Malawi National Medical Oxygen Ecosystem Roadmap 2021–2026

Government of the Republic of Malawi
Ministry of Health
Lilongwe
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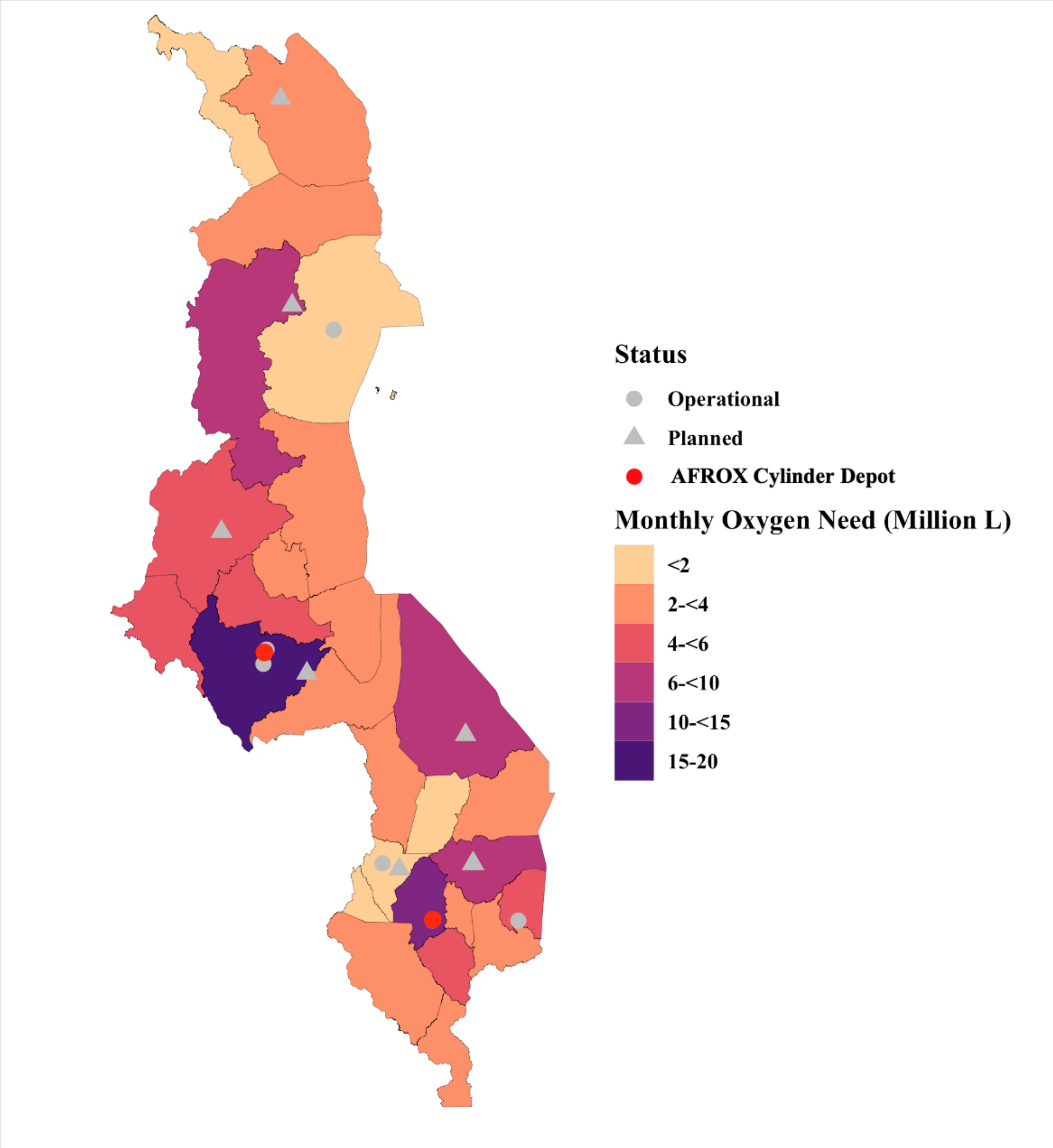
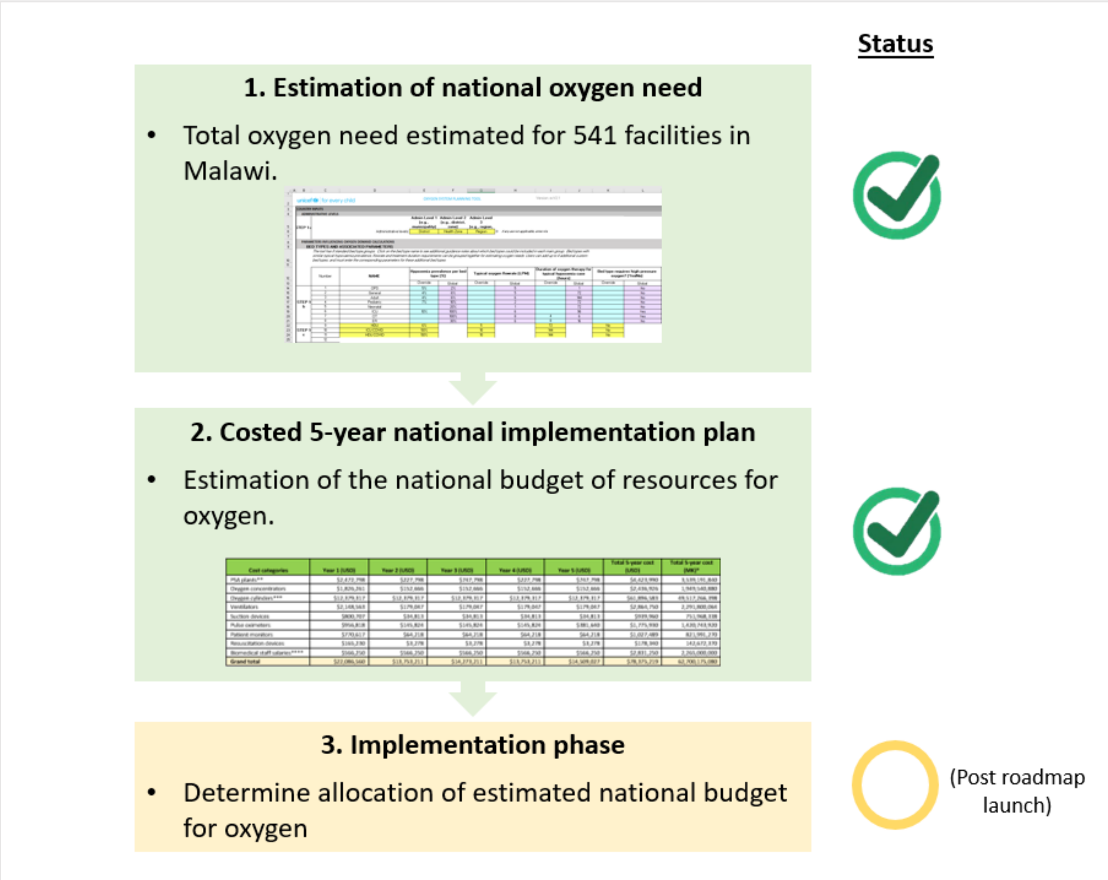
Estimated oxygen need by district as of 30 August, 2021



More information provided in section 5.3.1

Oxygen roadmap scope and intended process



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Foreword

Oxygen is an essential medicine used to treat a variety of health conditions which, if left untreated, result in high morbidity and mortality. It is a critical component of health service provision for maternal and newborn health, child health, prehospital and acute care, surgical care, inpatient medical care, and treatment of infectious respiratory diseases such as COVID-19. With the surge of oxygen demand from COVID-19, Malawi's insufficient systems for supplying and distributing oxygen have been further strained, resulting in even less availability of this critical resource, and emphasizing the lack of robust systems to support oxygen access.

Improving health outcomes for Malawians requires comprehensive investment in oxygen systems, including but not limited to the following:

- Increasing oxygen-generation capacity.
- Making distribution of oxygen more widespread and reliable.
- Procuring medical devices and associated technologies to facilitate safe oxygen provision.
- Building capacity of clinicians and biomedical engineers to use medical devices to administer oxygen and to maintain devices.
- Establishing standards, guidelines, and job aides for oxygen-generation equipment and oxygen administration.
- Monitoring the effect of interventions on population health and access to oxygen.

This medical oxygen ecosystem roadmap proposes national oxygen system improvements, using a set of strategic objectives and interventions, to implement from 2021 to 2026 and will complement the Malawi Ministry of Health's Emergency and Critical Care Strategy, which is a framework for implementing emergency and critical care services in Malawi for the next ten years. The recommendations are based on the estimated national oxygen need of health facilities in Malawi and observations about the failure, or lack, of systems to produce, distribute, and deliver oxygen to patients.

Interventions that scale-up oxygen supply capacity and human resource capacity should be prioritized in the short-term by government, donors, and stakeholders. Developing standards, guidelines, and job aides, and improving systems for monitoring and evaluation should be prioritized in the medium-term. Development of the oxygen supply market and implementation of robust distribution systems should be prioritized in the long-term. Additional analysis is required to assess tradeoffs in oxygen supply source procurement, placement of bulk oxygen supply, and properly size and structure an oxygen distribution system in Malawi.

Our hope is that this roadmap will build on existing oxygen work in the public and private sectors, support the optimization of medical oxygen investments, and guide future investments from government, partners, and private-sector actors. To accomplish this, Malawi must engage a diverse group of stakeholders to increase awareness of oxygen as an essential medicine, strengthen the country's technical expertise, and identify and pursue financing opportunities for medical oxygen.

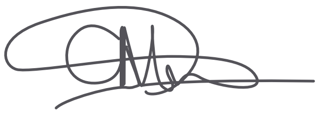
Honourable Khumbize Kandodo Chiponda, MP
Minister of Health

Acknowledgments

The *Scale-Up Roadmap for the Malawi Medical Oxygen Ecosystem* was commissioned by the Oxygen Task Force and clinical care experts of the Malawi Ministry of Health. The aim of the roadmap is to ensure equitable access to safe medical oxygen for all Malawians.

The Ministry of Health would like to express its profound gratitude to all stakeholders that have contributed to the development of the first ever oxygen roadmap in Malawi. The oxygen roadmap complements The Emergency Critical Care Strategy (ECCS), which is a framework for building and implementing emergency and critical care services in Malawi from 2021-2031, and describes how decentralizing availability and strengthening quality of emergency and critical care moves Malawi towards its goal of universal health coverage. Both the roadmap and ECCS provide stakeholders with recommendations to implement cross cutting and horizontal health interventions that will ultimately reduce the burden of emergency and critical care illness and morbidity and mortality in Malawi.

Technical support and writing were provided by PATH and UNICEF—the former under the COVID-19 Respiratory Care Response Coordination project, which is a partnership between PATH, the Clinton Health Access Initiative, and Every Breath Counts Coalition to support country decision-makers in the development and execution of a comprehensive respiratory care plan to meet the demands of COVID-19. The Ministry would also like to thank all individuals who took part either in the drafting, reviewing, or technical validation of the roadmap in Appendix A1. PATH is also thanked for providing the financial and technical expertise to conduct the 2020 Malawi Biomedical Equipment Survey which collected key data that was used in developing this Roadmap.



Dr. Charles Mwansambo
Secretary for Health

Abbreviations

Afrox	African Oxygen
ARI	acute respiratory infection
BMES	Biomedical Equipment Survey
CAPEX	capital expenditure
CEmONC	comprehensive emergency obstetric and newborn care
CH	central hospital
CHAM	Christian Health Association of Malawi
CLHP	Child Lung Health Programme
CMED	clinical medicine
COPD	chronic obstructive pulmonary disorder
COVID-19	coronavirus disease 2019
CPD	continuous professional development
DH	district hospital
DHIS2	District Health Information System 2
ECG	electrocardiogram
EHP	Essential Health Package
FBO	faith-based organization
FCDO	UK Foreign, Commonwealth & Development Office
FiO_2	fraction of inspired oxygen
Fr	French gauge
GOM	Government of Malawi
HDU	high-dependency unit
HMIS	Health Management Information System
HTSS	Health Technical Support Services (Directorate of the Ministry of Health)
ICU	intensive care unit
IMCI	Integrated Management of Childhood Illnesses
ISO	International Organization for Standardization
LMIS	Logistics Management Information System
LOX	liquid oxygen
LPM	liters per minute
M&E	monitoring and evaluation
MK	Malawi Kwacha
MMR	maternal mortality ratio
MOH	Ministry of Health
NGO	nongovernmental organization

Nm^3/h	normal cubic meter per hour
OPD	outpatient department
OPEX	operating expenditure
OT	occupational therapy
PAM	Physical Assets Management [division of MOH]
ppm	parts per million
PSA	pressure swing adsorption
QECH	Queen Elizabeth Central Hospital
RMU	referral maintenance unit
SEL	standard equipment list
SOP	standard operating procedure
SpO2	arterial hemoglobin oxygen saturation as measured by pulse oximetry
TB	tuberculosis
U5	children under 5 years old
UNICEF	United Nations Children's Fund
UPS	Uninterrupted power supply
vpm	volumes per million
v/v	volume per volume
WHO	World Health Organization

Glossary

Flow rate	For medical oxygen, the speed, in liters per minute, that oxygen is administered to a patient.
Hypoxemia	Insufficient levels of oxygen in the blood, identified by an SpO_2 level below 90%.
Hypoxia	Lower than normal tissue oxygenation.
Indications	For this roadmap, the signals used by clinicians to identify patient need for oxygen therapy.
Medical oxygen	Oxygen that is used for treatment of patients and meets certain standards of purity and other standards for clinical use.
Morbidity	Existence of disease, or ill condition, and generally assumed to detract from quality of life.
Mortality	Actual death from disease or ill condition.
Oxygen ecosystem	The collective people, processes, equipment, and logistics that are required for delivering oxygen from a production source to a patient.

Executive summary

Oxygen systems in Malawi do not meet the current needs of the population, resulting in excess morbidity and mortality from a variety of illnesses and conditions that can be treated with oxygen therapy. Childhood pneumonia, one of the largest causes of death in children under 5 years old in Malawi, can be treated with oxygen therapy, but such therapy is not available for many children in need. Additionally, surges in oxygen demand due to COVID-19 have emphasized shortfalls in oxygen-production capacity, shortages of equipment and supplies, and inability to quickly source oxygen from suppliers. Malawi also faces technical challenges to quantifying oxygen needs and determining an appropriate allocation of resources across health facilities.

To estimate the gap in oxygen access, a national oxygen needs estimation was completed using the UNICEF Oxygen System Planning Tool. Results show a monthly oxygen need across the country of 115,156,050 liters (equivalent to 16,935 "J" cylinders). Installed oxygen-production capacity in Malawi is currently insufficient to meet this need. Multiple factors contribute to this oxygen gap, including challenges to maintenance of pressure swing adsorption (PSA) plants and insufficient oxygen cylinders to capture and store oxygen, as well as a lack of distribution systems to reallocate supply. The plan for installing several PSA plants at health facilities should decrease this oxygen gap, but distribution of oxygen supply to facilities in need may remain a key challenge. It is highly recommended that Malawi evaluate options for strategic oxygen-production source placement and development of an oxygen-distribution network.

Improvements in oxygen access can be addressed through interventions in equipment and supplies availability and support of structural systems. Adequate oxygen provision in Malawi's health system should include the following:

- Oxygen cylinders for bedside administration, storage capacity, and patient transport.
- Oxygen concentrators of sufficient flow rates to manage severe and critically ill patients.
- Other oxygen-production modalities and infrastructure, including on-site PSA plants or bulk liquid oxygen storage at key secondary and tertiary health facilities, cylinder manifolds, and direct-to-bedside piping systems.
- Monitoring equipment, such as pulse oximetry and multiparametric monitors at all health system levels to guide safe oxygen administration.

Structural support systems should be implemented alongside oxygen scale-up, including:

- Development of policies, standards, and guidelines governing medical oxygen.
- Implementation of a system for building the capacity of health workers to safely use medical oxygen, pulse oximetry, and oxygen accessories.
- Strengthened monitoring and evaluation systems for oxygen-access programs and policies.
- Establishment of a protocol for maintenance of oxygen-production and oxygen-delivery equipment and supply of spare parts.
- Capacity-building of biomedical engineers and technicians for management and maintenance of respiratory care equipment.
- Strengthened advocacy, communications, and partnerships for oxygen.

It is intended for this roadmap to serve as a core reference document for oxygen policy development from 2021 to 2026.

Chapter 1: Background

Oxygen is an essential medicine used to treat a variety of health conditions which, if left untreated, result in high morbidity and mortality.[i] The focus of this chapter is to provide background on medical oxygen and describe the global public health imperative to develop adequate oxygen supply in health facilities and improve systems that support access.

CHAPTER 1 KEY TAKEAWAYS AND POLICY RECOMMENDATIONS:

- Oxygen is an essential medicine, and it is a global public health obligation to supply oxygen and improve systems that support increased access.
- Malawi must engage a diverse group of stakeholders to increase awareness of oxygen as an essential medicine, strengthen the country's technical expertise on oxygen and respiratory care, and identify and pursue financing opportunities for medical oxygen.
- There are several types of equipment for oxygen production and storage, as well as modalities for oxygen delivery, with which decision-makers, health facility managers, clinical staff, procurement specialists, and other stakeholders invested in medical oxygen should be familiar.

1.1 Oxygen as a global public health imperative

Oxygen is a critical medicine with a wide array of clinical uses, including prevention and treatment of hypoxemia in neonatal, pediatric, and adult patients with severe respiratory infections; anesthesia; surgery; and prehospital and hospital care of trauma patients. Due to its vital role in health systems, many international organizations are offering collaborative initiatives around increasing access to oxygen (*Text Box 1*).

Text Box 1. International initiatives for oxygen.

International efforts to increase access to oxygen continue to grow, with a few notable initiatives described here:

- **The Every Breath Counts Coalition** is a global public-private partnership with about 40 member organizations formed to drive global awareness about pneumonia and to support governments in ending preventable child pneumonia deaths by 2030.[1]
- **The Global Pulse Oximetry Project** was launched by the World Health Organization (WHO) in 2008 with the objective of supporting universal pulse oximetry as a screening and monitoring standard and providing guidance to country ministries of health and regulatory authorities, as well as manufacturers, on the standards and performance of pulse oximeters.
- **The Global Oximetry Initiative** is an international initiative by the World Federation of Societies of Anesthesiologists that brings together professional associations, private-sector companies, and academic and research institutions. It aims to increase the use of pulse oximetry and reduce the cost of oximetry devices in developing countries.[2]
- **The International Union Against Tuberculosis and Lung Disease** is an international voluntary scientific organization providing a platform for collaboration and advancement in the prevention and treatment of infectious and noncommunicable respiratory illness and has an interest in oxygen systems.[3]
- **United4Oxygen Alliance** is a consortium of government, industry, foundation, and civil society actors partnering to increase access to medical oxygen and pulse oximetry.[4]

These initiatives support international progress in promoting access and safe use of oxygen around the world. There also exist other initiatives for child and maternal health, safe surgery, and regional industrial gases

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[i] Oxygen is listed in the WHO List of Essential Medicines for Children and the Model List of Essential Medicines. The designation moved oxygen from recognition merely as an adjunct to treatment and anesthesia to a medicine essential for the management of hypoxemia and has strengthened efforts to prioritize procurement of oxygen and development and maintenance of oxygen systems.

associations that may offer opportunities for collaboration and technical support in the development and maintenance of oxygen systems and safe use of medical oxygen.

1.2 Medical oxygen

Oxygen therapy can treat hypoxemia, regardless of the underlying cause, making it a critical therapy for many health conditions.

1.2.1 Indications for oxygen therapy

The following are some of the indications for oxygen therapy:

- The primary indication is to treat hypoxemia. Because many medical conditions can cause hypoxemia, oxygen therapy is a cornerstone of good-quality health care.
- WHO guidelines suggest starting oxygen therapy in patients with an oxygen saturation (SpO_2) level below 90%.[5] Most other international guidelines support this measure.
- Once initiated, oxygen therapy should be titrated to maintain an SpO_2 in the approximate range of 92% to 96%. There is emerging evidence that higher SpO_2 goals can be harmful.[6]
- Supplemental oxygen is not a treatment for breathlessness not associated with hypoxemia. Pulse oximetry is critical in these situations to differentiate between other causes of breathlessness, such as metabolic disorders, and to enable timely treatment of these specific causes for good patient outcomes.
- Supplemental oxygen raises the concentration of oxygen in the air (*fraction of inspired oxygen,* or FiO_2) that a patient is breathing, enabling an SpO_2 increase to healthy levels. Atmospheric air that is inhaled is normally 21% oxygen; with supplemental oxygen therapy, this percentage (FiO_2) can be increased.
- Clinicians should be well trained on calculating FiO_2 based on the flow of oxygen provided and on titrating oxygen therapy, and therefore FiO_2, such that a patient is not at risk of hyperoxemia.

1.2.2 Diagnosis of hypoxemia

Pulse oximeters and multimodal devices (patient monitors equipped with functions such as electrocardiogram [ECG] and SpO_2 measurement) are critical to ensure safe oxygen administration. These devices help monitor the oxygen level in a patient's blood and alert the health care worker if oxygen drops below safe levels. This allows timely identification of hypoxemia and opportunity for a health care worker to quickly intervene. These devices are essential in wards where a patient receives oxygen (e.g., in surgery, emergency departments, intensive care units [ICUs], and treatment and recovery areas in hospital wards), as well as during treatment for respiratory disease, including but not limited to COVID-19. (For more detail on indications for supplemental oxygen therapy, see Appendix A2.)

Blood gas machines can also be used in critical care settings to evaluate a patient’s status. These machines can analyze patient oxygen and carbon dioxide levels and the pH of blood, as well as other parameters. Blood gas machines require taking a patient’s blood sample and performing the correct process to get a reliable result. Machines are highly sensitive, and therefore, careful operation and training are important for their use.

1.2.3 Modalities of oxygen delivery

In general, oxygen-delivery modalities can be characterized by their pressure (high vs. low) and flow rates (high vs. low). A thorough understanding of these modalities and their applications is helpful when considering approaches to oxygen supply.

Oxygen therapy is often delivered through masks or prongs and cannulas, depending on recommended flow rates, or with other means of respiratory support, such as noninvasive positive pressure ventilation,[ii] and in severe cases, through invasive mechanical ventilation.

1.2.4 Oxygen production and storage

There are a variety of mechanisms to produce oxygen, with the most common in Malawi being oxygen concentrators, located at the bedside of patients, and pressure swing adsorption (PSA) oxygen plants, based at health care facilities. Oxygen cylinders can be filled from the PSA oxygen plant and used at the patient bedside or connected to manifold systems to serve an entire ward or facility.

PSA oxygen plant

A PSA plant provides on-site, medium-scale oxygen generation. PSA plants use pressure to separate oxygen from the atmosphere and purify it to medical grade (i.e., 93% +/– 3% purity). A PSA plant can be located at a health facility and provide oxygen by either filling cylinders or piping oxygen directly to terminal wall units at patient bedsides. Both methods require additional equipment: a cylinder filling ramp or an oxygen piping system. A piping system is far more efficient than cylinders for supplying oxygen in a health facility. PSA plants also provide an opportunity for oxygen distribution to surrounding health facilities via cylinders.

Oxygen concentrators

Oxygen concentrators are small devices that intake ambient air, compress it, and filter out nitrogen to supply purified oxygen. These devices allow for provision of oxygen to patients in wards without centralized piping systems and can be easily moved. In general, the highest-rated models of concentrators can reach a maximum flow of 10 liters per minute (LPM). Oxygen provided via concentrators can be shared between multiple patients, depending on the concentrator model and output volume. Although concentrators provide a good source of oxygen, they are dependent on electricity and require regular maintenance to provide high-quality oxygen, which often pose challenges for their use in facilities.

Oxygen cylinders

Cylinders are refillable metal vessels used to store and transport oxygen in compressed gas form. Cylinders are refilled at central depots and/or facility-based PSA plants and therefore require routine distribution, potentially over long distances, to reach other facilities.

Liquid oxygen (LOX)

LOX has uses in industry and medicine and are normally operated by large national and multinational corporations.[7] LOX is produced through cryogenic air separation by large, industrial air separation units, commonly called "liquid oxygen plants."[8] These units operate by cooling air to its liquid phase and then using fractional distillation to separate pure oxygen from other components typically found in air. LOX plants can produce extremely pure oxygen (upwards of 95% pure) in large amounts. There currently are no LOX plants in Malawi.

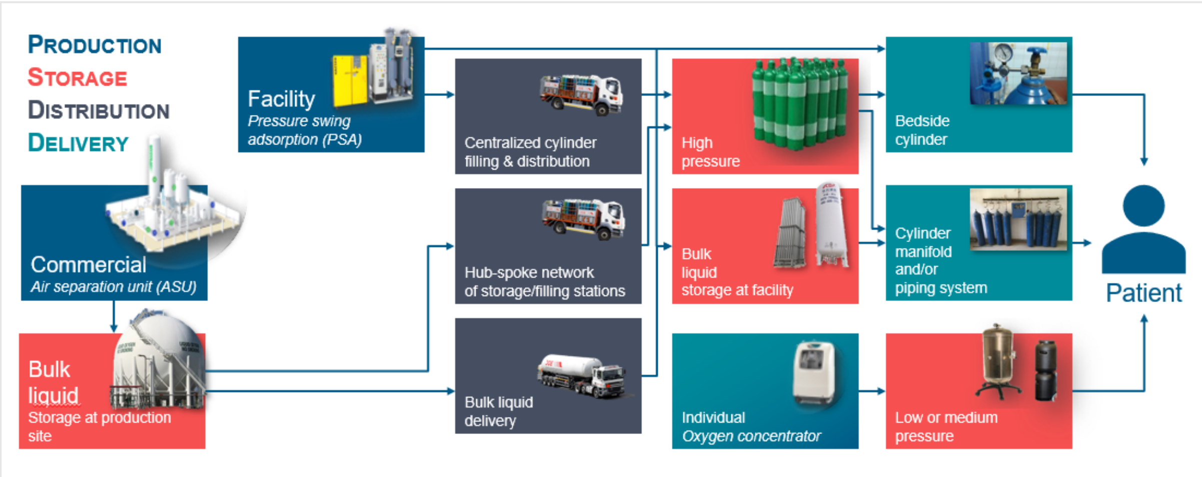
Filling stations

Filling stations are an important structural component of oxygen distribution in Malawi. Figure 1 describes different models:

[ii] Noninvasive positive pressure ventilation includes continuous positive airway pressure (CPAP) and bilevel positive airway pressure (BiPAP).

