Optimizing Oxygen Access and Reliability

Opportunities for scaling access and applications to other medical devices



This report provides an introduction to the **Oxygen Delivery Toolkit: Resources to plan and scale medical oxygen.** The toolkit provides materials to help decision-makers, implementers, and advocates plan, manage, and communicate the value of scaling up oxygen delivery systems and access to oxygen and pulse oximetry. The toolkit includes the following materials:

- Oxygen is Essential: A Policy and Advocacy Primer
- Health Facility Standards Guide
- Baseline Assessment Manual
- Consumption Tracking Tool
- Procurement Guide
- Quantification and Costing Tools
- Reference Pricing Guide
- Electricity Planning Guide
- Asset Management Guide

The toolkit is available at <u>www.path.org/oxygen-delivery-toolkit</u>.

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Acknowledgments

This report was written by PATH staff Zachary Clemence, Emily Gruber, Mike Ruffo, and Lisa Smith. The authors would like to thank the following individuals for their insightful feedback and support: Chizoba Fashanu (Clinton Health Access Initiative, Nigeria), Hamish Graham (University of Melbourne), Amina Ja'afar (Clinton Health Access Initiative, Nigeria), and Tayo Olaleye (Clinton Health Access Initiative, Nigeria).

Abbreviations

Aplikasi Sarana, Prasarana & Alat Kesehatan (Application Infrastructure and Medical Devices)
Center for Public Health and Development
disability-adjusted life year
essential medicines list
General Electric
Global Financing Facility
Lembaga Kebijakan Pengadaan Barang/Jasa Pemerintah (National Public Procurement Agency)
ministry of health
US Agency for International Development

Executive summary

Access to safe oxygen is essential for saving lives. However, oxygen remains undersupplied in many lowand middle-income countries, and often, patients who require oxygen for survival do not receive it. To close the gap in access, this guide outlines the high-level areas of engagement for countries to scale up access to safe oxygen, defined as a trained health care worker delivering oxygen from a reliable source and assisted by tools such as pulse oximeters. This guide is meant to be used by country decision-makers, global partners, and donors to understand the recommended activities and decision points within each area of engagement for scaling safe oxygen access.

Oxygen scale-up requires coordination across seven interrelated areas: policy and political commitment; financing; baseline assessment; quantification; procurement; distribution; and management and training. Within each area of engagement, there are decision points and actions to take, informational tools that can help countries achieve success in that area, and examples from illustrative countries. These areas of engagement are depicted in Figure 1 below. The symbol () denotes tools described in this guide.

Policy, political commitment, and financing are enabling factors for the other areas of engagement in oxygen scale-up. Countries can ensure political commitment to scaling oxygen by identifying champions within the ministries of health (MOHs) responsible for oxygen access and by creating oxygen task forces to align relevant stakeholders behind oxygen plans. Adding oxygen to national and subnational policies, such as national essential medicines lists (EMLs), ensures oxygen work has institutional backing. Financial commitment for oxygen in health budgets is crucial for funding scale-up and maintenance of oxygen services, and innovative financing mechanisms should be considered to allow for more efficient and increased spending on oxygen.

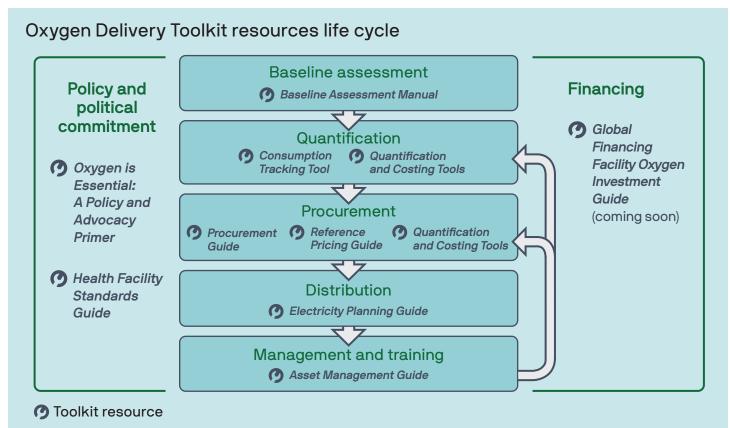
With the enabling factors in place, the first practical step is a **baseline assessment** that measures the current availability of oxygen within a health system. Next, oxygen **quantification** estimates countrywide patient need for oxygen during peak use, which can be compared with the baseline assessment to determine the current gap in functional and affordable access. Each of these steps has a corresponding tool to aid in measurement. **Procurement** will be required if a shortfall in oxygen delivery devices is identified from a baseline assessment. Health facility attributes must be identified to select and procure the best-suited oxygen delivery devices for a given context. These attributes are often referred to as the device use case and may comprise existing oxygen delivery device capacity, electricity availability, and available distribution system, among other considerations. After appropriate technical specifications for a facility are developed, procurement takes place based on these specifications.

An effective procurement process is aided by an understanding of the total cost of a device, which includes maintenance, electricity, and other factors along with the purchase price. Reference prices for a device can provide a benchmark for pricing negotiations with manufacturers and distributors. With information on costs and reference prices and an understanding of facility needs, appropriate devices may be purchased with competitive pricing and favorable sales terms. After procurement, **distribution** and installation of devices at the correct health facility are required.

Once devices are deployed, health workers will have the equipment necessary to deliver medical oxygen in treatment. However, work to increase safe oxygen access should not stop there. Systems for management of oxygen delivery devices and training programs for health workers are essential for continued functionality of devices and use at appropriate times for correctly identified patients. Appropriate medical oxygen use then provides essential information for improved quantification, procurement, and distribution over time. It is in this way that the seven areas for engagement work together to effectively scale access to safe oxygen in low- and middle-income countries.

While this report outlines tools and recommendations that exist for each area of engagement, further advocacy with country governments and financiers and further research on efficient, cost-effective, and integrated scale-up of approaches are merited. Future opportunities for continued investments to ensure safe oxygen scale-up are detailed at the end of this guide; they include research studies linking safe oxygen access to health outcomes across the health system rather than a specific disease area; exploration of results-based financing for facility reimbursement for oxygen; and expansion of oxygen-specific tools to apply to medical device scale-up more broadly.





How to use this guide

This guide presents a set of recommendations for scaling oxygen, defined as meeting the patient need for oxygen and pulse oximetry in a given geographic area. It is intended for use by country decision-makers, global partners, and donors to understand the decision points and recommended activities involved in safe oxygen scale-up, and how they fit together. Recommendations from exemplary countries and global partners engaged in scaling access to safe oxygen are found throughout the document to help provide concrete examples of the suggested steps.

The guide includes information on the <u>Oxygen Delivery</u> <u>Toolkit</u> resources and how they may be used as a high-level reference to guide investments in oxygen and pulse oximetry, with recommendations and links to other helpful tools.

The guide is organized in the following four sections:

• Making the case for investment in oxygen. This section provides an overview of why investments in oxygen are crucial for population health.

- Oxygen background: Technologies and supplies. This section reviews different devices involved in oxygen delivery to orient readers to the products relevant to scale-up efforts.
- Recommendations and considerations for investing in oxygen. This section outlines the seven areas for engagement in scaling access to oxygen and pulse oximetry. For each engagement area, existing resources, relevant tools from the <u>Oxygen Delivery Toolkit</u>, and recommendations for next steps are outlined to aid in decision-making and action. While recommendations are presented in a linear fashion in the narrative that follows, the steps are not strictly sequential and can happen simultaneously or out of the order given, depending on the context.
- Future opportunities for continued investment and research in oxygen. This section closes the report with an exploration of gaps in current knowledge and future opportunities.

Making the case for investment in oxygen

Oxygen is lifesaving and cost-effective, yet investment in strengthening the oxygen delivery systems is not always prioritized. This section explores this challenge and outlines the case for why oxygen is an important investment for broader health systems. In addition, it illustrates how recommendations within this guide apply to other medical devices.

