UNICEF and WHO described related current and future work in this space. The first key takeaway from this session is that oxygen is often overlooked or assumed to be available but there is limited awareness of functional availability. The second takeaway is that oxygen is a systems issue that requires coordination across disease areas and health services.

PATH

Presenter: Ray Cummings, Director, Market Dynamics

Convening goals include:

- Sharing lessons learned and expertise across countries.
- Facilitating connections and transparency between country leadership and suppliers.
- Discussing opportunities for accelerating improved access to safe oxygen delivery.

Over 100 participants joined the convening representing:

- 9 countries
- 8 partner organizations
- 5 financiers
- 21 private-sector companies

PATH's background in oxygen work included a series of hypotheses that led to the current scope of work:

- Hypothesis one: Existing oxygen delivery technologies require innovation to improve their use in LMIC.
  - Project finding: with some caveats, existing technologies can be deployed today for LMIC oxygen delivery.

Hypothesis two: Incentives and specific programs are needed to increase manufacturer engagement/sales in LMIC

- Project finding: many suppliers are selling safe oxygen delivery technologies in LMIC with at least one stringent regulatory approval.

Next step: Ensure the systems to procure, install, train staff on, and maintain equipment are functioning to facilitate continued access.

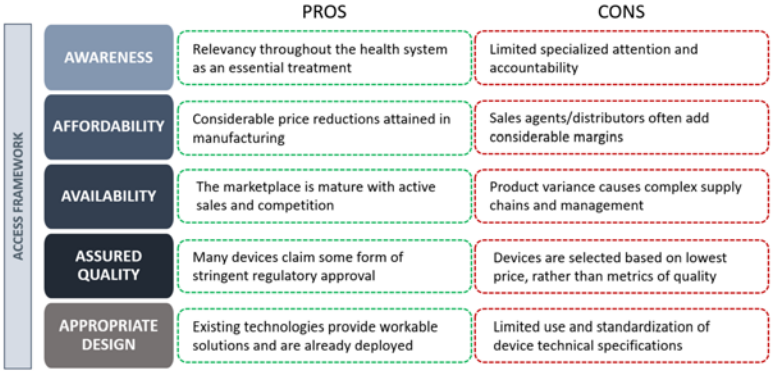


Figure 1: Pros and cons of existing safe oxygen access.

PATH's recent work in safe oxygen delivery found that:

- Designing solutions for safe oxygen delivery is complex (Figure 1).
- Safe oxygen supply requires supporting activities; however, lessons apply to many other medical devices.
- Solutions require engagement from stakeholders across the health system.

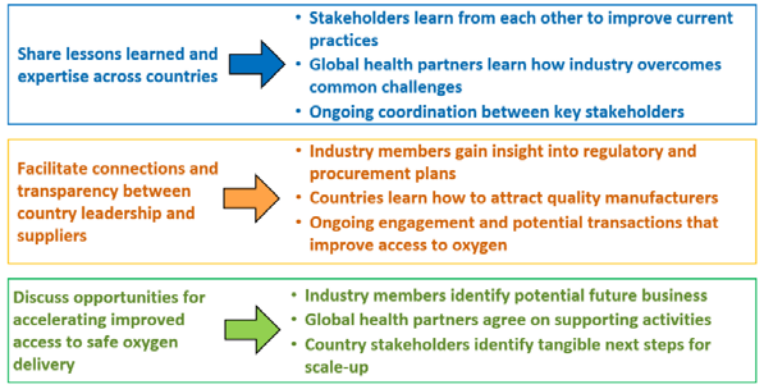


Figure 2: Examples of successful outcomes for the A2O2 convening.

PATH's welcome remarks ended with a brief discussion of successful convening outcomes (Figure 2) and an overview of the convening agenda.

Bill & Melinda Gates Foundation

Presenter: Dino Rech, Senior Program Officer

Oxygen is a health systems issue as it is essential to treatment for many conditions. Child health (e.g., treatment of pneumonia) is often the first focus for oxygen scale-up efforts.

However, broader cross-departmental efforts are needed to improve access. Beyond availability of devices, functional availability (e.g., devices that are available and functioning as intended) is limited in LMIC.

The Gates Foundation has several investments to support increased access to safe oxygen (Figure 3). The A2O2 convening will aid with priority setting for future investments in this space.

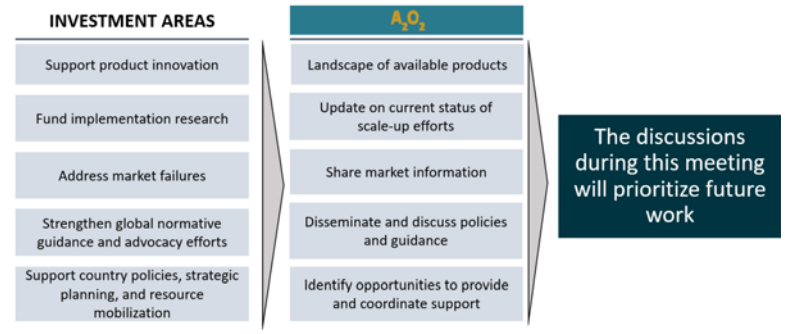


Figure 3: How A2O2 links to Gates Foundation investments

UNICEF

Presenter: Kristoffer Gandrup-Marino, Chief of Innovation

UNICEF serves as a core partner for governments around the world in ensuring improved maternal and newborn health outcomes. They are leading many efforts around pneumonia prevention and treatment; medical oxygen and pulse oximetry play a central role in the treatment of pneumonia.

UNICEF procured over $5 million worth of oxygen equipment between 2012 and 2016. The UNICEF catalogue currently carries ventilators, nebulizers, concentrators, and portable pulse oximeters for oxygen therapy delivery. UNICEF procures other oxygen devices and consumables in oxygen kits.

The Gates Foundation funded strategic collaboration between UNICEF and WHO to improve access to and utilization of oxygen therapy systems:

- Output 1: Interagency technical specifications and guidance for procurement of oxygen system products and components (tier 1).
- Output 2: UNICEF catalogue updated with specifications, technical guidance, and new procurement mechanisms to include a more robust and appropriate selection of oxygen system products.
- Output 3: Functioning prototype of oxygen therapy tool developed to provide strategic and technical support for oxygen system selection and upgrades at all levels of the health care system.

UNICEF's role in oxygen space:

- UNICEF is committed to improving access to and utilization of lifesaving oxygen system products globally.
- Its collaboration with WHO is in its first phase with longer-term oxygen work planned.
- Innovation remains an important facet of improving access to safe oxygen delivery for UNICEF.
- UNICEF will continue to engage country offices in oxygen scale-up efforts.

WHO

Presenter: Adriana Velazquez Berumen, Senior Advisor on Medical Devices

Medical devices are technologies indispensable for accomplishing the health-related Sustainable Development Goals. WHO is leading a variety of initiatives to provide guidance on the selection, deployment, maintenance, and disposal of essential medical devices. As with many other medical devices, safe oxygen delivery requires accurate quantification of need to ensure availability as well as proper use and maintenance to achieve sustainable impact.

WHO has contributed to oxygen normative guidance in a variety of ways. In 2017, WHO approved a change to the Essential Medicines List increasing the number of indications for which oxygen is recommended in treatment. The Model Essential Medicines List (EML) and Essential Medicines List for Children (EMLc) now include oxygen as an essential medicine for hypoxemia. WHO's partnership with UNICEF will result in development of technical specifications for related oxygen technologies: oxygen supply systems, delivery systems, oxygen monitoring tools, and technical support tools.

SESSION 1: OUTLINING THE OPPORTUNITY

During the first session of the convening, lead delegation members from five countries described local efforts underway to improve safe oxygen delivery.

This included a review of safe oxygen delivery access, quantification of gaps in functional availability, and reflections on successes and persistent challenges for increasing access to safe oxygen delivery in their countries. Each 30-minute session consisted of a 10-minute presentation followed by a 20-minute question-and-answer period led by Dino Rech from the Bill & Melinda Gates Foundation (Image 2).

Image 2. Dino Rech speaks with Dr. Yared Cherenet and Alemayehu Berhanu from Ethiopia. Photo: PATH/Spike Nowak

Presentations provided valuable context to industry and global health partners around the various stages of oxygen access and scale-up. For industry, it was particularly useful to understand the types of oxygen systems installed in each country as well as plans for selecting and financing oxygen delivery solutions to fill remaining gaps in access. For global health partners, it was helpful to understand which facets of oxygen access tend to be context-specific and which approaches can be applied across geographies. Quantification was also highlighted as an area that remains underutilized and several approaches were recommended depending on the data available and level of accuracy required.

Ethiopia

Presenters:

Dr. Yared Cherenet, Newborn and Child Health Programs Technical Assistant, Ministry of Health

Alemayehu Berhanu, Senior Program Officer, Clinton Health Access Initiative (CHAI)

Summary:

The Ethiopia delegation began presentations by highlighting its many accomplishments improving maternal, neonatal, and child health (MNCH), including safe oxygen delivery. Notably, Dr. Cherenet shared that Ethiopia achieved Millennial Development Goal 4 two years prior to the intended time.

With support from CHAI, an assessment of oxygen availability was done in 2015. This assessment demonstrated low functional availability in health centers and hospitals. Quantification efforts revealed a gap in oxygen and pulse oximetry availability of 234,000 M^3 per month and approximately 9,000 units, respectively. The number of additional pulse oximeters needed rises to approximately 24,000 units if health centers are included in the estimation.

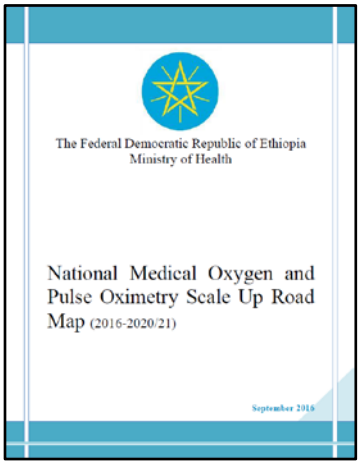


Image 3: Ethiopia National Medical Oxygen and Pulse Oximetry Scale Up Road Map (2016-2020/21).

Because of these findings, the Ministry of Health (MOH) committed to the development of a National Medical Oxygen and Pulse Oximetry Scale Up Road Map (Image 3). The road map was published in 2016. Under its implementation, clinical and biomedical engineering training modules were created, specifications were developed for oxygen concentrators and oxygen plants, and 130 biomedical engineers have been trained to support scale-up. Sustained political commitment has been key in medical oxygen and pulse oximetry scale-up progress thus far. Ensuring sufficient financing will be another major key to success.

Next steps under the road map include:

- Building capacity of clinicians and biomedical engineers.
- Improving supply and logistics for O2 and pulse oximetry.
- Strengthening maintenance capabilities.
- Increasing sustainable funding for continued scale-up.

Discussion questions:

What would you consider your greatest successes in scale-up of oxygen delivery and pulse oximeters?	The national road map provides a clear strategic direction for advocacy, resource mobilization, and planning. Government commitment and collaboration between partners (e.g., MOH, CHAI, and others) has been key to success thus far.
What would you consider your greatest challenge in scale-up of oxygen delivery and pulse oximeters?	Establishing a sustainable financial system to meet the goals set forth in the road map has been a challenging facet of this work.
How have you balanced financial resources from national and external sources?	Government will need to prioritize funding for this program and some of this support will come through scale-up of the health care financing system for hospitals that will soon have access to a revolving fund to procure oxygen. However, Ethiopia will not be able to provide 100 percent funding and so some assistance will be required.

India

Presenters:

Dr. Ajay Khera, Deputy Commissioner & In Charge, Child Health, Ministry of Health and Family Welfare
Dr. Anil Kumar, Additional Deputy Director General, Directorate General of Health Services, Ministry of Health and Family Welfare

Summary:

The India delegation emphasized its continued commitment to the Sustainable Development Goals and that the health of mothers and children remains the highest priority of the government of India. Within these initiatives, activities are underway at the national and state levels that will improve access to oxygen (Figure 4). However, oxygen has not been given adequate individual attention.