- A hub, for hub and spoke delivery of oxygen cylinders filled from a PSA plant to facilities within a catchment area.
- A cylinder filling station for conversion of bulk LOX to gaseous cylinder oxygen.
- A hub, for hub and spoke delivery of bulk LOX to facility-based LOX storage tanks.

Figure 1. Network for oxygen distribution.



Chapter 2: The use of medical oxygen in Malawi

The focus of this chapter is to describe oxygen use in Malawi and how oxygen is used across different health areas.

CHAPTER 2 KEY TAKEAWAYS AND POLICY RECOMMENDATIONS:

- Oxygen is integral to an effective and equitable health system that prevents morbidity and mortality from hypoxemia and supports essential services such as emergency medicine; maternal, newborn, and child health; safe surgery and anesthesia; postoperative care; and ambulatory care.
- Use of pulse oximetry for triage, patient monitoring, and patient referral should be widespread and standardized. Evidence shows pulse oximetry can greatly contribute to reduced morbidity and mortality across disease areas.
- Access to oxygen and pulse oximetry in Malawi is insufficient and needs comprehensive investment. Malawi must work to adopt a national standard for medical oxygen quality and equipment.
- The COVID-19 pandemic has caused surges in demand for oxygen therapy. This has highlighted gaps in access to medical devices to provide and facilitate respiratory care, as well as insufficient oxygen-production and oxygen-distribution capacities. Malawi must procure and install an appropriate mix of oxygen-supply sources, informed by baseline availability and absorptive capacity assessment.

2.1 History

Most medical oxygen has been provided in Malawi by the disparate use of oxygen concentrators in various hospitals without widespread ability to produce large quantities of oxygen. The British Oxygen Company (BOC) established the first private-sector oxygen plant in Malawi and supplied cylinder oxygen to public and private facilities through a mechanism of cylinder rental, with a refill tariff depending on cylinder size. In 1999, the Government of Malawi (GOM) requested support from the International Union Against Tuberculosis and Lung Disease to standardize the case management for severe forms of pneumonia in children in inpatient settings. The Union, GOM, and Bill & Melinda Gates Foundation created the Child Lung Health Programme (CLHP), which, among other interventions, provided oxygen concentrators that were installed in pediatric units in Malawi central and district hospitals between 2002 and 2004. Combined with standardized case management for pneumonia, the CLHP was responsible for a reduction in pneumonia case fatality from 18.0% in 2000 to 8.6% in 2005, with progressive annual reduction during the program years.[9] An assessment in 2007 showed that 97% of the concentrators under the CLHP continued to be functional, although 21% did not provide adequate levels of oxygen.[10]

Facility-level PSA oxygen plants have been installed by government partners in collaboration with the Ministry of Health (MOH) in public-sector facilities in the country. As of July 2021, seven active PSA plants are co-located at health facilities across the country, and nine more are planned or awaiting maintenance. *Table 1* shows the active PSA plants, in addition to the two Afrox cylinder depots.

Table 1. Pressure swing adsorption (PSA) plants currently active in Malawi as of 30 August 2021.

Facility name	Type	Status	Maximum production capacity (liters [L] / hour)	Monthly maximum production capacity (L)	Monthly maximum production in "J" cylinders (6,800 L)

Mercy James	PSA	Active	12,000	8,640,000	1,270
Neno District Hospital	PSA	Active	1,375	990,000	145
Nkhata Bay District Hospital*	PSA	Active	4,830	3,477,600	511
Daeyang Luke Hospital	PSA	Active	10,000	7,200,000	105
Queen Elizabeth Central Hospital	PSA	Active	50,000	36,000,000	5,294
Kamuzu Central Hospital	PSA	Active	50,000	36,000,000	5,294
Phalombe District Hospital	PSA	Active	49,000	35,280,000	5,189
Afrox Lilongwe	Private cylinder filling depot	Active	10,000**	7,200,000	1,058
Afrox Blantyre	Private cylinder filling depot	Active	10,000	7,200,000	1,058
Total				**141,987,600**	**19,924**

**At the time of this roadmap, Last Mile Health and Intakatech had just completed repairs at Nkhata Bay District Hospital.*
***Afrox capacity, at both depots, is estimated at 10,000 L/hr.*

More recently, the Malawi Liverpool Wellcome project has worked with the MOH to install a new PSA oxygen plant at the Queen Elizabeth Central Hospital in Blantyre. RICE360 has a large program in Malawi focused on neonatal care, which includes placing an oxygen concentrator in every neonatal ward. Additionally, UNICEF has supported the MOH to install a PSA oxygen plant at the Kamuzu Central Hospital in Lilongwe, with funding from the GOM, the UK government, and Gavi, the Vaccine Alliance.

Pulse oximetry has not been established routinely in Malawi as part of general triage or patient monitoring during oxygen therapy. Relatively small projects and individual donors have placed small numbers of oximeters in public health facilities over the years. A national assessment in 2020 by the MOH and PATH in 76 hospitals found only 450 oximeters across the country.[11]

2.2 Prehospital and acute care

Oxygen is a critical medicine for the prevention and treatment of hypoxemia in newborns and sick children and of severe infections and other medical indications, as well as for anesthesia, surgery, and prehospital and hospital care of trauma patients globally.

Pulse oximetry—measurement of blood oxygen levels—is critical for emergency triage of such conditions and for alerting health care workers to provide oxygen to hypoxemic patients.

Ambulances must also be equipped with oxygen for prehospital care and safe patient referral. Referral to higher levels of care becomes impossible if oxygen for transport is unavailable, essentially breaking the linkages between the levels of the health system.

2.3 Maternal and newborn health

Malawi's maternal mortality ratio (MMR) dropped by a third, from 675 per 100,000 live births in 2010 to 439 per 100,000 live births by 2016, making substantial progress but missing the targets for the Health Sector Strategic Plan I and the Millennium Development Goal 5 of reducing the MMR.[12] Newborn mortality also continues to be high at 30.9 infant deaths per 1,000 live births in 2019.[13] This is despite substantial gains in reducing mortality for children under 5 years old (U5) and meeting the U5 mortality rate reduction targets of the Millennium Development Goals by 2015; the Health Sector Strategic Plan II acknowledges that Malawi's newborn mortality ratio and MMR are among the highest in sub-Saharan Africa.

Each year, 30 million small and sick babies need special care at birth globally, which includes safe and reliable administration of oxygen therapy.[5] In Malawi, 42% of all infant deaths occur within the neonatal period, and 14% of all newborns have low birth weight, putting them at greater risk of complications and death.[14] Birth asphyxia and intrapartum complications necessitating newborn resuscitation, prematurity and low birth weight, and severe infections such as pneumonia and sepsis account for most newborn deaths—and all of these may manifest with hypoxemia.

The Essential Health Package (EHP) for reproductive, maternal, newborn, and child health provides guidelines for delivery, including for normal deliveries, Caesarian sections, and management of many essential and emergency interventions for both the mother and newborn.[15] (Please see Appendix A3 for a list of related EHP interventions.) Malawi has a high MMR and newborn mortality ratio despite a high proportion of deliveries being attended by a skilled birth attendant (90% in 2016).[16] This may imply that there remain care quality issues with the provision of the intervention package.

Use of pulse oximetry for the mother should be an integral part of partography (graphical record of key data during labor), alongside other vital readings and observations. Maternal hypoxemia must be addressed urgently with supplemental oxygen. Other peripartum applications of oxygen include instances where hypoxemia may not be apparent from oximetry, but tissue hypoxia may result, such as with preeclampsia and eclampsia.

Supplemental oxygen has several indications in the EHP during the perinatal period, including the following:[17]

- Non-reassuring fetal heart rate during labor and delivery.
- Obstetric shock, including hemorrhagic, anaphylactic, and septic shock.
- Preeclampsia and eclampsia.
- Basic newborn resuscitation.
- Caesarian section as part of safe anesthesia.
- Emergency hysterectomy as treatment for postpartum hemorrhage.

Beyond the perinatal and early newborn period, newborns and mothers can develop severe infections and present with other conditions that may be associated with hypoxemia, such as congenital health disease in newborns or cardiomyopathy in mothers. This means that oxygen should be available for maternal and newborn indications at both primary and secondary levels of care, and staff should receive training in the use of pulse oximetry, the safe use of oxygen for common obstetric and newborn indications, and the care of oxygen equipment. Particular attention should be paid to target SpO_2 in newborn care guidelines because of the risk of retinal damage from hyperoxia. Portable oxygen sources should also be available in ambulances and other transport vehicles for moving patients to secondary care in case of complications.

Other reproductive and maternal health procedures also may require oxygen for anesthesia during surgical and gynecological procedures. Some procedures in postabortion care, surgery for fistula repair, ectopic pregnancy, gynecological cancers, and gynecological examinations under anesthesia may require oxygen as an adjunct to anesthesia.

2.4 Child health

Pneumonia is the leading infectious cause of U5 death globally, causing about 18% of all U5 deaths, or around 800,000, in 2019.[18] Hypoxemia is the primary fatal complication of pneumonia, affecting 13.3% of children with pneumonia according to WHO.[5] This equates to about 4.1 million hypoxemic children with severe pneumonia in need of oxygen therapy every year. Oxygen is therefore highlighted as one of the key interventions in the Global Action Plan on Pneumonia and Diarrhea.

The UN Inter-Agency Group on Child Mortality Estimates concludes that about 26,000 children died in Malawi in 2019; the Malawi MOH estimates that 11% (2,860) of these deaths could be attributed to pneumonia.[19] Pneumonia interventions in the country include the following:

- Community- and primary health care–level interventions, such as pneumococcal vaccination.
- Integrated community-based case management with respiratory rate timers and dispersible amoxicillin.[iii]
- Health facility–based Integrated Management of Childhood Illnesses, including care of sick infants with possible serious bacterial infection;
- Secondary health facility interventions for inpatient child pneumonia, the feasibility of which was demonstrated by the Malawi CLHP, including hypoxemia detection and oxygen administration, with significant impact on reducing U5 mortality.[20]

Despite these measures, cases of severe pneumonia can still end up requiring admission for inpatient management, which frequently requires oxygen therapy.

Malaria, diarrhea, and other serious infections which are also managed under integrated community-based case management and health facility–based Integrated Management of Childhood Illnesses, as well as possible serious bacterial infection, often require referral to secondary-level health facilities if complications occur. A study by McCollum et al. in five hospitals showed that 5.3% of hospitalized Malawian children under 15 years old were hypoxemic and that, while there was more hypoxemia among children with respiratory illness, it was also spread across children with other diagnoses.[21] Pulse oximetry was not routinely used, and only 22.5% of children needing supplemental oxygen, as defined by WHO guidelines, were given oxygen.

2.5 Surgical care

Oxygen is an essential part of safe anesthesia and safe surgery. The Lancet Commission of Global Surgery, which was launched in 2014, estimates that capacity development for safe surgery and anesthesia has regressed in low- and middle-income countries and that this limits the quality of and access to surgical care. This gap results in deaths from easily treatable conditions such as obstructed labor, appendicitis, hernias, fractures, and cancers requiring surgery.[22] Hypoxemia occurs in about 30% of all surgical cases in the early postoperative period, and it is recommended that all surgical cases receive supplemental oxygen, which has been demonstrated to reduce the incidence of postoperative hypoxemia by over 90%.[23]

Caesarean section is the most common major surgical procedure in Malawi; a study across district and central hospitals in Malawi showed that perinatal mortality was associated with ruptured uterus and with halothane and ketamine anesthesia. Obstructed labor was the

[iii] While respiratory rate timers are sufficient for care in communities and village clinics using the Sick Child Recording Form, pulse oximetry should be available in health centers and secondary-level health facilities to allow timely detection and treatment of hypoxemia.

overwhelming indication in 65% of cases, and fetal distress, antepartum hemorrhage, and preeclampsia were the other significant minor indications for Caesarean section.[24]

Oxygen is used during surgery and in recovery to prevent or treat acute hypoxemia, which may be brought on by compromised ventilation or by respiratory depression from medications, including anesthetics, and which may have worsened effects due to postoperative inflammatory response. Poor availability of medical oxygen limits the availability of surgical care and can compromise the quality of surgical and anesthesia care provided in emergencies, leading to poor patient outcomes.

2.6 Inpatient medical care

Medical indications for supplemental oxygen include the treatment and prevention of hypoxemia from severe respiratory and non-respiratory infections and from critical illnesses with metabolic acidosis or poor tissue perfusion, such as hemorrhage, acute exacerbations of chronic airway diseases, and conditions that compromise the cardiovascular system. Oxygen therapy is often given through masks or prongs and cannulas, depending on recommended flow rates, or with other means of respiratory support, such as continuous positive airway pressure (CPAP) and, in severe cases, through invasive mechanical ventilation.

Noncommunicable respiratory diseases, such as asthma and chronic obstructive pulmonary disorder (COPD), are key causes of hypoxemia in acute cases. Clinical assessment should include pulse oximetry and treatment of associated hypoxemia with oxygen. Target SpO_2 concentrations for COPD should be adhered to through close monitoring and titration, using oximetry to prevent type 2 respiratory failure in susceptible patient categories.

2.7 Severe acute respiratory syndromes and pandemics

Late in 2019, the Chinese government alerted WHO to a cluster of pneumonias of novel presentation and shortly after isolated a novel coronavirus, eventually named Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV2) by WHO.[25] Over the following months the virus spread, becoming a global pandemic and sickening millions around the world. It reached Malawi in April 2020. The disease, caused by the coronavirus disease 2019 (COVID-19), is typically a mild systemic disease with primarily respiratory symptoms. At this point, it is unclear whether COVID-19 will become largely endemic with cyclic waves of infection or its prevalence and impact will diminish over time. It has, however, contributed to the urgency of setting up effective medical oxygen systems globally and, especially, in developing economies like Malawi.

WHO estimates that 14% of patients with COVID-19 will develop severe disease requiring hospitalization and that 5% of patients may need intensive care.[iv,26] Monitoring for hypoxemia is essential for the treatment of COVID-19, and all treatment units are recommended to have reliable pulse oximetry.

Patients with severe COVID-19 may have hypoxemia requiring low-to-moderate oxygen flow rates and use of ordinary masks (< 10 LPM for adults). Critical patients need high flow rates (> 15 LPM) and may need special masks and even mechanical ventilation. All centers treating COVID-19 should have pulse oximetry, clinically appropriate oxygen sources, and backup oxygen supply for continuity of oxygen therapy during the estimated period of hospitalization for these patients.

[iv] Guidance from WHO, released June 17, 2020.

Beyond COVID-19, there is the potential for other respiratory epidemics and/or pandemics. Influenza-type illnesses circulate in the environment, and other viruses have the potential to jump from animals to humans. The Malawi health system, like many others in Africa, was underprepared to treat a sudden surge in respiratory illness. Strengthening oxygen systems will help Malawi contend with future demand scenarios.

Chapter 3: National oxygen ecosystem roadmap

This chapter introduces the key objectives of the roadmap and describes the services that should be available in primary-, secondary-, and tertiary-level health facilities, as well as ambulance services and their oxygen requirements. The differences between each level are important to recognize, as the oxygen implementation plan will look different for each level.

CHAPTER 3 KEY TAKEAWAYS AND POLICY RECOMMENDATIONS:

- This roadmap provides a structured and attainable five-year plan to establish and maintain a comprehensive national medical oxygen ecosystem for Malawi, which considers all elements of oxygen delivery from source to patient.
- The oxygen roadmap complements **The Emergency Critical Care Strategy (ECCS),** which is a framework for building and implementing emergency and critical care services in Malawi from 2021-2031.
- Medical oxygen interventions must strengthen health service delivery across multiple areas of care, in each level of the health system.
- Malawi must invest in the scale-up of oxygen production; optimization of oxygen distribution and logistics; capacity-building of the clinical workforce and technicians; supply chain for oxygen equipment, accessories, consumables, and spare parts; and data management.
- Malawi must explore policy changes that create an enabling environment for oxygen system improvement, as well as implement sustainable financing mechanisms for oxygen.

3.1 Roadmap objective

The objective of this roadmap is to provide a structured and attainable plan to establish and maintain a comprehensive national medical oxygen ecosystem for Malawi. An oxygen "ecosystem" is the collective people, processes, equipment, and logistics required in delivering oxygen from a production source to a patient. By improving oxygen systems, Malawi can make progress towards reducing morbidity and mortality from hypoxemia and ensure that oxygen is available to treat all clinical cases in which supplemental oxygen would be beneficial. Strategic objectives are provided in the implementation section (Chapter 6) of this roadmap to guide improvements in the following areas:

- Financing.
- Policy development.
- Advocacy and international partnership.
- Capacity-building of clinicians and technical workers.
- Strengthening of monitoring and evaluation (M&E).
- Equipment and inventory management systems.
- Scale-up of oxygen-production capacity, equipment, supplies, and infrastructure.
- Considerations for an environmentally sustainable health sector.

This roadmap builds on ongoing oxygen work in the public and private sectors, supports the optimization of medical oxygen investments, and guides future investments from government, partners, and private-sector actors.

Target areas for oxygen-access scale-up include maternal, newborn, and child health, as well as anesthesia, surgery, medical use for adults and children, and ambulances. Additionally, this roadmap considers the oxygen need across different levels of the health system: primary, secondary, and tertiary. Implementation of this roadmap covers the period from 2021 to 2026 and is divided into short-term (2021 to 2022), medium-term (2021 to 2025), and long-term (2021 to 2026) time periods. This division prioritizes current needs and anticipates increased need over the next five years.

The oxygen roadmap complements **The Emergency Critical Care Strategy (ECCS),** which is a framework for building and implementing emergency and critical care services in Malawi from 2021-2031 and describes how decentralizing availability and strengthening quality of emergency and critical care moves Malawi towards its goal of universal health coverage. The ECCS describes how emergency and critical care services are a set of horizontally required services, cross cutting through the health system. Additionally, the ECCS describes in detail the staff, stuff, space, and systems (4 S's) that are required and associated with its 3 strategic intervention areas; intra-hospital care, entry to facility (either through A&E or OPD), and out-of-hospital care (community health, family medicine and transport).

Oxygen is an essential medicine that should be provided in emergency and critical care and is acknowledged in the ECCS as a critical component of all three strategic intervention areas. Whereas the ECCS describes oxygen as a vital input, the Malawi Oxygen Roadmap outlines the interconnected systems that facilitate oxygen production and supply, distribution, and delivery to patients. To provide the essential medicine of oxygen for the ECCS, the roadmap describes key decision-making processes related to oxygen, including but not limited to determining technology suitability, placement of production capacity, capacity building of human resources for health, standards and guidelines for safe oxygen administration, and recommendations for monitoring the success and impact of oxygen interventions. Overall, both the roadmap and ECCS provide stakeholders with recommendations to implement cross cutting and horizontal health interventions that will ultimately reduce the burden of emergency and critical care illness and morbidity and mortality in Malawi.

3.2 Oxygen systems for health system levels and ambulances

Different levels of the health system have different oxygen delivery and monitoring needs. These needs correspond to catchment area population, level of infrastructure, scope of services provided, and demand for services. Design of oxygen systems to fit district hospitals (primary and secondary level) will be different than those made to fit central hospitals (tertiary level). The following sections describe programs and services that should be available and oxygen systems required to adequately provide those services at each level. Exact quantities of oxygen equipment and supplies that should be available at each hospital type and facility level should be designated by a standard equipment list (SEL).[v] Development of the SEL is recommended as a key roadmap implementation activity. (More detail can be found in Chapter 6.)

3.2.1 Primary health facilities

Primary facilities include health centers, dispensaries, and clinics. At this level of care, the following wards should have oxygen and pulse oximetry:[27]

- Emergency and triage
- Labor and delivery
- Neonatal resuscitation corner
- General ward (where available)

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[v] The Physical Assets Management Department of the Malawi MOH is currently working on an SEL. (See Appendix A9 for how an SEL can be used to cost out equipment and supplies, such as oxygen concentrators, pulse oximeters, etc.).

- Oxygen for transport to referral
- Isolation ward

The EHP outlines services at this level; some of these services require hypoxemia diagnostics (pulse oximetry) and prompt oxygen therapy when hypoxemia is detected. The oxygen needs in primary health facilities can typically be satisfied by oxygen cylinders, especially when the facility is close to an oxygen plant and/or on a reliable cylinder distribution route. Facilities at the primary health level should stock a minimum of four oxygen cylinders. Oxygen concentrators may also be used in primary facilities but require either a sufficient power source or supplemental technologies.[vi] Concentrators with a capacity of 10 LPM offer flexibility for use with newborns, children, or adults, especially when used with a flow splitter (flowmeter stand) to deliver flows < 2 LPM, which is important for neonatal care. Figure 2 summarizes this guidance for primary-level health facilities.

Figure 2. Oxygen at primary health facilities.

Source: PATH.
Abbreviation: EHP, Essential Health Package; TB, tuberculosis.

3.2.2 Secondary health facilities

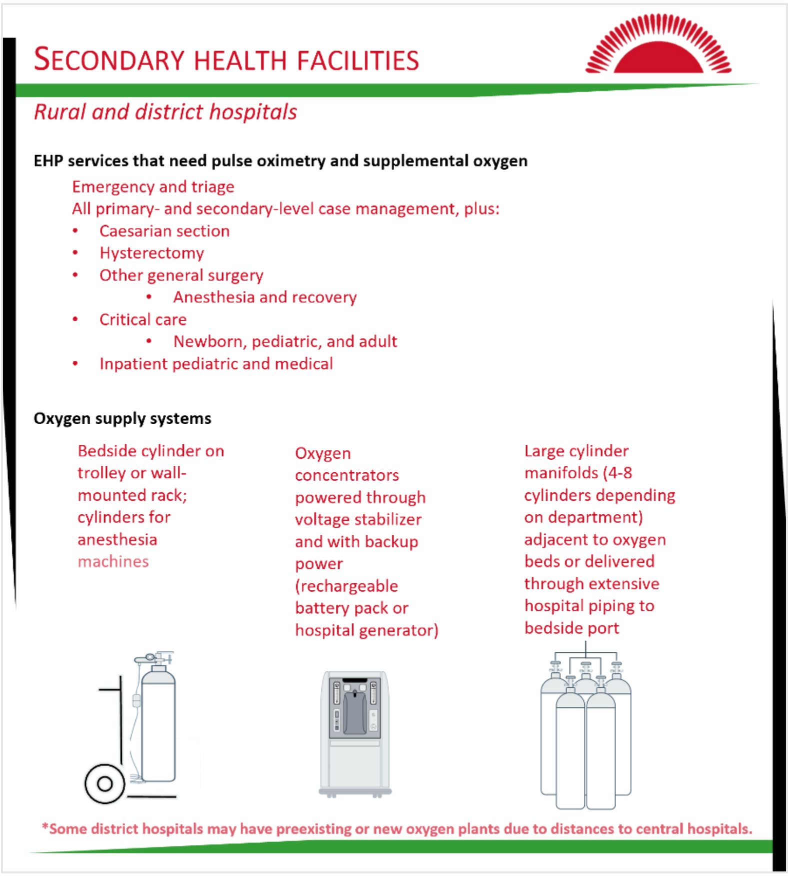
Secondary health facilities include district and rural hospitals and will typically provide general medical care, as well as some surgical and specialty care for children and adults. Areas that should have pulse oximetry and supplemental oxygen include the following:

[vi] Concentrators can be protected from power surges using voltage stabilizers. If power is unreliable at a facility using concentrators, it should have back-up power such as solar, a rechargeable battery pack with an inverter, or a generator.

- Emergency and triage
- Labor and delivery room
- Neonatal care
- Pediatric and adult ward
- Operating theatre and recovery room
- Critical care areas, typically high-dependency units (HDUs)
- Infectious diseases treatment center

Secondary health facilities should stock a minimum of 12 oxygen cylinders. They should also have a piping system that can supply oxygen directly to the patient's bedside from either an on-site PSA plant or a cylinder manifold. Oxygen concentrators should be available for additional oxygen-generation capacity. Figure 3 summarizes this guidance for secondary-level health facilities.

Figure 3. Oxygen at secondary health facilities.