Oxygen is lifesaving

Oxygen is a lifesaving medicine for hypoxemia (low levels of oxygen in the blood), which can occur in advanced stages of a wide array of medical conditions and is a major risk factor for death. Access to safe oxygen, defined as a trained health worker delivering oxygen from a reliable source and assisted by tools such as pulse oximeters, has the potential to decrease global morbidity and mortality from all diseases that may require oxygen therapy, including pneumonia, birth asphyxia, and obstetric emergencies.

Oxygen is crucial for health systems because it is indicated as treatment for a wide range of conditions that affect children and adults. See Figure 2 for examples of conditions that may require oxygen treatment. As such, increasing access to safe oxygen is a high-impact global health intervention with the potential to:

- Reduce childhood mortality due to pneumonia, the leading cause of death of children under 5 years old, by 35 percent.^{1,2}
- Prevent up to 400,000 neonatal deaths per year with application of full supportive care for infections, including antibiotics and oxygen therapy.¹
- Increase survival of mothers impacted by obstetric complications (15 percent of mothers worldwide), many of which require oxygen treatment.³
- Ensure safe surgery and effective anesthesia, for which oxygen is critical.⁴

Figure 2. List of conditions that may require oxygen treatment.

Oxygen is an essential component of robust health systems, as it treats a wide-ranging spectrum of conditions. The following is a non-comprehensive list of conditions that may require oxygen therapy:

Pneumonia	Birth asphyxia
Sepsis	Postpartum
Asthma	hemorrhage
Malaria	Shock
Chronic obstructive pulmonary disease	Surgical emergencies
Eclampsia	

Oxygen is cost-effective

Oxygen interventions require significant financial investment. However, as evidence shows, such investment is a cost-effective way to improve health care resources.

In Papua New Guinea, improved oxygen delivery systems for childhood pneumonia cost the system US\$50.00 per disabilityadjusted life year (DALY) averted.² Across the 15 countries with the highest pneumonia burden, providing pulse oximetry, combined with Integrated Management of Childhood Illness protocols, was found to cost between \$2.97 and \$52.29 per DALY averted.⁵ For comparison, the pneumococcal conjugate vaccine for pneumonia costs \$100.00 per DALY averted. While preventive measures, including vaccines, will always remain a first line of defense, curative care, including oxygen therapy, will always be essential for patients with conditions for which there is no vaccine or those with noncommunicable diseases who need oxygen. Relative to other health care interventions, pulse oximetry and oxygen therapy are cost-effective global health interventions.

Oxygen is underinvested in global health

Despite its value as an essential treatment in many disease areas, safe oxygen access is a consistently overlooked area of health systems. Studies suggest that supply of oxygen is inadequate and oxygen is often underprovided in low- and middle-income countries.⁶ There are multiple reasons for inadequate provision of oxygen, including broken devices or poor maintenance, lack of training for the health workforce on proper use of oxygen delivery devices, lack of awareness of the dangers of hypoxemia, or a shortage of funding dedicated to maintaining oxygen systems.⁶ The pervasiveness of oxygen use in a health system is perhaps the reason that it is so often overlooked and underfunded. Nearly every part of the health system and every disease area benefits from using oxygen, which means that responsibility is often diffused and no area takes major ownership for ensuring safe oxygen access. However, the all-encompassing need for oxygen can also be a benefit—investments in oxygen will have wide impact on population health, as safe oxygen access can lead to improved patient care across the health system.

Figure 3. Icons used to indicate the relevance of an oxygen intervention to other medical devices.

Investments proposed in this document will vary in their applicability to oxygen alone or durable medical devices more broadly. For each recommendation, an icon, shown in Figure 3, will be used to identify which oxygen interventions can be applied more broadly to other medical devices and which are specific to oxygen.



Broad application to other devices

The recommendation can be applied to other medical devices with no or very little adjustment.



Some application to other devices

The recommendation may be applied to other devices only under certain conditions. Or, the recommendation uses a tool that can be used for other medical devices but currently is only built to support oxygen devices.



Specific application to oxygen

The recommendation or tool is only applicable to oxygen devices and cannot be adjusted for use for other medical devices.

Oxygen interventions pave the way for broader medical device infrastructure

Oxygen is more than just a medicine: While most medications are provided through a supply chain that ends when the medicine gets to the patient, oxygen is delivered through devices that may require maintenance; supporting infrastructure, including electricity; and, in some cases, refill management. Oxygen is both a medical device and a medicine, which makes oxygen a unique investment in global health. For this reason, some recommendations for scaling oxygen are related to its status as a durable medical device and may benefit introduction and scale of other medical devices, whereas others pose unique challenges specific to oxygen due to its duality. Oxygen interventions are complex because health facilities need to have a constant supply of oxygen on hand, which requires transportation, electricity, supply chain management, maintenance, and training considerations. The benefit of this complexity is that comprehensive oxygen interventions are a proof of concept for investment in a wider array of medical devices. Improving procurement, supply chain management, and maintenance for reliable safe oxygen supply in a geographic region or specific health facility will benefit other durable medical devices requiring the same support (e.g., maintenance of ultrasound devices or restocking of surgical tubes).

Oxygen background: Technologies and supplies

Oxygen delivery and monitoring is a complex process that involves a variety of technologies and supplies. Pulse oximeters are simple devices used to detect hypoxemia and guide decisions on how much, and for how long, oxygen therapy should be delivered. Multiple sources are available for supplying oxygen medical gas in health facilities, including cylinders, concentrators, and central pipeline systems.

Pulse oximeter

Pulse oximeter is the measurement, using a simple, noninvasive device, of the amount of oxygen in the blood.⁷ The standard of care for detecting hypoxemia, pulse oximeter should be used to determine the need for oxygen therapy and to closely monitor the required concentration of oxygen.



Oxygen concentrators

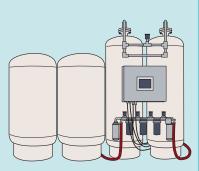
Oxygen concentrators draw air from the environment and concentrate oxygen, usually using a technique called pressure swing adsorption. Oxygen concentrators are usually small and transportable on wheels. They require a consistent supply of electricity and routine maintenance.



When power supplies are inadequate or susceptible to voltage fluctuations, power stabilizers or uninterruptible power supply may be needed.

Oxygen plants

Oxygen plants are centrally located industrial gas plants that generate oxygen in bulk. This can be done through pressure swing adsorption or vacuum

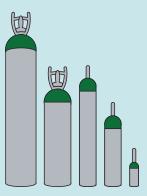


swing adsorption techniques (the same technologies as oxygen concentrators but at a larger scale) or cryogenic air-separation units, which produce liquid oxygen. Oxygen plants require large capital investment but can be an efficient method of oxygen delivery in high-use areas. Oxygen can be transported from a plant to a health facility through a pipeline system or through filling and delivering oxygen cylinders from the oxygen plant. Oxygen plants can range in size from small pressure swing adsorption/ vacuum swing adsorption plants providing oxygen for a single health facility to mass industrial gas production providing oxygen for a whole region or country.

For additional information, please see Oxygen Is Essential: A Policy and Advocacy Primer.

Oxygen cylinders or tanks

Oxygen cylinders or tanks contain set amounts of liquid or pressurized gas. They require continuous refills and are thus most useful where central refilling and transportation infrastructure are reliable and affordable.



Recommendations and considerations for investing in oxygen

Scaling up access to safe oxygen requires work in multiple areas of the health system, ranging from policy change to clinical training for health workers. This report breaks down the activities recommended for scaling oxygen into seven high-level areas for engagement: policy and political commitment; financing; baseline assessment; quantification; procurement; distribution; and management and training.

Each area of engagement in oxygen scale-up encompasses its own section of this report. The report section will begin with the importance of the given area, then provide specific recommendations for action. Exemplary case studies are included to show innovative country examples or adaptations of the recommendations based on country context.