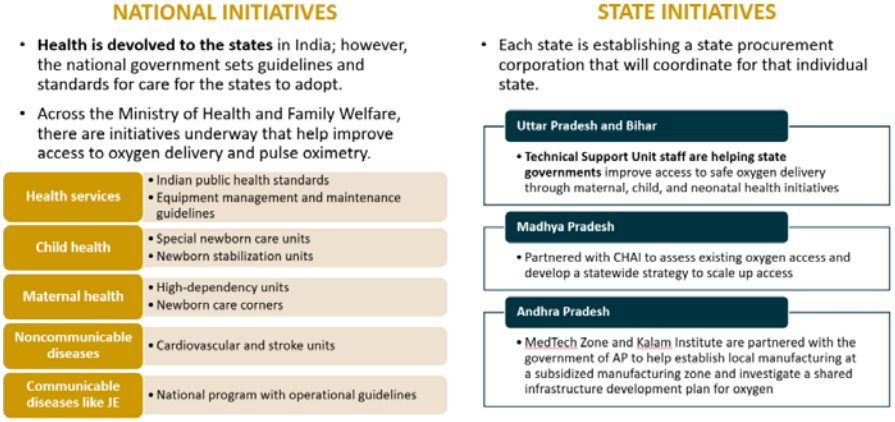


Figure 4. National and state initiatives underway to increase access to safe oxygen in India.

Additional information on the availability, capacity, and functionality of oxygen plants and cylinders is needed to accurately estimate the gap in oxygen availability. Most hospitals rely on liquid oxygen; however, there is very little known about the suppliers. A landscape of high-quality suppliers would be an asset for procurers. There is some discussion of developing an agency that focuses on medical devices to help ensure quality, as is done with pharmaceuticals. Effective supply chains and maintenance systems remain critical to ensure devices remain operational. Alerts in inventory management systems are being considered as a way to forewarn potential oxygen shortages. Efforts to improve the supply chain and maintenance of required equipment for newborn care units and vaccine cold chain have yielded important insights for safe oxygen delivery.

Rational use of oxygen is an issue the government will begin advocating for with health providers. States will lead the implementation of most oxygen scale-up activities. Future activities include:

- Conducting thorough needs assessments periodically.
- Developing/revising technical guidelines and standard operating procedures for oxygen.
- Performing medical college and hospital oxygen training through modular approach.
- Dedicating project implementation plan funds for procurement of oxygen equipment and consumables.

Discussion question:

How does India intend to coordinate a response across the national and state levels?	The National Health Mission was created through the universal health coverage mechanism. Health systems issues are managed by individual states under the National Health Mission. National stakeholders can help by declaring that oxygen is an essential part of the health care system. They can then conduct advocacy—for capacity-building with health care providers and to strengthen supply chain systems—with state program implementers and planners that oxygen is essential to high-quality care.

Indonesia

Presenter: Dr. Andi Saguni, Director of the Health Service Facility Directorate, Ministry of Health, Indonesia

Summary:

Dr. Saguni began his presentation by describing how the health system in Indonesia was decentralized in 2000. The goal is for all citizens to be covered by national health insurance by 2019. All health facilities that are covered by the national health insurance scheme must be accredited and comply with facility standards. National standards dictate equipment requirements for individual facilities.

Aplikasi Sarana, Prasarana & Peralatan Kesehatan (ASPAK) is the system in Indonesia used to track equipment in health facilities. This database is a valuable tool for tracking availability and gaps. Leveraging it, the MOH found that availability of oxygen is relatively high, with 87 percent of facilities reporting some type of oxygen delivery device. Mapping the data illustrated that oxygen is less available in remote regions (Figure 5). Analysis also showed that pulse oximeters were available in most hospitals but less so in lower-level facilities. With gaps identified, facilities can procure through an online catalogue called e-Katalog.

Figure 5. Availability of oxygen in the Indonesian public health system.

With knowledge of current availability, the delegation will now focus on determining the functional availability of equipment while also cascading training from central- and district-level groups to improve how oxygen is used. Further, Indonesia will continue to expand e-Katalog and build capacity for equipment maintenance by establishing a policy for provincial- and district-level maintenance services.

Discussion questions:

Are there any ways to improve on the ASPAK database?	Further integration of the ASPAK database between the central government and districts would benefit decision-makers. It will also be important to assess ASPAK data for quality and completeness to ensure policy decisions are made based on good data. Finally, linking the ASPAK system to routine monitoring and evaluation capabilities will allow tracking progress against national standards.
How can the global community leverage the experience of e-Katalog to make pricing more transparent?	There is room for improvement, but the e-Katalog has greatly improved the process from previous direct-procurement processes. This experience is something other countries can leverage in their procurement of medicines and medical devices.

Kenya

Presenter: Dr. Jackson Kioko, Director of Medical Services, Ministry of Health, Kenya

Summary:

Health is a devolved function with most service delivery responsibilities falling on the 47 counties. The national government is responsible for policies, strategies, and capacity-building. Primary health care services are provided free, including pregnancy and delivery procedures. One of the largest challenges around commodity availability is the capacity to quantify and forecast. Findings from a recent survey of 18 counties found that only 15 percent of facilities provide oxygen. Oxygen availability tended to be higher in major hospitals than in primary health centers. Only 6 percent of facilities had pulse oximetry, most in higher-level facilities. There were 46 oxygen plants throughout Kenya, many providing oxygen to a single ward.

Kenya has established many innovative programs to improve medical device and oxygen access, including the managed equipment services program, the Hewa Tele oxygen plant, and a platform to strengthen primary health care. Persistent challenges include coordinating initiatives across counties, fragmented procurement, limited capacity to manage medical equipment, and inefficient allocation of financing. Kenya is now in the process of designing a comprehensive strategy to scale access to safe oxygen outlined in Figure 6.

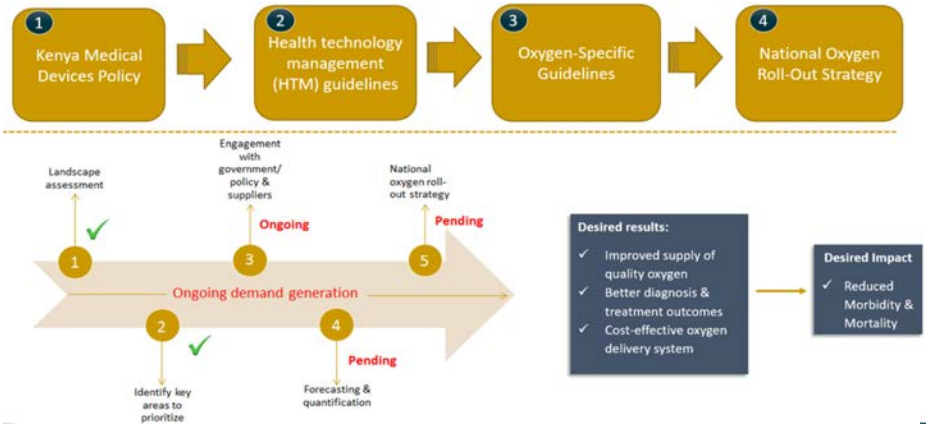


Figure 6. Kenya's path forward to increase access to oxygen.

Discussion questions:

Can you provide more detail on how the public-private partnerships (PPPs) work and how you are leveraging them to improve health outcomes?	A dedicated ministry unit, chaired by the cabinet secretary, oversees private-sector equipment. Partnerships with the private sector bring new medical devices and the skills to maintain them to the Kenyan health system.
Is there a significant difference in cost when comparing PPP delivery with pure government delivery model?	The government is always seeking sustainability and efficiency in the provision of care. It is difficult and costly for the government to maintain equipment. PPPs are considered cost-effective.
How can the Global Financing Facility (GFF) be leveraged to improve reproductive, maternal, neonatal, and child health (MNCH) outcomes?	Oxygen is an important treatment for MNCH. The Kenya delegation will investigate how oxygen can be included in future GFF support.

Nigeria

Presenters:

Dr. Gilbert Shetak, Senior Medical Officer, Ministry of Health, Nigeria
Tayo Olaleye, Associate, Essential Medicines, Clinton Health Access Initiative (CHAI)

Summary:

Pneumonia is the single greatest cause of under-five mortality in Nigeria, responsible for 17.8 percent of all deaths. A baseline assessment completed in eight focal states found that 11 percent of secondary and tertiary health facilities with inpatient departments had functional pulse oximeters. One-third of children admitted with probable hypoxemia (n = 434) received an order for oxygen therapy; however, only 77 percent of these received oxygen. There are at least 30 oxygen generation plants in Nigeria with an estimated production capacity of approximately 100 million liters of oxygen per month, which remains short of the estimated oxygen need.

The Federal Ministry of Health and the National Primary Health Care Development Agency have revised four key policies for safe oxygen delivery, including a national policy on medical oxygen in health facilities and a national strategy for scale-up of medical oxygen in health facilities (Image 4). In addition, a national oxygen desk has been established, a joint investment is under development for three northern states, and many activities have been identified as part of a long-term scale-up strategy (Figure 7).

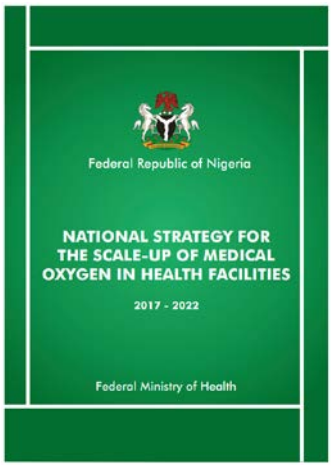


Image 4. Nigeria National Strategy for Scale-Up of Medical Oxygen in Health Facilities, 2017–2022.

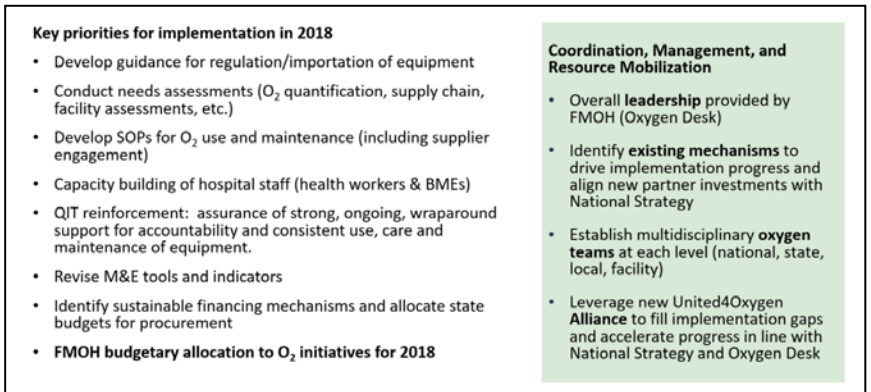


Figure 7. Plans for oxygen scale-up in Nigeria.

Discussion questions:

How do you plan to disseminate the oxygen scale-up strategy?	The scale-up strategy is launching at the same time as the health infrastructure annual gathering at the National Council on Health. The strategy will be disseminated during this meeting.
Is there a sense of the product mix that will be used to meet the oxygen need?	There are no set plans at this time; however, each state will likely require a mix of products. The scale-up strategy provides a template for states to individualize their oxygen plans.
What is the single biggest challenge to scaling oxygen?	The single biggest challenge for Nigeria is ensuring adequate funding. The national currency was recently devalued, which presents additional challenges for funding.

Summary—Outlining the opportunity

Presenter: Spike Nowak, Market Dynamics Associate, PATH

Summary:
To close the first convening session, Spike Nowak walked through an issue relevant to each country delegation presentation—approaches to oxygen quantification. It is important to balance accuracy of quantification efforts against the available resources and the decisions this information will inform. The essential questions are (1) what is the goal? (2) what data are readily available? and (3) what level of accuracy is needed? There are four main models for oxygen.

Quantification Approach	Use Case	Accuracy
Historic oxygen use	Generally applicable for single facility	Very accurate
Facility-level estimation for new facility	Calculate using number of beds and types of wards	Very accurate
National health facilities	Based on number of facilities, number of general and critical beds (Figure 8)	Moderately accurate
Epidemiologic national health facilities	Based on number of facilities, number of general and critical beds; also based on hypoxemia rates and facility occupancy rates	Moderately accurate

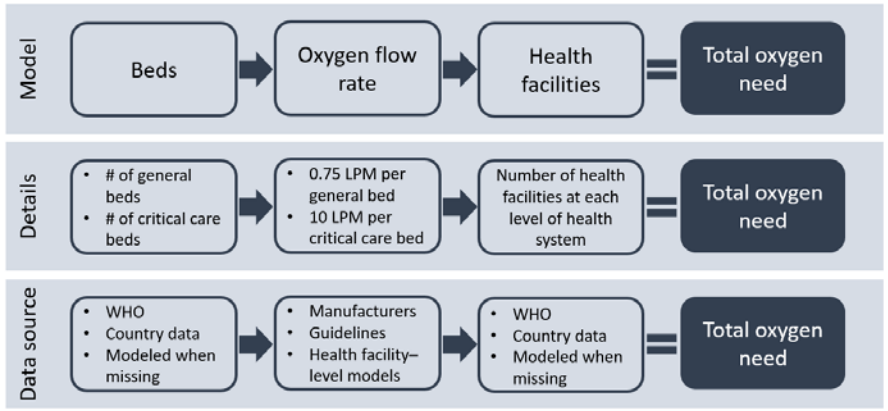


Figure 8. A simple model to estimate oxygen need.