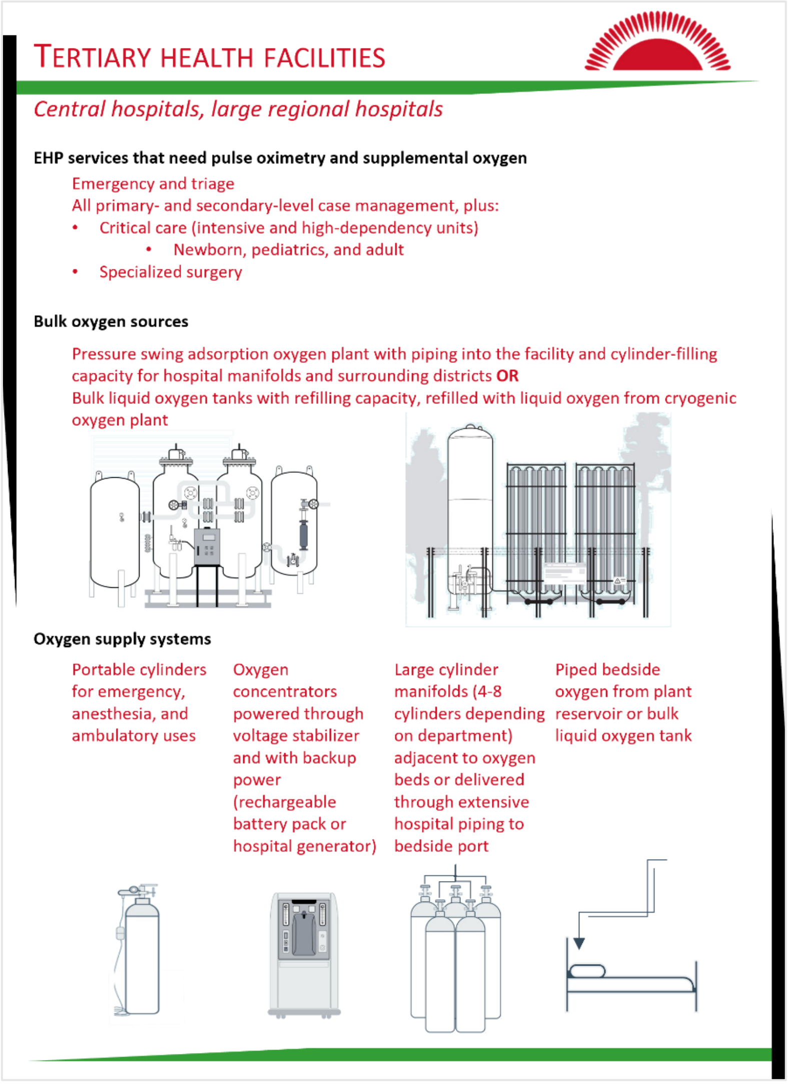


Source: PATH.
Abbreviation: EHP, Essential Health Package.

3.2.3 Tertiary health facilities

All central hospitals are expected to be directly connected to oxygen plants that may be capable of regional oxygen cylinder-filling capacity or have bulk LOX units. Mobile gas-generating systems should also be available at this level of care. Key wards of these health facilities should have piped oxygen with bedside ports. Other wards that use oxygen, especially when the hospital is large, may have oxygen supplied through local piping from manifolds. Concentrators and portable oxygen cylinders can supplement remaining oxygen needs. Cylinders can also support ambulatory oxygen needs and be used when moving patients between wards and hospital departments. Infectious disease treatment centers should be available at this level of care. Figure 4 summarizes this guidance for tertiary-level health facilities.[vii]

Figure 4. Oxygen at tertiary health facilities.



Source: PATH.
Abbreviation: EHP, Essential Health Package.

3.2.4 Oxygen for ambulances

Ambulances are used to transport patients in emergencies, either from facility to facility during patient referral or from the place of incident to a facility. Patients referred to other facilities for further management may have hypoxemia or develop hypoxemia en route and therefore benefit from continuous monitoring and availability of supplemental oxygen. Patients with sudden serious illness or injury also require assessment for hypoxemia and often need supplemental oxygen; they may, in some cases, need resuscitation.

Because of space and portability considerations, ambulances typically use small- and medium-sized cylinders. Handheld or fingertip pulse oximeters are used for diagnosis of hypoxemia and monitoring of oxygen therapy. Battery-powered multiparameter patient

[vii] This guidance should also be considered for emergency field hospitals.

monitors also are often installed in ambulances for patient monitoring. Figure 5 summarizes guidance for ambulances.

Figure 5. Oxygen in ambulances.

Source: PATH.

3.3 Developing a national oxygen-supply ecosystem for Malawi

3.3.1 Components of the strategic objective

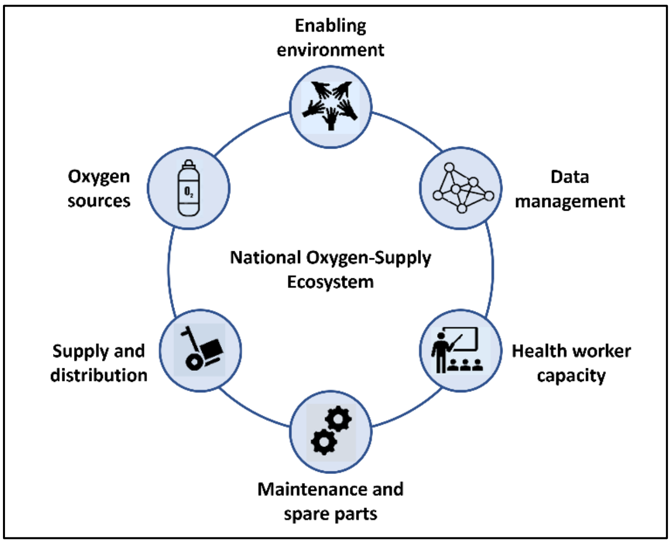
Overview

The roadmap envisages a comprehensive oxygen-supply ecosystem comprising the following:

- Large oxygen-generation sources at regional sites—in central hospitals and selected district hospitals.
- A distribution network that links to oxygen-generation sources and can reliably deliver filled cylinders and retrieve empty cylinders from health facilities.
- Supplemental oxygen generation at health facilities via oxygen concentrators.
- A trained workforce of biomedical engineers and technicians who are supplied with adequate spare parts, equipment, and tools to support and maintain medical devices.
- Facilities and ambulances with adequate infrastructure and a full stock of necessary oxygen accessories.
- Adequate clinical staff, trained and supported with pulse oximetry to detect hypoxemia, administer oxygen safely, monitor treatment, and initiate referral of patients when needed.
- Results monitoring of oxygen system interventions.

The strategic objectives of this roadmap are based on the components of a national oxygen-supply ecosystem shown in *Figure 6*; these components are identified as critical to achieving the characteristics listed previously. The following section describes what actions Malawi must take to realize each component.

Figure 6. Components of a national oxygen-supply ecosystem.



Enabling environment

Creating an enabling environment includes addressing the policy, strategy, and regulatory gaps that may cause barriers to effective scale-up of medical oxygen. This requires analysis of the existing gaps and creation of an adaptable roadmap that will guide implementation of improvements by program and district managers, government partners, and private-sector actors. Lastly, an enabling environment anticipates and addresses the administrative needs of oxygen systems at facility, district, and national levels.

Oxygen sources

Improving the provision of oxygen will entail the determination of the optimal source mix for different levels of care. This will depend on the particular EHP intended for each level and the procurement and installation of the mix of concentrators, PSA oxygen plants, and LOX. Key to this is the distribution of concentrators by health facility and the geographical distribution, capacity, and intended catchment area of planned oxygen plants. Methods for ownership, management, and replacement of oxygen sources need to be anticipated and accompanied by guidance. The power requirements of oxygen sources also need consideration. For example, concentrators need voltage stabilizers to protect from surges and preserve equipment life span. Supply of electrical power in Malawi is usually unreliable, with lengthy outages, especially common in rural areas. Health facilities that rely on concentrators will need to have power backup systems such as generators, solar power, and battery storage, or mains-rechargeable uninterrupted power supply (UPS) systems. These must be sized to outlast the typical duration of outages. Oxygen plants are gross power consumers that should have the correct type of mains power, usually 3-phase, and a properly sized backup generator and/or UPS.

Supply and distribution

Development and maintenance of a dedicated distribution system for oxygen cylinders, filled from PSA plants, and integration of the procurement, distribution, and replacement of pulse oximeters, their sensor probes, and other oxygen accessories are essential for availability and safe use of medical oxygen. This includes cylinders and other reusable accessories, such as cylinder trolleys, flow meters, humidifiers, and flow splitters, as well as patient accessories, such as masks of various kinds and sizes, and oxygen tubing accessories, such as cannulas and nasal prongs. Procurement, distribution, and clinical staff must be familiar with oxygen accessories so that they know which ones are single use and which need sterilization before reuse.

Maintenance and spare parts

Oxygen equipment such as plants and oxygen concentrators—as well as oxygen-distribution infrastructure such as manifolds, oxygen piping, and bedside ports—must be maintained to preserve function and ensure safety. Biomedical engineers must be familiar with preventive and basic corrective maintenance of this equipment, as well as quality assurance measures such as equipment calibration, electrical safety testing, and oxygen concentration testing. This requires training in general and specialized maintenance of equipment and tools, as well as spare parts, such as filters and adsorbent cartridges for concentrators. Some equipment may benefit from use of voltage stabilizers and power surge protectors in places where electrical power may be unstable and damage equipment. UPS or power outage alarms may be necessary where concentrators are used for patients highly dependent on oxygen. There should be a record of the inventory of oxygen equipment, as well as maintenance schedules and logs.

Health worker capacity

Safe oxygen use, as well as increased aversion of morbidity and mortality from hypoxemia, requires health workers to receive training and have access to guidelines and job aides at the point of service. Treatment guidelines also need to be reviewed and, where necessary, updated to integrate supplemental oxygen use into standard case management. Health workers and biomedical engineers must also have the knowledge and skills to correctly use and maintain oxygen equipment and accessories. Occupational safety considerations should go together with clinical knowledge/skills and equipment care practices.

Data management

Oxygen systems should be monitored to support quantification and projection of needs, assessment of clinical and maintenance practices, and measurement of the impact of oxygen provision on clinical outcomes for patient categories receiving oxygen. Data also guide distribution planning for cylinder oxygen and may be used to reallocate transportable oxygen resources, such as cylinders, concentrators, and accessories to health facilities with greater need.

3.3.2 Major roadblocks

Several areas may pose a challenge to improvements of Malawi's national oxygen-supply ecosystem, including competing health system priorities, technical expertise, financial resources, and reliable power.

Competing health system priorities

Government decision-makers need increased exposure to the importance of efficient oxygen-supply systems, the need for increased oxygen, and the impact that comes with oxygen system improvements to enable informed decisions on how to allocate scarce resources for health. Engagement with technical assistance partners, collaboration with civil society, and formation of focused working groups can help elevate the awareness of oxygen as an essential component of basic health care. The COVID-19 pandemic has highlighted the importance of oxygen systems and the detrimental effect to other health services when inadequately resourced.

Resource allocation and prioritization

Within the oxygen interventions recommended in this roadmap, stakeholders at the central and district level must prioritize resource allocation. This will be important for maximizing impact, as well as keeping the implementation plan on track. There are several ways stakeholders can think about resource allocation; for one, they can consider the balance between investments in horizontal and vertical health programs that use oxygen. Ideally, investments in oxygen are determined through an evaluation of needs, agnostic of disease condition. However, investing oxygen resources to target high impact disease areas like pneumonia or malaria may be required in areas where such disease is endemic. On the other hand, investing in horizontal programs like emergency and critical care may be a better prioritization of resources in other locations. Additionally, stakeholders and donors should consider prioritizing the type of oxygen interventions that will be implemented in the short, medium, and long-term. For example, scaling up oxygen generation and storage capacity may be a short-term intervention that rapidly increases oxygen availability, but increased recruitment of biomedical engineers and other maintenance staff must follow-up this intervention in the medium-term, to maintain the initial gains from increased equipment availability.

Technical expertise

There may be a lack of technical expertise among decision-makers in Malawi, as well as among clinical and technical staff within the health system. Health worker capacity-building, setting of standards and guidelines (along with concerted efforts to support their dissemination), and community-based education and advocacy around oxygen can all support development in this area.

Financial resources for procurement and maintenance of equipment

In lower-resource settings, which may lack the finances to support regular biomedical equipment maintenance, equipment can become prematurely nonfunctional, and health facilities rely on small donations of equipment and supplies from outside organizations. However, procurement of new equipment is costly, and it is always in the best interest of a health facility to first maintain existing equipment as much as possible and then supplement with new equipment as demand increases. The MOH should dedicate more resources to biomedical equipment maintenance, equipment management systems, and training on basic maintenance and equipment upkeep. For procurement of bulk oxygen, the MOH could explore new financing mechanisms or government financing assistance such as public private partnerships to help build credit among health facilities, allowing them to contract oxygen more reliably from a gas supplier. Public-private partnerships could also be explored.

Availability of reliable power

Many respiratory care devices, such as ventilators, oxygen concentrators and PSA plants, rely on power of good quality and steady availability. Assessment should be conducted to identify facilities facing power challenges and the impact such challenges have on oxygen access. If improved power solutions cannot be established, such as UPS, backup generators, or solar power, facilities could reevaluate their oxygen-supply source type and emphasize low-to-zero power-requiring sources (e.g., oxygen cylinders) over other devices like oxygen concentrators.

Chapter 4: A situational analysis of the current medical oxygen ecosystem in Malawi

This chapter characterizes Malawi's current oxygen availability using data collected by PATH and the MOH in 2020/21. The data include observations about respiratory care equipment availability in health facilities across Malawi, as well as oxygen-production capacity and distribution. Additionally, insights on various aspects of oxygen production, supply, standards and regulations, and clinical use have been solicited from technical experts and consolidated here. The situational analysis provides a more detailed scope of the oxygen ecosystem gaps in Malawi and draws attention to systems and structures affecting the effective production and supply of medical oxygen in the country across all tiers of the health system.

CHAPTER 4 KEY TAKEAWAYS AND POLICY RECOMMENDATIONS:

- Current oxygen systems in Malawi need comprehensive improvement, as shown through data collection on baseline oxygen availability.
- Identification of hypoxemia and provision of oxygen therapy is poor, due to lack of devices and non-standardized clinical practice.
- Common oxygen-supply sources in Malawi include PSA plants, oxygen concentrators, and oxygen cylinders, which have trade-offs in production capacity, cost, technology suitability, and maintenance requirements. Assessment of technology suitability and absorptive capacity of health facilities should become part of standard procurement practice.
- Capacity-building of health care workers and biomedical engineers is urgently needed in Malawi.
- There are many areas where updated policies, regulations, and guidelines could improve availability and management of oxygen. Such areas include regulation of gas suppliers, oxygen purity, distribution of gas cylinders, and technical specifications of equipment, as well as standard operating procedures (SOPs) and guidelines for medical devices, pulse oximetry, maintenance, and oxygen administration by health care workers.
- When adopting and implementing standards, consider the organization of standards and whether they are directly transferrable across health systems of different countries and remember that standards are not self-enforcing; pairing standards with regulation can ensure effective implementation.
- Staying involved in global initiatives and partnerships can help Malawi stay abreast of the latest research and guidelines pertaining to respiratory and critical care.

4.1 The health system in Malawi

The health care delivery system in Malawi mainly consists of public (government) facilities, at 51% of the total, and facilities under the Christian Health Association of Malawi (CHAM), at 14% of the total. Most of Malawi's population rely on the public sector for health. Accessibility to health care facilities is a challenge to many Malawians, with only 46% of the citizens living within a 5 km radius of any kind of health facility.[28]

Malawi's health system is organized at three levels: primary, secondary, and tertiary. These levels are linked to each other through an established referral system. Primary-level care, including community-based care, and secondary-level care fall under district councils. Community health services are provided by health surveillance assistants at health posts, dispensaries, village clinics, and maternity clinics. These health surveillance assistants are responsible for a catchment area of 1,000 people. The primary level also includes health services provided by health centers and community hospitals. Health centers offer outpatient and maternity services and are meant to serve a population of 10,000. Community hospitals have greater bed capacity and treatment capacity than health centers. They offer outpatient and inpatient services and conduct minor procedures. The secondary level of care consists of district hospitals and CHAM hospitals of equivalent capacity. Secondary-level health care facilities account for 9.5% of all health care facilities. They are the referral-level facilities for health centers and community hospitals and provide their surrounding populations with both outpatient and inpatient services. The tertiary level consists of central hospitals. They ideally provide specialty health services at the regional level and provide referral services to district hospitals within each of their regions. In practice, however, around 70% of the services they provide are either primary or secondary services due to lack of secondary-level facilities in cities with central hospitals.[viii] While this is so, the Emergency and Critical Care Strategy proposes mechanisms which will support improvement in the delivery of care. The delivery of emergency and critical care services that require oxygen will be delivered through the out of hospital care and intra hospital care system. The out of hospital care system will be supported by a new cadre of paramedicals. *Table 2* provides a breakdown of health facilities by various characteristics.

The public sector includes all health facilities under the MOH; district, town and city councils; Ministry of Defense; Ministry of Home Affairs and Internal Security; and the Ministry of Natural Resources, Energy and Mining. The private for-profit (PFP) sector consists of private hospitals, clinics, laboratories, and pharmacies. Traditional healers are also prominent and would be classified as private for-profit. The private not-for-profit sector comprises religious institutions, nongovernmental organizations (NGOs), statutory corporations, and companies. The major religious provider is CHAM. Most of both private for-profit and private not-for-profit providers charge user fees for their services.[12]

There are five tertiary hospitals, also known as the central level, which are expected to offer advanced, specialized care. However, 70% of services offered at the tertiary level are for conditions that should be treated at primary care or district hospitals. Again, this is due in part to a lack of secondary-level facilities.

Oxygen equipment is procured by Health Technical Support Services (HTSS) for all facilities. However, partners and other donors are engaged to finance some of the procurement. Oxygen supply has been included in the Standard Treatment Guidelines and Essential Medicines List, which means oxygen-related equipment will be procured using the drug budget. This will improve availability of oxygen.

Table 2. Health facilities in Malawi by various characteristics as of September 2020.

Characteristic	Specification	Number
Region	North	224
	Central	452

[viii] The Emergency and Critical Care Strategy proposes improvements in the delivery of care. The delivery of emergency and critical care services that require oxygen will be delivered through the out-of-hospital care and intra-hospital care systems. The out-of-hospital care system will be supported by a new cadre of paramedical personnel.

	South	583
Level/type of facility	Hospital	107
	Health center	492
	Dispensary	63
	Clinic	438
	Health post	124
Ownership of facility	Government	630
	Christian Health Association of Malawi (CHAM)	169
	Private for-profit	272
	Private not-for-profit	89
	Nongovernmental organization	64
Geographical distribution	Rural	834
	Urban	390
Total		1,224

4.2 The 2020 Malawi Biomedical Equipment Survey (BMES)

In response to the COVID-19 pandemic, and with consideration of oxygen needs beyond the pandemic, a BMES designed by WHO and adapted to the Malawi context was conducted in 76 health facilities across all 28 districts of Malawi. The purpose of the BMES was to observe existing oxygen-delivery and oxygen-production equipment, consumables for administering oxygen therapy, bed capacity, and facility infrastructure characteristics relevant to providing respiratory care. The facilities sampled included all central hospitals, all district hospitals, a sample of CHAM hospitals, and select rural and community hospitals. The inclusion criteria for community hospitals were based on whether a facility routinely provides inpatient care, is anticipated to admit patients with respiratory problems in addition to COVID-19 patients and possesses equipment to care for severely ill patients. The following sections describe the availability of oxygen-related equipment and supplies at these health facilities. The 2021 *Biomedical Equipment for COVID-19 Case Management: Malawi Facility Survey Report* gives a detailed description of facility observations.[11]

4.2.1 Oxygen production and supply sources

Malawi's common sources of medical oxygen include oxygen concentrators, oxygen cylinders, and PSA plants in selected health facilities. The typical make of oxygen concentrators in Malawi varies widely, but Airsep and DeVilbiss are the most common. Availability of oxygen production and technology in regions and at tertiary hospitals reveals significant variation across Malawi. *Tables 3 and 4* present data on the availability of oxygen technology at the time of the BMES and show this variation. There is no current use of on-site LOX at health facilities in Malawi.

Table 3. Availability of oxygen technology in Malawi, by health zone as of 30th August 2021.

Health zone	Population of health zone[29]	PSA oxygen plants	Oxygen cylinders	Oxygen concentrators
Central East	2,806,834	0	12	22
Central West	4,719,326	2	204	43
North	2,286,960	1	75	22
South East	5,087,986	1	92	49
South West	2,662,643	4	183	37

Total	17,563,749	8	566	173

Abbreviation: PSA, pressure swing adsorption.

Table 4. Availability of oxygen at central hospitals in Malawi.

Facility	PSA oxygen plants	Oxygen cylinders	Oxygen concentrators
Mzuzu Central	0	30	1
Mercy James*	1	17	1
Kamuzu Central	1	100	25
Queen Elizabeth	1	100	19
Zomba Central	0	16	7
Total	**3**	**263**	**53**

Abbreviation: PSA, pressure swing adsorption.
**Mercy James is a pediatric specialty facility, supported by the pop star Madonna, sharing premises with Queen Elizabeth Central Hospital; however, PSA plants are not shared between the facilities.*

4.2.2 Oxygen concentrators

Concentrators are the most common source of oxygen in the country. Most health facilities have oxygen concentrators that supply oxygen at 5 LPM. Low-flow oxygen concentrators (e.g., 5 LPM and below) will be appropriate for most patients receiving basic oxygen therapy, but patients with severe and critical COVID-19 will require 10 LPM concentrators at a minimum and often other sources of higher-flow oxygen supply altogether. (Please see Appendix A4 for additional data on functional and nonfunctional oxygen concentrators observed in the BMES.)

4.2.3 Oxygen cylinders

In Malawi, the British Oxygen Company Afrox of the Linde Group distributes oxygen to health facilities via cylinders at a fee. Cylinders are filled in conversion depots in Lilongwe and Blantyre. They can be used directly at the patient's bedside along with accessories and consumables to control oxygen flow and delivery or connected to subcentral manifold systems (groups of cylinders linked in parallel) to pipe oxygen through the facility. Cylinders do not need electricity and have low maintenance requirements; however, they do require accessories and consumables to administer oxygen to patients. They also require reliable refilling and, therefore, a good supply chain and logistic system in place.

The total number of cylinders across health zones in Malawi varies significantly. For example, facilities surveyed in the South West Health Zone reported the highest number of cylinders, at 183 (32%). In comparison, the Central East Zone reported the fewest cylinders, at 12 (2%). This shows that some health zones have much greater reliance on oxygen cylinders as an oxygen source. It was also observed that very few oxygen manifolds are available across facilities. It is important to note that the exact numbers of cylinders have changed within the last several months of the COVID-19 pandemic due to increased interest and involvement of various actors to supply cylinders.

4.2.4 PSA plants

At the time of the BMES assessment, Malawi had only five active PSA oxygen plants, and three of them were located in the South West Health Zone. Since the assessment, additional plants have been completed at Kamuzu Central Hospital in Lilongwe (Central West Health Zone) and Phalombe District Hospital (South West Health Zone). The MOH Oxygen Task Force tracks existing and planned PSA plants and their functional status, and these data have been presented in *Table 5.* Maximum production capacity would be the amount of oxygen that PSA plants could produce if running 24/7 at their highest production volume. This is unrealistic, given that plants require maintenance and may have additional downtime from poor power quality or from not operating 24/7. *Table 5* totals the maximum production capacity from all existing (active) PSA plants, as well as totals the maximum production capacity that is expected from all existing and planned facility-based PSA plants in Malawi.

Table 5. Facility-based pressure swing adsorption plants in Malawi, existing and planned as of 30 August 2021.

Facility name	Health zone	Model	Operational status	Maximum production capacity of facility (L/hr.)	Filling capacity
Daeyang Luke Hospital	Central West	MVS Engineering Ltd./ Medical Oxygen Plant	Active	10,000	No
Kamuzu Central Hospital	Central West	Intakatek	Active	50,000	Yes
Karonga District Hospital	North	-	Planned	23,800	Yes
Mercy James	South West	Intakatek	Active	12,000	No
Mzuzu Central Hospital	North	-	Planned	50,000	Yes
Neno District Hospital	South West	Foxolution	Active	1,375	Yes
Nkhata Bay District Hospital	North	Intakatek	Active	4,830	Yes
Nkhoma Mission Hospital	Central West	-	Planned	21,000	Yes
Phalombe District Hospital	South West	Oxywise	Active	49,000	Yes
Queen Elizabeth Central Hospital	South West	Intakatek	Active	50,000	Yes
Zomba Central Hospital	South East	-	Planned	50,000	Yes
Lisungwi Community Hospital	South West	-	Temporarily out of order	6,900	Yes
Kasungu	Central East	-	Planned	-	Yes
Mangochi	South East	-	Planned	-	Yes
Bwaila	Central West	-	Planned	-	Yes
Grand total for existing plants					**177,205 L/hr.**
Grand total for all plants, existing and planned					**328,905 L/hr.**

Note: "-" denotes where information is unknown or unavailable.

4.2.5 LOX

Currently, the country does not have any facilities with LOX. However, LOX is an alternative form of oxygen supply that the roadmap considers as a viable option in the oxygen-source mix. LOX has the potential to be cheaper because it can be shipped in such large quantities compared to gaseous cylinder oxygen. When stored at a health facility, LOX does not require any electricity, unlike a PSA plant or oxygen concentrator. The drawback to LOX is that it is only really feasible when produced and distributed by a large supplier, given the high capital investment cost and need for technical expertise to enable LOX-production capacity. In this regard, it is unlike PSA plants, which allow for production on-site at a facility.