Policy and political commitment

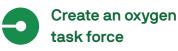
As with any large undertaking in global health, scaling up access to safe and reliable oxygen requires long-term commitment from the public health sector in low- and middle-income countries, as well as from the global health community. Oxygen interventions are health systems interventions—when implemented at a broad scale, they require interaction between health facilities and larger systems, such as distribution networks and maintenance systems. Because cost-effective oxygen interventions can be scaled at a national level, coordination within the health system is essential and high-level leadership is needed to foster that coordination. Along with leadership to promote safe oxygen access, a policy foundation is a critical driver of oxygen scale-up, forming a reference point for high-priority activities within health systems strengthening.

This section walks through recommendations for ensuring political commitment to providing safe oxygen and supporting that commitment through national and subnational policy.



Identify oxygen ownership

Because oxygen is included in many aspects of a health system, there are often no specific owner(s) to ensure consistent supply. Identifying owners and champions for safe oxygen access ensures dedication to implementing scale-up solutions. Ideally, there should be ownership of oxygen work within the MOH, either as part of a separate oxygen task force or within other areas of the ministry, such as medical devices, health systems, maternal and child health, or facilities management. To capitalize on the far-reaching nature of oxygen interventions, oxygen champions should foster and maintain connections with many divisions within the MOH (e.g., maternal, newborn, and child health; noncommunicable diseases; surgery).



Creation of an oxygen technical task force has been a successful method for coalition building around oxygen in multiple countries working to scale up oxygen. An oxygen task force helps to gather all parties who have a stake in safe oxygen scale-up, and it formalizes coordination.

Oxygen technical task forces typically have a variety of stakeholders from different organizations and with different skills and backgrounds. Task force members from MOHs can be from different sectors, including health systems, biomedical engineering, clinical services, pneumonia programs, medical equipment, and maternal and child health. Additionally, a task force can include members from multilateral organizations, civil society organizations, private-sector organizations, donor organizations, and health workers. An oxygen task force fosters partnership among these disparate groups and aligns all parties on safe oxygen scale-up plans. A task force can also be used to engage stakeholders for a short period of time around a specific objective. For example, in India, the Ministry of Health and Family Welfare created an oxygen committee as a short-term committee with a specific objective to frame technical guidelines for an oxygen supply system in the Indian public health care system. Whatever the form, the role of a task force is both technical and political to inform policymaking, prioritize safe oxygen access, and develop plans for how to accomplish safe oxygen scale-up.

Identify policy avenues in which to include oxygen

Advocating for inclusion of safe oxygen access in national and/or subnational public health commitments can be crucial for making change, whether it be a policy change, an assessment of current oxygen availability, or increased funding for oxygen technologies. The tool <u>Oxygen is</u> <u>Essential: A Policy and Advocacy Primer</u> is a helpful place for advocates and decision-makers considering scaling up access to oxygen to begin this process.

The primer is an essential resource for undertaking the process of advocating for oxygen policy change and systems improvements. It includes:

- An explanation of the global need for oxygen and data on current undersupply of oxygen.
- Descriptions of the different types of oxygen delivery devices.
- Policy recommendations for safe oxygen access and the audience for each recommended policy.
- Language and messaging to be used for conversations with decision-makers, including a messaging map that highlights key evidence for advocating for increased access to oxygen.

In addition, while not exhaustive, inclusion of oxygen in the following types of policies can facilitate commitment to improve oxygen service delivery:

• EMLs. In 2017, the World Health Organization updated the listing of oxygen in its Model List of Essential Medicines for adults and children, designating oxygen as an essential medicine for the treatment of hypoxemia. By prioritizing essential medicines, national EMLs inform procurement decisions and allocation of financial resources toward medicines included on the EML. National EMLs should align with the World Health Organization language where appropriate, emphasizing oxygen's therapeutic indications.

COUNTRY CASE STUDY Nigeria's national oxygen scale-up strategy

In 2017, Nigeria's Federal MOH published the <u>National</u> <u>Strategy for the Scale-up of Medical Oxygen in Health</u> <u>Facilities</u>, which detailed the state of safe oxygen access, a problem analysis of the reasons for oxygen undersupply, and implementation plans for national scale-up of pulse oximetry and oxygen. Over a six-month period, Nigeria's Federal MOH, with its partner organization, the Clinton Health Access Initiative, led the stakeholder identification, policy drafting, review, and publication process.

Nigeria's success in efficient and detailed policy creation is due to their aligning of varied stakeholders in a technical working group and their creativity in resource utilization. The technical working group in Nigeria consisted of stakeholders from the Federal MOH, nongovernmental organization partners, privatesector oxygen manufacturers, academics, global experts, biomedical engineers, regulatory bodies, and clinicians. Leadership from the Federal MOH was essential in driving meeting attendance and deadlines. Among the stakeholders, the team identified passionate oxygen champions, who spearheaded subcommittees working on different policy sections.

The team took a comprehensive approach, simultaneously updating the essential equipment list and clinical oxygen guidelines to create a suite of oxygen-relevant policy updates. This holistic approach greatly increased their time efficiency, setting the stage for rapid improvements to the oxygen system in Nigeria. As an added benefit, this process led to the creation of a permanent oxygen desk within the Federal MOH, a specific position to manage oxygen policy and scale up efforts.

Under Nigeria's decentralized governance structure, states are given autonomy to prioritize, budget, and implement interventions, so the implementation of the suggested policies is varied. However, Nigeria's efficient and comprehensive strategy for defining oxygen policy is a prime example for countries aiming to define the landscape around oxygen policies nationally with state-level implementation.

- National health strategic plans, guidelines, and budgets. Because oxygen fits into many areas of the health system, plans for oxygen interventions may be included in various national policies, guidelines, and budgets—those related to maternal and child health, medical devices, emergency care, or health systems strengthening. National policy guidelines and implementation strategies from at least one of these health areas should explicitly include the maintenance of an adequate supply of safe oxygen, as well as provider training.
- National standards for medical devices in health facilities. Pulse oximeters and oxygen delivery devices should be added to relevant national device or equipment lists to prioritize their procurement and maintenance. Standards and norms documents are a country-specific set of guidelines on infrastructure or medical device specifications recommended in each health facility level. These documents may include suggested medical devices at each level, requirements on the location/infrastructure of facilities, staffing requirements, and health services provided.
- <u>Health Facility Standards Guide</u> provides recommendations to improve country-specific standards and norms documents and uses oxygen as a specific case study. The guide:

Financing

Scaling access to safe oxygen requires monetary investment and sustainable financing to provide access throughout health systems.

Aspects of safe oxygen scale-up that require funding include:

- Capital expenditures for oxygen delivery devices and pulse oximeters (costs for device purchasing, distribution, installation, device accessories).
- Operating expenditures for oxygen delivery devices and pulse oximeters (costs for electricity, labor for device maintenance, cylinder refills or device replacements, and spare parts).
- Staffing costs for projects to analyze device need.
- Payment for development of training resources for clinical staff.
- Training staff on use of new equipment.

Supporting oxygen delivery systems requires initial financial investments for device purchasing and distribution, as well as ongoing investments around maintenance or cylinder refills. Additionally, any development of large-scale infrastructure around procurement or supply chain will likely include significant up-front costs. For these reasons, budgeting for oxygen work within health financing budgets is critical. This section will describe possible avenues for funding oxygen and ideas for using funding efficiently.

- Compiles similarities, differences, and best practices from a review of standards and norms documents from countries across income levels and world regions.
- Offers suggestions for improving standards and norms documents for all medical devices.
- Uses oxygen as a specific case study to evaluate if there is additional value that can be generated by including more detail regarding guidelines for deployment of oxygen delivery systems and pulse oximeters.

Understanding the basic requirements for medical devices at each level of the health system can improve quality of care by aligning medical device needs with the appropriate scope of service at each level. Basic equipment requirements can also be used as a reference point for facility accreditation or budget allocation for new purchases. Evaluating a country's existing health facility standards and norms alongside the *Health Facility Standards Guide* can lead to improvements in equipment availability that may generate increased access to safe oxygen among all levels of the health system.