The most appropriate model will depend on the role of the decision-maker, the available data, and the required accuracy. Another important consideration is the oxygen delivery product mix required to meet the need (i.e., the number of cylinders, concentrators, oxygen plants, and liquid oxygen tanks). Product mix can be informed by the oxygen sources already available. Additional factors to consider when modeling oxygen:

- Backup systems to account for downtime.
- Existing production capacity.
- Outpatient care based on bed count.
- Some models use flow rate of 15 liters per minute (LPM) for operating and critical care beds.
- Quality of oxygen, based on the use case.

In summary, the two outcomes of this presentation were (1) three questions to ask when planning an oxygen estimation approach and (2) a simple framework to help choose the most appropriate oxygen quantification model based on its intended use.

SESSION 2: ACCELERATING ACCESS

Introduction

Presenter: Betsy Wilskie, Procurement Officer, PATH

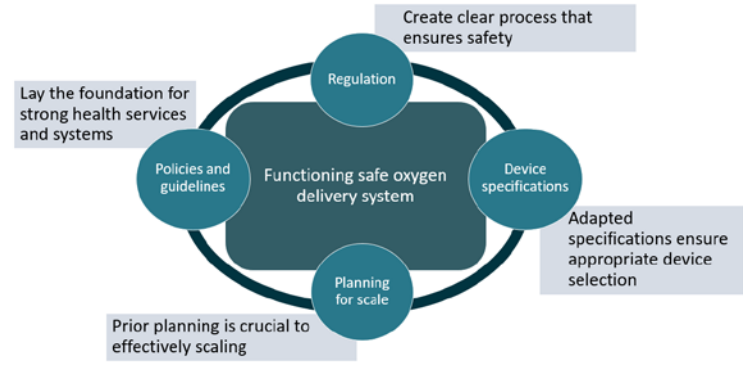


Figure 9. Aspects to facilitate access to safe oxygen.

The afternoon session focused on the components required to enable access to safe oxygen delivery. These components include policies and guidelines, regulation, strategic planning, and clear device requirements. When functioning properly, planning sets the stage for implementation, policies lay the foundation for health systems, regulations create processes that ensure safety, and specifications guide appropriate device selection (Figure 9). A main point from this session was that all of these components are linked and often require cross-departmental coordination. During discussion, it also became clear that needs assessments are essential to understanding and addressing gaps in access. These 30-minute sessions consisted of 10-minute presentations with 20 minutes of discussion.

Enabling policy environments

Presenter: Bonnie Keith, Senior Program and Policy Officer, PATH
Facilitator: Dr. Khadija Abdalla, Health Specialist, UNICEF Kenya

The motivating factors for new policy development vary. In most countries there is a trigger—whether new data on gaps in access, a public health emergency, etc.—for implementing an oxygen policy. Coordination across health areas (e.g., noncommunicable disease [NCD], MNCH), engagement with public and private health sectors, and civil society are crucial in policy development and dissemination. Financing is another critical component of policy development; the budgetary implications of a new policy and sufficient financing for execution are essential considerations. Finally, oxygen-specific policies should balance thoughtful integration of oxygen with broader health policy changes.

Other important elements of enabling policy environments:

- Policy champions increase awareness of the policy issue and help influence key decision-makers.
- Including industry in coordination with health sectors helps industry understand expectations of the health care system and the motivation behind the policy.
- Monitoring policy implementation is limited and/or not rigorous; specific measures are needed to evaluate policy execution.
- End user training—existing devices are not being properly used by health care providers—tied to adequate financing to provide training.

Country-specific and global product planning tools

Presenters:
Audrey Battu, Director, Essential Medicines, CHAI
Kristoffer Gandrup-Marino, Chief of Innovation, UNICEF Supply Division

A variety of activities are included in the planning process for safe oxygen delivery. Global tools can outline general considerations, which countries can customize further at a local level. For example, in Nigeria, a generic planning tool would be preferable due to the considerable variation in needs and infrastructure from state to state. Further, within countries, it is important to track the current state of safe oxygen availability and integrate this with other tools that countries are leveraging for general medical device management (e.g., budgeting, quantification, procurement specifications).

Linking oxygen to existing cost-effective models and impact modeling efforts like the Lives Saved Tool can help prioritize oxygen interventions and advocate for financing. In addition to cost-effectiveness, total cost of ownership is integral to planning device procurement, deployment, and ongoing maintenance. Understanding not only initial costs but also operating costs over time informs contracting for different ownership models and financing approaches. Finally, there is a close link between policy dissemination and product planning; if policy dissemination is weak, product planning may fail. Clear guidelines and standards are essential to broad adoption of scale-up plans.

Implications of global medical device regulation changes

Presenter: Srinivasa Reddy, Senior Engineer, Andhra Pradesh MedTech Zone
Facilitator: Ray Cummings, Director, Market Dynamics PATH

Finding detailed medical device regulatory information for individual countries is routinely challenging for industry members. Country-specific regulations for use instructions and labeling requirements further complicate market entry. Regulatory requirements coupled with unclear product demand, order lead times, and the financial risks of carrying country-specific stock disincentivizes industry engagement in LMIC.

Less established or new regulatory processes in LMIC often reference established systems in the United States and/or the European Union. While this helps clarify the process for industry, regulatory harmonization initiatives have further benefit to industry. Harmonization initiatives intentionally streamline forms and processes and have demonstrated considerable impact where implemented. These initiatives may be part of a broader economic cooperation/trade partnership or they may be specific to regulation of health products—pharmaceuticals, vaccines, diagnostics, and devices.

Other important considerations in global medical device regulation:

- The regulatory process can be further complicated when oxygen is regulated as a drug.
- It is important to have clear delineation of regulatory responsibilities between manufacturers and their local agents or distributors.
- Stakeholders often ask whether WHO can increase transparency in regulatory processes by establishing a centralized database that outlines current processes.

Key considerations in technical specifications for safe oxygen delivery products

Presenter: Adriana Velazquez Berumen, Senior Advisor on Medical Devices, WHO
Facilitator: Michael Ruffo, Market Dynamics Officer, PATH

Carefully developed technical specifications can save time and money in the long term. However, it can be challenging to create and/or update technical specifications due to the amount of time and resources required. This is particularly true when new products regularly enter the market. WHO is leading a piece of

work to update technical specifications for oxygen-related devices. WHO-published technical specifications provide a baseline, but they do require adapting at the country level. Technical specifications can inform procurement specifications but require further revisions. They must integrate into each country's procurement policy/process and tendering guidance.

It is also important to integrate procurement of different medical devices to ensure the devices throughout a health facility can function together when necessary. If devices do not work together effectively, it can create an undue burden on health care workers. It can be challenging to ensure different devices are compatible, particularly once specifications are designed and handed off to an entirely separate procurement unit. Ensuring appropriate device selection requires good coordination and communication between programs submitting requests for devices, those that set standards, and finally, those that manage procurement. One of the main challenges cited in the execution of this process is weighing the trade-offs in cost and quality. Linking total cost of ownership is one method for aiding in judgment of this trade-off.

DEVICES & DRINKS EVENT

Devices & Drinks took place at the end of the first day of the A2O2 convening. This session was structured as an informal exhibition of oxygen delivery devices and pulse oximeters. Displays included general and country-specific information, pulse oximeters, oxygen concentrators, and various other oxygen-related devices. Every booth was supplied with electricity, so manufacturers could turn on devices and demonstrate to participants or allow participants to test out devices firsthand.

Image 5. Participants interact during Devices & Drinks. Photo: Spike Nowak, PATH

Perhaps the greatest outcome of this exhibition was that it facilitated improved communication between companies and country delegations. Both parties were able to express their interests and needs in an informal setting, establishing relationships for future engagements. Industry representatives used this time to showcase their products, network with country purchasers, and communicate remaining opportunities for innovation with interested financiers. Non-industry participants were able to ask questions, have hands-on experience with devices, and network with A2O2 attendees more generally.

DAY TWO—WEDNESDAY, 8 November 2017

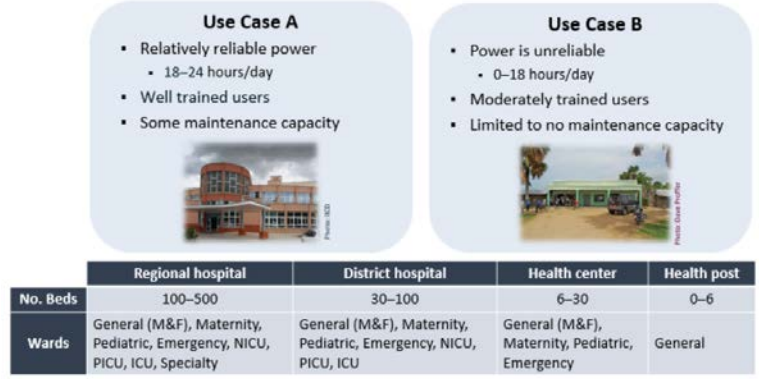
On the second day of the A2O2 convening, the focus shifted to industry perspectives on current device use and innovation potential. Similar to the first day of the convening, the afternoon of the second day was spent in small-group discussions where the aspects of supportive systems for safe oxygen delivery in LMIC were considered.

SESSION 3: INDUSTRY INSIGHTS

The morning session was structured as a panel with members of industry providing perspectives on device use in LMIC. The goal of this session was to promote information sharing and discuss the challenges faced on both sides of the market. A key point from industry members was the importance of financial commitments from countries to encourage market entry and improve competition. Countries indicated that industry could facilitate scale-up by supporting innovative financing mechanisms. Panelists prepared responses to questions focused on device use cases, the limitations of existing technologies, and innovations that could help increase access. Audience questions touched on potential innovations for replacement parts and the role of distributors.

Introduction

Industry plays a vital role in helping increase access to safe oxygen. Twenty companies attended the A2O2 convening. The purpose of the panels was to provide industry an opportunity to discuss the challenges of doing business in LMIC and to inform country stakeholders about the array of products available to meet the needs under different use cases. Two use cases were defined for discussion during the panels: use case A and use case B (Figure 10).



	Regional hospital	District hospital	Health center	Health post
No. Beds	100–500	30–100	6–30	0–6
Wards	General (M&F), Maternity, Pediatric, Emergency, NICU, PICU, ICU, Specialty	General (M&F), Maternity, Pediatric, Emergency, NICU, PICU, ICU	General (M&F), Maternity, Pediatric, Emergency	General

Figure 10: Use cases for industry panel.

Appropriate SPO2 monitoring systems

Facilitator: Michael Ruffo, Market Dynamics Officer, PATH

Panelists:
Grant Aaron, Director of Global Health, Masimo
Arash Taki, Marketing Manager, Middle East, Africa, Central Asia, and Turkey, Medtronic
Linda Cheng, CEO, Acare Technology

Niels Buning, Venture Manager, Philips Healthcare
Walter Holbein, Physiologist, Nonin Medical, Inc.

Challenges:

1. Device procurement and maintenance

Common factors that cause devices to fail in LMIC include the power environment and limited maintenance. Surge protectors and/or voltage regulators are recommended to accompany electromedical equipment. When devices need service, it often takes months to receive spare parts and maintenance. The audience asked:

- Is there a way for local distributors to stock more spare parts?
- Can technical support be provided in local distribution centers?

Image 6. Grant Aaron, Niels Buning, and Linda Cheng discuss SPO2 monitoring. Photo: PATH/Spike Nowak

Manufacturers responded by saying that improving service delivery is a continuous challenge. They consider after-sales services an important aspect of sales and try their best to train the various stakeholders interfacing with devices, but it can be difficult to reach all responsible parties. Further, it is important for a manufacturer to visit the areas where their products are sold to ensure contracted partners are providing satisfactory service. Panelists reflected that often local service providers are only able to make minor repairs.