4.2.6 Health facility infrastructure and capacity

Health facility infrastructure plays a critical role in the delivery of oxygen. In most health facilities, oxygen delivery is through bedside concentrators and cylinders. Most facilities do not have an on-site PSA plant, and oxygen piping systems and cylinder manifolds are available in a limited number of facilities. These infrastructure elements however, are far more efficient for providing oxygen to patients. Additionally, oxygen distribution within facilities can be constrained by insufficient wall units to service all beds. Power outages and irregular voltage can prevent the use of or cause damage to oxygen concentrators. *Table 6* shows standard power requirements and recommendations for power backup sources for the oxygen-production equipment discussed previously.

Table 6. Oxygen equipment and power requirements.

Equipment type	Approximate average power usage (watts)	Size	Power continuity options
Gas cylinder	0	Portable cylinder that can be moved with ease	No power needed
Liquid oxygen tank	0	Tank that requires piping	No power needed
Oxygen concentrator*	350-700	Small device that requires electricity to produce bedside oxygen	Generator/solar
Pressure swing adsorption plant**	450,000- 90,000	Full system the size of a shipping container	Industrial-scale generator
Air separation unit plant***	833,000	Industrial-scale manufacturing plant	Industrial-scale power plant

Source: PATH. Electricity Planning Guide. Seattle: PATH; 2020. https://www.path.org/resources/electricity-planning-guide/.
**Power usage for a 5 LPM–10 LPM oxygen concentrator.*
***Power usage for a 30 Nm3/h–60 Nm3/h PSA plant.*
****Power usage of a 100 ton/day air separation unit plant.*
Abbreviations: LPM, liters per minute; Nm3/h, normal cubic meter per hour.

The BMES includes indicators on infrastructure-related questions, such as whether an oxygen piping system was installed and what source of electricity was used. The most common electricity source was a central grid with a backup generator, reported at 63 facilities (83%). Most facilities (70, or 92%) reported not having any kind of central piping system, and only 6 (8%) reported having a piping system that could pipe medical oxygen.

Facility infrastructure varies by facility level in the health system; for example, services through ICUs are limited to referral hospitals, and only large facilities will have a PSA plant. Conducting a proper infrastructure assessment of health facilities is the next step to identify infrastructure challenges to providing safe and reliable oxygen. With this information, decision-makers can be better positioned to improve oxygen systems in facilities.

4.2.7 Pulse oximetry and multimodal devices

The BMES collected data on three type of pulse oximeters: fingertip, tabletop, and handheld. Fingertip and handheld devices were the most common across facilities. However, the total count of devices was low, considering it is recommended to always administer oxygen therapy with pulse oximetry. Furthermore, devices were unequally distributed across facilities, with facilities in the Central and South East Zones reporting far more devices. Patient monitors with and without integrated ECG were also surveyed; results showed that the most common device type across facilities included ECG, implying that it is a more desirable feature. The South West Zone has the most recorded patient monitors at a total of 112. This represents 32% of all recorded patient monitors; however, the South West Zone only has 12 facilities and represents 16% of the entire dataset. This shows that patient monitors are unequally distributed across facilities and that there is a significant need to procure many pulse oximeters and patient monitors to increase the ability to safely administer oxygen therapy.

4.2.8 Ventilators

Ventilators assist patients' breathing in cases of severe respiratory failure. The BMES collected data on various types of ventilators, including portable ones and intensive care ventilators for pediatrics and adults. Ventilators are not available in most hospitals. For example, only 72 functional ventilators were reported in all 76 health facilities surveyed. Additionally, ventilators are inequitably distributed, with 62% of all ventilators present in the Central and

South West Zones. There is a significant need to procure and distribute additional ventilators as evidenced in the following sections. Additionally, patient monitors and pulse oximeters should be procured and paired with these devices for safe oxygen administration. Increasing the number of staff trained in invasive mechanical ventilation and intubation will also improve safe practices around oxygen therapy.

4.3 Clinical use guidelines and training

4.3.1 Identification of oxygen need

Routine assessment of patients using pulse oximetry is by far the weakest aspect of oxygen administration due to poor device availability and unstandardized clinical practice. A study in five Malawi hospitals observed that none of the hospitals used pulse oximetry routinely, and only 22% of children with diagnosed hypoxemia received oxygen therapy.[21] With a lack of available devices, most hypoxic patients are not identified, and their need for oxygen therapy goes unmet.[30] Without pulse oximetry, health workers often rely on the physical manifestations of difficulty in breathing or breathlessness before initiating a patient on oxygen. This is despite studies showing oxygen has less impact in patients who have difficulty breathing. A Malawi-based study from 2016 measured the increase in referrals of severely hypoxemic children after health care workers received training in pulse oximetry; the results showed that children with hypoxemia danger signs, like chest indrawing, were twice as likely to be referred to a higher level of care, and children without hypoxemia danger signs were 27% more likely to be referred. The study estimates that without pulse oximetry, approximately 68% of severely hypoxemic children at rural health centers would not have been identified for referral.[31]

Oxygen administration is also shrouded with cultural beliefs that it speeds the dying process. Pulse oximetry could be a pathway to alleviating this stigma. In one qualitative assessment of Malawian health care workers' perceptions of pulse oximetry value and challenges, it was identified that pulse oximetry increased patient trust and acceptance of referral and treatment decisions. Health care workers also reported that showing literate mothers the SpO_2 reading from a pulse oximeter increased acceptance for giving their babies oxygen.[32]

4.3.2 Clinical practice of oxygen administration

Most patients start receiving oxygen upon admission to a ward. Very few health facilities provide oxygen in the emergency departments where patients are seen first, especially true in the case of district hospitals. This could be attributed to either poor resource allocation (oxygen resources are not located in areas with the greatest need for them), an overall resource scarcity (there is not enough oxygen to supply it everywhere), or constraints from other resources' availability (e.g., not enough beds in the emergency department to have inpatients stay and receive oxygen). As far as oxygen supply, oxygen concentrators are the usual choice in most health facilities. However, concentrators need continuous electricity, and in some health facilities where blackouts are common, these devices can become unreliable supply sources. Another challenge for clinicians is limited knowledge about oxygen-administration devices. Questions such as when to use various types of face masks or nasal prongs are frequently encountered. Most health workers will use whatever is on hand, without understanding how each device works or affects the oxygen percentage patients receive.

4.3.3 Guidelines and training on oxygen use

Oxygen therapy should be initiated immediately after a patient has been identified as hypoxemic. Stand-alone or integrated guidelines on oxygen administration are limited, training on oxygen use is not common among health workers, and there is very little information collected on the training health workers receive. Previous studies have shown that guidelines in critical and emergency care are some of the least available guidelines in health facilities in Malawi,[33] despite these areas of care being some of the most likely to require oxygen therapy.

Clinicians often have no instruction on how much oxygen should be given to patients, and the fact that oxygen therapy is not static—that it needs to be actively titrated—is not always well understood. This is due in part to the limited availability of pulse oximetry making staff unfamiliar with how to integrate it into clinical algorithms for oxygen delivery. Most information sources (not official guidelines) will only state which patients should receive oxygen (e.g., if SpO_2 is < 90%, start oxygen). This makes no differentiation between a patient saturating at 60% and one saturating at 90%. Clinicians resort to simply monitoring the liters a patient receives. Additionally, many clinicians are unaware of SpO_2 goals during oxygen therapy, and oxygen is generally not titrated once initiated. This results in either patient hypoxia or hyperoxia, which can be harmful.

Lastly, there are general practices adjacent to oxygen therapy or use of medical devices that can be overlooked easily in the absence of guidelines for health care workers. For example, many facilities reuse oxygen interfaces (e.g., tubing, cannula, face masks) by washing with chlorine. If chlorine is not completely washed off the tubing, then this can cause inhalation injury. Such details are important for consideration when attempting to create comprehensive SOPs for oxygen and critical care.

There is a wealth of resources available through various organizations and groups that intend to provide respiratory and critical care tools with global reach. These include consolidations of the latest research, guidelines for clinicians and biomedical engineers, and online training programs for clinical staff. *Text Box 2* provides links to several of these global resources.

Text Box 2. International clinical guidelines and resources for respiratory and critical care.

- **Assist International Global Oxygen Therapy & Critical Care program sessions**: https://assistinternational.org/clinicalsessions/
- **Agency for Healthcare Research and Quality (AHRQ) COVID-19 resources**:* https://www.ahrq.gov/coronavirus/index.html
- **Guideline Central** (for additional links to resource and research repositories): https://www.guidelinecentral.com/alternatives-to-ahrqs-national-guidelines-clearinghouse/
- **PATH's COVID-19 Catalog of Training Resources for Health Care Workers**: https://tableau.path.org/t/COVID-19RespiratoryCare/views/COVID-19CatalogofTrainingResources/GuidedTrainings?%3AisGuestRedirectFromVizportal=y&%3Aembed=y
- **Stanford's Global Anesthesia and Critical Care Learning Resource Center**: https://www.stanesglobal.com/pages/home
- **WHO's *Clinical Care of Severe Acute Respiratory Infections – Tool Kit***: https://www.who.int/publications/i/item/clinical-care-of-severe-acute-respiratory-infections-tool-kit

**AHRQ is a US-based institution.*

4.4 Provision of medical oxygen; biomedical engineering perspective

The three most common sources of medical oxygen in health care facilities are compressed gas cylinders, oxygen concentrators, and PSA oxygen plants. Suitability of an oxygen source for a health facility depends on multiple factors, such as oxygen need, cost to contract supply and/or own devices, reliability of the supply chain for local production and delivery of medical gases, reliability of electricity, and access to maintenance services and spare parts. In addition to the oxygen source, many other oxygen system components are required at the facility level to get oxygen to patients who need it. These include:

- Infrastructure for oxygen distribution within the facility, such as piping, cylinder manifolds, and wall outlets.
- Accessories to control pressure, flow, humidity, and concentration of oxygen delivery.[ix]
- Consumables for delivering oxygen to patients.[x]
- Monitoring devices, such as pulse oximetry or patient monitors with SpO_2.[xi]

Other devices that may be relevant given the general infrastructure of health care facilities include voltage-monitoring devices, oxygen analyzers, voltage stabilizers, and UPS. These devices are needed to protect equipment from poor-quality mains electricity or provide continuity of power during mains power interruptions. A large challenge at health facilities is frequent power outages, which limit use of oxygen concentrators and can affect oxygen purity at a PSA plant. For this reason, it is recommended that all facilities with plants have either UPS or a backup generator.

Piping oxygen from an on-site PSA plant directly to the patient's bedside is a convenient oxygen-supply method when a facility has a substantial oxygen need and enough financing to cover capital and operational expenses. It is strongly recommended that wards that require routine oxygen provision be connected to a plant through a piping system. Such wards include the ICU, HDU, emergency department, operating theatre, casualty ward, labor ward, nursery ward, and pediatric ward. Successful oxygen provision from a PSA plant requires ongoing maintenance of the plant, appropriate infrastructure, and training of clinical staff on the correct consumables to use when facilitating oxygen delivery. An example of what this looks like in practice is at Kamuzu Central Hospital. The hospital has a gas-generating system that includes a PSA plant, vacuum plant, and cylinder filler, and the whole system is regularly inspected by the MOH's Physical Assets Management (PAM) program.

Lower-level facilities commonly rely on oxygen cylinders and concentrators to supply oxygen at bedside. These may be the best oxygen-supply sources if electricity and/or maintenance ability is less reliable. Oxygen cylinders have their own associated risks and challenges, however. They are highly pressurized, and mismanagement poses a risk of combustion. They also are very heavy and therefore difficult to transport within facilities, and they have the potential to fall on patients if improperly propped at a patient's bedside. One recommended solution is to install cylinder manifolds and piping systems at lower levels of care.

Standardized safety precautions should be instituted in all health facilities operating oxygen-related equipment. This should be accompanied by SOPs that ensure safety precautions are followed. For instance, gas plants and cylinders should have stickers with safety rules and operation guidelines clearly stated,[xii] and before using filled cylinders, users should make sure oxygen purity has been tested and verify that cylinders are sealed and clearly labeled.

[ix] Regulator, flow meter, flow meter stand (flow splitter), humidifier (heated and non-heated), blender.

[x] Nasal cannula, nasal catheter, masks, tubing.

[xi] Patient monitor, pulse oximeter.

[xii] For cylinders, these stickers may allow the user to make note of what a cylinder's serial number, fill date, batch number, and filling pressure (in kPa, or kilopascal) are and whether a cylinder was checked for leaks, an empty cylinder was purged with oxygen, and/or a cylinder was vented.

In Malawi, there is an urgent need to build the capacity of biomedical engineers and on-site technicians available for quick response to equipment maintenance and repair needs. It has been observed that having to wait for engineers (who are based outside of the country and maintain equipment through a service contract) results in loss of life. Overall, capacity to maintain oxygen therapy equipment must be improved, which, in addition to human resources, requires tools to test the functionality of the equipment, as well as spare parts to keep it functioning.

4.5 Standards and regulatory landscape

4.5.1 Malawi standards for oxygen

There is an urgent need to develop respiratory care standards and guidelines for Malawi. While COVID-19 incentivized the development of clinical oxygen guidelines for neonates, children, and adults, more work remains. These standards must be created for all health tiers and accompanied by due diligence to disseminate and implement them in health facilities and ambulances. Regulations and standards for oxygen-production quality and oxygen distribution should be reviewed and accompanied by concerted implementation efforts. Section 4.5.2 on international standards provides more detail on the challenges of creating and implementing, as well as reacting to poor fulfillment of, standards.

The following are areas in which standards for medical oxygen management and provision could be improved by policy, regulation, and guidelines for health facility staff and other decision-makers concerned with respiratory care.

Procurement process for oxygen medical devices

Moving toward a standardized procurement process that considers the continuum of care at different facility levels is important. For example, facilities could institute routine situational assessments, such as a facility readiness assessment that can help determine procurement needs and absorptive capacity of the facility (i.e., which devices are supported by existing infrastructure and other facility characteristics).

Staff workflows

Having SOPs for health facility staff, as well as routine assessments of clinical care workflow, will help health facilities optimize their ability to provide oxygen therapy.

Maintenance of oxygen devices

Across primary- and secondary-level health facilities and at oxygen plants, routine maintenance and serviceability are not prioritized beyond the standard warranty period. Given the unreliable power infrastructure and climate, it is important to prioritize and prepare for long-term serviceability through comprehensive Service Level Agreements that include product and labor, as well as conditional maintenance.

Market regulation

Most vendors do not undertake sufficient due diligence or situational assessment to understand the health systems for which they are designing devices or the demand for oxygen delivery in-country. Policy that mandates technical specifications for devices can improve the technology suitability of devices that get procured by health facilities. Also, policy can help incentivize suppliers to offer different products, increase volume of products available for purchase, or encourage new market entrants and competition that can potentially lower prices.

Referral systems

The demand for new services often results in increased service use at the point of service delivery. This strains the down-referral and up-referral chains of care. It is therefore important to analyze oxygen- and respiratory care–related service availability at each level of care and align availability with policy for service provision.

Data management

Standards for data collection, using either the District Health Information System 2 (DHIS2) or another health metrics program, should be implemented at each level of care, and health metrics should be tracked that are appropriate for that level of care. For example, metrics for oxygen delivery at the level of primary care should be related to acute management, improved saturation, or timely referrals and not to decreased mortality or morbidity.

Supply chain management

Equipment and inventory management systems and SOPs at the facility level should be implemented for sustainable provision of essential commodities and spare parts.

4.5.2 International standards

International standards for medical oxygen and oxygen therapy devices are wide ranging: from guidelines for oxygen production, distribution, storage, and clinical use to recommended availability by health system level and health discipline to technical specifications for devices, and more. This section highlights a few notable standards for medical oxygen that have been provided by technical experts, and general considerations for adopting and implementing standards, as well as lists some global repositories for respiratory and critical care–related guidelines and research and other resources.

Medical oxygen standards may mandate the following:

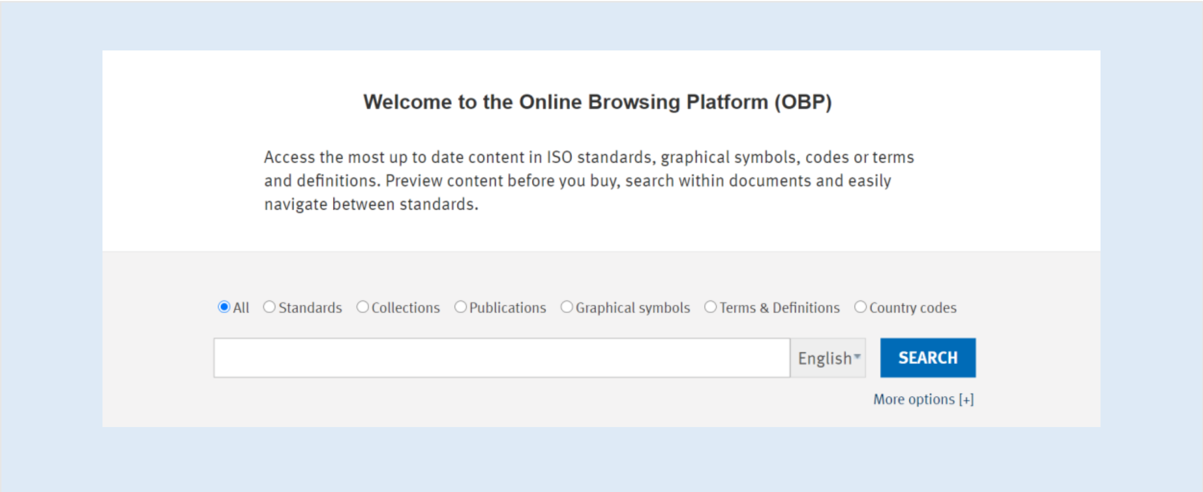
- Medical oxygen is of an acceptable purity to qualify for medical oxygen therapy. The latest standards for oxygen purity produced by PSA plants recommend purity of 93% ± 3%.[34] However, this standard often differs depending on its source, as can be seen in Appendix A8, which compares global standards for oxygen purity.
- Medical oxygen does not include gases that may be harmful to the patient or the delivery and storage apparatus.
- Medical oxygen remains free of chemical reactions during generation, storage, and delivery.
- Medical oxygen is easily identifiable to avoid confusion with other medical gases and errors in administration.
- Medical oxygen is delivered using calibrated and standardized equipment at accurate flow rates.

Many standards exist related to medical devices (i.e., oxygen therapy devices), including but not limited to standards for cylinders, cylinder fittings, and storage tanks; pipes, ports, and other oxygen infrastructural hardware; and oxygen-generating units, such as concentrators and plants. WHO and UNICEF provide additional detail on this topic in their *Technical Specifications and Guidance for Oxygen Therapy Devices*.[27]

Considering the following general characteristics of standards may help policymakers adopt or implement international standards and design better processes for implementation:

- **Standards and guidelines are constantly evolving as new research is conducted.** For this reason, it is important to actively review and disseminate peer-reviewed research, participate in global partnerships, and generally stay up to date on new findings.
- **Breakdown of health system levels are often country specific, resulting in standards that can vary widely between countries**. Additionally, organization of standards can be by health system level, health discipline (e.g., standards specific to emergency care), or even by ward in a facility. Wherever possible, using health information data and discrete units of comparison (such as ICU bed counts) can help draw parallels between standards with different conventions.
- **Standards and regulations are not the same**. A standard is generally used in place of a prescriptive regulation and is created by a third-party organization (e.g., the International Organization for Standardization, or ISO [see *Figure 7*]).[35] There is no official mandate that accompanies an adopted standard unless it is paired with regulation and decided on and enforced by policymakers and stakeholders.

Figure 7. International Organization for Standardization (ISO) online browsing platform.



Source: ISO website. Online Browsing Platform (OBP) page. https://www.iso.org/obp/ui#home. Accessed August 2021.
Note: *This platform allows users to search for pay-to-use standards.* Potential search terms: *medical oxygen, critical care, respiratory care, acute care, medical devices, oxygen therapy devices*.

Chapter 5: Estimation of national oxygen need

This chapter discusses the methods and results of the national oxygen need estimate. This estimation is significant because it has been done using the most recent and comprehensive data available on Malawi's oxygen requirements. Additionally, the objectives and the modeling inputs have been informed by a range of technical experts and decided in collaboration with the Malawi MOH to achieve the most accurate and consensus-driven needs estimation based on all available input and data. The recommendations driven by these results are core tenets of the roadmap and will strategically inform Malawi's health policy for oxygen for the next several years.

CHAPTER 5 KEY TAKEAWAYS AND POLICY RECOMMENDATIONS:

- The UNICEF Oxygen System Planning Tool was used to estimate baseline national oxygen need. Data inputs for the tool were compiled and refined by PATH, UNICEF, the Malawi MOH Oxygen Task Force, and an assortment of technical experts to reach an accurate and agreeable estimation for national oxygen need.
- Investments must be made in many areas to reduce the oxygen gap in Malawi. This includes but is not limited to the following:
    - Increasing uptime of facility-based PSA plants by conducting sufficient preventative and corrective maintenance and improving power quality and reliability.
    - Increasing production capacity by repairing PSA plants that are working suboptimally.
    - Procuring sufficient oxygen cylinders to capture excess PSA plant–produced oxygen.
    - Procuring appropriate cylinder accessories and adhering to equipment guidelines to safely store and use cylinders to prevent leakage or waste.
    - Implementing distribution systems to transport oxygen cylinders to health facilities with insufficient supply.
- Malawi's planned PSA plants will decrease the oxygen gap, but without strategic intervention, accessing oxygen supply will remain a key challenge for rural and Northern Region health facilities due to the centralization of oxygen-production sources and limited ability to distribute oxygen cylinders.
- Malawi is facing both production and distribution problems and increasing oxygen access must include both capital investments in increased production and investment in logistical solutions.

5.1 Methods of estimation using the UNICEF Oxygen System Planning Tool

This section discusses the methods used to estimate baseline national oxygen need in Malawi health facilities. Oxygen need estimates were calculated using the UNICEF Oxygen System Planning Tool,[36] which specializes in estimating oxygen needs at the national, subnational, or health facility level.[xiii] The UNICEF Oxygen System Planning Tool has two functionalities that made it well suited for this needs estimation.

5.1.1 Functionality 1: Producing two types of estimations that describe national oxygen need

A user can enter data for as many facilities as desired into the tool, which first estimates oxygen need for each facility and then aggregates need across facilities for subnational and

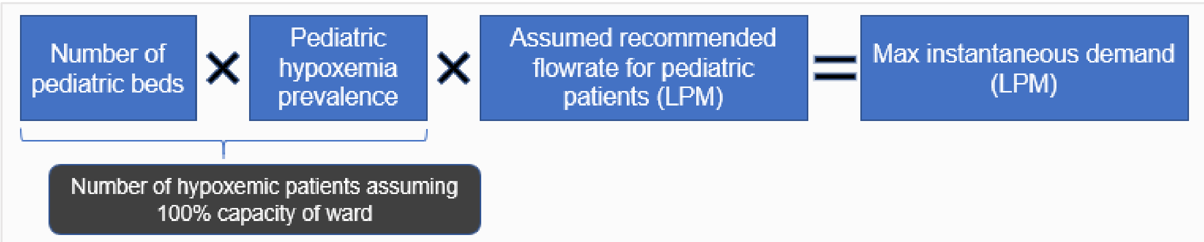
[xiii] Other tools have been created to estimate oxygen needs and/or make recommendations about oxygen system improvements, such as the WHO COVID-19 Essential Supplies Forecasting Tool and the PATH Quantification and Costing Tool for Oxygen Delivery Sources; however, these tools have different functionalities and were less suited for this activity (for detail about these tools, please see Appendix A6).

national estimates. The tool produces two types of estimations that help describe national oxygen need: max instantaneous demand and annual oxygen demand.

Max instantaneous demand

Max instantaneous demand is the absolute maximum flow rate of oxygen that could be required by a health facility at an instant if a facility is at 100% capacity.[xiv] Hypoxemia prevalence and recommended flow rate are inputted for each bed type according to the bed type's occupying patient population. For example, the hypoxemia prevalence differs for adult and pediatric populations; hence, the adult prevalence would be used for the adult beds, and the pediatric prevalence for the pediatric beds. The values for each bed type are summed up to determine the maximum flow rate required for an entire facility at 100% capacity. Research-driven default values[xv] for hypoxemia prevalence and flow rate are programmed into the tool to help estimate typical oxygen need for patients of different wards / bed types. *Figure 8* illustrates this calculation for pediatric beds.

Figure 8. Max instantaneous demand calculation for a pediatric ward.



Abbreviation: LPM, liters per minute.

This estimation is primarily useful for quantifying fixed assets like concentrators and planning PSA plant sizes. The rationale for using maximum instantaneous demand is that such assets are less flexible to respond to peak demand and thus should be able to entirely supply a facility that is at 100% capacity. It is important to note that this is an unlikely scenario, and the typical oxygen demand will be much lower than this estimate.