As funding options are wide-ranging and often contextspecific, this guide does not fully review all possible funding avenues but instead includes ideas for guiding direction and further exploration.

Allocate health financing toward oxygen

Financing for oxygen scale-up can originate from domestic health budgets or global development assistance. While there is a trend toward increasing domestic health funding, development assistance remains an important source of financing for low- and middle-income countries. For safe oxygen scale-up, funding from the donor community can be used to cover large start-up costs that ideally countries can later maintain. Multilateral donors have funded work to increase access to safe oxygen in the past and can be important partners for oxygen scale-up. While not an exhaustive list, Table 1 provides selected projects related to oxygen scale-up funded by global development assistance.

Regardless of how funding is obtained, oxygen should be included in domestic health resource-allocation discussions, whether it is funded under budgets for maternal and child health, health systems and infrastructure, or emergency care. This may require increased expenditure by the MOH.

Table 1. Summary of donor and funding interests for scaling up oxygen.

Donor	Funding interests
Bill & Melinda Gates Foundation	The Gates Foundation's oxygen investments focus on improving treatment for severe pneumonia, as well as broader maternal and child health goals. The Foundation has invested in the development and/or refinement of global and national normative standards through policy change. They have also made considerable investments in the markets for safe oxygen delivery, in both health system and technological innovation.
General Electric (GE) Foundation	The GE Foundation invests in public-private partnership models to build oxygen plants in low- and middle-income countries to increase reliable oxygen supply. These investments are part of the GE Foundation's broader commitment to funding sustainable maternal and child health solutions.
Global Financing Facility (GFF)	Oxygen scale-up is aligned with the GFF focus areas of high-impact, cost-effective, and systems-focused interventions for strengthening maternal, neonatal, and child health. Oxygen is listed as a high-priority investment for maternal, neonatal, and child health in the GFF investment cases for Tanzania and Uganda.
"la Caixa" Banking Foundation	"la Caixa" works closely with the United Nations Children's Fund as a partner in their initiative to better treat pneumonia, of which increased access to oxygen therapy is a key component. "la Caixa" investments fund research to test effectiveness of new diagnostic tools for identifying hypoxic children. ⁸
Unitaid	Unitaid is supporting existing projects to study the effect of wide-scale provision of and training on pulse oximetry. This includes development of multimodal technologies to measure oxygen saturation along with other basic vital signs. Unitaid investments are part of a broader goal to improve primary health care workers' ability to diagnose severe disease, particularly for children.
US Agency for International Development (USAID)	USAID investments from the maternal and child health programs and Center for Innovation and Impact focus on landscaping pneumonia treatment, including access to safe oxygen in Ethiopia. Additionally, USAID country missions often involve some aspect of oxygen scale-up in their maternal, newborn, and child health work.



Spend money allocated to oxygen more efficiently

With limited financial resources, financing scale-up of safe oxygen requires efficient investments that ensure value for money. Many other sections in this report target ways to spend smarter for oxygen. The "Understand reference prices" section discusses reference price resources for oxygen delivery devices to aid in price comparison and allow for purchasing supplies at the right cost. More coordinated procurement and supply chain systems, mentioned in the "Procurement" and "Distribution" sections, decreases administrative costs, taking advantage of the larger purchasing power of many health facilities, regions, or countries combined. Economies of scale can be very relevant in oxygen scale-up, as oxygen is needed throughout a country's health system and coordination can provide increased resource efficiency. Total cost of ownership calculations described in the "Understand costs" section will aid in comparing costs among different types of oxygen delivery devices to facilitate more informed procurement decision-making.

In addition to the aforementioned tools, PATH has developed a proposal for a new oxygen supply method, referred to as <u>Oxygen as a Utility</u>. Under this model, oxygen is treated like a public utility, such as water or electricity. Firms are contracted to generate, deliver, and supply oxygen as a service. The anticipated impact of implementing this model is increased competition among oxygen firms and longer-term, more reliable contracts that result in lower prices for oxygen services and expanded access.

Results-based financing is another approach that has gained popularity in health financing and can be applied to oxygen systems to improve spending efficiency. Results-based financing ties ongoing provision of money (to health providers or facilities) to the ability to meet certain performance indicators. The effectiveness of results-based financing is promising but currently needs additional research.^{9,10} A results-based financing scheme for oxygen delivery systems could attach a higher financial reimbursement to a health facility from the government or third-party financier based on that facility providing more reliable oxygen supply. If the facility meets the target, it receives additional payments. To date, no results-based financing schemes for oxygen are known, but this may be a promising area for exploration.

Public-private partnerships should also be explored as a method for better using funding for oxygen scale-up. This leverages private-sector expertise in large-scale oxygen production and delivery to provide more cost-efficient oxygen supply.

COUNTRY CASE STUDY Hewatele in Kenya

Hewatele is a social enterprise run under the Center for Public Health and Development (CPHD), a Kenyan nonprofit organization. In 2013, a health facility assessment showed that the need for oxygen in Kenya was not met by supply. To address the supply gap, a consortium of partners including CPHD, Assist International, GE Foundation, Frog Design, and Siaya District Hospital—designed Hewatele as a social enterprise dedicated to increasing safe oxygen access. In 2014, Hewatele worked with local governments to build an oxygen plant in Siaya County, which now produces and distributes oxygen to health facilities in over ten Kenyan counties. To date, Hewatele has scaled up construction of oxygen plants to two additional counties.

The Hewatele oxygen plants contract with health facilities to supply oxygen through cylinder delivery. Because Hewatele is a social enterprise and is not purely profit motivated, they can sell oxygen at cheaper prices than the commercial market. The result is that health facilities receive a reliable supply of oxygen for patients at low prices. Hewatele is owned and operated privately, with plans to transfer ownership of the oxygen plants to local governments when the investment is recouped.

Hewatele is an example of how a public-private partnership can increase spending efficiency by providing oxygen delivery at a low cost while maintaining quality standards. For such a public-private partnership, considerations should be made to explore availability of adequate start-up funding, establish quality standards, and create a financing model that can prove profitable for the private entity while keeping prices low. Additionally, strategies for the planned transition of ownership to government and a third-party evaluation of its impact on safe oxygen access are important for creating an effective public-private partnership.

Baseline assessment

Policy, political commitment, and financing provide an enabling environment for increasing access to oxygen. With some or all of those enabling factors in place, an initial step to increasing oxygen and pulse oximetry access is understanding the current state of oxygen availability. Performing a one-time baseline assessment is critical for scoping the landscape of oxygen availability in a country and determining the gap that needs to be filled for ensuring safe oxygen access for patients.



An understanding of oxygen availability can be compared with the estimated oxygen need to calculate the gap in availability. Once the gap in availability is understood, methods to meet the unmet need can be developed and costed as part of a scale-up strategy. The results from the baseline assessment can also be used as an advocacy tool to provide evidence of the gap in oxygen availability and the urgent need to act.

The Baseline Assessment Manual can be used to collect data regarding the availability of oxygen in health facilities. It is a ready-made digital survey tool for facility-level data collection on the availability of oxygen at a cross section in time. The tool collects data on all types of oxygen sources (concentrators, cylinders, plants), all levels of the health system, and all wards in a hospital. The data collection software is compatible with tablets or Android phones and is accompanied by a training curriculum for data collectors, introducing them to various types of devices and guiding them through use of the tool. The training ensures that data are collected properly and can be trusted for use in future decisions on oxygen delivery device purchasing. Use of the Baseline Assessment Manual can allow for a complete understanding of the current availability of oxygen, enabling identification of underproviding health facilities and streamlining efforts to increase supply to meet population need.

Quantification

After understanding the current state of oxygen availability, comparing the current state with total patient need for oxygen determines the gap in supply to be addressed by any oxygen scale-up efforts. This one-time quantification of patient need is included within the <u>Quantification and Costing</u> <u>Tools</u> described in the "Understand costs" section. A more continuous quantification process of regular monitoring of oxygen consumption to improve understanding of patient need over time is described in the section below.