Another point manufacturers made is that it is important to plan for consumables and replacement parts early in the budgeting and procurement process. Some argued that it could be easier to manage maintenance and replacement parts with a less fragmented market. That is, if countries coordinated ordering to purchase only a few different brands and models of device, it would be easier to maintain them and simpler for local agents to stock spare parts and compatible consumables. In addition to the role of the manufacturers and distributors, local biomedical engineers are another excellent resource for maintenance, planning, and training. WHO has data on biomedical engineers on their website.

2. Training

Adequate training not only improves patient outcomes and safety but also reduces improper use resulting in device failure (e.g., training to properly release a locking probe during replacement so as not to break the locking mechanism). It is not unreasonable to expect manufacturers to provide some type of device training. Manufacturer training services may include courses that are offered online, at regional training centers, or on-site.

It can be costly to reach some areas with training and often distributors or local agents are the key to local training. When distributors are not able to meet training needs, global health partners can provide support. There may be room to include broad training that is brand agnostic (e.g., when to use pulse oximetry, what the readings mean) into company-specific training. For example, Lifebox has developed training tools that are available for all to use.

3. Unclear business case

Companies judge whether to sell products in countries based on the clarity of the business potential. Often, it is difficult for industry to discern the market opportunity from the public and private health sectors. The regulatory process and perceived barriers therein are other aspects companies consider in choosing where to sell their products. The wide range of languages and large variations in the degree to which medical devices are regulated are challenging. Transparent regulatory processes, as opposed to processes that are opaque and subject to change, can reduce the barriers to entry. For other companies, finding a high-quality local agent is often the largest challenge.

Use cases:

It is essential to determine the intended use of the pulse oximeter prior to device selection. Different health areas (pneumonia, chronic obstructive pulmonary disease, surgery, etc.) may require different features and therefore different device models. WHO encourages pulse oximeters to be more widely available at health posts because it helps with many different interventions and diseases. Pulse oximeters are seen as a way to empower health care workers.

Organizations such as the American Society of Testing and Materials have standards for emergency medical services equipment. These standards require robust and durable devices and could be used to inform specifications for use case B devices. Use case B requires a robust device with longer battery life and reusable probes. It is also better suited for a spot-checking device that is easy to use and can reliably help health care workers decide if they need to refer patients or treat them on-site. In these cases, it is important to have devices that the health care workers trust and that are not overly complicated.

Technology:

1. Specificity and sensitivity

Specificity and sensitivity are often important specifications in device selection. Panelists shared that there are regulations and standards (e.g., International Organization for Standardization) that devices should meet. Sensitivity is often a function of the proprietary software a company develops. Two of the most challenging scenarios for pulse oximeters are the ability to take accurate measurement when moving (issue with children) and core profusion.

2. Aid in diagnosis

Algorithms on smartphones and tablets are being developed that have the potential to serve as clinical decision tools to guide appropriate diagnosis. Campaigns and classes about pneumonia and malaria can also provide opportunities to facilitate accurate diagnosis through training. Second-generation devices integrate respiratory rate counters and pulse oximeters to further aid in diagnosis.

3. Standardized interfaces

Audience participants were curious whether industry felt it would be technologically possible to create a probe with a standard interface (like USB) to make it easier to purchase replacement probes. Panelists responded by saying that probes need to be certified to work with a specific pulse oximeter to ensure accuracy. Using a probe that is not properly calibrated to the device could reduce accuracy and manufacturers would not be able to certify them for safety. Designing a universal probe that could be used

on any brand or model of device would require coordination across multiple manufacturers, which is not only complex but also lacks adequate incentives for companies to cooperate.

However, related to other replacement parts, Masimo has developed a charger interface that is compatible with the charging cord used for radios and other common devices. Philips is also investigating micro-USB charging capabilities. That way, when a charger is lost or broken, devices will be compatible with commonly used electronics chargers.

Innovations to improve access:

Masimo	Designed specifically for use in LMIC, the Masimo Rad-G device is about to be launched.
Philips	Philips has an automated respiratory rate timer specifically designed for use in LMIC that is now on the market.
Acare	Acare developed a probe that is accurate in use on multiple age groups from neonate to adult.
Nonin	Nonin has a line of low-power products that are aimed at military and emergency medical services.
Medtronic	Medtronic has many products in use in LMIC and is at the same time engaged in research and development to better understand how best to add value in LMIC. It also has a probe that can be used on children and adults.

Appropriate oxygen delivery technologies

Panelists:
Angelo Barberic, Regional Sales Manager, AirSep Corporation
Joseph Krawczyk, President/CEO, Nidek Medical Products Inc.
José Vale Machado, CEO, Sysadvance
Andy Gouws, Commercial and Business Development Manager, African Oxygen Limited (Afrox)
Ole Mulyadi, Chairman and Owner, PT Fyrom International

Challenges:
1. Ongoing maintenance
Industry experiences shared during the oxygen delivery panel were often much broader than medical uses alone. This includes installing oxygen systems in complex areas and harsh environments (e.g., deserts for refineries, Himalayas for climbers). It is important to understand how companies support their products. In other words, do they provide local support for installation and maintenance? Will they send technicians from headquarters to provide after-sales services? Most issues with device functionality arise when equipment is put in places that are difficult to reach and/or where conducting maintenance is difficult. Maintenance issues for oxygen delivery devices are typically related to the compressors.

2. Financing and payment delays
Governments are often the biggest purchasers of oxygen. When they delay payment, it leaves oxygen providers without the cash flow they require to operate their business. Governments need to prioritize payments for oxygen as they would a utility. Alternative contracting approaches can be helpful in this regard. Models such as own, rent, and/or split ownership (i.e., a public-private partnership [PPP]) could

improve the efficiency of payments. Assist International has helped establish a PPP model for supplying O2 plants to hospitals that enable hospitals to share in the investments long term.

3. Cost comparison

Country delegations mentioned to industry that they could use more information to help them determine the most cost-effective oxygen delivery solution. They expressed an interest in having better data to understand the trade-off in purchasing an oxygen plant versus buying and refilling oxygen cylinders from a private provider. Manufacturers expressed a willingness to provide this information and assist in this decision-making process.

Panelists elaborated further that there are five different models for life cycle total cost of ownership calculations, which can be made available. To determine whether to buy an oxygen plant, facilities need to calculate the required output and up-front capital investment. From company to company, pressure swing adsorption oxygen generation plants are similarly priced. Variations in costs are introduced with different levels of pressure or additional components that require power. Manufacturers also shared that the main challenge for them in responding to country tenders is that there is never an opportunity to explain the economics behind pricing. It would be helpful if tender documents provided space to include further detail around the pricing rationale.

4. Managing distributor margins

Countries often struggle with prices that seem much higher than expected. When asked about pricing strategies, manufacturers cited that distributors play a critical role in setting the final price of products. Country delegations request a public price list from manufacturers so that they can more effectively plan and negotiate products and services from distributors. Most manufacturers don't establish prices because it varies so considerably from one market to the next. However, they recommended that if purchasers think a price is unfair, they should tell the manufacturer. This information helps manufacturers better understand the market and can influence their choice of distributors.

Most LMIC have strict regulations about local distributors. This can force companies to select partners who fit the requirements but may not be best in the market. This is a barrier for manufacturers to provide purchasers with the best support. In selection of local distributors, manufacturers like to have a local distributor that is well trained and carries stocks of replacement parts as a standard practice. Sometimes, for those distributors that have invested time in technical training, manufacturers will discount prices to the distributor further.

Use cases:

Neonates require special considerations for safe oxygen delivery. The MixSafe device is the result of a unique collaboration between clinicians and industry to develop a specific product that serves an unmet need. The MixSafe device provides oxygen with blending and CPAP capabilities so that patients can be stabilized and referred to higher levels of care. This device prevents retinopathy of prematurity by using an oxygen blender, and the CPAP feature runs off a lithium battery.

Panelists also discussed whether there is an opportunity to further innovate oxygen concentrator technologies. Concentrators are generally reliable; however, battery backups and solar power remain

challenging sources of backup electricity. If reliable power is not available, it may help to think of a strategy where a small-/medium-size hospital has a concentrator as well as cylinders.

Technologies:

1. Oxygen concentrators
   - o Originally designed for home care market, but have progressed to clinical use as source of oxygen.
   - o 5-LPM, 10-LPM devices can service individual patients or 30-LPM system can service a small clinic.
   - o Battery-operated oxygen concentrators are more appropriate for home use and traveling with patients.
   - o Some larger (30 LPM) systems have pressure output high enough to use with ventilators.

2. Pressure swing adsorption/vacuum pressure swing adsorption plants
   - o Oxygen generation plants are typically found in larger facilities and can be piped directly to facility and/or fill cylinders.
   - o Plant capacity and configuration are customizable, depending on the use case.
   - o Companies typically require each facility to complete a questionnaire to design the piping configuration; this questionnaire typically requests the number of beds, operating theaters, etc., and the layout of the hospital.
   - o Plants can be mission critical to health services, providing 8,000 hours per year of continued usage.

3. Liquid oxygen/cylinders
   - o Liquid oxygen is typically used in larger health facilities, often included under use case A.
   - o However, an added benefit of liquid oxygen storage tanks is that they do not require electricity.
   - o Managing facility piping installation and use requires well-trained staff.
   - o Refills are still required for liquid oxygen; however, the frequency of refills may be less than gas cylinders, depending on the size of the liquid oxygen storage tank.

4. Oxygen piping
   - o Most distributors are qualified to install oxygen piping in health facilities.
   - o In some countries, there are regulatory processes to ensure safety in central piping systems. Regular audits and specifications for high-quality products help ensure safety in use.
   - o With new construction, companies typically work with architects to ensure the piping is effectively integrated.
   - o Older hospitals are more difficult to manage due to leaks and less conducive infrastructure, so it is best to conduct a complete audit before retrofitting piping systems.
   - o Oxygen leaks can be expensive in terms of wasted oxygen and repairs.

Innovation:

There may be opportunities for innovation in the way countries procure gas oxygen. Cooking gas for use in the home could provide a useful example. The user pays a deposit for the cylinder, but you can go anywhere to refill the cylinder because there is a universal regulator. Audience participants were curious to know if a universal regulator for cylinders is feasible for medical oxygen. Manufacturers responded by saying this is not feasible. Cooking gas is a low-pressure system while medical oxygen is high pressure. To be safe, fillers need to be certified and qualified. There are various ways of filling cylinders, with varying levels of complexity. Companies have concerns with the liability of having other companies refill their cylinders.

There are opportunities to improve supply chain inefficiencies. Learning from the experience in the United States, countries can improve the reliability of the supply chain for cylinder or liquid oxygen refills by establishing new distribution models (e.g., hubs or bulk distribution).

SESSION 4: SUSTAINING SUPPORTIVE SYSTEMS

Introduction

Presenter: Lisa Smith, Market Dynamics Officer, PATH

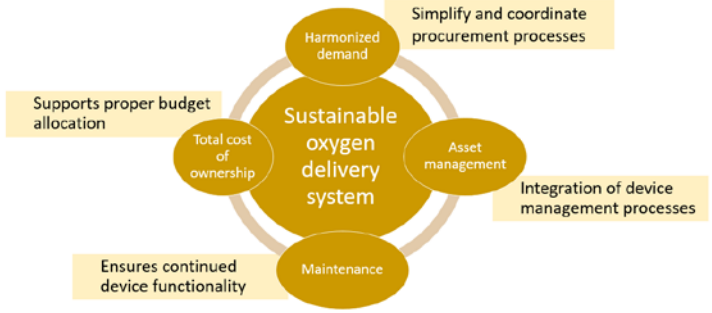


Figure 11. Components of supporting systems.

The afternoon of the second day built on the first day and highlighted methods to ensure sustained operation of medical devices. These methods, shown in Figure 11, include systems to streamline procurement through coordinated ordering, asset management systems, maintenance strategies to ensure continued functionality, and budgeting practices that account for costs overtime. A key takeaway from the discussion included that innovation in financing and payment processes could reduce oxygen service interruptions. Another takeaway was that improving the budgeting and tender process for oxygen would result in procurement of more appropriate devices. This session, combined with the Accelerating Access session from the previous day, provide a good basis of information regarding processes and systems that support medical devices. Like the day before, the sessions were 30 minutes consisting of a ten-minute presentation to introduce the topic and 20 minutes of discussion.