Annual oxygen demand

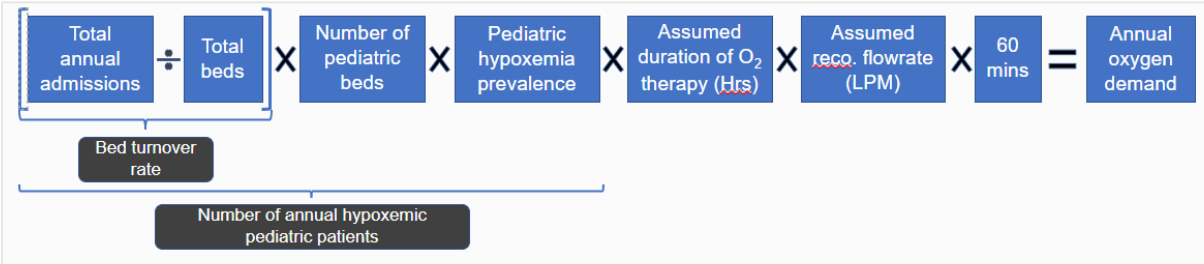
Annual oxygen demand is an estimation of the typical oxygen demand in liters that a facility may face over one year. As such, the calculation uses outpatient admissions and bed turnover rate[xvi] of a facility to estimate the annual number of patients admitted to a given bed type. This value is then multiplied by hypoxemia prevalence, recommended flow rate, and duration of oxygen therapy to calculate annual oxygen demand in liters for the bed type. The default values for hypoxemia prevalence and flow rate are the same as in the calculation for "max instantaneous demand." A default value for duration of oxygen therapy is used, as well. This calculation assumes total beds in a group (e.g., pediatric) are equivalent to admissions that are classified by that bed type. For example, if 40% of beds in a facility are pediatric, 40% of admissions are assumed to be pediatric. The population using a facility may not be

[xiv] Oxygen demand is calculated for each ward and then summed across all wards for a facility demand.
[xv] Default values in the UNICEF Oxygen System Planning Tool are informed by literature regarding oxygen, but there are options in the tool to change each default if the user has a more accurate or context-specific value. In the case of Malawi, technical experts were consulted, and Malawi-specific literature was reviewed to improve inputs.
[xvi] Bed turnover rate = total annual admissions / total no. beds (e.g., 9,000 admissions per year / 125 beds = 72). Data for annual admissions and bed capacity were collected from Malawi's DHIS2 and the PATH BMES.

distributed proportionally to their bed type, which could lead to over- or underestimation of demand.

Additionally, this calculation assumes a single flow rate and duration of therapy for all patients of a given bed type group (e.g., pediatric). This is not a perfect estimation since patient oxygen demand fluctuates over the course of treatment. *Figure 9* shows the calculation for annual oxygen demand.

Figure 9. Annual oxygen-demand calculation for a pediatric ward.



Abbreviations: LPM, liters per minute; reco, recommended.

5.1.2 Functionality 2: Creating "archetypes" from available facility data to fill in for missing data points

The UNICEF Oxygen System Planning Tool requires a comprehensive set of data points for each facility. These data points include:

- Facility name.
- Facility type.
- Facility geographic coordinates.
- Annual outpatient department (OPD) admissions.
- Total bed count.
- Bed count by bed type group (e.g., number of pediatric beds, number of adult beds, number of neonatal beds).
- Bed occupancy rate.
- Bed turnover rate.
- Average hours of reliable power.
- Facility oxygen piping status.

Facility name and type are required of all facilities for which oxygen need and oxygen-access recommendations are being calculated. Recognizing that not all facilities will have such comprehensive data available, the UNICEF Oxygen System Planning Tool uses facility "archetypes" to fill in data points for facilities that lack them. Archetypes represent the set of average value for a given data point (e.g., bed occupancy rate) for a given type of facility (e.g., a health center). These average values are used to fill in a data point only when a facility lacks them. For example, if the number of general beds at Benga Health Center is unknown but the average number of beds for health centers is 12, it is assumed that Benga Health Center has 12 general beds. The more facilities of a certain type that have a given data point, the more robust the archetype for that facility type is. As a last resort, if no values in the dataset exist for a given data point for a certain facility type, a value can be assumed for the archetype which will be applied across all facilities of the facility type. For example, if general bed count is not provided for any district hospitals, an assumed value such as "200" can be inputted and will be used for calculations for all district hospitals.

Many of the data inputs required by the tool are not routinely or centrally tracked for Malawi, except for a few key DHIS2 data points. Most of the data, therefore, were collected by PATH through the BMES and Facility Oxygen Survey. Since neither of these surveys collected data nationally (i.e., for all health facilities), archetypes were important for extrapolating and applying the available data to estimate oxygen needs at the national level.

5.2 Dataset refinement

The UNICEF tool has both default values and data inputs that the user is required to enter, which go into the oxygen needs estimation. This section describes how these data inputs were compiled and refined.

The following data types are defaults in the UNICEF tool and are critical to estimating max instantaneous demand and annual oxygen demand:

- **Hypoxemia prevalence per bed type (%)**. The percentage of patients that are typical hypoxemic (SpO_2 < 90%) per bed type.
- **Typical oxygen flow rate (LPM)**. The typical amount of oxygen in LPM required by patients per bed type.
- **Duration of oxygen therapy (hr.)**. The typical length of time in hours that oxygen therapy is provided to patients per bed type.

These values are based on literature findings and designated as "global" defaults because they are not country specific. To improve the oxygen needs estimation, technical experts were consulted to refine the data inputs with specific data for Malawi. Additionally, scientific literature and research studies focusing on oxygen use in Malawi were reviewed. *Table 7* shows the Malawi-specific data inputs that were used for hypoxemia prevalence, oxygen flow rate, and duration of oxygen therapy for a typical patient, specified for each bed type.

Table 7. Malawi-specific data inputs.

Bed type	Hypoxemia prevalence per bed type (%)	Typical oxygen flow rate (liters per minute)	Duration of oxygen therapy for typical hypoxemia case (hours)
Outpatient department	5%	5	1
General	4%	5	72
Adult	4%	6	144
Pediatric	7%	2	72
Neonatal	20%	1	72
Intensive care unit (ICU)	10%	6	96
Occupational therapy	100%	8	4
Emergency room	30%	6	8
High-dependency unit (HDU)	6%	5	72
ICU COVID-19	50%	10	144
HDU COVID-19	50%	10	144

Please see Appendix A7 for additional detail on the data inputs for the UNICEF Oxygen System Planning Tool.

5.3 Results

This section describes the results of the national baseline oxygen needs estimation. Specific data points discussed are as follows:

- Estimated bulk oxygen need, in LPM, across all health facilities.
- Bulk oxygen-production capacity.
- Distribution of oxygen-production sites.
- Oxygen gap.

5.3.1 Estimated bulk oxygen need

***Table 8* summarizes total national oxygen needs**. Data from 541 facilities were used to produce the totals shown. The most important numbers in this table are "monthly oxygen demand (L)" and "annual oxygen demand (L)" because these numbers quantify the oxygen that Malawi must produce and distribute to meet the estimated oxygen need. These values are also represented in terms of "J" cylinders (6,800 L) to make the estimates more tangible. By this estimate, each of the five central hospitals must reliably supply at least 498 "J" cylinders every month (a total of 2,492 cylinders across the five hospitals).

Table 8. Summary of estimated national oxygen needs.

Health facility type	Number of health facilities	Number of hypoxemic cases per year	Daily oxygen demand (L/day)	Daily oxygen demand in "J" cylinders (6,800 L)	Monthly oxygen demand (L)	Monthly oxygen demand in "J" cylinders (6,800 L)	Annual oxygen demand (L)	Annual oxygen demand in "J" cylinders (6,800 L)
Central hospital	5	100,579	564,740	83	16,942,200	2,492	206,130,000	30,313
Community hospital	2	1,107	6,045	1	181,350	27	2,206,500	324
District hospital	25	171,868	985,393	145	29,561,790	4,347	359,668,380	52,892
Health center	457	618,396	1,315,745	193	39,472,350	5,805	480,246,900	70,625
Mission hospital	27	55,471	689,403	101	20,682,090	3,041	251,632,080	37,005
Rural hospital	25	59,497	277,209	41	8,316,270	1,223	101,181,420	14,880
Grand total	**541**	**1,006,918**	**3,838,535**	**564**	**115,156,050**	**16,935**	**1,401,065,280**	**206,039**

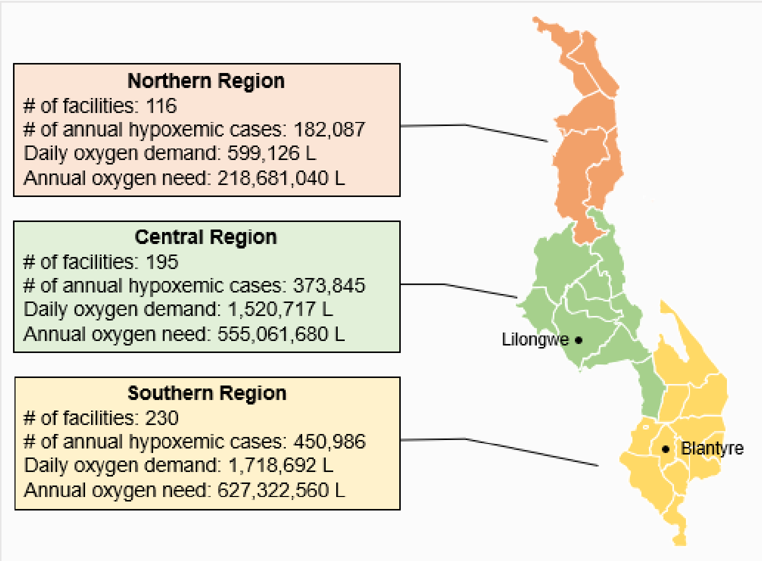
***Table 9* summarizes typical oxygen needs for a specific facility type**. These numbers are based on facility archetypes and therefore are the average oxygen need for a facility of a particular type. What can be learned from the facility type average is what the likely oxygen need may be for a facility where existing data are unavailable. Central-level hospitals are expected to have the highest oxygen need, followed by district hospitals, mission hospitals, and then rural hospitals.

Table 9. Summary of estimated oxygen needs by facility archetype.

Health facility type	Number of hypoxemic cases per year	Daily oxygen demand (L/day)	Daily oxygen demand in "J" cylinders (6,800 L)	Monthly oxygen demand (L)	Monthly oxygen demand in "J" cylinders (6,800 L)	Annual oxygen demand (L)	Annual oxygen demand in "J" cylinders (6,800 L)
Central hospital	20,116	112,948	17	3,388,438	498	41,226,000	6,063
Community hospital	554	3,023	0	90,678	13	1,103,250	162
District hospital	6,875	39,416	6	1,182,471	174	14,386,735	2,116
Health center	1,353	2,879	0	86,373	13	1,050,868	155
Mission hospital	2,054	25,533	4	766,003	113	9,319,707	1,371
Rural hospital	2,380	11,088	2	332,651	49	4,047,257	595
Grand total	**33,332**	**194,887**	**29**	**5,846,615**	**860**	**71,133,817**	**10,461**

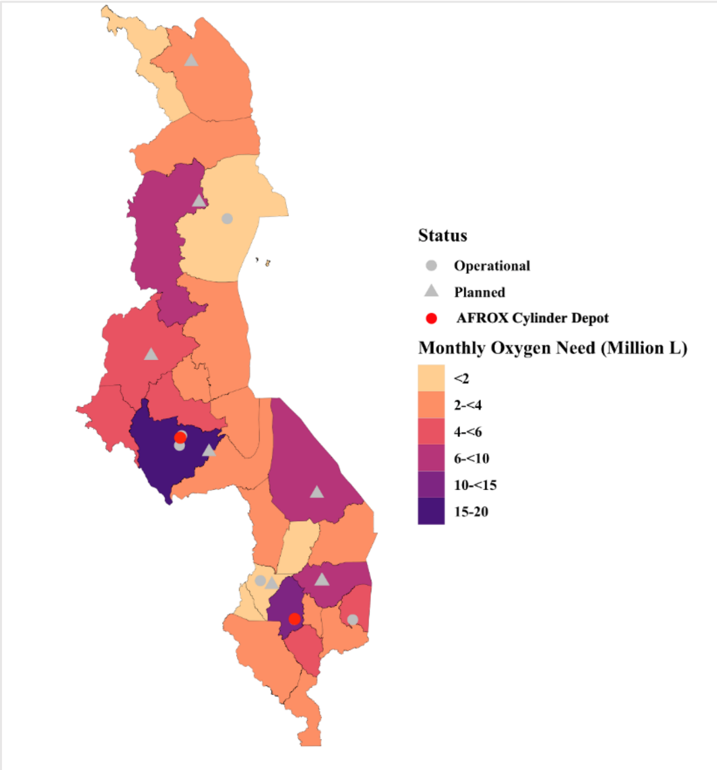
***Figure 10* shows demand, aggregated by region.** The Southern Region has the highest demand, which is attributed to the high number of total facilities and high concentration of central and district hospitals in this region.

Figure 10. Estimated oxygen need by region.



Lastly, Figure 11 is a map of oxygen need by district. This map is particularly useful for understanding relative oxygen need between districts. Additionally, the mapping of PSA plant locations shows whether there is currently a bulk oxygen supply source in a district, available to meet some proportion of the total need.

Figure 11. Oxygen need by district



5.3.2 Bulk oxygen-production capacity

Table 10 lists all bulk oxygen-production sites in Malawi. Several plants are in the planning stage or otherwise currently nonfunctional. The capacity of these plants is not certain at the time of this roadmap. Due to this uncertainty, two grand totals are calculated: total production capacity excluding the capacity of planned plants, and total production capacity including planned plants.

Table 10. Bulk oxygen-production sites in Malawi as of 30 August 2021.

Facility name	Operational status	District	Health zone	Maximum production capacity of facility (L/hr.)	Maximum production capacity of facility in "J" cylinders / hr.	Monthly production in liters (assuming 100% activity)	Monthly production in "J" cylinders (assuming 100% activity)
Afrox Blantyre*	Operational	Blantyre	South West	10,000	1	7,200,000	1,059
Afrox Lilongwe*	Operational	Lilongwe	Central West	10,000	1	7,200,000	1,059
Daeyang Luke Hospital	Operational	Lilongwe	Central West	10,000	1	7,200,000	1,059
Kamuzu Central Hospital	Operational	Lilongwe	Central West	50,000	7	36,000,000	5,294
Karonga District Hospital	Planned	Karonga	North	23,800	4	17,136,000	2,520
Mercy James	Operational	Blantyre	South West	12,000	2	8,640,000	1,271
Mzuzu Central Hospital	Planned	Mzuzu	North	50,000	7	36,000,000	5,294
Neno District Hospital	Operational	Neno	South West	1,375	0	990,000	146
Nkhata Bay District Hospital	Operational	Nkhata Bay	North	4,830	1	3,477,600	511
Nkhoma Mission Hospital	Planned	Lilongwe	Central West	21,000	3	15,120,000	2,224
Phalombe District Hospital	Operational	Phalombe	South East	49,000	7	35,280,000	5,188
Queen Elizabeth Central Hospital	Operational	Blantyre	South West	50,000	7	36,000,000	5,294
Zomba Central Hospital	Planned	Zomba	South East	50,000	7	36,000,000	5,294
Lisungwi Community Hospital**	Temporarily out of order	Neno	South West	6,900	1	4,968,000	730
Kasungu	Planned	Kasungu	Central East	Unknown	Unknown	Unknown	Unknown
Mangochi	Planned	Mangochi	South East	Unknown	Unknown	Unknown	Unknown
Bwaila	Planned	Lilongwe	Central West	Unknown	Unknown	Unknown	Unknown
Grand total for existing plants				**197,205**	**27**	**141,987,600**	**20,881**
Grand total for all plants, existing and planned				**348,905**	**49**	**251,211,600**	**36,943**

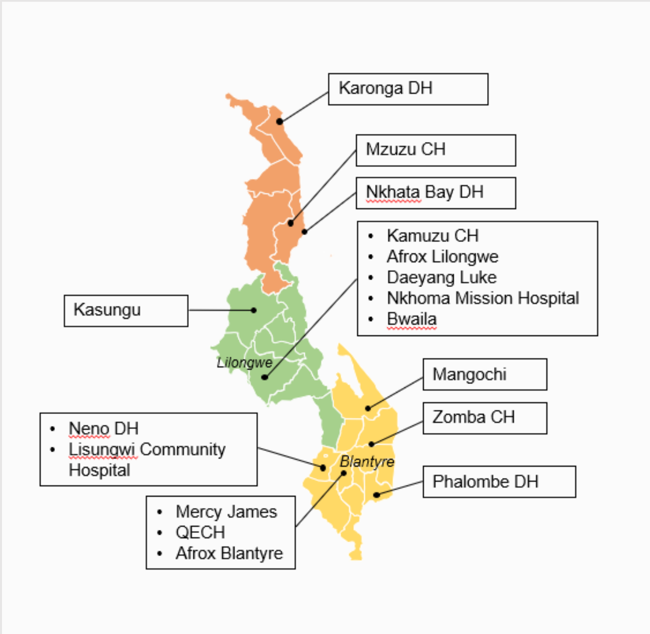
**Cylinder filling sites, not capable of production.*

***Capacity included in the total for existing and planned plants.*

5.3.3 Distribution of oxygen-production sites

Understanding bulk oxygen-production capacity is very important, but it is equally important to understand the distribution of supply. *Figure 12* highlights that most production sites are concentrated near the urban centers of Lilongwe and Blantyre. This leaves a greater demand for oxygen in the Northern Region and in rural areas. Distribution of cylinders to far-reaching facilities is logistically challenging and expensive, whether distribution of cylinders is done by a government-owned facility with a PSA plant or by a private supplier.

Figure 12. Distribution of oxygen-production sites in Malawi.



Abbreviations: CH, Central Hospital; DH, District Hospital; QECH, Queen Elizabeth Central Hospital.

The DAK Foundation, in partnership with African Mission Healthcare, is instituting a novel distribution network of oxygen cylinders from the planned Nkhoma Mission Hospital PSA plant. This plan involves upsizing Nkhoma's PSA plant and distributing approximately 50 cylinders per week of free oxygen to nearby facilities. The quantity of cylinders distributed is expected to decrease over the next two to seven years, as Nkhoma Mission Hospital's internal oxygen demand is expected to grow. Recipient facilities of cylinders will therefore need to scale up their on-site oxygen resources in parallel to maintain oxygen access in the period when free oxygen supply is decreasing.

Similar models of oxygen distribution from government-owned PSA plants to nearby facilities (which have less production capacity) have been explored in other African countries, such as Kenya.[37] These models may have significant benefits related to cost, matching of supply and demand, and local ownership of oxygen-supply systems. Continued exploration and investment in this area should be prioritized for Malawi.

5.3.4 Oxygen gap

Subtracting estimated oxygen-production capacity from the estimated oxygen need across health facilities produces the oxygen gap that Malawi may have to fill. *Table 11* shows the result of this calculation for different time frames (daily, monthly, annually) for the current production capacity scenario, for both the operational production sites only (oxygen gap 1) and the planned production capacity scenario (oxygen gap 2).

It is essential to note that oxygen-production capacity is an overestimate. The estimate assumes PSA plants are operating at maximum capacity 24/7. This is unrealistic due to power challenges, maintenance requirements, and facility operating hours. Furthermore, PSA plant–produced oxygen must be either piped directly to a patient's bedside or captured in oxygen cylinders. Therefore, having an insufficient quantity of oxygen cylinders on-site is a major constraint in capturing supply. Leakage from cylinders, which can be as high as 30%, is also not accounted for in this estimate. Finally, matching supply and demand is not frictionless, which necessitates that an excess amount of oxygen be available.[xvii]

Table 11. Oxygen gap given current production capacity and planned production capacity.

	Daily oxygen demand (L/day)	Daily oxygen demand in "J" cylinders (6,800 L)	Monthly oxygen demand (L)	Monthly oxygen demand in "J" cylinders (6,800 L)	Annual oxygen demand (L/year)	Annual oxygen demand in "J" cylinders (6,800 L)
Oxygen need	3,838,535	564	115,156,050	16,935	1,401,065,280	206,039
Existing oxygen-production capacity	4,732,920	696	141,987,600	20,881	1,703,851,200	250,566
Oxygen gap 1	+894,385	+132	+26,831,550	+3,946	+302,785,920	+44,527
Planned oxygen-production capacity	8,373,720	1,231	251,211,600	36,943	3,014,539,200	443,315
Oxygen gap 2	+4,535,185	+667	+136,055,550	+20,008	+1,613,473,920	+237,276

Although oxygen gap 1 shows that supply is greater than need, it is important to remember that this does not reflect the true situation in Malawi due to the overestimation of oxygen-production capacity. Additionally, oxygen need is underestimated in these calculations because it reflects only the baseline situation in Malawi and neither the oxygen need due to COVID-19 nor the expected increase in need from a growing population.

Investments must be made in many areas to reduce the oxygen gap in Malawi, such as the following (not a comprehensive list):

- Increasing uptime of facility-based PSA plants by conducting sufficient preventative and corrective maintenance and improving power quality and reliability.
- Increasing production capacity by repairing PSA plants that are working sub optimally.
- Procuring sufficient oxygen cylinders to capture excess PSA plant–produced oxygen.
- Procuring appropriate cylinder accessories and adhering to equipment guidelines to safely store and use cylinders to prevent leakage or waste.
- Implementing distribution systems to transport oxygen cylinders to health facilities with insufficient supply.
- Decreasing the cost of oxygen per liter.[xviii]

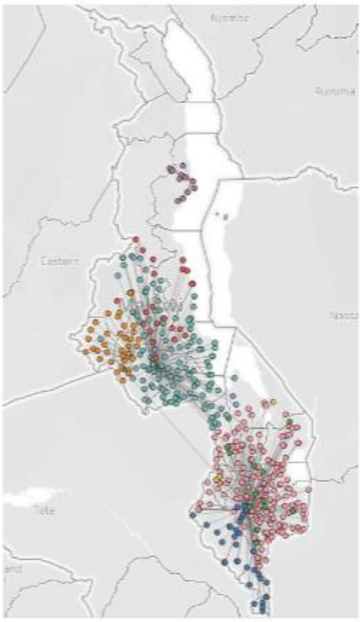
Oxygen gap 2 also shows that supply is greater than need for the scenario in which all the planned PSA plants are implemented and constructed to the capacities listed in *Table 10.* Again, it is very important to remember that this is an overestimate. **Furthermore, increasing bulk production alone does not solve the current challenges contributing to Malawi's oxygen gap. Until Malawi can reliably capture and reallocate excess supply, health facilities without PSA plants will not benefit from increased national production capacity**. *Text Box 3* further discusses this challenge and what solutions may be available.

[xvii] Excess oxygen at a health facility cannot be instantly available at a facility with an oxygen deficit.

[xviii] As Malawi increases national oxygen-production capacity, efforts should be made to track price reductions in oxygen. See indicators in Chapter 7.

Text Box 3. Recommendations for filling the oxygen gap.

Figure 13. Modeled baseline scenario with existing PSA plants.



Note: Assumes a 200 km catchment area for cylinder distribution.

Oxygen production situation in Malawi

Malawi's current oxygen-production capacity is highly centralized, resulting in uneven demand fulfillment in rural areas and in the Northern Region. The country is also lacking distribution systems to reallocate oxygen to areas with increased need, and lacking robust systems for referral and transport of hypoxemic patients . Given these supply and distribution problems, increasing oxygen access in Malawi must include capital investments in increased production, as well as investment in logistical solutions.

For logistical solutions, PATH recommends using a novel network design model to further characterize Malawi's ability to match oxygen supply with demand and analyze the cost and oxygen-access impacts that could be seen under different oxygen source installation scenarios. These scenarios will allow stakeholders to evaluate different logistical solutions to oxygen-supply and oxygen-distribution challenges in Malawi.

Value of the network design model

- The model allows for the comparison of the cost of different supply ownership models. For example, distribution could be government owned and operated or contracted with a supplier.
- Modeled scenarios can be designed with ministry priorities and constraints in mind, including but not limited to what type of facilities are eligible for PSA plant installation and the distance to which facilities will distribute cylinder oxygen.
- Key metrics allows for quick evaluation of trade-offs between modeled scenarios.

Chapter 6: Implementation plan

The success of this roadmap depends on effective implementation, which is supported by the strategic framework for implementation (*Table 12*) and the equipment and supplies costing (*Table 13*) laid out in this chapter. The strategic framework collates the challenges and observations on respiratory and critical care throughout this roadmap and identifies specific activities to address them in the short, medium, and long-term future. An additional section on human resources for health, follows the implementation framework, and leverages and tailors existing policy guidance to make recommendations to strengthen human resources for oxygen systems. Lastly, this chapter clarifies the roles and responsibilities of national and subnational groups.

CHAPTER 6 KEY TAKEAWAYS AND POLICY RECOMMENDATIONS:

- Roles and responsibilities for roadmap implementation are divided between the MOH, the national-level advisory group, international NGOs and implementing partners, and subnational groups such as regional-, zonal-, district-, and facility-level leadership.
- The ten strategic objectives of the implementation framework include improvements in
  - financing;
  - policy development;
  - advocacy and international partnership;
  - capacity-building of clinicians and technical workers;
  - M&E strengthening;
  - equipment and inventory management systems;
  - scale-up of oxygen-production capacity, equipment, supplies, and infrastructure; and
  - considerations for an environmentally sustainable health sector.
- This roadmap complements existing policy by offering recommendations for building the capacity of health workers to support oxygen systems. The interventions and recommendations proposed build off cross cutting policy, that describes interventions for systematically improving the number of skilled workers that are equitably distributed in country, as well as recommending interventions to improve recruitment, deployment, retention, and management of staff.
- Each implementation activity should have a designated lead, output, and timeline. Greater specificity with implementation goals will improve progress monitoring. Implementation will require significant investment over the next five years, with equipment and supplies alone projected to cost approximately MK 60,925,389,639 (or US $76,156,737); total cost of equipment and supplies will vary depending on the oxygen-supply source mix or infrastructure investments chosen for health facilities.
- It is the responsibility of the MOH to conduct the costing of additional activities in future workshops, organized in collaboration with activity leads listed in the implementation framework.