Estimating the need for oxygen is an important step for ensuring oxygen supply meets the need and has utility at all levels of the health system—for individual facilities and at the subnational and national levels. Estimates of future oxygen need can inform oxygen use at new health facilities; forecast oxygen need for the procurement budget for a single facility, a region, or an entire country; or demonstrate the size of a potential market to plan investments. At the facility level, one way to estimate future oxygen need for facilities that already have an adequate supply of oxygen is based on past oxygen use. However, many facilities

Procurement

When gaps in oxygen supply are discovered by comparing current baseline with quantified need, procurement of additional oxygen delivery devices and pulse oximeters is necessary to fill the gap. Procurement can also occur regularly as additional need develops or devices break. An efficient procurement process for oxygen and other medical devices can save costs and ensure reliable purchasing of devices needed to support patient needs. This section introduces a procurement guide, which integrates all of the steps to procuring medical devices, a costing tool for oxygen delivery systems, and a pricing guide for comparing quoted prices to reference prices.

Establish a procurement process

Procurement processes play a critical role in selecting costeffective and sustainable safe oxygen delivery solutions appropriate for the unique needs of different health facilities.

The <u>Procurement Guide</u> describes the key steps that should be followed when procuring and contracting for an oxygen currently do not have efficient ways of tracking the amount of oxygen used at a granular level from plants, cylinders, and concentrators.

The <u>Consumption Tracking Tool</u> is used to track daily oxygen use in facilities. The tool tracks metrics on patient information along with metrics related to the volume of oxygen use. This information can then be used to monitor current oxygen usage, determine methods to budget appropriately and save costs, and estimate future oxygen need. The <u>Consumption Tracking Tool</u> should only be used for future planning if a facility has scaled up safe oxygen access and is meeting patient need. If this tool is used for a facility that is not meeting patient need, future planning and purchasing will be based on an underestimation of ideal oxygen supply.

If a facility is uncertain if it has an adequate supply of oxygen, the quantification tab within the <u>Quantification</u> <u>and Costing Tools</u>, described in the "Understand costs" section, can be used to estimate the full need at the facility, subnational, or national level. This estimate can then be compared to the data collected by using the <u>Consumption</u> <u>Tracking Tool</u> to understand whether the current supply is sufficient or whether there is a gap.

delivery system. It includes consideration of which oxygen delivery device is most appropriate for a particular health facility based on electricity, supply chain networks, and existing facility capacity (supply chain considerations for this decision are referenced in the "Distribution" section of this guide). The *Procurement Guide* also identifies the key stakeholders who should be involved in the procurement process and the tools and resources that can be used at each step to support the procurement process.

The *Procurement Guide* is intended to help procuring agencies:

- Understand the sequence of critical decisions that need to be made to support effective identification, selection, procurement, and introduction of oxygen delivery systems.
- Identify the analytical tools and resources that can be used by key stakeholders—such as end users, program personnel, procurement staff, and biomedical engineers or technicians—to support an integrated, effective decision-making and procurement process for oxygen delivery systems.

Information provided in the *Procurement Guide* can be drawn upon by procurement personnel and incorporated into their existing procurement processes to help ensure the effective selection, procurement, and introduction of oxygen delivery systems. Countries have taken various approaches to coordinating procurement, including Indonesia's innovative e-procurement system.

COUNTRY CASE STUDY Indonesia's e-Katalog

The responsibility for procurement in many low- and middle-income countries is decentralized and therefore often costly, with poorly coordinated demand. Indonesia is a large, dispersed island nation where governance decisions are made at the district level. If every district were to buy medical devices separately, there would be considerable duplication in transaction costs with device suppliers and, generally, in the administration of procurement processes. Instead, to take advantage of shared knowledge and create consolidated purchasing power, Indonesia created e-Katalog, a centralized online procurement system.

At the central level, the Lembaga Kebijakan Pengadaan Barang/Jasa Pemerintah or National Public Procurement Agency (LKPP) negotiates with device suppliers, who bid to have their devices included in the catalogue. If approved, LKPP negotiates prices and distribution costs and lists the device within the e-Katalog. Multiple stakeholders (e.g., LKPP, MOH, device users) assess the quality of devices. When a facility wants to purchase a device, it orders a device through e-Katalog, using prenegotiated prices and preapproved supplier agreements.

Because LKPP is negotiating prices for the whole country, it has a more streamlined administration and supply chain, and it can obtain quantity discounts. In addition, LKPP can limit the number of models for any given device on e-Katalog, which means that clinical users and biomedical engineers only have to be trained on certain types of devices, and replacement parts only need to be available for that set. Room for improvement in the e-Katalog process includes taking better advantage of purchasing power for negotiating lower prices. e-Katalog is an innovative and effective means to improving procurement processes for pulse oximeters and oxygen delivery devices in Indonesia and is a model for medical device procurement globally.



Understand

costs

Cost is an important factor in procurement decision-making. However, it can be difficult to evaluate which purchasing options are most appropriate for a given facility because of varying cost structures and infrastructure requirements. Additionally, comparisons between prices of different purchase options typically omit the costs of device operation postpurchase, which can be substantial. The Quantification and Costing Tool: Oxygen Delivery Sources and Quantification and Costing Tool: Pulse Oximetry Devices intend to help procurement decision-makers overcome these challenges by providing a holistic view of cost across oxygen delivery sources and pulse oximetry devices, based on facility needs, facility conditions, and the marketplace. The total cost of ownership to meet the health facility needs long-term is calculated differently for oxygen delivery devices and pulse oximeters; therefore, two separate tools were developed for cost comparisons.

The first module of the quantification and costing tool for oxygen delivery sources consists of formula-based

quantification for oxygen/oxygen device need and pulse oximetry need. In the oxygen tool, the number of beds by type, bed occupancy rate, and average oxygen flow rates are used to determine the ideal oxygen capacity for a health facility or group of health facilities. In the pulse oximetry tool, the need for pulse oximeters is calculated by examining the number of beds by type, and the number of devices needed per bed type. This quantification then informs the costing module of the tool; however, the quantification module can also be used as a stand-alone calculator for baseline ideal oxygen capacity or pulse oximetry need for a health facility.

The cost planning modules of the oxygen and pulse oximetry quantification and costing tools are designed to be used early in the process of procurement and strategic planning for oxygen by technical staff. These cost planning modules leverage the quantification modules and information about a given facility/facilities to support planning and budgeting of device purchases by calculating the required quantity and displaying the available device options and their associated costs. The oxygen tool has four device types, while the pulse oximetry tool has three device types. Overall, the outputs of each tool are the quantified need and the cost to fill this need over a specified planning period. These outputs are crucial for informed budgeting and procurement decisions.



Understand reference prices

In order to effectively negotiate reasonable prices with device suppliers while procuring new pulse oximeters or oxygen delivery devices, it is helpful to have a reference price to use as a benchmark for price comparison. Reference prices are an important safeguard against overcharging by device manufacturers and distributors, but obtaining a reference price for a device can be challenging. It is often difficult to make like-to-like price comparisons between devices with different specifications or order quantities. To assist in the process of creating reference prices for devices, the Reference Pricing Guide presents a guiding framework to MOHs for decision-making based on reference prices. The guide explains the importance of using reference pricing as a negotiating tool and can be broadly applied to reference pricing for all medical devices, using oxygen and pulse oximetry as examples. The guide helps government ministries create budgets to ensure the selection of appropriate and sufficient devices to generate health outcomes and includes discussions on safeguards against lowest-cost bias in situations where low cost can result in poor quality. The guide is limited in its capacity to provide a ready-to-use solution, as it requires past-purchase and other data to provide a reliable reference price estimation. However, the guide provides a starting point, as well as steps for customizing the reference price framework offered for a particular country, region, or medical device.

Distribution

As health facilities purchase new medical devices, the devices must be distributed to the facilities. Because gas oxygen cylinders need to be consistently refilled, distribution occurs frequently between the oxygen gas-generation site and the facilities. With oxygen concentrators or piping systems, distribution of spare parts for maintenance or replacement devices must be transported in an efficient and timely manner to the facility where they are located.