Total cost of ownership to inform procurement and maintenance

Presenter: Martha Gartley, Technical Advisor, CHAI
Facilitator: Spike Nowak, Market Dynamics Associate, PATH

The total cost of ownership presentation focused on how/if countries can shift to estimating the cost of not only the initial capital expenditure of a device but also operating costs over time. The group discussed how the tender process could be modified to accommodate total cost of ownership in procurement and that general technical assistance may be needed to help countries with this transition. Different ownership models, in particular leasing and rental models, share similar inputs as total cost of ownership. These arrangements require estimating operating costs like power and maintenance and contracting those services up front. They also track monthly and yearly costs and improve the knowledge and transparency of financing required to keep devices operational.

The group discussed some challenges associated with introducing total cost of ownership. Even with total cost of ownership integrated into standard tendering practice, it can still be difficult to compare variations in quality across devices with similar specifications. Further, other stakeholders (potentially outside the MOH) may need to be involved in establishing a methodology and beginning a new costing process.

Methods for harmonizing demand in centralized and decentralized procurement systems

Presenter: Agus Prabowo, Chairman, LKPP
Facilitator: Betsy Wilskie, Procurement Officer, PATH

An online procurement system can improve the efficiency of purchasing for health facilities in decentralized and centralized health systems. Many questions from the group discussion focused on how to operationalize an online procurement catalogue, in this case Indonesia's e-Katalog, while maintaining quality products and transparent processes. For e-Katalog the supplier bidding process is public and shipping costs are listed on the catalogue based on the destination of the device. Further, multiple stakeholder groups (e.g., the procurement agency, MOH, and device users) are involved in assessing the quality of included products. The public may at any point report or flag vendors in the system that are not meeting quality standards.

Other discussion points included how to guarantee and benchmark pricing. The managing entity for e-Katalog negotiates pricing at a national level under umbrella agreements that are then leveraged by hospitals and districts throughout the country. Supplier agreements are renegotiated on an annual basis. Some participants discussed whether the same approach could be utilized at a regional or state level.

Medical device asset management and tracking

Presenter: Anjaney, Consultant, Healthcare Technologies (Medical Devices), National Health Systems Resource Center (NHSRC)
Facilitator: Mike Ruffo, Market Dynamics Officer, PATH

Effective device management creates a process for ensuring continued functionality of equipment after its procurement until its disposal. Creating a system for medical device management and tracking can be complicated, but an approach has been trialed in India under the NHSRC. One of the first steps to design a management system is to determine how devices will be defined. There are various nomenclature systems for devices (e.g., GDMP system), but none are free of cost, which can be a barrier for some countries. WHO is speaking with the European Union commission on this issue and anticipates further updates soon. A harmonized nomenclature is not only useful within a country but also helps track progress across countries.

Once a system is agreed upon, countries must understand what devices are currently available. With guidance from NHSRC, individual states tendered and contracted service providers. Contracted firms manage the repair of broken equipment, support ongoing maintenance, supply consumables and spare parts, and track device functionality overtime. Across India, ten companies were identified as having the capacity to support a wide range of medical devices.

As with e-Katalog, convening participants were interested in how to operationalize a program like this. They wanted to understand how functionality was defined, what analysis was done of the data, and what key performance indicators were used for routine tracking of functionality. In the case of oxygen, service providers used oxygen analyzers to confirm output greater than 93 percent oxygen and to verify the accuracy of device displays. Inventory data were used to create state-specific dashboards to track continued device functionality. Contracted service providers log maintenance calls in the online system and the dashboard immediately updates with a revised device uptime.

Strategies for sourcing medical device maintenance and training

Presenter: Dr. Steve Adudans, Executive Director, Center for Public Health and Development
Facilitator: Lisa Smith, Market Dynamics Officer, PATH

Government-led initiatives, PPPs, and private-sector business models are all strategies for ensuring medical device functionality. There is a continuum of insourcing and outsourcing maintenance services. Countries do not want to ignore the capacity of biomedical engineers, but at the same time they acknowledge how difficult it can be to train engineers to maintain all device brands and models. A balance between investments that more effectively leverage and incentivize government biomedical engineers and outsourced after-sales services is often the key. Recent innovations in after-sales services like the MediQuip Global model highlight that there are alternative approaches to financing (e.g., social impact investing, grants, repayable loans). Maintenance (including training) needs to be thought of early and often in the procurement process so that suppliers or service providers are contracted for the appropriate terms and conditions.

Several participant questions highlight persistent challenges with maintenance:

- How do you maintain equipment that is too inexpensive to lease, is too expensive to replace, and is deployed to a remote region without consistent biomedical engineering staff? One could argue that this is a unique use case that is not adequately addressed by existing approaches.
- How do you source spare parts if they are not included in the maintenance contract? This typically requires a competitive bidding process where genuine and generic parts compete. If price is the decision-making factor, generic parts typically win, but they go against the manufacturer-recommended product.

Day 2 closing remarks

Presenters:
Dino Rech, Program Officer, Bill & Melinda Gates Foundation
Ray Cummings, Director, Market Dynamics, PATH

At the close of the large group meeting, the key message to participants was to focus next on prioritization of efforts. It is clear from the first two days that resource mobilization is needed. Dino Rech shared that financiers are holding a meeting on the third day of the convening to discuss next steps.

Each stakeholder group plays a role in improving access to safe oxygen delivery. The cross-pollination of supply-side and demand-side actors was essential and would not have been possible without strong representation from national ministries and industry partners. Now connections are made, and networks are built. Global health partners can help facilitate ongoing communications and connections between countries, manufacturers, and partners. It is important to maintain ongoing communication and transparent information sharing. This is just the beginning, and the convening organizers look forward to seeing how lines of communication can be further developed.

DAY THREE—THURSDAY, 9 November 2017

On the third day, country delegations outlined work plans to increase access to oxygen in their countries. The goal of this country-led planning session was to identify next steps and (depending on the countries' progress to date) revise, or begin to develop, oxygen and pulse oximetry scale-up strategies. An element that was common across countries was that it is important to coordinate planning and resources across health directorates and partners to most efficiently use resources. The importance of training to ensure proper use of oxygen also came out as a common element.

SESSION 5: COUNTRY COORDINATION

Best practices for planning to scale oxygen

Presenter: Audrey Battu, Director, Essential Medicines, CHAI

Because oxygen delivery is essential across the health system, planning for scale-up is essential. It is important not only to optimize supply and distribution to ensure availability but also to encourage rational and appropriate use. This session highlighted some core components to consider when planning safe oxygen delivery scale-up based on experiences in Ethiopia, Nigeria, and Uganda. These components include conducting a needs assessment to understand functional availability, quantification to fill the identified gaps, defining the appropriate product mix to meet the need, developing metrics to measure progress (Figure 12), and identifying any unique financial or political factors that could affect decision-making.

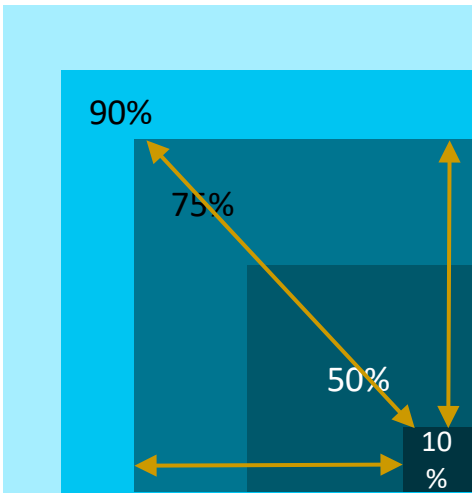


Figure 13. Illustrative diagram of the oxygen use gap, which describes the difference between having oxygen equipment in a facility and patients receiving oxygen at the right time, in the right way, and for the right duration.

☑ **Pre-strategy development work**
- Availability & functionality assessment (facility)
- Knowledge assessment (clinical audit)
- Quantification
- Gap analysis (supply, functionality, financing, knowledge, etc.)
- Stakeholder mapping (directorates, etc.)

☑ **Functional system and supply**
- Number of functioning oxygen concentrators (and number non-functional). Number of full and working oxygen cylinders (and number empty or non-functional).
  - It is really important that some kind of functional assessment is done, preferably with an oxygen analyzer.
  - Have consumables required, have electricity, have a gauge, etc.
- Procurement planning (i.e., x% of est. need fulfilled)
- Maintenance and clinical training indicators (development, rollout)

☑ **Clinical indicators (also see Appendix)**
- Routine use of pulse oximetry during initial assessment
- Regular monitoring of SPO2 for admitted patients
- Oxygen treatment prescribed for patients with hypoxemia (SPO2 < 90%)
- Regular monitoring of oxygen treatment
- Patients with hypoxemia who recover
- Routine measurement of respiratory rates during initial assessment for children 2–59 months
- WHO classification for respiratory illnesses used

☑ **Other indicators that are important for your country**
- Example: If cost is a known barrier, and interventions are aiming to reduce the cost burden, important to measure and track. Indicator: Cost to patient for one day of O2 therapy or one cylinder.

Figure 12. Metrics for measuring oxygen scale-up progress.

Importance of providing oxygen for all

Presenter: Dr. Hamish Graham, Pediatrician, Research Fellow, University of Melbourne Centre for International Child Health

Oxygen therapy has been used in clinical practice for over 100 years, and yet many patients in LMIC still do not receive it appropriately when they need it (Figure 13). There is a need to think about oxygen differently. Oxygen is a medicine but, unlike most medicines, it requires a medical device to

administer it. Oxygen therapy is also considered a medical practice and relies on changing the behavior of nurses and doctors.

There are two important questions when considering oxygen access for patients:

1. Is every patient screened by pulse oximetry?
2. Does every hypoxemic patient get oxygen?

Increasing the use of pulse oximetry has been demonstrated to increase the number of hypoxemic patients who receive oxygen. Pulse oximetry also makes oxygen use more efficient. Training health care providers to consider pulse oximetry as a routine vital sign is necessary to increase pulse oximetry use. Additionally, oxygen should be considered from a health systems perspective. Oxygen access relies on the availability of equipment, technicians, and maintenance, and appropriate oxygen use requires skilled health care providers, strong management, and good practices. It is imperative that we think of oxygen therapy use for more than pneumonia and encourage stakeholders from all disease areas (MNCH, NCD, etc.) where oxygen is a valuable treatment to work together.

Summary of next steps determined by country delegations

Ethiopia

- The Ethiopia delegation intends to dissolve the existing oxygen working group and integrate oxygen into all technical working groups. It is also developing training manuals for clinicians and has rolled out biomedical trainings. Its aim is to standardize training and integrate different training guides. Maintenance will be integrated into a routine maintenance scheme.
- Short-term goals include building capacity, implementing checklists, reviewing demand in states, and reviewing and updating technical specifications for oxygen technologies and supplies, including pulse oximeters, oxygen concentrators, and plants. Ethiopia is planning to deploy one pulse oximeter per health post, two per health center, and five per hospital (minimum) and would like to procure these devices quickly.
- Ethiopia remains interested in funding from development partners. The MOH is creating an agenda to pursue funding to support their oxygen efforts. Assist International is helping to scale up a PPP for installing and operating oxygen plants. A need remains for more evidence generation on the impact of oxygen and pulse oximetry in Ethiopia.

India

- India expressed commitment to increasing access to oxygen. Good availability of oxygen within the health system was assumed, but initial oxygen assessment revealed gaps in functional availability. Furthermore, oxygen is currently underutilized. Clinical practices can be a challenge. The delegation agreed that a checklist for end users can help ensure functionality of oxygen devices.

Image 7. The delegation from India and partners discussing next steps. Photo: PATH/Conner House

- India's first steps include conducting thorough assessments of functional availability at the state level to understand gaps in oxygen delivery. Their working hypothesis is that the practice is the barrier, but it is possible that it is due to limited functional availability. India is seeking partner assistance to conduct the gap analysis and support plans to address gaps at various types of health facilities, including those in urban and remote locations. India could also use partner assistance to develop protocols and training programs, leveraging existing guidelines from WHO and other countries.
- The India delegation is considering changing policies and guidelines to include pulse oximetry in primary health care facilities and delivery point subcenters; however, there is a need for partner assistance to investigate the potential for pulse oximetry at subcenters. The delegation also desires to update its tender process to find oxygen suppliers that can provide wraparound services for a region that includes training, consumables, and maintenance.