6.1 Roles and responsibilities

The following strategic framework (*Table 12*) is for developing and maintaining a national oxygen ecosystem for Malawi. The intervention areas, and their associated activities, map to the aforementioned components of a national oxygen-supply ecosystem (see Figure 6) and should help Malawi increase detection and treatment of hypoxemia in health facilities, expand availability of safe anesthesia nationally, and ultimately reduce morbidity and mortality from hypoxemia. At the national level, the implementation of the roadmap will be led by the Directorate of Clinical Services, with strong support from the Directorate of HTSS and the Planning Directorate. Dissemination workshops for the roadmap will be critical to clarifying the implementation responsibilities of various ministry groups. Lastly, activity leads will need to make connections between their implementation activities and indicators for M&E.

6.1.1 National-level leadership

Malawi MOH

Development of policy and guidelines is primarily the responsibility of the MOH. Different departments within the MOH will assist in development of various components. The MOH will also be responsible for supportive supervision, including documentation, spot checks for progress, practical evaluation of the progress of the evaluation plan, and enforcement of compliance with guidelines. Additionally, the MOH will facilitate mentorship and coordinate and conduct zonal review meetings to monitor progress of the roadmap implementation.

Oxygen Task Force

This group will be responsible for developing and updating guidelines, coordinating technical working group meetings, coordinating partner roles, reviewing progress of the roadmap implementation, identifying and disseminating the latest technical research on respiratory and critical care, monitoring policy implementation, and reporting progress to top MOH executives. Ideally, similar task forces will be created at the regional level and lower administrative levels. At the facility level, existing committees, such as Drug and Therapeutics Committees or medical equipment committees, can assist implementation of this roadmap. Such ownership of roadmap implementation at subnational levels will be key for supply planning, financing, and data management.

International NGOs, implementing partners, and the private sector

For this roadmap to be effectively implemented, the GOM will create an enabling environment for all players to take part. Government, partner organizations, and the private sector will contribute to rapidly increasing access to oxygen. Partner organizations will support policy development and roadmap activity implementation and provide funding for implementation activities, perform facility-level mentorship, develop training curricula related to implementation, support procurement and maintenance of equipment and supplies, and support data collection and analysis in close partnership with the national-level leadership. Professional associations, both local and international, will be engaged to provide professional guidelines in all specialties.

6.1.2 Implementation and supervision of activities

Many implementation activities in this roadmap will be carried out at the district and facility levels. Malawi has a decentralized health structure, which means budgeting and funding allocation for oxygen and respiratory care will be done at the central hospitals and the district health offices. Such groups will be responsible for receiving the periodic allocations from the central Ministry of Finance. The amount of money budgeted for oxygen and respiratory care may be decided by Drug and Therapeutics Committees at these levels. Central hospitals receive money directly and so can procure directly, while each district health office is responsible for procuring supplies and equipment for facilities in its jurisdiction. These groups are responsible for making financial investments in oxygen and respiratory care that align with the roadmap’s strategic objectives and activities. The PAM Unit at MOH headquarters and the Regional Maintenance Unit will play a critical role in developing appropriate capacity for biomedical engineers and technicians and provide supervision at the hospitals and health centers. The Clinical and Nursing Directorate will be responsible for building capacity and supervising health workers to ensure proper administration of oxygen.

Table 12. Strategic framework for implementation.

No.	**Strategic objective and key activities**	**Output**	**Lead**	**2021–2022**	**2022–2023**	**2023–2024**	**2024–2025**	**2025–2026**
Create an enabling environment for development and maintenance of a sustainable national oxygen ecosystem in Malawi.								
1.1	***Disseminate the national roadmap and coordinate the national task force, other government stakeholders, and departments**. The roadmap will serve as a reference document for decision-makers who are responsible for creating oxygen policy. Implementers must also be coordinated to put oxygen policy into practice.*	*Verification that the roadmap is accessible at national and subnational levels.*	*MOH (Planning, Clinical, and HTSS)*					
1.2	***Carry out additional baseline assessment of need and existing capacity at the national level**. There may be gaps in the baseline assessment which can be filled by an additional biomedical equipment assessment at health facilities and scoping of oxygen-supply system infrastructure and health care worker capacity and skills.*	*Datasets and/or development of routine reporting systems.*	*MOH (Clinical and HTSS)*					
1.3	***Develop sustainable funding for the national medical oxygen ecosystem and associated policy**. Identify and leverage available national-level funding mechanisms, such as the Health Sector Joint Fund, and bilateral, multilateral, and nongovernmental partners interested in supporting oxygen systems or specific programs involving oxygen and respiratory and critical care.*	*Documentation of financing for oxygen and respiratory care; increased partnership.*	*MOH (Planning, Clinical, and HTSS)*					
Review and develop policies, standards, and guidelines governing medical oxygen.								
2.1	***Develop national standards and guidelines for medical oxygen**. The standard(s) may be newly developed or an endorsed international standard but should be made official through collaboration between the MOH and the Malawi Bureau of Standards. Standards for medical oxygen should encompass the following:* *a) Technical specifications for devices, especially oxygen concentrators.* *b) Purity standards for oxygen generation.* *c) Clinical use of oxygen-generating equipment.* *d) Regulations for suppliers.* *e) Service-level agreements.* *f) Improvement of procurement processes.*	*Policy document, disseminated at national and subnational levels.*	*MOH (Planning, Clinical, and HTSS) and Malawi Bureau of Standards*					
2.2	***Develop an SEL**. The SEL is a critical reference document for implementers at district and health facility levels. Such a document will guide future procurement of respiratory care equipment and supplies. The SEL should place particular emphasis on emergency treatment units. Development may include review of the existing SEL as well as of other sources.*	*Revised policy/ standards/norms/ guidelines, disseminated at national and subnational levels.*	*MOH (Planning, Clinical, and HTSS)*					

No.	Strategic objective and key activities	Output	Lead	2021–2022	2022–2023	2023–2024	2024–2025	2025–2026
2.3	***Integrate oxygen and pulse oximetry into the norms, standards, and clinical guidelines for each level of health facility*** *and identify cadres of health workers who may prescribe oxygen under various circumstances.*	*Revised policy/ standards/norms/ guidelines, disseminated at national and subnational levels.*	*MOH (Clinical)*					
2.4	***Evaluate and recommend oxygen provision that should be at each level of care under the Essential Health Package****; create a standard for what oxygen products and sources should be available and a standard for their allocation within facilities (e.g., by ward or service area) to ensure oxygen is located where it is used.*	*Policy document, disseminated at national and subnational levels.*	*MOH (Planning, Clinical, and HTSS)*					
Institute a system for building the capacity of health workers to safely use medical oxygen, pulse oximetry, and oxygen accessories.								
3.1	***Develop an oxygen curriculum and train workers on oxygen use****. Building on existing clinical guidelines for conditions in which oxygen use is indicated, the WHO curriculum, and other international curricula, the MOH Clinical Services team should work with specialists from MOH partners to develop a national curriculum for training clinical workers in the detection of hypoxemia, rational and safe use of medical oxygen, care of oxygen equipment and accessories, logistics for oxygen consumables, and monitoring of oxygen systems.*	*Development of national curriculum for clinical workers.*	*Clinical Services Team*					
3.2	***Develop SOPs, job aides, and guidelines for administration of medical oxygen****. The MOH will lead partners and specialists to develop and disseminate:* *a) SOPs for medical oxygen—including for oxygen plant procedures, transport and distribution of cylinder oxygen, logistics management for oxygen cylinders and accessories, and installation and handling of oxygen equipment in health facilities.* *b) Job aides—including dosing charts, how to calculate flow rates for administering oxygen therapy, and which types and sizes of accessories (e.g., masks, tubing) to use for different devices or flow rates.*	*SOPs and job aids, disseminated at national and subnational levels.*	*MOH (Planning, Clinical, and HTSS)*					
3.3	***Develop SOPs, job aides, and guidelines for the use of pulse oximetry****. Clinical guidelines should be updated to include provisions for detection and treatment of hypoxemia where gaps exist in current guidelines and development of maintenance and care guidelines for oxygen equipment. Pulse oximetry should always be paired with oxygen delivery.*	*SOPs, job aids, and guidelines for pulse oximetry, disseminated at national and subnational levels.*	*MOH (Clinical and HTSS)*					
3.4	***Establish a system for continuous professional development (CPD) in oxygen systems****. This will integrate guidelines on oxygen use and the latest clinical recommendations into national CPD systems for users. This will also support additional training of biomedical engineers on emerging technologies in medical*	*Establishment of CPD system that is available to health care workers and*	*MOH (Clinical)*					

No.	Strategic objective and key activities	Output	Lead	2021–2022	2022–2023	2023–2024	2024–2025	2025–2026
	oxygen, such as integration of solar power and the use of concentrators with oxygen reservoir vessels.	*a training curriculum for biomedical engineers.*						
3.5	***Develop an occupational health and safety plan (OHSP) for oxygen**. The HTSS Directorate, technical experts, and government will be responsible for creating the OHSP, which will build on existing standards.* It will include safety considerations for workers at oxygen plants, workers involved with cylinder distribution, health workers, staff, and patients and provide guidance on installation of oxygen plants, health facility oxygen infrastructure, transport of oxygen cylinders, and specifications for fittings and lubricants for cylinder accessories. ***	*OHSP for oxygen, disseminated at national and subnational levels.*	*HTSS*					
Strengthen monitoring and evaluation of oxygen system improvements.								
4.1	***Establish indicators for oxygen use and system status in the HMIS**. HMIS metrics for oxygen use and oxygen systems are proposed in Chapter 5. Inclusion of these metrics into the HMIS will support performance management and course correction for the national oxygen ecosystem. It will also provide actionable information for the district and national levels, such as for procurement, training, and budgeting.*	*Indicators for oxygen, integrated into HMIS.*	*MOH (Clinical, CMED, and HTSS)*					
4.2	***Conduct baseline assessments to establish national-level baselines for oxygen- and COVID-19-related indicators**. Potential indicators are listed in the tables in Chapter 7. Many of these indicators for oxygen have never been tracked at a national level. Baseline assessment is a critical first step before setting targets for these indicators.*	*National-level baseline data on oxygen- and COVID-19-related indicators.*	*PAM, MOH (Clinical, CMED, and HTSS)*					
4.3	***Establish systems for ongoing tracking of oxygen- and respiratory care–related indicators and oxygen use**. Indicators listed in Chapter 7 must be collected routinely to evaluate oxygen-access scale-up over time (e.g., oxygen consumption, equipment and supplies availability, clinical outcomes). A system for tracking must be developed (DHIS2 may be applicable). Roles and responsibilities for tracking data must be established at all relevant levels (national and subnational).*	*Ongoing data collection for oxygen and respiratory care.*	*PAM, MOH (Clinical, CMED, and HTSS)*					
4.4	***Strengthen documentation of oxygen use and adherence to clinical parameters**. Oxygen guidelines will include tools for documentation of oxygen use. Supervisors at health facility and district levels must ensure that these tools are available at points of care and that clinical supervision includes a review of patient records for indication, dosing, weaning, and total duration of oxygen use.*	*Development of tools for documentation; proof of improved documentation of oxygen use and*	*MOH (Clinical), district health managers, facility supervisors*					

No.	Strategic objective and key activities	Output	Lead	2021–2022	2022–2023	2023–2024	2024–2025	2025–2026
		adherence to clinical guidelines.						
4.5	***Include oxygen systems and use in integrated clinical supervision**. Integrated clinical supervision and supervision of hospital managers should include assessment and support of oxygen systems, including adherence to guidelines, care and inventory of oxygen equipment, and commodity management of oxygen consumables.*	*Revision of supervision protocols to include oxygen; dissemination to subnational levels.*	*MOH (Clinical)*					
4.6	***Evaluate impact of improved oxygen systems on key indicators**. Periodic assessment of oxygen systems as part of routine annual Service Availability and Readiness Assessment, assessment of key supported services (e.g., CEmONC and inpatient pneumonia outcomes), and general evaluations (e.g., Malawi Demographic and Health Survey and Multiple Indicator Cluster Survey) will be linked to the performance of oxygen systems for learning and improvement.*	*Workshops to evaluate indicators for oxygen.*	*MOH (Planning, Clinical, and HTSS)*					
Establish a maintenance system for oxygen-production and oxygen-delivery equipment and supply of spare parts, as well as build capacity of biomedical engineers and technicians.								
5.1	***Develop and maintain local biomedical engineering capacity for oxygen systems**. Oxygen plants require dedicated biomedical engineering technicians trained in the operation and maintenance of plants. All biomedical engineering technicians attending to oxygen equipment should have the knowledge, skills, and equipment to carry out these main tasks:* *a) Preventive maintenance in accordance with a maintenance schedule.* *b) Basic corrective maintenance.* *c) Calibration and monitoring of equipment performance.*	*Development of tools to support biomedical engineers; tracking of labor force size and skill building.*	*MOH (HTSS)*					
5.2	***Strengthen supply chain and logistics for equipment maintenance**. Maintenance of oxygen equipment will require the availability of spare parts and specialized tools and equipment. Electronic inventory and equipment management systems will also be developed on which equipment age, operation logs, maintenance schedules, and maintenance logs are kept. This will enable equipment tracking, timely maintenance, and supervision to ensure safety.*	*Rollout of inventory and equipment management systems.*	*MOH (HTSS)*					
Scale oxygen-production capacity and availability of mixed-supply sources to satisfy the national need.								
6.1	***Procure and install an appropriate mix of oxygen sources** by carrying out phased procurement and equitable allocation of oxygen plants to regional sites and concentrators to health facilities in accordance with the assessment of need and demand; revise allocations based on monitoring of use and demand.*	*Tracking of oxygen procurement, availability, and other equipment indicators; workshops to evaluate oxygen system needs.*	*MOH (Planning, Clinical, and HTSS)*					

No.	Strategic objective and key activities	Output	Lead	2021–2022	2022–2023	2023–2024	2024–2025	2025–2026
6.2	***Estimate health facility capacity to absorb and effectively manage oxygen-production and oxygen-delivery equipment**. Total cost of ownership includes the cost of acquisition and operating costs over the life span of the equipment and influences how effectively a facility will be able to manage equipment over time. This must be decided prior to procurement to ensure that equipment remains functional and safe and works effectively and that there is planning for replacement at the end of the usable life span. Management of concentrators at the district level may support the redistribution of units where oxygen demand is low. Oxygen plants may need to be owned and operated by the national MOH since their maintenance will entail substantial expenditures in district budgets, and oxygen distribution should ideally cover areas larger than one district.*	*Coordination between national and subnational levels to estimate absorptive capacity, allocate funds, and procure/allocate appropriate equipment.*	*MOH (Planning, Clinical, and HTSS)*					
Ensure reliable and sufficient supply and distribution of oxygen, pulse oximeters, and oxygen accessories to points of use in target health facilities.								
7.1	***Prepare and implement procurement and distribution plans of pulse oximeters**. Pulse oximetry will be integrated into the following areas of care, at the appropriate levels of care: a) Triage and ambulances. b) Treatment of childhood illnesses. c) Surgery, anesthesia, and postoperative care. d) Delivery, postpartum, perinatal, and early newborn care. e) General patient monitoring.*	*Pulse oximetry availability at prescribed levels of care.*	*MOH (Planning, Clinical, and HTSS)*					
7.2	***Prepare and implement procurement and distribution of key oxygen accessories**. Key categories of accessories for safe oxygen use include: a) Cylinder accessories, such as trolleys, regulators, humidifiers, and key wrenches. b) Masks for newborn, pediatric, and adult use and of various types, such as simple face masks, venturi masks, non-rebreather masks with reservoir, tracheostomy masks, etc. c) Tubing, such as plain tubing, cannulas, nasal prongs, adapters, and connectors. d) Flow accessories, such as flow meters and splitters.*	*Oxygen accessories availability at prescribed levels of care; development of inventory management systems to maintain stock.*	*MOH (Clinical and HTSS)*					
7.3	***Establish national network for distribution of cylinders from plants to health facilities**. Distribution of cylinder oxygen should be done using dedicated vehicles specially fitted with transport racks to secure cylinders upright during transport and with mechanical lifting devices for occupational safety. It is therefore necessary that a logistics system is developed to facilitate transport of full cylinders to health facilities and return of empty cylinders to plants. While plants may have a specific number of districts in its catchment area, there should be mechanisms to cover for plant downtime, such as using supply from neighboring*	*Distribution system for oxygen cylinders between government-owned health facilities.*	*MOH (Planning, Clinical, and HTSS)*					

No.	Strategic objective and key activities	Output	Lead	2021–2022	2022–2023	2023–2024	2024–2025	2025–2026
	oxygen plants. In some regions, it may be useful to consider having depots for localized distribution using smaller vehicles.							
7.4	***Establish a supply management system for oxygen accessories****. All necessary oxygen accessories currently not listed or stocked by the Central Medical Stores will be listed and product specifications prepared. They will also be integrated into the LMIS to enable facilities to report inventory and consumption and make requisitions for replenishment.*	*LMIS inclusion of oxygen supplies; development of product specifications.*	*MOH (Planning, Clinical, CMED, and HTSS)*					
Improve infrastructure that supports oxygen systems.								
8.1	***Procure equipment and accessories to improve power quality and availability****. Generators and UPS are important for reliable administration of oxygen during power interruptions. Devices to modulate power disturbances, such as surge protectors and voltage stabilizers, can protect equipment from damage during power interruptions or from poor power quality. Additionally, installing infrastructure like generators and UPS can open the door to supporting more complex equipment and expanding oxygen-supply source options.*	*Evaluation of power quality challenges in health facilities and procurement of supportive equipment.*	*MOH (Planning and HTSS)*					
8.2	***Install an oxygen piping system and/or cylinder manifold, which can increase efficiency of oxygen delivery from supply source to patient bedside****. It is important as well to install all component pieces of such a system (e.g., wall outlets). These streamlined oxygen-delivery methods can contribute to increased safety and reduced interruptions in care (e.g., having to switch cylinders).*	*Evaluation of health facility infrastructure; procurement of equipment to improve oxygen delivery.*	*MOH (Planning, Clinical, and HTSS)*					
8.3	***Procure cylinder-filling equipment and compressors****. Availability of cylinder-filling equipment and compressors could allow for facilities with PSA plants to store and/or distribute filled cylinders to other facilities.*	*Increased ability to store oxygen via cylinders.*	*MOH (Planning, Clinical, and HTSS)*					
Increase advocacy, communications, and partnership.								
9.1	***Conduct targeted efforts to disseminate updated policy, standards, and guidelines and train health care workers at different levels of care****.*	*Workshops and advocacy campaigns, resulting in increased access to policy, standards, and guidelines.*	*MOH (Planning, Clinical, and HTSS)*					
9.2	***Conduct community advocacy campaigns that teach communities about the value of pulse oximetry and oxygen therapy to treat childhood illness****.*	*Improved community understanding and*	*MOH (Clinical)*					

No.	Strategic objective and key activities	Output	Lead	2021–2022	2022–2023	2023–2024	2024–2025	2025–2026
	Community-based efforts can help alleviate stigma around administration of oxygen therapy.	*acceptance of oxygen therapy.*						
9.3	***Explore and develop relationships with global groups, civil society, and other organized advocates****. There are many partnerships that can be formed with groups dedicated to monitoring and reducing the burden of diseases that can be managed with supplemental oxygen (see Text Box 1). Partnerships with diverse stakeholders have many benefits (e.g., including civil society in technical working groups devoted to oxygen will increase involvement and representation).*	*Increased partnerships and diverse representation.*	*MOH (Planning and Clinical) and civil society*					
Consider environmental and climate impacts of the health sector.								
10.1	***Facilitate conversation with a diverse group of stakeholders on the role of the health sector in preserving the environment****. Engagement can be done through either workshops or a technical working group, but it should bring together stakeholders from civil society, industry, government, and partner organizations who can share and implement environmentally sustainable interventions in health. Advocacy efforts should be pursued to disseminate information on the importance of environmentally sustainable health care.*	*Development of partnerships focused on sustainable health care; increased advocacy.*	*MOH (Planning, Clinical, and HTSS)*					
10.2	***Identify and implement environmentally conscious interventions that may have dual impact on the population's health****. Some interventions may include adding pollution control standards for local industry, developing parks, or planting trees. The rationale is that poor air quality and environmental degradation may lead to increased respiratory conditions and illness. Implementing regulations for pollution control by industry can encourage new market entrants or a shift in standard manufacturing practices over time, making sustainably produced products more widespread and cheaper.*	*Investment in public health projects; development of regulation focused on sustainability.*	*MOH (Planning, Clinical, and HTSS) and civil society*					
10.3	***Explore partnerships with industry and/or encourage local businesses that provide environmentally sustainable and climate-conscious health products****. Start-up awards/lottery could be set up by the MOH to encourage innovation among local businesses. Suppliers and/or facilities implementing sustainable practices could be rewarded through incentive programs.*	*Development of a market for sustainable health businesses.*	*MOH (Planning, Clinical, and HTSS)*					

Note: The filler color denotes the years in which implementation of the activities could likely take place.

Abbreviations: CEmONC, comprehensive emergency obstetric and newborn care; CMED, clinical medicine; DHIS2, District Health Information System 2; HMIS, Health Management Information System; HTSS, Health Technical Support Services; LMIS, Logistics Management Information System; MOH, Ministry of Health; PAM, Physical Assets Management (division of MOH); SEL, standard equipment list; SOP, standard operating procedure; UPS, uninterrupted power supply.

** Malawi's Occupational Safety, Health and Welfare Act outlines the legal requirements that apply to workplaces in general and specifically to gas plants (in section 48 and gas cylinders in section 49). The occupational health and safety plan should build on the Malawi Bureau of Standards (MBS) standards, the requirements of the act, and public works norms and standards.*

*** Oxygen, while not itself flammable, supports combustion, and high concentrations of oxygen can support vigorous combustion, including combustion of unusual materials not normally deemed to be a fire risk. Oxygen cylinders and storage tanks are also heavy and highly pressurized; damage to cylinders, tanks, and their valves can therefore lead to explosions. Unsecured cylinders can fall and hurt personnel or damage other equipment. The occupational health and safety plan would aim to prevent fires, accidents, and contamination of medical oxygen and to protect the staff who operate oxygen equipment and others who come close to the equipment in clinical areas.*

6.1.3 Human resources for health

Malawi's guiding policy document on human resources is the "**Malawi Human Resources for Health Strategic Plan, 2018-2022**". The policy aligns with the HSSP 2, and its goals of achieving universal health coverage. The goal of this roadmap is not to create redundant policy guiding investments in human resources for health (HRH), but to complement the existing policy by offering recommendations for building the capacity of health workers to support oxygen systems. The following section first describes the goals and contents of existing policy, then identifies interventions and recommendations that can be either leveraged (from the existing policy) or tailored to strengthen HRH for oxygen systems.

The Malawi Human Resources for Health Strategic Plan is a cross cutting policy, that describes interventions for systematically improving the number of skilled workers that are equitably distributed in country, as well as recommending interventions to improve recruitment, deployment, retention, and management of staff. These goals are obtained through four strategic objectives:

1. Strengthening data systems to inform policy and planning for HRH.
2. Strengthening governance, leadership, and management systems for HRH to improve recruitment, deployment, retention, and management of staff.
3. Increase Malawi's ability to produce skilled HRH by strengthening the programs and institutions that train HRH and improving monitoring and evaluation of training programs.
4. Promote collaboration between health sectors, government and other stakeholders in order to identify new funding streams and strengthen referral networks between public and private health.

All four of these strategic objectives should be considered when looking to increase human resources for oxygen. The following list of interventions and recommendations considers these strategic objectives, as well as current challenges and processes to increase HRH.

- Creating new data systems or integrating existing data systems with indicators specific to tracking oxygen needs, such as clinical provision of oxygen therapy, functional and nonfunctional oxygen equipment, and number of staff skilled in maintenance of oxygen equipment, will help identify the gaps in human resources that can support oxygen systems.
- Disseminating this roadmap amongst central level and district level leadership and individuals involved in the functional review process, may help them provide justification for requesting new staff positions that are dedicated to oxygen. For example, understanding the

complex maintenance requirements for PSA plants can help central and district level health facilities request biomedical engineers that are trained, and dedicated to operation and repair of PSA plants.

- Creating training programs specific to oxygen (either clinical provision, or management of oxygen resources and equipment) at Malawi's primary Health Training Institutions (HTIs) will increase the production of HRH skilled in oxygen systems. Establishing these as standard training programs will systematically increase the number of health staff that can fill vacancies across horizontal health programs (such as in emergency and critical care), which drives Malawi towards its goal of universal health coverage.
- There are several ways in which donors or private sector stakeholders could assist in rapid scale-up of human resources for oxygen:
  - Providing funding or technical assistance to district level and central level leaders to conduct functional reviews. This formal process for evaluating HRH needs and submitting requests for new positions and financing from central leadership, is constrained by funding. In the last year, functional reviews stalled out in various locations due to lack of financing and technical support, overall creating a roadblock to increasing HRH.
  - Directly employing or paying the salaries of HRH to fill a known vacancy. There is a shortage of skilled HRH in Malawi, and as a result, positions will be left unfilled even when they have already been created and are known to be essential for a facility's operation. Identifying vacancies in clinical staff to provide oxygen therapy, staff to manage oxygen resources, or biomedical engineers and technicians for management of oxygen equipment, is the first step, to be followed by mobilization of resources.
  - Providing financial or technical assistance to employ interns, thus rapidly scaling-up human resources for oxygen. This is a work around to the time consuming and rigorous functional review process; intern positions can be created without formal request to central leadership. As interns learn on the job and become skilled workers, they can have their positions made permanent through the functional review process. At this point, it may be easier for district and central level leadership to justify the criticality of a position that has already demonstrated impact, and therefore increase the likelihood to secure funding for those positions in the long-term.