In addition to providing recommendations for optimizing distribution networks, this section discusses considerations for the product mix of oxygen delivery devices that would be appropriate for a given health facility, a decision that is strongly linked to the distribution capacity and infrastructure within a country.



Evaluate electricity capacity

Many essential medical devices (including oxygen concentrators) require electricity to function; however, access to consistent electricity is still limited in many lowand middle-income countries. Further, when electricity is available, frequent surges and sags in voltage, or dirty electricity, adversely affect the functionality of devices. These complexities in access and quality have led to device failures and the often-cited equipment graveyards investments in health care that do not reach their maximum potential.

The <u>Electricity Planning Guide</u>, with specific application to oxygen delivery devices, helps country decision-makers plan for deployment of medical devices in an environment with intermittent electricity access. The guide:

- Outlines the technology requirements decision-makers should consider before purchasing an electromedical device, including the electricity requirements for a specific device (e.g., voltage specifications and anticipated electricity draws).
- Outlines the wraparound technologies that should be procured along with any electromedical device (e.g., a voltage stabilizer and surge protector).
- Discusses methods for collecting electricity data—both electricity accessibility and quality data—to inform device selection and placement.

Choosing between an oxygen concentrator that requires electricity and a cylinder-based oxygen supply that requires no electricity can be a more-informed and evidence-based decision when the recommendations outlined in the resource guide are adopted and effectively implemented.



A coordinated supply chain and distribution process for oxygen delivery devices helps ensure that health facilities receive oxygen cylinder refills, liquid oxygen tank refills, or oxygen concentrator spare parts at the right time. The following decision points should be explored when designing a distribution network for oxygen delivery devices that ensures coverage for all health facilities in a country or region.

Device product mix decisions that affect distribution

Distribution will look different for health facilities based on their given product mix of oxygen delivery devices. For health facilities primarily using oxygen cylinders, regular cylinder refills are necessary for maintaining a constant supply of oxygen. Before choosing to rely mainly on oxygen cylinders, frequency of cylinder refills, travel time from an oxygen-generation site, and any difficulty navigating road networks should be considered. Any issues with travel to a health facility will significantly impact facilities relying heavily on oxygen cylinders. Similar considerations should be made for facilities using liquid oxygen tanks as a source of oxygen, which have the benefit of greater storage capacity because of higher density but may need larger trucks to distribute.

Centralized vs. hub-and-spoke vs. decentralized distribution

Distribution of oxygen cylinder refills and spare parts can take place from a central distribution site or from various

hubs throughout a country or can be decentralized to oxygen plants located at individual hospitals. Under a centralized distribution structure, all distribution begins at a central location where large-scale oxygen production takes place. In a hub-and-spoke system, oxygengeneration plants or storage facilities act as distribution hubs throughout the country, and health facilities receive supply from their nearest hub. Hubs are routinely resupplied from a central production location. Lastly, oxygen distribution can be decentralized if oxygen plants are built at hospitals and provide oxygen supply directly to those facilities.

In evaluating these options for distribution, factors to consider include:

- The size of a country and the distribution distances, for example the distance and travel time to each health facility based on ease of navigation through road networks.
- The amount of storage room at each health facility.
- The level of the health system with the capacity to properly maintain systems (e.g., oxygen plants require ongoing maintenance).

Cost-effectiveness is also an important consideration for example, distribution may be quicker with many individual oxygen-generation plants; however, oxygen plants are a capital-intensive investment, with costly operating expenses, and may not be the most efficient use of resources. Additional research is required for a more thorough recommendation regarding the most efficient supply chain system; however, the above considerations are important factors in distribution network planning.

COUNTRY CASE STUDY Ethiopia's decision tree for oxygen products

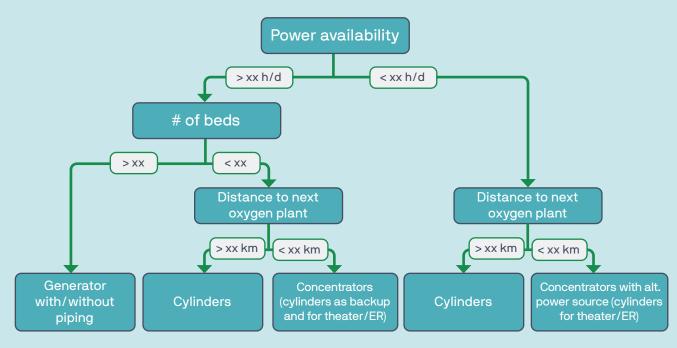
An important aspect of procurement of oxygen delivery devices is the selection of the product mix of oxygen delivery devices (concentrators, cylinders, or plant piping systems).

In 2016, Ethiopia created the <u>National Medical Oxygen</u> <u>and Pulse Oximetry Scale Up Road Map</u>, which outlined its plan for scaling oxygen and pulse oximetry throughout the country. Part of that Road Map was a consolidated decision tree meant to guide health facilities toward which type of oxygen delivery device would be best suited for that facility. The decision tree takes into account electricity availability, number of beds, and

Figure 4. Ethiopia's decision tree for oxygen products.

distance to an oxygen plant to determine the primary recommended method for oxygen delivery (see Figure 4).

The innovative aspect of this algorithm is its simplification of oxygen delivery-device recommendations to make the procurement and maintenance processes more straightforward for health facilities. Of course, the decision tree does not take every factor in purchasing into account, such as existing device capacity or the road network capability. For this reason, it is not meant as a strict rule for facilities but rather as a guide to make the decision process easier.



Note: alt, alternative; ER, emergency room; h/d, hours per day; km, kilometer.

Management and training

Once procured and deployed, use of pulse oximeters and oxygen delivery devices by health workers becomes an essential focus. This stage is broken down into two subareas: device management and clinical training.

To have an ongoing supply of safe oxygen for patients, management, maintenance, and repair must be ensured for resupplying oxygen cylinders or for repairing broken pulse oximeters and oxygen delivery devices. The first part of this section will walk through the necessity of functioning asset management systems and reliable deployment of biomedical engineers for management of oxygen systems. Recommendations for device management will include key considerations for maintenance, an asset management guide, and innovative country examples.



Make key maintenance decisions

Deciding how to structure device maintenance systems requires analysis of key decision points. This section walks through considerations for those decisions that are to be made by either facilities' management or biomedical engineering teams within the MOH.

Decentralized vs. centralized maintenance

Biomedical engineers can be employed at the facility level, district level, or country level. Table 2 outlines considerations for decentralized versus centralized maintenance structures. In many countries, there is a mixed staffing model—large central hospitals with significant need may employ in-house engineers, whereas smaller health facilities share centralized staffing for maintenance engineers. employed engineers can, at times, lead to a cost-quality trade-off. In countries with fewer biomedical engineers, private firms may be the only option for employment, if higher salaries at private companies attract engineers away from public-sector employment.

Leasing devices vs. owning devices

Biomedical device maintenance can take on a different structure, depending on whether devices are owned or leased at the time of purchasing. In an ownership model, responsibility for device maintenance falls to the purchaser, whereas in a leasing model, the leasing contract can include responsibility for device maintenance by the seller.

Leasing models for device purchasing are less common in low- and middle-income countries but have important benefits to consider. Benefits of leasing include:

- Ability to upgrade to a newer model after the lease expires, allowing for use of new, cutting-edge device innovations.
- Ability to include maintenance obligation of the seller, which can increase the reliability of device maintenance and lengthen the lifetime of a device.
- Ability to bundle the cost of maintenance and purchasing.

However, leasing models can be a challenge for countries because of inflexible budgeting structures. While a device is often leased for a five- or ten-year period, government budgets are structured annually, and there may not be a process for consideration of future leasing costs within annual budgets. The value and quantity of the group of devices being procured need to be considered, as complex leasing negotiations are often not appropriate for small purchases.