Indonesia

- The Indonesia delegation expressed interest in building capacity and training with support from WHO, analyzing data to support product mix modeling with support from PATH and WHO, and developing maintenance programs leveraging their ASPAK data for the currently underdeveloped eastern part of the country. The data analysis has been requested by government officials, but capacity to complete this analysis is limited.
- Although standards are in place for the use of oxygen, it is unclear how closely they are being followed. Additionally, decision-making needs to ensure political forces are aligned across not only the MOH but also the office of budgeting.
- It remains important to leverage bioengineers to help with oxygen planning. Recommendations from the delegation include placing a biomedical engineer within each facility to train nurses on device use and reduce "adverse events." Biomedical engineers could also be trained to analyze/utilize ASPAK data and could help evaluate adverse events according to the "five whys." Regional biomedical engineers could train local technicians if there is a shortage of biomedical engineers. Private industry may still be needed to fill maintenance capacity gaps.

Indonesia has developed the following objectives and activities to achieve its goal of providing safe oxygen therapy to all patients in need in all appropriate health facilities.

Objectives	Activities
Objective 1: Strengthen the coordination within the MOH for oxygen therapy services	• Establish an oxygen coordination task force within the MOH for oxygen therapy. • Hold quarterly coordination meetings of the oxygen coordination task force. • Prepare protocols for ensuring coordination between oxygen therapy stakeholders.
Objective 2: Use all appropriate data to determine gaps in oxygen equipment or gas	• Check ASPAK completeness and accuracy for estimating oxygen equipment inventories. • Use ASPAK database to determine gaps in oxygen equipment by district. • Carry out projection of oxygen therapy needs at various health facility levels. • Perform a quantification of oxygen needs based on projection of needs and equipment gaps.
Objective 3: Provide the appropriate guidelines and standards for provision of oxygen therapy	• Update national standards and policies for oxygen therapy in health facilities. • Develop national guidelines for oxygen therapy delivery in various programs. • Socialize standards, policies, and guidelines at provincial and district levels.
Objective 4: Ensure providers have the capacity and knowledge regarding oxygen therapy	• Develop the necessary capacity-building material for oxygen therapy. • Carry out capacity-building activities as necessary.
Objective 5: Provide equipment maintenance program for oxygen therapy delivery systems	• Establish a district equipment maintenance program that will support oxygen therapy equipment. • Socialize and provide technical assistance to districts to support equipment maintenance activities.

Kenya

- Kenya is working to finalize the CHAI/MOH assessment and locate gaps in oxygen delivery. After this assessment is complete, the Kenyan delegation plans to hold a stakeholder forum to enhance coordination, map stakeholders, and engage private partners and industries.

Image 8. Dr. Mohamed Sheikh presents the next steps for Kenya's oxygen scale-up. Photo: PATH/Mike Ruffo

- The delegation would also like to conduct a situational analysis to identify gaps and challenges and develop a Kenya total cost of ownership summary.
- A complete umbrella policy for safe oxygen delivery is currently in draft stage and needs to be finalized. This would support the creation of oxygen policies and guidelines, including health technology management guidelines for all medical devices. The delegation would like to create a road map and eventually scale up oxygen. This could expand oxygen plants to various parts of the country and support the creation of crosscutting steering groups.

Malawi

- The Malawi delegation plans to compile a report with insights learned at the A2O2 convening. The Chief of Health Services will present this report to the senior management of the Malawi MOH.
- The delegation also plans to conduct a needs assessment at the health facility level. This will include a review of policy documents to examine how oxygen is included and a review of data collection to support the development of a road map to increase access and use of oxygen.

- The delegation identified a set of key stakeholders to engage, including partners—USAID, WHO, Rice University, UNICEF, PATH, and other organizations; MOH departments—planning, clinical and nursing services, asset management, and malaria/TB/HIV programs; professional associations; and private-sector representatives.
- The Malawi delegation will include oxygen as a priority issue in the country's GFF investment.

Nigeria

- Nigeria has an oxygen strategy and now plans to disseminate and put that strategy into action. The delegation plans to leverage existing medical associations to disseminate and quickly reach a broad audience. Similarly, it plans to leverage existing training structures to improve supportive supervision systems and training for oxygen delivery.
- National MOH financing helps to ensure states include oxygen in fiscal plan 2019. However, state MOH advocacy and convening at regional levels is needed for stakeholders to review the upcoming fiscal year budget and to ensure oxygen is included. The Nigeria delegation is also working with CHAI to look for creative financing programs, such as private-sector engagements, catalytic funding, and consolidated and aligned financing approaches. The Nigeria delegation plans to follow up with the Kenya team for best practices in PPP financing models.
- The delegation would also like to leverage India's and Indonesia's asset audit approaches to conduct a strategies gap analysis and fill identified gaps. Metrics will be developed to determine whether funding allocations and clinical parameters have been achieved. The delegation would also like to update the National Health Mission Information System data to track progress.

Senegal

- Senegal's health system includes 35 hospitals, 89 health centers, and 1,321 health posts. Oxygen is the second-highest expense for some hospitals.
- Funded entirely by the government of Senegal, the MOH in Senegal has supported medical oxygen installation in all 35 hospitals in 2012 (planned since 2009). Maintenance and training costs are also covered by the government of Senegal, resulting in USD 14 million of government spending on oxygen supply. Implementation of this work continues in phases—beginning with hospitals and eventually including health centers. As of November 9, 2017, 23 level 2 and 3 hospitals had oxygen installed and 12 mobile plants for level 1 facilities are expected in the second half of 2017.

Image 9. Adriana Velazquez Berumen and Diouf Awa Ndiaye present the work Senegal has done to increase access to oxygen. Photo: PATH/Spike Nowak

  - Phase 1—8 hospitals
  - Phase 2—15 hospitals
  - Phase 3—12 hospitals

- However, access is still limited in eastern Senegal as the focus has been on western areas with higher populations. The plan is that all health centers and health posts will have oxygen. Senegal hopes to partner with UNICEF, WHO, and other partners, including those working in reproductive, maternal, neonatal and child health, NCDs, and cancer, to support the oxygen scale-up in Senegal.

Tanzania

- Champions are forming at the national level who are working with directors, different MOH divisions, private partners, and stakeholders.
- Tanzania would like to assess oxygen need to quantify the problem. It would then like to develop an oxygen road map and strategy, which would include roles for stakeholders and partners who can assist with oxygen delivery. The delegation also intends to review the national essential drugs list to make sure oxygen and related supplies are included.
- Key stakeholders include the chief pharmacist, regional medical officers, global health partners, professional associations, and members of the directorates of curative medicine, nursing, and bioengineering.

Uganda

- Uganda is focused on getting its national scale-up plan approved, launched, and disseminated. This is a catalytic step to mobilize stakeholders. Gap analysis from a needs assessment created three years ago needs to be refined with documentation for total cost of ownership.
- Now that plants are in place, Uganda is working on creating a regional distribution framework. This includes installing piping and decentralized manifold systems in hospitals, procuring equipment and logistics for regional supply, and mobilizing resources to develop and approve curriculum for biomedical engineers. Uganda is looking at a framework of maintenance of plants and equipment, including insourced and outsourced maintenance, to see how to support scaling up private-sector medical oxygen production.
- There will still be unmet demand after plants. The Uganda delegation is seeking to increase government capacity and sees opportunity in collaboration, including integrating the issue into existing technical working groups (material child health, PPP group, etc.) rather than standalone initiatives. Stakeholder and resource mapping could help identify opportunities for coordinated equipment programs, such as PPP.

CONCLUSIONS AND NEXT STEPS

Speaker: Dino Rech, Program Officer, Bill & Melinda Gates Foundation

At the end of the third day, the group reflected that the convening produced a great deal of enthusiasm and engagement. Stakeholders ended the meeting with actionable next steps and optimism about what is possible. A continued focus on the patients, particularly the children, we seek to serve will keep this issue a priority. Thank you to all stakeholders for your engaged participation.

Accelerating Access to Oxygen

7–9 November 2017, Dubai, United Arab Emirates

APPENDIX A: CONVENING AGENDA

Time	Session	Topic		Location	Facilitator(s)	Presenter(s)
7:30 - 8:00AM	Event Registration			Level Seven Restaurant		
8:00 - 9:00AM	Welcome, global health background, and overview of convening scope	Welcome, introductions, convening activities, and purpose		Great Room	Ray Cummings, Market Dynamics Director, PATH	Ray Cummings, Market Dynamics Director, PATH
		Setting the stage for improved oxygen access		Great Room		Dino Rech, Senior Program Officer, Bill and Melinda Gates Foundation
						Ray Cummings, Market Dynamics Director, PATH
						Kristoffer Gandrup-Marino, Chief of Innovation, UNICEF
						Adriana Velazquez Berumen, WHO
9:00 - 9:15AM	Break			Pre Function		
9:15 - 9:45AM	Outlining the Opportunity Topics discussed: Sizing the need for oxygen, determining current oxygen availability in specific countries and reviewing country plans for scaling oxygen access Expected outcomes: Understanding of key considerations in sizing the total oxygen need, potential gaps in availability in several, specific countries, and country strategies, plans, and priorities for improving access to oxygen Format: Three person facilitated conversations	Ethiopia		Great Room	Dino Rech, Senior Program Officer, Bill and Melinda Gates Foundation	Dr. Yared Tadesse, FMoH/MCH Directorate - Child Health Cares Team, Ethiopia Alemayehu Birehanu, CHAI, Ethiopia
9:45 - 10:15AM		India				Dr. Ajay Khera, Deputy Commissioner of Child Health and Immunization, India Ministry of Health and Family Welfare (TBC) Dr. Anil Kumar, Additional DDG, Directorate General of Health Services, India Ministry of Health and Family Welfare (TBC)
10:15 - 10:45AM		Indonesia				Dr. Andi Saguni, Director of Health Service Facility, Indonesia MOH
10:45 - 11:15AM		Kenya				Dr. Jackson Kioko, Director of Medical Service, Ministry of Health, Kenya
11:15 - 11:45PM		Nigeria				Dr. Gilbert Shetak, Federal Ministry of Health, Nigeria Dr. Tayo Olaleye, Associate Essential Medicines, CHAI, Nigeria
11:45 - 12:15PM		Summary of "Outlining the Opportunity" & quantifying the LMIC need			Spike Nowak, Market Dynamics Associate, PATH	
12:15 - 1:15PM	Lunch			Pre Function		
1:15 - 1:30PM	Accelerating Access Topics discussed: Trends in medical device regulation, defining device use cases and technical specifications, and determining the optimal product mix for safe oxygen delivery Expected outcomes: Strategies for and industry perspectives on selecting safe oxygen delivery equipment in countries, recommended scope for an online product mix tool, market impact of CE regulatory changes on LMIC medical device regulation, and country and industry perspectives on the utility of technical specifications Format: Rotating small group discussions	Introduction: Managing device selection		Great Room	Betsy Wilskie, Procurement Officer, PATH	Betsy Wilskie, Procurement Officer, PATH
1:30 - 3:30PM		Roundtable Sessions	Creating an enabling policy environment for oxygen access (30 minutes)	Studio 1	Dr. Khadija Abdalla, Health Officer, UNICEF	Bonnie Keith, Senior Policy Officer, PATH
			Designing a country-specific and global oxygen product planning tool (30 minutes)	Studio 2	Audrey Battu, Director Essential Medicines, CHAI	Audrey Battu, Director Essential Medicines, CHAI; Kristoffer Gandrup-Marino, Chief of Innovation, UNICEF
			Implications of upcoming changes in global medical device regulation (30 minutes)	Studio 3	Ray Cummings, Market Dynamics Director, PATH	Srinivasa Reddy, Senior Engineer, Andhra Pradesh MedTech Zone
			Key considerations in technical specifications for safe oxygen delivery (30 minutes)	Studio 4	Mike Ruffo, Market Dynamics Officer, PATH	Adriana Velazquez Berumen, WHO
3:30 - 4:00PM		Break		Levels 4 & 5		
4:00 - 4:30PM		Summary		Great Room	Betsy Wilskie, Procurement Officer, PATH	Each group facilitator
4:30 - 6:30PM	Devices & Drinks	Exhibition of pulse oximeters and oxygen delivery technologies		Le Patio at the St. Regis	Industry representatives	