All these proposed interventions and recommendations may require technical and financial resources for implementation, for which additional cost analysis should be performed. Additionally, existing government structures that manage HRH should engage with donors, the private sector, and other stakeholders to develop robust implementation plans for implementing any of the above interventions for increasing human resources for oxygen.

6.2 Costing

Implementing the interventions described in the framework above will require significant investment over the next several years, with equipment and supplies alone projected to cost approximately US$76,156,737. *Table 13* describes these estimated costs for equipment and supplies for the five-year implementation period. Additional detail on the assumptions and approach involved in costing equipment and supplies is available in Appendix A9.

Table 13. Annualized costs of implementation of the oxygen ecosystem roadmap.

Cost categories	Year 1 (USD)	Year 2 (USD)	Year 3 (USD)	Year 4 (USD)	Year 5 (USD)	Total 5-year cost (USD)	Total 5-year cost (Mk)*
PSA plants**	$2,472,798	$227,798	$747,798	$227,798	$747,798	$4,423,990	3,539,191,840
Oxygen concentrators***	$1,826,261	$152,666	$152,666	$152,666	$152,666	$2,436,926	1,949,540,880
Oxygen cylinders****	$12,501,870	$12,501,870	$12,501,870	$12,501,870	$12,501,870	$62,509,351	50,007,480,956
Ventilators	$2,148,563	$179,047	$179,047	$179,047	$179,047	$2,864,750	2,291,800,064
Suction devices	$800,707	$34,813	$34,813	$34,813	$34,813	$939,960	751,968,338
Pulse oximeters	$956,818	$145,824	$145,824	$145,824	$381,640	$1,775,930	1,420,743,920
Patient monitors	$770,617	$64,218	$64,218	$64,218	$64,218	$1,027,489	821,991,270
Resuscitation devices	$165,230	$3,278	$3,278	$3,278	$3,278	$178,340	142,672,370
Grand total	$21,642,864	$13,309,514	$13,829,514	$13,309,514	$14,065,330	$76,156,737	60,925,389,639

** Conversion of US dollar (USD) to Malawi Kwacha (MK) was done on July 14, 2021. Conversion rate: 1 USD = MK 800.*
***See Appendix A9 for pressure swing adsorption (PSA) plant costing scenarios. Scenario 1 is displayed here.*
**** Total costs for oxygen concentrators include flow splitter, voltage stabilizer, surge suppressor, and oxygen analyzer, as well as maintenance and spare parts costs which includes replacement filters.*
***** Includes both size "J" cylinders (6,800 L) and size "F" cylinders (1360L). Includes cost of cylinder, distribution, and refill (does not include cylinder accessories). See Appendix A9 for more details.*

It is important to recognize that total cost of equipment and supplies will vary depending on the oxygen-supply source mix or infrastructure investments chosen for health facilities. For instance, the cost of oxygen cylinders in *Table 13* represents an upper bound because it estimates the potential cost to Malawi's health system if the entire annual oxygen demand was filled by size J oxygen cylinders sourced from a Malawi-based supplier.[xix] Additional costs for cylinders comes from equipping ambulances and district and central hospitals with size F (1360L) cylinders for patient transport. The costing for cylinders also assumes that cylinders are leased and refilled by a supplier. Oxygen cylinder costs could be reduced if more cost-effective investments are made in infrastructure or alternative oxygen-supply sources.

Additionally, the costing in this roadmap does not consider the costs to supply liquid oxygen. This strategic decision was made for several reasons. First, the health facilities that are most eligible for installation of an on-site LOX tank (have existing infrastructure such as oxygen piping systems)

[xix] This excludes the oxygen demand from facilities with PSA plants that are assumed to cover their own oxygen needs.

already have sunk costs in installed PSA plants. Additional analysis must be done to evaluate the cost tradeoffs between transitioning between primary oxygen sources or installing dual bulk supply sources at a facility (a PSA plant and a LOX tank on-site). Second, there is no Malawi-based supplier of LOX. Additional market analysis must be done to evaluate tradeoffs between sourcing LOX from other countries and cultivating a local supply market, either through facilitating supply deals or new market entrants. Third, effective use of LOX requires large capital investments in facility infrastructure and supply systems. There are likely scenarios where use of LOX would be cost-effective for Malawi, however additional analysis is needed to identify where supply should be based and how to properly size a distribution system to match supply and demand. PATH is interested and well positioned to support the Malawi Ministry of Health in conducting this analysis and identifying scenarios where investments in LOX can be made.

Human resources, such as biomedical engineers and technicians, are a critical component of oxygen systems but are not included in this costing. This is because the process for identifying HRH needs requires a rigorous functional review, that is conducted across central and district level hospitals. Through this functional review process, district and central hospitals identify the number of health staff they require, and then submit these requests to the central level for evaluation. If there is sufficient justification to create new positions, the central level can mobilize funds from the treasury to pay the salaries of these new HRH. This decentralized process of evaluating HRH requirements makes it unrealistic for this roadmap to recommend a national level cost for increasing staff. However, the previous section in this chapter on "Human resources for health" (section 6.1.3) describes a set of interventions, and areas where funding could be committed to scale-up human resources for oxygen.

Lastly, there are many activities in the Chapter 6 implementation framework (*Table 12*) for which costs are not listed due to the complexity of costing capacity-building-type activities and developing standards, policies, and guidelines. It is the responsibility of the MOH to lead the costing of these activities in future workshops, organized in collaboration with activity leads listed in the implementation framework.

Chapter 7: Supervision and M&E

Robust supervision and M&E are critical to the success of oxygen system improvements. At the facility level, it is necessary to integrate clinical supervision and mentorship, as well as assess adherence to guidelines and job aides. Monitoring availability of oxygen-production and oxygen-delivery equipment such as pulse oximeters, oxygen accessories, oxygen concentrators, and PSA plants is critical across all health facility levels and should be implemented. Additionally, biomedical engineering supervision involving the care of equipment, inspection of state of equipment, and supply status tracking should be implemented in parallel. Such data can be consolidated and reviewed by the highest levels of the MOH. This is key to interpreting the success of and monitoring the gaps in the health system, identifying whether oxygen provision meets Malawi's needs, and informing policy to support oxygen systems when and where standards are not met.

The goal of the following chapter is not to provide a comprehensive M&E framework. This roadmap is primarily meant to provide a high-level overview of how stakeholders and donors can organize to address key challenges in supplying reliable and safe medical oxygen. When adoption of this roadmap is finalized, it will be critical to create a robust and detailed M&E plan for implementation of the 5-year implementation framework. This robust M&E plan will describe interventions to be performed each year, as well as provide guidance and methods to track mobilized resources for investments in oxygen, as well as the impact of these interventions. Tracking of contributions may be facilitated by donors and the Malawi Oxygen Task Force.

CHAPTER 7 KEY TAKEAWAYS AND POLICY RECOMMENDATIONS:

- Successful implementation of the oxygen roadmap requires robust M&E at national and subnational levels, all the way down to the facility level. Information should flow seamlessly between levels, through well-developed reporting processes, to rapidly collate data, evaluate progress and challenges, and course-correct if indicator targets are not being met.
- Supervision tools and mentorship programs should be available at all levels of the health system to strengthen monitoring ability and build skill among clinical and biomedical staff.
- The indicator framework lists indicators for tracking oxygen and respiratory care system development and progress towards improved health outcomes:
  - Many indicators may not have an established baseline, which happens when data collection in that area has not been routinely conducted. Plans should be made to establish baselines where they do not exist.
  - Indicator targets guide M&E of the impact of the roadmap over the course of its intended implementation period (2021–2026). Different divisions of the MOH are responsible for setting targets and communicating them to subnational levels.

7.1 Supervision

7.1.1 Key personnel

Biomedical engineers, nurses, and clinicians are the key personnel to monitor the use of oxygen-supply systems. Biomedical engineers should monitor the functionality of the machines, collect data on equipment performance (such as uptime), conduct preventive maintenance, and ensure the devices are used correctly. Regular preventive maintenance of the oxygen equipment by biomedical technicians within the facility should be done every week. Nurses and clinicians should monitor preventive maintenance since some maintenance tasks are recommended to be done daily to ensure correct operation of devices by clinical staff. Health facilities should prepare monthly reports on availability and uptime of the equipment and share them with referral maintenance units (RMUs), who will then share the reports with the HTSS Directorate.

At the national level, the HTSS Directorate is an overall structure that looks at the availability, functionality, purity, and safety of oxygen-supply systems. The HTSS Directorate will conduct quarterly supervision of RMUs, as well as ad hoc supervision when need arises. At the zonal level, there are RMUs that conduct supervision, on-the-job training, equipment user training, and corrective maintenance. They use a biomedical checklist to assess the competence of the technician and users, as well as availability and functionality of the equipment.

7.1.2 Supervision tools for oxygen systems

Tools available for supervising oxygen systems and progress against the roadmap strategic framework for implementation include the following:

- Direct supervision.
- A ward assessment tool.
- Case management assessment tools.
- Biomedical tools to integrate oxygen systems.

Currently, no supervision tools are available for specific disciplines of care (e.g., neonatal versus intensive care). Such tools should be developed.

At the zonal level, biomedical engineers conduct on-the-job training and mentorship to district biomedical engineers. At the district level, the trained biomedical engineers mentor health workers on the proper use and maintenance of oxygen systems. Biomedical engineers from the RMUs might also mentor the health workers directly, depending on the type of equipment used in the oxygen system. Consideration should be given to implementing similar mentorship and supervision programs at lower levels of care.

7.2 Reporting

Work Improvement Teams and Quality Improvement Support Teams (QIST) should conduct facility review meetings monthly to review progress reports submitted by the health facility. At the national level, quarterly review meetings should be conducted to review data and monitoring reports from the districts and health zones. These review meetings will allow for periodic course correction and tracking of progress against the roadmap strategic framework for implementation. Quarterly review meetings should also be conducted at the district level to review data and reports from all facilities.

7.3 M&E

7.3.1 Potential indicator tables

Tables 14–18 list potential indicators for monitoring oxygen systems and health outcome improvements at national and subnational levels. For many oxygen- and COVID-19-related indicators, there may not be existing data at the national level to establish the current baseline. These indicators have grayed-out boxes in the tables below. It will be a critical and immediate implementation activity to conduct baseline assessments for indicators with unknown baselines.

Health outcome targets may exist already at the program level or have been set in other policy documents, such as Malawi *Health Sector Strategic Plan II 2017–2022* and *National Health Indicators Handbook for Monitoring Health Sector Performance*. For this roadmap, stakeholders may adhere to existing indicator targets or create new targets, which may be informed by a variety of sources, including the Sustainable Development Goals or the WHO Global Reference List of 100 Core Health Indicators.[38] Indicator targets for equipment and supplies are the responsibility of the PAM division of the MOH.

Table 14. Indicators for financing.

No.	Indicator	Baseline (most recent data year)*	Midterm target	Target 2026	Tracking method or product
1.	**Total mobilized funds for oxygen and respiratory care**				
2.	**Budget allocation by health facility level**				
3.	**Budget allocation by district level**				

** Grayed-out boxes = lack of existing data at the national level to establish the current baseline.*

Table 15. Indicators for oxygen equipment and supplies.

No.	Indicator	Baseline (most recent data year)*	Midterm target	Target 2026	Tracking method or product
1.	**Total # of government-owned oxygen plants established**	5 (2021)			
2.	**Uptime of installed plants**				
3.	**Total production capacity of installed plants**	GOM plants: 2,952,840 L/day			
4.	**Total cylinders filled at on-site PSA plants**	209 L/day			
5.	**Cost of oxygen per liter for PSA plant–produced oxygen**				
6.	**Quantity of cylinders distributed from on-site PSA plants to nearby regions**				
7.	**Total annual cylinders received from gas supplier, per facility**				
8.	**# of functional oxygen concentrators**				
9.	**# of nonfunctional oxygen concentrators**				
10.	**# of functional ventilators**				
11.	**# of nonfunctional ventilators**				
12.	**# of functional suction devices**				
13.	**# of nonfunctional suction devices**				
14.	**# of functional pulse oximeters**				
15.	**# of nonfunctional pulse oximeters**				

** Grayed-out boxes = lack of existing data at the national level to establish the current baseline.*
Abbreviations: GOM, Government of Malawi; PSA, *pressure swing adsorption.*

Table 16. Indicators for support systems.

No.	Indicator	Baseline (most recent data year)*	Midterm target	Target 2026	Tracking method or product
1.	**# of health care workers trained on administration of oxygen therapy**				
2.	**Total # of biomedical technicians employed to service public health facilities**	67			
3.	**# of facilities with on-site biomedical engineers**	4 central hospitals, 23			

No.	Indicator	Baseline (most recent data year)*	Midterm target	Target 2026	Tracking method or product
		district hospitals			
4.	# of facilities with inventory management systems	0			
5.	# of facilities with equipment management systems	0			
6.	# of spare parts orders fulfilled				
7.	Reporting rates by facility for DHIS2				DHIS2
8.	Availability of guidelines and job aids				
9.	# of new standards created for oxygen quality, distribution, and production				
10.	Total # of ambulances with available oxygen and pulse oximetry				

** Grayed-out boxes = lack of existing data at the national level to establish the current baseline.*
Abbreviation: DHIS2, District Health Information System 2.

Table 17. Indicators for health outcomes, adults.

No.	Indicator	Baseline (most recent data year)*	Midterm target	Target 2026	Tracking method or product
1.	COVID-19 mortality rate				DHIS2
2.	Pneumonia mortality rate				DHIS2
3.	Institutional MMR	653.8/100,000 live births (2021)			DHIS2
4.	Oxygen therapy use in malaria case management rate				DHIS2
5.	Inpatient oxygen therapy rate				DHIS2
6.	Surgical care oxygen therapy rate				DHIS2
7.	Maternal care oxygen therapy rate				DHIS2
8.	Prehospital and acute care oxygen therapy rate				DHIS2

Data sources: (1) UNICEF website. Datasets page. https://data.unicef.org/resources/resource-type/datasets/. Accessed May 12, 2021. (2) DHIS2 Malawi https://dhis2.health.gov.mw/dhis-web-commons/security/login.action.
** Grayed-out boxes = lack of existing data at the national level to establish the current baseline.*
Abbreviations: DHIS2, District Health Information System 2; MMR, maternal mortality ratio.

Table 18. Indicators for health outcomes, children.

No.	Indicator	Baseline (most recent data year)*	Midterm target	Target 2026	Tracking method or product
1.	CEmONC mortality rate				DHIS2
2.	Number of patients treated with oxygen per facility (disaggregated), annually				DHIS2
3.	U5 mortality rate	42/1000 (2019)			DHIS2
4.	Infant mortality rate	31/1000 (2019)			DHIS2
5.	Institutional neonatal mortality rate	10.8 (2021)			DHIS2
6.	Care seeking for ARI: percentage of U5 with ARI for whom advice or treatment was sought from a health facility or provider.	77% (2016)			DHIS2
7.	Pneumonia mortality				
8.	Child oxygen therapy rate				DHIS2
9.	Child hyperoxia incidence[xx]				

[xx] The indicator "oxygen reserve index" (ORi™), developed by Massimo, is one method that can be used to detect hyperoxia at early stages and morbidity. https://link.springer.com/article/10.1007/s00540-021-02938-4

Data sources: (1) UNICEF website. Datasets page. https://data.unicef.org/resources/resource-type/datasets/. Accessed May 12, 2021. (2) DHIS2 Malawi https://dhis2.health.gov.mw/dhis-web-commons/security/login.action.
** Grayed-out boxes = lack of existing data at the national level to establish the current baseline.*
Abbreviations: ARI, acute respiratory infection; CEmONC, comprehensive emergency obstetric and newborn care; DHIS2, District Health Information System 2; U5, children under 5 years old.

7.3.2 Use of indicators for emergency planning and long-term health systems needs

Indicators related to oxygen and COVID-19 can support both emergency response planning and long-term strengthening of oxygen systems in Malawi.

For emergency response, a list of three to five indicators related to oxygen need and availability can support emergency teams with quick decision-making. An oxygen dashboard created by UNICEF[39] gives an example of how such indicators can be represented visually. For long-term monitoring of health system capacity and oxygen needs, it is important to consider both demand- and supply-side indicators. Demand-side indicators could track initial use, continuous use, and population coverage, and supply-side indicators could track commodities, human resources, or geographic access. *Text Box 4* provides additional recommendations for supervision and M&E.

Text Box 4. Tips for supervision and M&E.

- M&E may be scheduled for different periods, depending on the type of evaluation needed. For example, recording patient health indicators in DHIS2 is a daily activity, while assessment and reporting of PSA plant production capacity may be less frequent; reporting for PSA plants could align with a monthly schedule for biomedical engineer servicing conducted by the government.
- There are multiple ways to structure monitoring. For instance, ongoing supervision may be most effective to maintain good clinical practices. Comprehensive supervision may be conducted on an annual or biannual basis to provide more detailed information about the status of oxygen systems. A rapid assessment may be done to quickly compile data and make quick decisions. All these approaches may have trade-offs in time requirements, complexity to structure and conduct, thoroughness of the assessment, cost, and human resources required.[40]
- Keeping abreast of international and global standards can help benchmark Malawi's progress towards oxygen system improvements.
- Thorough M&E of oxygen system scale-up, Malawi has the potential to set a global example, especially if the collected data are used to expand its involvement in global oxygen and pneumonia initiatives. Involvement in such interventions has added benefits, including collaboration with new partners, exposure to state-of-the-art science, fundraising, and global opportunities.

Conclusion

Malawi faces major challenges to providing safe and reliable oxygen access. Health facilities in Malawi have insufficient respiratory equipment and supplies, which limits oxygen delivery to patients; insufficient installed bulk oxygen-production capacity; and limited ability to capture, store, or reallocate oxygen, which creates an overall supply shortage. Equipment often becomes prematurely nonfunctional due to lack of biomedical engineering capacity and supporting systems for preventive and corrective maintenance. Clinical and biomedical staff also face challenges in using and managing equipment, as well as in properly treating patients in need of oxygen therapy, due to a lack of available or implemented standards and guidelines around safe oxygen use. The national oxygen need estimation in this roadmap did not account for the additional burden of COVID-19, expansion of the number of health facilities or beds in Malawi's health system, or generally, the prospective need that is ensured with a growing population. Malawi must invest in increased oxygen-production capacity to keep up with this demand. The several planned PSA plant installations may reduce the oxygen gap; however, oxygen access will remain a key challenge in the Northern Region and rural areas without implementation of an oxygen-distribution system.

Over the course of the past year, COVID-19 has placed additional strain on Malawi's oxygen systems. Although support has been given by the global community, and stakeholders in-country have worked tirelessly to prioritize respiratory care, it will be critical to maintain and grow investments in oxygen in the coming years. In a relatively short period of time, equipment procured as part of COVID-19 emergency response efforts will become nonfunctional if not maintained. Newly installed PSA plants could be underutilized if clinical and biomedical staff are not expanded and supported with training. And lastly, COVID-19 has spurred increased global attention on oxygen, but opportunities for grants and other financing for oxygen may be harder to come by as global attentions shift.

To bring this roadmap to life, government decision-makers need to become champions of this document, assuring it is read widely and discussed by diverse stakeholders who have financing and policymaking capabilities. Malawi must explore and invest in infrastructure, partnerships with the private sector, and supply chain and logistical solutions to scale up oxygen access cost-effectively. Leaders must be established at national and subnational levels who can direct teams to complete implementation activities listed in the Chapter 6 framework, confirm progress, and help navigate challenges. Workshops must be organized to establish baselines and targets for the indicators listed in Chapter 7; otherwise, implementers will have no reference points by which to measure progress and evaluate impact. And lastly, supervision and monitoring roles and tools must be established to facilitate project management.

Appendices

A1: Primary contributors to the Malawi Oxygen Ecosystem Roadmap

- **Hannah Erdy,** PATH Market Dynamics Associate; first author, review facilitator, and document consolidator
- **Mayeso Mphande,** PATH Market Dynamics Officer; contributor, part author
- **Raphael Kazidule Kayambankadzanja**, PATH Market Dynamics Consultant; former intensive care unit nurse, Queen Elizabeth Central Hospital, Blantyre
- **Paul Makaula,** PATH Market Dynamics Consultant; contributor
- **Petros Chirambo,** former PATH Market Dynamics Officer; contributor
- **Zach Clemence,** PATH Market Dynamics Senior Officer; contributor
- **Ravi Doshi,** PATH Market Dynamics Associate; contributor
- **Conner House,** PATH Market Dynamics Project Manager; reviewer
- **Carrie Hemminger,** PATH Market Dynamics Senior Communications Officer; reviewer
- **Beverly Bradley,** Technical Specialist, UNICEF Supply Division; contributor
- **Mansi Dalal,** Technical Consultant, UNICEF Supply Division; contributor
- **Anne Detjen,** Child Health Specialist, UNICEF HQ; contributor
- **Bejoy Nambiar,** Health Systems Strengthening Specialist, UNICEF Malawi Country Office; contributor
- **James Wariero,** Health Systems Consultant, UNICEF Malawi Country Office; contributor
- **Mr Norman Lufesi,** Acting Chief of Emergency Medical Services Officer, Hospital Emergency and Critical Care Services, Ministry of Health
- **Pakwanja Desiree Twea,** Principal Economist, Ministry of Health; reviewer
- **Trish Araru,** Health Cluster Coordinator, Ministry of Health; reviewer
- **Rumbani Sidira,** Chief Biomedical Engineer, Health Technical Support Services, Physical Assets Management Division, Ministry of Health; contributor
- **Harold Chimphepo,** Deputy Director, Health Technical Support Services, Ministry of Health; contributor
- **Godfrey Kadewere,** Director of Health Technical Support Services, Ministry of Health; contributor
- **Dr. Tim Baker,** Consultant in Anaesthesia & Intensive Care; contributor
- **Dr. Bernard Olayo,** Center for Public Health and Development, Nairobi, Kenya; contributor
- **Karthik Subbaraman,** Program Director, Centre for Public Health & Development; contributor
- **Venancio Bonongwe,** Acting Head of Department (Referral Maintenance Unit, Central), Kamuzu Central Hospital; contributor
- **Charlo Kapalamula,** Senior Biomedical Engineer, Kamuzu Central Hospital; contributor
- **Dr. Emilia Connolly,** Partners In Health, Chief Health Systems Policy Advisor, Malawi; contributor

- **Dr. Paul Sonenthal,** Associate Physician**,** Division of Pulmonary and Critical Care Medicine, Brigham and Women's Hospital, and Partners In Health Clinical Consultant; contributor
- **Andy Gouws,** Business Development Manager, Emerging Africa, Afrox Linde Group; contributor
- **Marnie Rickards,** DAK Foundation; contributor

Malawi roadmap workshop participants

The following is a full list of participants who attended the Malawi roadmap workshop in April 2021. The workshop was facilitated by Mayeso Mphande, PATH, and Norman Lufesi, Ministry of Health (MOH). These participants are here acknowledged for their review of and contributions to the roadmap at a critical stage of development:

- Alfred Chanra, MSH-LL
- Joster Banda, Principal Clinical Officer at Mzuzu Central Hospital
- Peter Chaziya, Surgeon at Mzuzu Central Hospital
- Gloria Mpachika, Anesthetic Clinical Officer at Zomba Central Hospital
- Samuel Mtegha, Anesthetic Clinical Officer at Kamuzu Central Hospital
- Rachel Fletcher, Emergency Health Unit Field Hospital Operations Lead, Save the Children
- Rumbani Sidira, Chief Biomedical Engineer, Physical Assets Management, MOH
- Yusuf Mtende, Principle Medical Officer at Kamuzu Central Hospital
- Maloni Nyirenda, Principal Nursing Officer at RCH
- Harold Chimphepo, Deputy Director, Physical Assets Management, MOH
- Owen Malema, Anesthesiologist, Queen Elizabeth Central Hospital
- Lydia Magombo, Children's Nurse at Queen Elizabeth Central Hospital
- Dyson Telela, HIV Treatment and Prevention Programs Manager at Clinton Health Access Initiative
- Clement Banda, Associate Director, Infectious Diseases at Clinton Health Access Initiative
- Godwin Nyirenda, STA 2
- Godfrey Kadewere, Director, Department of Health Technical Services
- Yakobe Machira, Senior Medical Officer, Ntchisi District Hospital

A2: Indications for supplemental oxygen provision

Text Box 5 summarizes common indications for use of supplemental oxygen.

Text Box 5. Summary of common medical indications for supplemental oxygen therapy.

Emergency and critical care
Acute hypoxemia of undiagnosed cause
Cardiac arrest or resuscitation
Shock, sepsis, major trauma, drowning, anaphylaxis, major pulmonary hemorrhage, status epilepticus
Major head injury
Stroke
Myocardial infarction, acute coronary syndromes

Noncommunicable respiratory diseases
Acute asthma
Lung cancer
Acute exacerbations of interstitial lung disease
Chronic obstructive pulmonary disease, bronchiectasis, cystic fibrosis

Lower respiratory tract infections and severe systemic infections
Pneumonia
Tuberculosis
Malaria, sepsis, meningitis

Conditions of cardiopulmonary compromise
Pulmonary embolism
Acute heart failure
Severe anemia
Pneumothorax
Pleural effusion
Neuromuscular disease
Morbid obesity

Poisoning and metabolic disorders
Carbon monoxide poisoning*
Poisoning and drug overdose
Metabolic and renal disorders

Source: O'Driscoll BR, Howard LS, Earis J, Mak V. British Thoracic Society Guideline for oxygen use in adults in healthcare and emergency settings. BMJ Open Respiratory Research. 2017;4(1):e000170. https://doi.org/10.1136/bmjresp-2016-000170.
** Hypoxemia may not be seen by pulse oximetry in carbon monoxide poisoning due the similar optical absorbance of carboxyhemoglobin and oxyhemoglobin.*

A3: Essential Health Package (EHP) interventions

Tables 19 and *20* list EHP interventions for child and maternal/newborn health, respectively.