Private vs. public sector

Biomedical engineers responsible for maintaining oxygen delivery devices can be contracted from the public or private sectors. When contracting with the private sector, one advantage is that private firms may specialize in biomedical device maintenance and provide high-quality and timely services. If, instead, biomedical engineers are public employees contracted either by the health facilities themselves or by local governments, the government will likely pay less for services, as opposed to a private firm marking up service prices. Paying lower salaries to publicly

Table 2. Decentralized versus centralized maintenance structures.

Considerations	Decentralized maintenance	Centralized maintenance
Engineer employment structure	Employed directly at a health facility and responsible for a single facility	Employed at a higher level (usually district or country level) and responsible for multiple health facilities
Patient need considerations	Assumes high patient load causes high demand for device maintenance; enables engineers to be available at the facility whenever needed	Assumes device maintenance need at each facility is lower, as engineers cannot always be at a facility
Budget considerations	Includes engineer salary within health facility budget	Spreads engineer salary out among multiple health facilities
Engineer availability considerations	Assumes engineers are available for employment, which is often only true in populated, urban areas	Allows for travel of engineers to meet need in less-populated areas where engineers may not be available

Leasing models have seen success in Bhutan with a laboratory equipment leasing program and in Kenya with the Managed Equipment Services program. The Kenyan program contracts firms to oversee specialized medical device functionality for entire hospital units, including their supply, installation, testing, maintenance, replacement, and training. Ongoing payments are tied to device functionality, so there is an incentive for the contracted firm to provide high-quality maintenance services.

In either purchasing scenario, negotiating the purchasing agreement is critical. In particular, detailed devicemaintenance arrangements will ensure accountability to the appropriate party—public or private.

Handling donated devices

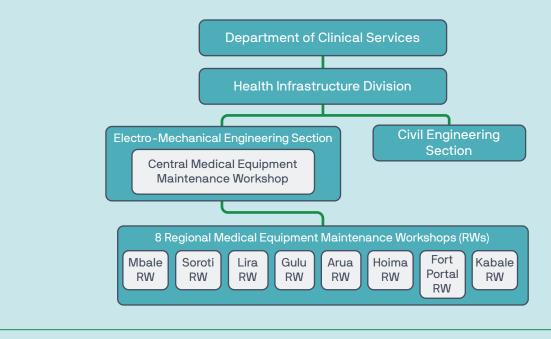
Donated medical devices can be a fundamental resource for subsidizing existing medical device inventory for facilities in need, allowing supply of such devices to catch up to need. However, a key to device donation management is to have a robust device donation policy that outlines the types of devices that are needed and accepted. Additionally, training on and maintenance of donated devices should be considered to avoid inappropriate or underutilized equipment. Ideally, there should be a method for incorporating donated medical devices into existing device maintenance systems. The World Health Organization has developed resources to guide countries on decisions pertaining to medical device donations, located here: https://www.who.int/medical_devices/ management_use/manage_donations/en/.

COUNTRY CASE STUDY Uganda's Regional Workshop maintenance model

To tackle the country's shortage of engineers in certain regions, the Ugandan MOH implemented a tiered maintenance model.¹¹ Under its Regional Workshop system, the country is split into eight regions, each housing a Regional Workshop of engineers responsible for medical device maintenance within that region, the exception being national referral hospitals that have their own engineering departments. Device users themselves are encouraged by Regional Workshop engineers to perform simple fixes for devices. A single Central Workshop supports Regional Workshops by fielding referrals for complex work and supervising Regional Workshops.

The tiered support model used in Uganda creates a clear structure of responsibility for device maintenance and employs engineers at a high-enough level to extend to rural or hard-to-reach areas.

Figure 5. Organizational diagram for Uganda's Regional Workshop model.





Establish an asset management system

Systems for device maintenance by trained biomedical engineers only work when engineers know where they have to go to fix a device and when the device is broken. Device inventories allow facilities to understand their current capacity of functioning medical devices, but they are only useful as long as the inventory is up to date. An asset management system can help operationalize real-time tracking of device inventory information, allowing procurement, restock, or maintenance decisions to be informed by reliable data. The <u>Asset Management Guide</u> provides a structure to design new, as well as improve existing, asset management systems at the facility and country levels. The guide outlines approaches to asset management already in use globally and includes a complete set of considerations that can be used in creating a robust inventory and asset management system. The resource guide walks through decisions on what data to collect and maintain for device maintenance and usage—spare parts, power requirements, and other important information about device life span, training, and specifications. Asset management databases at individual facilities can be aggregated for the state, region, or country level to allow for improved procurement decision-making and more reliable planning for device maintenance.

COUNTRY CASE STUDY Indonesia's ASPAK

Aplikasi Sarana, Prasarana & Alat Kesehatan, or Application Infrastructure and Medical Devices (ASPAK) is a countrywide asset management system in Indonesia run by the health facility unit of the MOH. ASPAK is a web-based database with information on medical device availability in every health facility in the country, as well as water and electricity availability. Facility managers are motivated to send in the data on device availability because it is linked to accreditation of the health facilities, which in turn is linked to funding allocation. The database is also used to manage device purchasing; if a facility wants to make a purchase, it makes a case to the MOH, and the MOH uses data from ASPAK to aid their decision. ASPAK is at the forefront of technologies for medical device maintenance and is used by the Indonesian MOH to track countrywide availability of oxygen delivery devices and pulse oximeters to identify high-priority districts or hospitals. Figure 6 provides an example of the use of ASPAK data showing the location and percentage of facilities in Indonesia with access to oxygen. A challenge of the ASPAK system is that the medical device inventories are self-reported by health facilities, which may provide conflict of interest, as the data are linked closely to funding. ASPAK is not integrated with the procurement database e-Katalog at this time. ASPAK is a prime example of an inventory management system to promote data use informing funding and action.



Figure 6. Heat map of Indonesian facilities with access to oxygen, created from ASPAK data.

COUNTRY CASE STUDY India's biomedical equipment maintenance program

When studies in India showed that an estimated 30 to 60 percent of medical devices in health facilities were nonfunctional, the National Health Systems Resource Centre, a technical assistance unit under the Indian Ministry of Health and Family Welfare, came up with an innovative public-private partnership solution for medical device management.¹² The Ministry of Health and Family Welfare's Biomedical Equipment Management and Maintenance Program created a contracting framework for private maintenance-service firms to be in charge of medical device maintenance for a given Indian state and period of time. Under the contract, the firm's duties include periodic assessment of medical equipment inventory and function, regular device maintenance, and the purchasing and use of spare parts. Individual states contract with maintenance-service providers under guidance from the National Health Systems Resource Centre, and regular payment to the maintenance firms is linked to data on device functioning in facilities. It also helped to do away

with separate annual maintenance contracts for different equipment, which are costly and time consuming.

India's biomedical maintenance program helps solve the problem of having few biomedical engineers in rural areas by centralizing biomedical device maintenance. In addition, the contracting model simplifies costs so that equipment, spare parts, labor, and transportation are all consolidated under one budget. Finally, device functionality is more reliable when firms have specific expertise and are financially responsible for ensuring reliability. A challenge in this work has been inconsistency in device inventory data between Indian states, where each has contracted with a different firm. When considering such an approach for medical device maintenance, it is important to have multiple large maintenance-service providers that can compete for the contract. Without a concentration of large maintenance firms, such a program would not be feasible.

Ultimately, however, patients only benefit from reliable supply of safe oxygen if health workers are adequately trained to diagnose hypoxemia and administer oxygen. While a critical element of realizing health impact, clinical training is often an afterthought in oxygen scale-up efforts.

Establish oxygen delivery device training for clinical users

Multiple studies have shown low provider knowledge on oxygen administration in resource-poor settings where oxygen may not be given frequently.⁶ In a study of hospitals in Malawi, every participating hospital had sufficient oxygen availability to meet the need of hypoxic patients, but only 22.5 percent of hypoxic patients received adequate oxygen treatment.¹³ Failings were not due to lack of supply but rather to poor diagnosis of hypoxemia due to reliance on clinical signs instead of use of pulse oximetry. While ensuring supply is an essential first step and a central focus of this report, appropriate administration with adequate clinical training should be a parallel focus.