Time	Session	Topic		Location	Facilitator(s)	Presenter(s)
8:30 - 9:00AM	Brief review of Day 1	-		Great Room	Dino Rech, Senior Program Officer, Bill and Melinda Gates Foundation	-
9:00 - 9:15AM	Industry insights Topics discussed: Use cases for pulse oximeters and oxygen delivery technologies, innovative strategies companies utilize to improve access, remaining limitations of existing technologies, and pipeline innovations Expected outcomes: Understanding of key considerations in selecting an appropriate device model based on the use case, opportunities for replicating manufacturer-led initiatives to improve access to safe oxygen delivery identified, gaps in innovation with the potential to leapfrog access prioritized Format: Panel discussions	Introduction: Leveraging existing technology to improve access now and innovation later		Great Room	Mike Ruffo, Market Dynamics Officer, PATH	Mike Ruffo, Market Dynamics Officer, PATH
9:15 - 10:15AM		Panel: Appropriate SPO2 monitoring systems *Masimo (US)* *Philips (US)* *Acare (Taiwan)* *Nonin (US)* *Nellcor/Medtronic (US)*			Mike Ruffo, Market Dynamics Officer, PATH	Grant Aaron, Masimo, Director of Global Health Niels Buning, Philips, Venture Manager, Africa Healthcare Strategy & New Business Development Linda Cheng, Acare, CEO Walter Holbein, Nonin, Physiologist Dr. Arash Taki, Nellcor (Medtronic), Marketing Manager, Middle East, Africa, Central Asia, & Turkey
10:15 - 10:30AM		Break		Pre Function		
10:30 - 11:30AM		Panel: Appropriate oxygen delivery technologies *Nidek (US)* *Chart Industries (US)* *Sysadvance (Portugal)* *BOC (Kenya)* *Fyrom (Indonesia)*		Great Room	Mike Ruffo, Market Dynamics Officer, PATH	Joe Krawczyk, Nidek, President & CEO Angelo Barberic, Chart Industries, Region Manager Jose Vale Machado, Sysadvance, CEO Millicent Onyonyi, BOC, Managing Director Dr. Ole Mulyadi, Fyrom, Chairman
11:30 - 12:00PM		Summary			Mike Ruffo, Market Dynamics Officer, PATH	Mike Ruffo, Market Dynamics Officer, PATH
12:00 - 1:00PM	Lunch			Pre Function		
1:00 - 1:15PM	Sustaining supportive systems Topics discussed: Medical device procurement and management including ongoing maintenance Expected outcomes: Key considerations in comparing devices based on the estimated total cost of device ownership and pros and cons of different approaches to improve management of medical devices by both country stakeholders and industry members Format: Rotating small group discussions	Introduction: Managing medical device procurement and service		Great Room	Lisa Smith, Market Dynamics Officer, PATH	Lisa Smith, Market Dynamics Officer, PATH
1:15 - 3:15PM		Roundtable Sessions	Using total cost of ownership to inform procurement and maintenance	Studio 1	Spike Nowak, Market Dynamics Associate, PATH	Martha Gartley, Technical Adviser, CHAI
			Methods for harmonizing demand in centralized and decentralized procurement systems	Studio 2	Betsy Wilskie, Procurement Officer, PATH	Agus Prabowo, Chairman, LKPP
			Medical device asset management and tracking	Studio 3	Mike Ruffo, Market Dynamics Officer, PATH	Anjaney, Consultant Healthcare Technologies (Medical Devices), NHSRC
			Strategies for sourcing medical device maintenance	Studio 4	Lisa Smith, Market Dynamics Officer, PATH	Dr. Steve Adudans, Executive Director, Center for Public Health and Development (CPHD)
3:15 - 3:30PM		Break		Levels 4 & 5		
3:30 - 4:00PM		Summary		Great Room	Lisa Smith, Market Dynamics Officer, PATH	Lisa Smith, Market Dynamics Officer, PATH
4:00 - 5:00PM	Wrap-up and closing remarks	Prioritization of future efforts		Great Room	Dino Rech, Senior Program Officer, Bill and Melinda Gates Foundation	
5:00 - 5:15PM		Closing remarks				
6:00 - 9:00PM	Dinner			Seasonal Tastes Restaurant at the Westin		

Time	Session	Topic		Location	Facilitator(s)	Presenter(s)
8:30 - 9:00AM	Brief review of industry participation	Future engagement with manufacturers & the role of distributors in improving access		Great Room	Mike Ruffo, Market Dynamics Officer, PATH	Mike Ruffo, Market Dynamics Officer, PATH
9:00 - 10:00AM	Country coordination Topics discussed: Next steps and/or action plans for country stakeholders based on convening information Expected outcomes: Draft plans developed by country stakeholders and continued engagement between delegation members after the convening Format: Country delegation discussions	Introduction: Key considerations and tools for work planning		Great Room	Audrey Battu, Director Essential Medicines, CHAI	Audrey Battu, Director Essential Medicines, CHAI
10:00 - 11:30AM		Roundtable Sessions	Ethiopia		Alemayehu Birehanu, CHAI, Ethiopia	Delegation discussion
			Kenya		Janet Shauri, Consultant, PATH; Dr. Khadija Abdalla, Health Officer, UNICEF	Delegation discussion
			India		Dr. Rajiv Tandon, Technical Director, MNCHN+A, PATH, India	Delegation discussion
			Indonesia		Russ Vogel, PATH consultant, Indonesia	Delegation discussion
			Nigeria		Chizoba Fashanu, CHAI, Nigeria	Delegation discussion
			Tanzania		Betsy Wilskie, Procurement Officer, PATH	Delegation discussion
11:30 - 11:45AM		Working Break		Pre Function		
11:45 - 12:15PM		Summary/delegation report-outs		Great Room	Dino Rech, Senior Program Officer, Bill and Melinda Gates Foundation	Dino Rech, Senior Program Officer, Bill and Melinda Gates Foundation
12:15 - 12:45PM	Wrap-up and closing remarks			Great Room	Dino Rech, Senior Program Officer, Bill and Melinda Gates Foundation	All participants
12:45 - 1:30PM	Lunch			Level Seven Resturaunt		
1:30 - 3:30PM	Financier meeting (closed door)			TBD	Dino Rech, Senior Program Officer, Bill and Melinda Gates	Funding agencies

APPENDIX B: PARTICIPANT CONTACT LIST

Name (First, Last)	Title	Organization	Country	Email
Abdul Mohamed	Investment Manager	Grand Challenges Canada	Canada	abdul.mohamed@grandchallenges.ca
Adriana Velazquez Berumen	Senior Advisor on Medical Devices	World Health Organization	Switzerland	velazquezberumena@who.int
Agus Prabowo (Dr.)	Chairman	Indonesia National Procurement Board (LKPP)	Indonesia	prabowo@lkpp.go.id
Ajay Khera (Dr.)	Deputy Commissioner & In Charge	Ministry of Health and Family Welfare, India	India	ajaykheramch@gmail.com
Alemayehu Berhanu Belete	Senior Program Officer	Clinton Health Access Initiative (CHAI)	Ethiopia	aberhanu@clintonhealthaccess.org
Andi Saguni (Dr.)	Director of the Health Service Facility Directorate	Ministry of Health, Indonesia	Indonesia	andi_saguni@yahoo.com
Andrew Omidvar	Vice President of Enterprise and Government R&D	Philips Healthcare	Denmark	Andrew.omidvar@philips.com
Andy Gouws	Commercial and Business Development Manager	African Oxygen Limited (Afrox)	South Africa	andy.gouws@afrox.linde.com
Angelo Barberic	Regional Sales Manager	AirSep Corporation	United States of America	Angelo.Barberic@chartindustries.com
Anil Kumar	Additional Deputy Director General, Directorate General of Health Services	Ministry of Health and Family Welfare, India	India	dr.anilkumar@nic.in
Anjaney	Consultant—Medical Devices	National Health Systems Resource Center	India	anjaney@nhsrcindia.org
Anthoni Mkhotya	Civil Engineer	Ministry of Health, Tanzania	Tanzania, United Republic of	amkhotya2@gmail.com
Arash Taki (Dr.)	Marketing Manager, Middle East, Africa, Central Asia, and Turkey	Medtronic	United States of America	arash.taki@medtronic.com
Asfaw Afework Bekele	Senior Biomedical Engineer, Technical Advisor	Ministry of Health, Ethiopia	Ethiopia	asfawafe@gmail.com
Ata Özcan	Technical Manager	Özcan Kardeşler	Turkey	ataozcan@ozcankardesler.com
Audrey Battu	Director, Essential Medicines	Clinton Health Access Initiative (CHAI)	United States of America	abattu@clintonhealthaccess.org

Beluh Mabasa Ginting	Head of Standardization Section (Clinical Engineering)	Ministry of Health, Indonesia	Indonesia	bmginting@yahoo.com
Ben Creelman	Product Development Engineer	PATH	United States of America	bcreelman@path.org
Bev Bradley	Programme Coordinator (Oxygen Therapy)	UNICEF	Denmark	bev.bradley@gmail.com
Bob Schlehr	Vice President Sales & Marketing	Oxygen Generating Systems Intl. (OGSI)	United States of America	bschlehr@ogsi.com
Bonnie Keith	Senior Program & Policy Officer	PATH	United States of America	bkeith@path.org
Brenda Mbathi	Executive Director, Government Affairs & Policy, Eastern Africa, CSR Africa	GE Foundation	Kenya	brenda.mbathi@ge.com
Candia Tom Aliti	Assistant Commissioner, Planning	Ministry of Health, Uganda	Uganda	aliti68@yahoo.com
Celina Schocken	Commercialization Advisor	Global Good	United States of America	cschocken@intven.com
Chao Liu	Sales Director	Yuyue Medical	China	liuchao@yuyue.com.cn
Charles Mwansambo	Chief of Health Services, Malawi	Ministry of Health, Malawi	Malawi	cmwansambo@gmail.com
Charles Olaro (Dr.)	Director, Clinical Services	Ministry of Health, Uganda	Uganda	olarocharles@gmail.com
Chizoba Fashanu (Dr.)	Deputy Director, Essential Medicines for CHAI Nigeria	Clinton Health Access Initiative (CHAI)	Nigeria	cfashanu@clintonHealthAccess.org
Christina Widaningrum (Dr.)	Head of National Pneumonia Program	Ministry of Health, Indonesia	Indonesia	ning.inolep@gmail.com
Collins Cheruiyot	Program Analyst	Clinton Health Access Initiative (CHAI)	Kenya	ccheruiyot@clintonhealthaccess.org
Conner House	Program Assistant, Market Dynamics	PATH	United States of America	chouse@path.org
Cyrus Sira Sitra Mulepo (Eng.)	Senior Engineer, Medical Equipment	Ministry of Health, Uganda	Uganda	sitraik@hotmail.com
Daniel Lieberman	Principal Investigator	Global Good	United States of America	dalieberman@intven.com
Demeweze Fikadu	Medical Device Regulation Expert (BME)	Ethiopia Food, Medicine, and Healthcare Administration and Control Authority	Ethiopia	Demoze021@gmail.com

Deni Herdiana (Dr.)	Staff, Pre Marketing for Medical Devices, Directorate General for Drug and Medical Device Support	Ministry of Health, Indonesia	Indonesia	deni.herdiana2004@gmail.com
Dhanaraju Sanjeevarayappa	Director, Health and Family Welfare	Government of Madhya Pradesh	India	drs.loksevak@gmail.com
Dino Rech	Program Officer	The Bill & Melinda Gates Foundation	United States of America	Dino.Rech@gatesfoundation.org
Diouf Awa Ndiaye	Director	Direction des Infrastructures, de L'Equipement et de la Maintenance	Senegal	awandiayediouf@yahoo.fr
Dirk Westhues	Managing Director	Kröber Medizintechnik GmbH	Germany	DWesthues@kroeber.de
Edmealem Tiruneh	Health Commodity and Supply Service and Distribution Core Process Owner	Amhara Regional State Health Bureau	Ethiopia	edmealemadmasu@yahoo.com
Elizabeth (Betsy) Wilskie	Procurement Officer	PATH	United States of America	bwilskie@path.org
Emin Adhy Muhaemin	Head, "e-Katalog" Department	Indonesia National Procurement Board (LKPP)	Indonesia	muhaemin@lkpp.go.id
Emma Hawkins	Program Assistant	The Bill & Melinda Gates Foundation	United States of America	Emma.Hawkins@gatesfoundation.org
Frankline Keter (Dr.)	Manager	Clinton Health Access Initiative (CHAI)	Kenya	fketer@clintonhealthaccess.org
Gerald Mrema	Deputy Head of Radiology and Imaging Services	Ministry of Health Community Development, Gender, Elderly, and Children—Headquarters	Tanzania, United Republic of	gmrema@moh.go.tz
Gilbert Shetak (Dr.)	Senior Medical Officer	Ministry of Health, Nigeria	Nigeria	shetakg@gmail.com
Grant Aaron	Director of Global Health	Masimo	United States of America	gjaaron@masimo.com
Hamish Graham (Dr.)	Paediatrician, Research Fellow	University of Melbourne Centre for International Child Health	Australia	Hamish.Graham@rch.org.au
Handy Purama	Marketing Director	PT Fyrom	Indonesia	handypurnama@ymail.com
Hanneke Heitling	Director of Sales—EMEA	Nonin Medical Inc.	United States of America	hanneke.heitling@nonin.com
Hashim Warfa (Dr.)	Head, Neonatal, Child Health, and Adolescent Health	Ministry of Health, Kenya	Kenya	owarfa@yahoo.com
Hassan Yashim	Biomedical Engineer	Ministry of Health and Human Services, Nigeria	Nigeria	yashimhassan@yahoo.com