Diagnosis of hypoxemia using pulse oximeters is an especially important facet of clinical training. In a study in 12 Nigerian hospitals, approximately 20 percent of children with hypoxemia received oxygen.¹⁴ At the same time, 38.5 percent of children receiving oxygen were not actually hypoxemic, demonstrating a misuse of scarce resources. Overoxygenation is also dangerous and is linked in neonates to retinopathy of prematurity, a cause of blindness. Especially in settings with limited oxygen access, proper diagnosis of hypoxemia is essential for safe and efficient use of a limited supply of oxygen. To ensure timely and proper administration of oxygen to patients, training for health workers on pulse oximetry and oxygen administration should be a key consideration in oxygen scale-up.

Because oxygen indications are so widespread, many types of clinical users may use pulse oximeters or administer oxygen therapy. Individuals operating oxygen delivery devices and, therefore, requiring training span the health system and include clinicians in pediatric and neonatal care, obstetrics, trauma, emergency care, surgery and anesthesia, intensive care, and primary care.

Training for oxygen should include explanations of¹⁵:

- Clinical indications for oxygen provision.
- Directions on how to screen and monitor patients for hypoxemia using pulse oximetry.
- Practical instruction on use of oxygen concentrators, cylinders, and piping systems, including fitting and using device accessories, such as nasal prongs.
- Clinical directions for appropriate oxygen doses and flow rates.

Table 3. Resources to draw on for developing oxygen training.

Title	Source	Use	Link
Oxygen Therapy for Children	World Health Organization, 2016	Clinical guidelines for oxygen administration	Link
		Use of oxygen equipment, routine maintenance and cleaning, accessory specifications (Annexes 1, 2, 3)	
Pulse Oximetry Training Manual	World Health Organization, 2011	Pulse oximetry use and proper reading, common alarms	<u>Link</u>
		Clinical causes of hypoxemia	
Pocket Book of Hospital Care for Children, 2nd Ed.	World Health Organization, 2013	Sick child triage steps, including appropriate oxygen indications and doses	<u>Link</u>
Surgical Care at the District Hospital	World Health Organization, 2003	Clinical guidance on safe oxygen use in surgery	<u>Link</u>
		Oxygen delivery device use and maintenance recommendations	
Device user manuals and videos	Specific oxygen delivery device manufacturers	Videos by device manufacturers on their websites describing use of their specific device technology	Manufacturer website
Pulse oximetry training video	Graham H. Pulse Oximetry & Oxygen for Children and Newborns [video].	Visual examples and clinical directions for pulse oximeter use	<u>Link</u>
	Melbourne: Centre for International Child Health, Royal Children's Hospital, University of Melbourne, Australia; 2015.	Common problems with pulse oximeters and solutions	

- Simple instructions on operation, cleaning, and preventive maintenance of oxygen equipment.
- Common device faults or alarms for oxygen delivery devices and how to address them.

Health facilities should have a person responsible for overseeing supervision of training to make sure that training is being conducted and that the appropriate health workers receive training, especially in settings with high staff turnover. This individual would be responsible for all continuing medical education, not solely for oxygen training. Table 3 lists resources to draw on for oxygen training.

Changing health worker behavior through training is challenging. However, strategies to increase the effectiveness of training include discussing the "why" behind the workflow change to motivate learners; using applied learning through clinical case problem-solving; providing a supportive learning environment; and using job aids to enforce learned behavior.¹⁶ Training at the provider's health facility itself is important for making training realistic and can uncover any environmental barriers to proper device use (e.g., finding the location of electrical outlets within a hospital ward). Additionally, peer training can be pivotal, and identifying a multidisciplinary group of well-regarded clinicians who themselves use pulse oximeters and oxygen delivery devices correctly can be an effective method for training the health workforce.⁶ Training need not be costly—a day-long training on use of pulse oximetry in Malawi cost about \$13 per trainee.¹⁷

Many of the above training techniques were successfully used in a Rwandan hospital, where clinical workers were trained on oxygen use with 45 minutes of classroom training, provision of pulse oximeters, and posters above patient beds showing the ideal SpO2 range.¹⁸ This training program increased the percentage of days where oxygen was given appropriately for all patients from 18.7 percent to 42.0 percent. During that time, the amount of oxygen used actually decreased from 32 tanks per day to 16 tanks per day (before the intervention, oxygen was administered to patients who did not need it). The training intervention was doubly effective in that it both increased proper oxygen administration for patients in need and decreased oxygen waste in the system.

Solely having oxygen available in a facility is not sufficient for improving health outcomes. Training on the use of pulse oximeters and oxygen delivery devices is hugely impactful for getting oxygen to patients in need, even in settings where oxygen supply is limited.

Future opportunities for continued investment and research in oxygen

While significant progress has been made in understanding the critical need for safe oxygen and creating tools and programs to optimize oxygen delivery systems, more work is necessary to truly scale access to safe oxygen in low- and middle-income countries. The following are areas for continued investment and research in oxygen that are high impact or help move the needle beyond current approaches and conventions.

Research studies linking increased oxygen access to health outcomes

Advocacy for oxygen interventions can be hindered by the lack of data directly linking increased oxygen access to improvements in health outcomes. Because oxygen is indicated as a treatment for many diseases, the totality of oxygen's impact is not well documented. A study correlating increased access to oxygen in a health facility to decreased pneumonia mortality, decreased maternal mortality, and better surgery outcomes, for example, would be impactful in advocating for oxygen scale-up. Even small-scale data collection efforts combined with thoughtful modeling could contribute to existing understanding of health impact. Continued work to develop a research strategy and implement a study (or studies) linking oxygen interventions to better health system outcomes is a crucial next step for pushing oxygen scale-up forward.

Additional cost-effectiveness studies for oxygen delivery devices

Often, a main barrier to oxygen scale-up for countries is the perception of high costs for health-systems-wide oxygen interventions. Prioritization of health spending often hinges on cost-effectiveness, and while there have been costeffectiveness studies for oxygen interventions, the number and geographic diversity of cost-effectiveness studies are limited. A larger evidence base for the cost-effectiveness of oxygen would likely bring in vastly increased funding for and attention to oxygen scale-up. Expanded studies on costeffectiveness of medical device scale-up more generally are also merited.

Increased understanding of oxygen product mix and supply chain optimization

High-income countries use primarily liquid oxygen with decentralized production hubs; this method has been assumed as infeasible in low- and middle-income countries, without concrete evidence. Future projects to model optimal oxygen product mix and time- and cost-efficient distribution networks have the potential to make oxygen access cheaper and more reliable for patients.

Results-based financing for oxygen interventions

To this point, oxygen interventions have not been included within results-based financing schemes, but results-based financing has shown promise for achieving the dual aims of lower costs and better results. Pilots for financing medical device reimbursement through results-based budgeting can demonstrate options for innovative financing to achieve wider safe oxygen access.

Development of a standard metric for measuring sufficient oxygen delivery

Measurement and evaluation are becoming increasingly prevalent in global health, and metrics are used for provision of funding, tracking of progress toward a public health goal, and adaptive management. The oxygen space would benefit from a globally agreed-upon metric for measuring adequate supply of oxygen and proper administration of oxygen to patients. Measurement of this metric should be standardized for cross-country comparison. This metric could be used as an indicator in country implementation plans, allowing countries and the larger global health community to track progress toward global safe oxygen access. Presence of such a metric would bring increased attention to oxygen as governments and funders are focusing more and more on data and measurement to assess priorities.

Translation of oxygen tools to broader medical device use

As noted in this guide, many lessons learned for oxygen can be applied to broader medical device infrastructure, but some of the tools developed remain specific to oxygen scale-up. Tools like the <u>Quantification and Costing Tools</u> can be more broadly impactful if they increase in scope to include other medical devices. The work done in the oxygen space can have a multiplicative effect on health systems if tools are extended to apply broadly to different types of medical devices.

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