Hekali Zhimomi	Secretary, Medical Health	Government of Uttar Pradesh	India	secupmhfw@gmail.com
Iain Wilson (Dr.)	UK Board of Trustees	Lifebox	United Kingdom	iainhwilson@me.com
Jackson Kioko (Dr.)	Director of Medical Services	Ministry of Health, Kenya	Kenya	jackson.kioko@health.go.ke
Janet Shauri	Market Dynamics Team Member	PATH	Kenya	jshauri@path.org
John Murima (Dr.)	Medical Superintendent/ Senior Deputy Director Medical Services	Rift Valley Provincial General Hospital Nakuru	Kenya	rvpghnakuru@yahoo.com
José Vale Machado	CEO	Sysadvance SA	Portugal	jmvm@sysadvance.com
Joseph Krawczyk	President/CEO	Nidek Medical Products Inc.	United States of America	Joe_krawczyk@msn.com
Juma Mfinanga	Emergency Medicine Specialist	Muhimbili National Hospital, Tanzania	Tanzania, United Republic of	jumamfinanga@gmail.com
Kamilu Mudi Salisu	Acting Managing Director	Drugs and Medical Consumables Supply Agency, Kano State	Nigeria	kamilusalisu@gmail.com
Katerina Galluzzo	Technical Officer	UNITAID	Switzerland	galluzzok@unitaid.who.int
Khadija Abdalla (Dr.)	Health Specialist (MNH)	UNICEF Kenya	Kenya	kabdalla@unicef.org
Kristoffer Gandrup-Marino	Chief of Innovation	UNICEF	Denmark	kgandrupmarino@unicef.org
Linda Cheng	CEO	Acare Technology Co., Ltd.	Taiwan	linda@acarecorp.com
Lisa Hsu	Sales Manager	Acare Technology Co., Ltd.	Taiwan	lisa@acarecorp.com
Lisa Smith	Market Dynamics Officer	PATH	United States of America	lsmith@path.org
Lorna Muhirwe (Dr.)	Associate Director	Clinton Health Access Initiative (CHAI)	Uganda	lmuhirwe@clintonhealthaccess.org
Machdian Muharrom Amarulloh	Engineer, Senior Management Team	PT Fyrom International	Indonesia	mahdian_71@yahoo.com
Macpherson Mallewa	Chairperson of the Paediatric and Child Health Association of Malawi	University of Malawi College of Medicine	Malawi	vp@medcol.mw
Martha Gartley	Technical Advisor, Oxygen Access	Clinton Health Access Initiative (CHAI)	Netherlands	mgartley@clintonhealthaccess.org
Martin Owino (Eng.)	Head, Medical Engineering and Technologies Unit	Ministry of Health, Kenya	Kenya	martin.owino@health.go.ke

Michael Ruffo	Market Dynamics Officer	PATH	United States of America	mruffo@path.org
Millicent Onyonyi	Managing Director	British Oxygen Company (BOC) Kenya Limited	Kenya	millicent.onyonyi@boc.com
Mohamed Sheikh (Dr.)	Head, Division of Family Health	Ministry of Health, Kenya	Kenya	headdfh2016@gmail.com
Mutiu Bakare (Dr.)	Project Manager	Oxygen Implementation Project	Nigeria	aadebayobakare@gmail.com
Niels Buning	Venture Manager	Philips Healthcare	Netherlands	Niels.buning@philips.com
Norman Lufesi	Program Manager	Ministry of Health, Malawi	Malawi	nlufesi@yahoo.com
Ole Mulyadi (Dr.)	Chairman and Owner	PT Fyrom International	Indonesia	olemulyadi@yahoo.com
Olivier Robberechts	Access Oxygen Project Director	Air Liquide	France	olivier.robberechts@airliquide.com
Priscilla Rozé-Pagès	Inclusive Business Director	Air Liquide	France	priscilla.roze-pages@airliquide.com
Rajiv Tandon (Dr.)	Technical Director	PATH	India	rtandon@path.org
Ray Cummings	Director, Market Dynamics	PATH	United States of America	rcummings@path.org
Rinawati Rohsiswatmo (Dr.)	Pediatrician/Senior Member of the Indonesian Pediatrician Association	Private Medical Practitioner	Indonesia	rinarohsis@gmail.com
Robert Neighbour	Managing Director	Diamedica UK Ltd.	United Kingdom	r.neighbour@diamedica.co.uk
Roger Rassool	Director	FREO2 Foundation Australia	Australia	roger@freo2.org
Rosemary Kihoto	Program Director, MNCAH	Clinton Health Access Initiative (CHAI)	Kenya	rkihoto@clintonhealthaccess.org
Russell Vogel	Independent Consultant	PATH	United States of America	russjsi2009@gmail.com
Samba Ka	After-Sales Service Director	Carrefour Medical	Senegal	sambaka@cosemad.sn
Simret Amha (Dr.)	Team Leader, Clinical Services Directorate	Ministry of Health, Ethiopia	Ethiopia	brnt3475@gmail.com
Smita Kumar	Senior Newborn Advisor	USAID	United States of America	smkumar@usaid.gov
Spike Nowak	Market Dynamics Associate	PATH	United States of America	snowak@path.org
Srinivasa Reddy Pilli	Senior Technical Officer	Andhra Pradesh MedTech Zone Ltd.	India	srinivasa.reddy@amtz.in
Stephen Yun	Sales Manager	EDAN Instruments Inc.	China	Stephen.Yun@edan.com.cn
Steve Adudans (Dr.)	Executive Director	Center for Public Health and Development	Kenya	steve.adudans@cphdev.org

Steven Cowan	Director, Partnership Development	Assist International	United States of America	scowan@assistinternational.org
Tayo Olaleye (Dr.)	Associate, Essential Medicines	Clinton Health Access Initiative (CHAI)	Nigeria	tolaleye@clintonhealthaccess.org
Vincent Rouvier	Director Dialysis Program + Inclusive Business Healthcare referent	Air Liquide	France	vincent.rouvier@airliquide.com
Walta Embaye	Medical Equipment Specification Preparation and Evaluation Senior Expert (BME)	Ethiopia Pharmaceutical Fund and Supply Agency	Ethiopia	Walsmovment@gmail.com
Walter Holbein	Physiologist	Nonin Medical Inc.	United States of America	walter.holbein@nonin.com
Yared Cherenet (Dr.)	Newborn and Child Health Programs Technical Assistant	Ministry of Health, Ethiopia	Ethiopia	chexpert8.mch@gmail.com

APPENDIX C: ADDITIONAL RESOURCES PROVIDED ON FLASH DRIVE

Root Directory

- Participant List
- Agenda

Folders

1. **Accelerating Access to Oxygen (A2O2) Convening Materials**
   - A. Action Workbook
   - B. Note-Taking Template
   - C. Site Maps
2. **World Health Organization (WHO) Publications on Oxygen Delivery**
   - A. Strengthening access to oxygen delivery systems
     - i. 20th edition Model List of Essential Medicines (March 2017, amended August 2017)
     - ii. 6th edition Model List of Essential Medicines for Children (March 2017, amended August 2017)
     - iii. Interagency List of Medical Devices for Essential Interventions for Reproductive, Maternal, Newborn, and Child Health, 2015—English/French
   - B. Clinical recommendations on oxygen therapy for hypoxemia management
     - i. Better Hospital Care for Children Final Technical Report 2016—English
     - ii. Clinical management of severe acute respiratory infections (SARI) when novel coronavirus is suspected, 2016—English
     - iii. Clinical management of severe acute respiratory infection (SARI) when Middle East respiratory syndrome coronavirus (MERS-CoV) infection is suspected, 2016—English
     - iv. Guidelines on Basic Newborn Resuscitation, 2012—English/French
     - v. IMAI district clinician manual: Hospital care for adolescents and adults, 2011, Volume 1—English
     - vi. IMAI district clinician manual: Hospital care for adolescents and adults, 2011, Volume 2—English
     - vii. Managing Complications in Pregnancy and Childbirth: A Guide for Midwives and Doctors, 2007—English
     - viii. Managing Newborn Problems: A Guide for Doctors, Nurses, and Midwives, 2003—English
     - ix. Oxygen Therapy for Children: A Manual for Health Workers, 2016—English/French
     - x. Pediatric emergency triage, assessment, and treatment: Care of critically ill children: Updated Guidelines, 2016—English
     - xi. Pocket Book of Hospital Care for Children, 2013—English/French
     - xii. Recommendations on Interventions to Improve Preterm Birth Outcomes, 2015—English/French
   - C. Oxygen technologies and supplies
     - i. Compendium of Innovative Health Technologies for Low-Resource Settings, 2015—English
     - ii. Pulse Oximetry Training Manual, 2011—English
     - iii. Technical Specifications of Neonatal Resuscitation Devices, 2016—English
     - iv. Technical Specifications for Oxygen Concentrators, 2015—English/French/Spanish
   - D. Monitoring and evaluation of oxygen delivery systems
     - i. Essential Surgical Care (IMEESC): Essential Emergency Equipment List, 2009—English

ii. Essential Surgical Care (IMEESC) toolkit: Tool for situational analysis to assess emergency and essential surgical care, 2009—English
iii. Safe Childbirth Checklist: Implementation Guide, 2015—English/French/Spanish
iv. Service Availability and Readiness Assessment (SARA): Implementation Guide, 2015—English
v. Medical device technical series
vi. Global Atlas of Medical Devices, 2017—English
vii. Health Technology Assessment of Medical Devices, 2011—English/French/Spanish
viii. Human Resources for Medical Devices: The Role of Biomedical Engineers, 2017—English
ix. Introduction to Medical Equipment Inventory Management, 2012—English/French
x. Medical Equipment Maintenance Programme Overview, 2011—English
xi. Needs Assessment for Medical Devices, 2011—English/French
xii. Press Catalogue: Health Technologies, 2017—English
xiii. Procurement Process Resource Guide, 2011—English/French

3. USAID Do No Harm Technical Brief

A. USAID Safe and Effective Oxygen Use for Inpatient Care of Newborns, 2017—English

4. Additional Websites and Resources

A. A2O2 Additional Websites and Resources Document
B. Ethiopia National Medical Oxygen and Pulse Oximetry Scale Up Road Map, 2016–2020/21
C. IVAC Pneumonia & Diarrhea Progress Report, 2017

5. HO2PE Oxygen Gives Life—Campaign Resources

A. Oxygen Gives Life—Infographic
B. Advocate for Oxygen—Infographic
C. Social Media Graphics Toolkit 2017

6. PATH Guidance Documents

A. PATH Markets Matter Guide
B. Regulatory and Procurement Briefs
i. Ethiopia Procurement Brief
ii. Ethiopia Regulatory Brief
iii. India Procurement Brief
iv. India Regulatory Brief
v. Indonesia Procurement Brief
vi. Indonesia Regulatory Brief
vii. Kenya Procurement Brief
viii. Nigeria Procurement Brief
ix. Nigeria Regulatory Brief
x. Tanzania Procurement Brief
xi. Tanzania Regulatory Brief
xii. Uganda Procurement Brief
xiii. Uganda Regulatory Brief