Table 19. EHP interventions requiring oximetry and supplemental oxygen in child health.

EHP category	EHP intervention package	Intervention	Level of care
Integrated Management of Childhood Illnesses (IMCI)	IMCI package	Pneumonia treatment (children)	Primary/Secondary
		Treatment of severe pneumonia (oxygen)*	Primary/Secondary
		Oral rehydration solution	Primary/Secondary
		Zinc	Primary/Secondary
		Treatment of severe diarrhea (intravenous fluids)*	Primary/Secondary
		Community management of nutrition in U5 (PlumpyNut, micronutrient powder, vitamin A)	Primary
		Rapid diagnostic tests for U5	Primary
Nutrition	Nutrition package	Vitamin A supplementation in pregnant women	Primary/Secondary
		Management of severe malnutrition (children)*	Primary/Secondary
		Deworming	Primary/Secondary
		Vitamin A supplementation in infants and children 6–59 months old	Primary/Secondary
Malaria	Complicated malaria treatment	Complicated malaria (adults, injectable artesunate)	Primary/Secondary
		Complicated malaria (children, injectable artesunate)*	Primary/Secondary
Tuberculosis (TB)	TB package	Isoniazid preventive therapy for children in contact with TB patients	Primary/Secondary
		First-line treatment of new TB cases for children*	Secondary
		First-line treatment for re-treatment of TB cases for children*	Primary/Secondary
		Case management of multidrug-resistant TB cases*	Primary/Secondary

*Note: **Bold** = delivery package of interventions in which oximetry is essential and supplemental oxygen may be indicated.*
** Oxygen availability is essential where medically indicated; pulse oximetry is essential.*
Abbreviations: EHP, Essential Health Package; U5, children under 5 years old.

Table 20. EHP interventions requiring oximetry and supplemental oxygen in maternal and newborn health.

EHP category	EHP intervention package	Intervention	Level of care
Reproductive, maternal, newborn, and child health	Delivery package	Clean delivery and immediate essential newborn care (in facility)	Primary/Secondary
		Active management of the third stage of labor*	Primary/Secondary
		Management of eclampsia and preeclampsia**	Primary/Secondary
		Neonatal resuscitation (institutional)*	Primary/Secondary
		Caesarian section with indication***	Secondary
		Caesarian section with indication (with complication)***	Secondary
		Vaginal delivery, skilled attendance*	Primary/Secondary
		Newborn sepsis, full supportive care*	Primary/Secondary
		Antenatal corticosteroids for pre-term labor	Primary/Secondary
		Maternal sepsis management*	Primary/Secondary
		Cord care using chlorhexidine	Primary/Secondary
		Hysterectomy***	Secondary
		Treatment of antepartum hemorrhage*	Primary/Secondary
		Treatment of postpartum hemorrhage*	Secondary
		Antibiotics for premature rapture of membranes	Primary/Secondary

*Note: **Bold** = delivery package interventions in which oximetry is essential and supplemental oxygen may be indicated.*
** Oxygen availability is essential where medically indicated; pulse oximetry is essential.*
*** Supplemental oxygen should be administered for relief of tissue hypoxia, even in normoxemia.*
**** Oxygen to be used during surgery and recovery with anesthesia and for prevention of early postoperative hypoxemia.*
Abbreviation: EHP, Essential Health Package.

A4: Additional Biomedical Equipment Survey data for oxygen concentrators

Table 21 lists the number of functional and nonfunctional concentrators, by district.

Table 21. Oxygen concentrator availability and functionality by district.

District	# of functional concentrators	# of nonfunctional concentrators
Lilongwe	168	87
Blantyre	81	28
Mzuzu	55	22
Karonga	31	11
Mangochi	30	11
Mchinji	29	11
Thyolo	29	15
Nsanje	28	10
Zomba	27	10
Salima	26	10
Rumphi	24	4
Ntcheu	23	4
Ntchisi	22	0
Dowa	21	2
Chiradzulu	19	8
Nkhotakota	19	4
Mzimba	17	16
Dedza	15	9
Chikwawa	14	10
Mulanje	12	7
Mwanza	12	2
Kasungu	11	1
Neno	10	3
Phalombe	9	1
Machinga	8	3
Chitipa	7	8
Nkhata Bay	7	11
Likoma	6	1
Balaka	3	1
National	**809**	**310**

A5: COVID-19 needs estimations

Overview

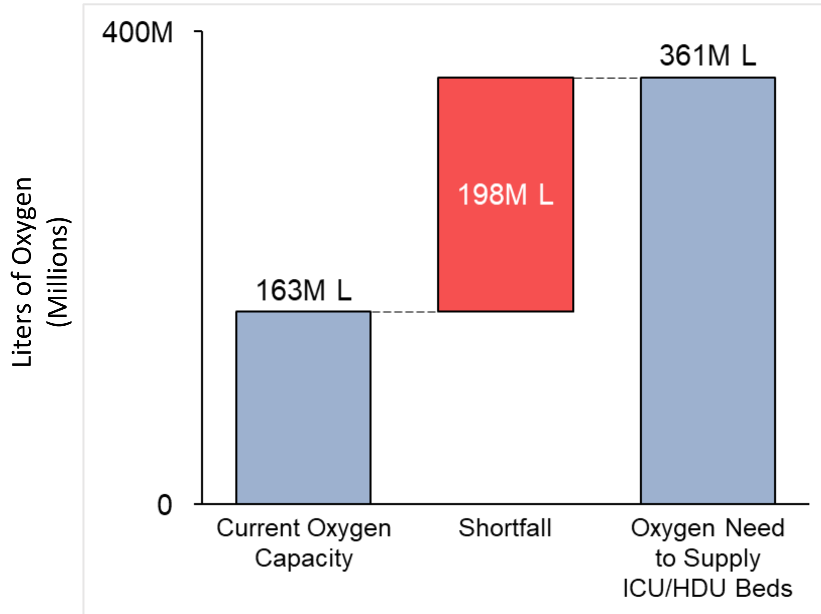
The 2020 Biomedical Equipment Survey and Facility Assessment Report estimate oxygen need due to a COVID-19 surge, which is a heavy-demand scenario over a short period of time (six months). The gap assessment created from this scenario recommends the quantity of respiratory care equipment that facilities must procure to meet the oxygen need at peak demand. This modeling and gap estimate is provided in detail here for policymakers and relevant oxygen-focused stakeholders. It is important to note that this modeling and gap estimate is included as supplementary material, because it does not estimate national oxygen required to treat hypoxemia across diseases and conditions on a typical basis. Furthermore, oxygen systems in Malawi need comprehensive improvements, including and extending beyond procurement of respiratory care equipment. Therefore, the estimations included in the Malawi Oxygen Ecosystem Roadmap are highlighted because they estimate the oxygen need required to treat patients regardless of underlying cause of disease and recommend oxygen interventions that contribute to health system strengthening.

The COVID-19 model estimates the gap between existing oxygen-delivery capacity in Malawi and the required oxygen-delivery capacity needed to respond to a six-month COVID-19 outbreak peaking at 200 new cases a day nationwide. Two scenarios are proposed: the "base case" estimates oxygen need with the current bed capacity observed at health facilities, and the "future emergency preparedness" scenario estimates oxygen need with scaled-up bed capacity in the same facilities.

Base case results

Given a six-month COVID-19 outbreak scenario peaking at 200 new cases a day, an oxygen need of approximately **361 million liters** is estimated to adequately supply intensive care unit (ICU) and high-dependency unit (HDU) beds at the five central hospitals (*Figure 14*).

Figure 14. Oxygen shortfall in "base case" scenario with 200 new COVID cases/day over a 6-month period.



Abbreviations: HDU, high-dependency unit; ICU, intensive care unit.

National oxygen needs in a scenario of 200 new COVID-19 cases a day were estimated using a model which presumed that 20% of active COVID-19 cases at any given point would require hospitalization with some degree of oxygen therapy. Three-quarters (75%) of these hospitalized cases were presumed to be in the "severe" category, requiring 10 liters per minute (LPM) of oxygen for one week. The remaining 25% were presumed to be in the "critical" category, requiring 30 LPM of oxygen for two weeks.[xxi]

Predictions about the number of COVID-19 cases in Malawi over the six-month period were created using the WHO Essential Supplies Forecasting Tool, v. 2. A Susceptible-Infectious-Removed case forecast was specified, which was further informed by epidemiological inputs observed in Malawi, such as case-doubling rate, average number of contacts,[xxii] clinical attack rate, and reproduction number. Data on COVID-19 case progression were taken from the Malawi Ministry of Health (MOH) COVID-19 National Information Dashboard.[41]

Through the 2020 Biomedical Equipment Survey, health facilities of all levels in each of the 28 districts were surveyed by PATH to quantify ICU and HDU bed capacity, current oxygen-production capacity, and availability of essential respiratory care equipment for treating COVID-19 patients. The survey did not collect information on every piece of equipment in the essential equipment list, so where data were unavailable, the model assumed zero pieces of that equipment type. It was also assumed that 40% of total beds (HDU + ICU) would be reserved for non-COVID-19 patients.

Shortfalls in respiratory care equipment to service ICU and HDU beds at the five central hospitals were also modeled. *Tables 22* and *23* outline the current respiratory care equipment availability, both nationwide and in the five central hospitals, and estimate the shortfall in equipment to adequately service ICU and HDU beds at the five central hospitals. *Table 22* shows durable equipment (reusable for care of multiple patients), and *Table 23* shows consumable equipment (usable for treatment of only a single patient).

Table 22. Durable equipment supply gaps nationwide and for central hospitals ("base case" scenario).

Equipment	Nationwide	Central hospitals only		
	Current equipment availability	Current equipment availability	Equipment needed to fully supply beds	Estimated equipment shortfall
Infrared thermometer	0	0	6	6
Pulse oximeter (adult + pediatric probes)	254	36	113	77
Patient monitor, multiparametric with electrocardiogram (ECG), with accessories	269	146	25	0
Patient monitor, multiparametric without ECG, with accessories	78	21	22	1
Oxygen source (i.e., concentrator, cylinder, or pipe supply)	174	53	113	60
Laryngoscope (direct or video type)	377	64	17	0
Patient ventilator, intensive care, with breathing circuits and patient interface	48	39	17	0
Continuous positive airway pressure (CPAP) device, with tubing and patient interfaces, with accessories	141	51	4	0

[xxi] Flowrates were taken from the WHO Essential Supplies Forecasting Tool, v. 2. 2020.

[xxii] Average number of contacts was based on country-specific percentage changes in mobility from the Institute for Health Metrics and Evaluation, which were collected from mobile phone data.

High-flow nasal cannula, with tubing and patient interfaces	2	0	4	4
Electronic drop counter, intravenous fluids	0	0	88	88
Infusion pump	0	0	22	22
Blood gas analyzer, portable with cartridges and control solutions	0	0	3	3
Ultrasound, portable, with transducers and trolley	0	0	3	3
Drill, for vascular access, with accessories and transport bag	0	0	3	3
Electrocardiograph, portable with accessories	0	0	3	3
Suction pump	645	110	47	0
Bubble humidifier, non-heated	0	0	97	97
Tubing, medical gases, int. diam. 5 mm	0	0	3	3
Flow splitter, 5 flow meters 0–2 liters per minute (LPM), for pediatric use	219	27	3	0
Flow meter, Thorpe tube, for pipe oxygen 0–15 LPM	312	172	8	0
Conductive gel, container	0	0	208	208
Catheter, nasal, 40 cm, with lateral eyes, sterile, single use; different sizes: 10 Fr, 12 Fr, 14 Fr, 16 Fr, 18 Fr	26	10	839	829
Compressible self-refilling ventilation bag, capacity > 1,500 mL, with masks (small, medium, large)	1,749	509	8	0

Table 23. Consumable equipment supply gaps nationwide and for central hospitals ("base case" scenario).

Equipment	Nationwide	Central hospitals only		
	Current equipment availability	Current equipment availability	Equipment needed to fully supply beds	Estimated equipment shortfall
Nasal oxygen cannula, with prongs, adult and pediatric	6,615	3,716	8,420	4,704
Mask, oxygen, with connection tube, reservoir bag and valve, high-concentration single use (adult)	2,047	714	8,420	7,706
Venturi mask, with percent O_2 lock and tubing (adult)	485	215	8,420	8,205
Airway, nasopharyngeal, sterile, single use, size 20 Fr, 22 Fr, 24 Fr, 26 Fr, 28 Fr, 30 Fr, 32 Fr, 34 Fr, 36 Fr	795	46	5,537	5,491
Airway, oropharyngeal, Guedel, set, in sizes No. 2 (70 mm), No. 3 (80 mm), No. 4 (90 mm), No. 5 (100 mm)	1,263	588	5,537	4,949
Colorimetric end tidal CO_2 detector single use (adult)	360	206	5,537	5,331
Cricothyrotomy, set, emergency, 6 mm, sterile, single use	0	0	2,768	2,768
Endotracheal tube introducer	619	375	5,537	5,162
Tube, endotracheal	0	0	5,537	5,537
Laryngeal mask airway	496	72	5,537	5,465
Lubricating jelly, for critical patient gastro-enteral feeding, airway management, and intubation	0	0	208	208
Heat, moisture exchanger, and filter; high efficiency, with connectors, for adult	0	0	8,222	8,222

Future emergency preparedness results

PATH was advised that the Malawi MOH is considering a plan to increase ICU bed counts at each central hospital to 25 beds and add 12 HDU beds to every district hospital. To support this effort, PATH modeled equipment and oxygen needs to adequately service the increase in beds anticipated by the MOH plan. Similar to the "base case" analysis shown above, a six-month outbreak scenario with a peak of 200 new COVID cases a day was used. All other assumptions and methods, with the exception of available HDU and ICU beds, were maintained from the base case. *Table 24* outlines the anticipated HDU and ICU bed counts by facility per the MOH's Emergency and Critical Care Strategy.

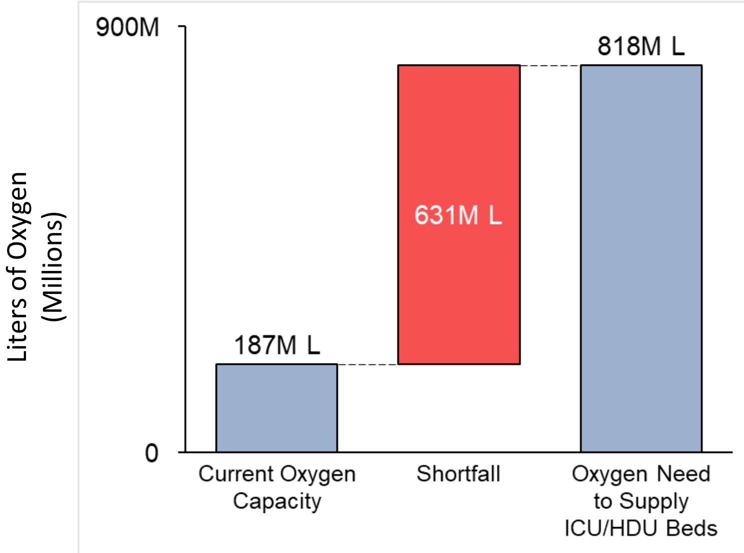
Table 24. Projected Ministry of Health plan for intensive care unit (ICU) and high-dependency unit (HDU) beds, by facility.

Type	Health facility	ICU beds	HDU beds
Central hospitals	Queen Elizabeth Central Hospital	25	39*
	Mercy James	4*	4*
	Mzuzu Central Hospital	25	20*
	Kamuzu Central Hospital	25	25*
	Zomba Central Hospital	25	0*
District hospitals	Balaka District Hospital	0	12
	Bwaila District Hospital	0	12
	Chikwawa District Hospital	0	12
	Chiradzulu District Hospital	0	12
	Chitipa District Hospital	0	12
	Dedza District Hospital	0	12
	Dowa District Hospital	0	12
	Karonga District Hospital	0	12
	Kasungu District Hospital	0	12
	Machinga District Hospital	0	12
	Mangochi District Hospital	0	12
	Mchinji District Hospital	0	12
	Mulanje District Hospital	0	12
	Mwanza District Hospital	0	12
	Mzimba District Hospital	0	12
	Neno District Hospital	0	12
	Nkhata Bay District Hospital	0	12
	Nkhotakota District Hospital	0	12
	Nsanje District Hospital	0	12
	Ntcheu District Hospital	0	12
	Ntchisi District Hospital	0	12
	Phalombe District Hospital	0	12
	Rumphi District Hospital	0	12
	Salima District Hospital	0	12
	Thyolo District Hospital	0	12
Total		**104**	**388**

**Currently existing HDU beds in central hospitals. The Ministry does not have plans to project or estimate HDUs in central hospitals according to the Emergency and Critical Care Strategy. However, the strategy projects 25 ICU beds in central hospitals and 12 HDU beds per each district hospital. For Mercy James, there are already 4 ICU beds and 4 HDU beds.*

Given a six-month COVID-19 outbreak scenario peaking at 200 new cases a day, an oxygen need of approximately **818 million liters** is estimated to adequately supply anticipated ICU and HDU beds at the five central hospitals and 25 district hospitals under the MOH's Emergency and Critical Care Strategy. Therefore, a shortfall of 631 million liters is estimated, as shown in *Figure 15.*

Figure 115. Oxygen shortfall in "future emergency preparedness" scenario with 200 new COVID cases/day over 6 months.



Note: Figure *assumes* alignment with Ministry of Health (MOH) *plan to increase* intensive care unit (ICU) *bed counts at each central hospital to 25 beds* and high-dependency unit (HDU) bed *counts at each district hospital to 12 beds.*

Shortfalls in respiratory care equipment to service ICU and HDU beds at the five central hospitals and 25 district hospitals were also modeled. *Tables 25* and *26* outline the current respiratory care equipment availability, both nationwide and in the considered health facilities, and estimate the shortfall in equipment to adequately service both type beds at the considered facilities. *Table 25* shows durable equipment (reusable for care of multiple patients), and *Table 26*, consumable equipment (usable for treatment of single patient only).

Table 25. Durable equipment supply gaps nationwide and for central and district hospitals ("future emergency preparedness" scenario).

Equipment	Nationwide	Central hospitals (5) and district hospitals (25)		
	Current equipment availability	Current equipment availability	Equipment need to fully supply beds	Estimated equipment shortfall
Infrared thermometer	0	0	17	17
Pulse oximeter (adult + pediatric probes)	254	123	331	208
Patient monitor, multiparametric with electrocardiogram (ECG), with accessories	269	196	124	0
Patient monitor, multiparametric without ECG, with accessories	78	46	52	6
Oxygen source (i.e., concentrator, cylinder, or pipe supply)	174	126	331	205
Laryngoscope (direct or video type)	377	132	83	0
Patient ventilator, intensive care, with breathing circuits and patient interface	48	39	83	44
Continuous positive airway pressure (CPAP) device, with tubing and patient interfaces, with accessories	141	112	21	0
High-flow nasal cannula, with tubing and patient interfaces	2	1	21	20
Electronic drop counter, intravenous fluids	0	0	207	207
Infusion pump	0	0	52	52

Blood gas analyzer, portable with cartridges and control solutions	0	0	8	8
Ultrasound, portable, with transducers and trolley	0	0	8	8
Drill, for vascular access, with accessories and transport bag	0	0	8	8
Electrocardiograph, portable with accessories	0	0	8	8
Suction pump	645	333	176	0
Bubble humidifier, non-heated	0	0	228	228
Tubing, medical gases, int. diam. 5 mm	0	0	8	8
Flow splitter, 5 flow meters 0–2 liters per minute (LPM), for pediatric use	219	137	8	0
Flow meter, Thorpe tube, for pipe oxygen 0–15 LPM	312	223	41	0
Conductive gel, container	0	0	628	628
Catheter, nasal, 40 cm, with lateral eyes, sterile, single use; different sizes: 10 Fr, 12 Fr, 14 Fr, 16 Fr, 18 Fr	26	15	1,584	1,569
Compressible self-refilling ventilation bag, capacity > 1,500 mL, with masks (small, medium, large)	1,749	884	41	0

Table 26. Consumable equipment supply gaps nationwide and for central and district hospitals ("future emergency preparedness" scenario).

Equipment	Nationwide	Central hospitals (5) and district hospitals (25)		
	Current equipment availability	Current equipment availability	Equipment need to fully supply beds	Estimated equipment shortfall
Nasal oxygen cannula, with prongs, adult and pediatric	6,615	4,669	12,740	8,071
Mask, oxygen, with connection tube, reservoir bag and valve, high-concentration single use (adult)	2,047	1,270	12,740	11,470
Venturi mask, with percent O_2 Lock and tubing (adult)	485	263	12,740	12,477
Airway, nasopharyngeal, sterile, single use, set, size 20 Fr, 22 Fr, 24 Fr, 26 Fr, 28 Fr, 30 Fr, 32 Fr, 34 Fr, 36 Fr	795	528	16,759	16,231
Airway, oropharyngeal, Guedel, set in sizes No. 2 (70 mm), No. 3 (80 mm), No. 4 (90 mm), No. 5 (100 mm)	1,263	711	16,759	16,048
Colorimetric end tidal CO_2 detector single use (adult)	360	208	16,759	16,551
Cricothyrotomy, set, emergency, 6 mm, sterile, single use	0	0	8,379	8,379
Endotracheal tube introducer	619	434	16,759	16,325
Tube, endotracheal	0	0	16,759	16,759
Laryngeal mask airway	496	199	16,759	16,560
Lubricating jelly, for critical patient gastro-enteral feeding, airway management, and intubation	0	0	628	628
Heat, moisture exchanger, and filter; high efficiency, with connectors, for adult	0	0	24,886	24,886

A6: Comparison of oxygen need estimation tools

Table 27 provides a comparison of tools available for estimating oxygen need.

Table 27. Comparison of tools for oxygen need estimation.

Tool	Purpose	Inputs	Outputs
PATH Quantification and Costing Tool for Oxygen Delivery Sources	The purpose of this tool for oxygen and pulse oximetry is to help procurement decision-makers and health facility planners understand the amount of oxygen or pulse oximeters needed to meet patient demand and all costs associated with owning these devices over time.	• Number of facilities at each health level • Average number of beds (across level) • Average bed occupancy rate (across level) • Average beds with added services • Average number of critical care beds • Average critical care occupancy rate • Average hours of operation of facilities • Source of power by facility level • Urban/rural facility split • Number of years in planning estimate	• Total oxygen need • Product mix recommendations • CAPEX and OPEX costs
UNICEF Oxygen System Planning Tool	The aim of this tool is to help planners at the national, subnational, or health facility level to plan their oxygen-supply system, from the oxygen source to the patient delivery device.	• Health facility name and type • Average number of beds of each type (OPD, general, adult, pediatric, neonatal, ICU, OT, emergency room) at each health facility level • Bed occupancy rate by facility • Bed turnover rate by facility • Current oxygen availability • Piping system availability • Average power availability • Geographic location • Plant availability and capacity	• Annual oxygen demand • Max instantaneous oxygen demand • Product mix recommendations • CAPEX and OPEX costs
WHO Essential Supplies Forecasting Tool v. 2	The purpose of this tool is to forecast/estimate equipment and supply needs for COVID-19 response. Estimation is done at the national level.	• Current COVID-19 cases in-country The tool provides defaults from the World Bank, or the user can manually enter data on the following: • Number of patients experiencing types of case severity (i.e., severe, critical) • Number of health care workers and staff • Hospital infrastructure • Labs and testing capacity • Oxygen use • Equipment use	• Total oxygen need at peak of COVID-19 cases • Quantity of equipment and supplies • Equipment and supplies cost

Abbreviations: CAPEX, capital expenditure; ICU, intensive care unit; OPD, outpatient department; OPEX, operating expenditure; OT, occupational therapy; UNICEF, United Nations Children's Fund; WHO, World Health Organization.

The tools above can be found in the following links:

- PATH's *Quantification and Costing Tool: Oxygen Delivery Sources*: https://www.path.org/resources/quantification-and-costing-tools/#:~:text=The%20Quantification%20and%20Costing%20Tools,need%20with%20different%20device%20types.
- UNICEF's *Oxygen System Planning Tool*: https://www.unicef.org/innovation/documents/oxygen-system-planning-tool.
- WHO's *COVID-19 Essential Supplies Forecasting Tool*, v. 2: https://apps.who.int/iris/handle/10665/333284.

A7: UNICEF Oxygen System Planning Tool data inputs

Required data inputs

There are multiple data inputs that must be entered by the tool user. PATH and UNICEF collected these data from several sources, which are listed in *Table 28*.

Table 28. UNICEF Oxygen System Planning Tool data inputs, by source.

Data source	2020 Biomedical Equipment Survey (BMES)	2020 Malawi Facility Oxygen Survey	DHIS2 data	UNICEF Malawi Master Facility List
Data inputs	• Bed counts for central and district hospitals • Oxygen plant information	• Ward-specific bed counts (e.g., pediatric, neonatal)	• Bed occupancy • Bed turnover • OPD volume • Bed capacity, where not available from BMES	• Names and geographic coordinates of 500+ health facilities across Malawi

Abbreviations: DHIS2, District Health Information System 2; OPD, outpatient department; UNICEF, United Nations Children's Fund.

Oxygen plant information

The 2020 Biomedical Equipment Survey (BMES) provided data on oxygen-production sources (PSA plants) that were on-site at the facilities surveyed. This was not comprehensive of all production sources in Malawi, and further data were collected to compile a final list of sources, which was used for Oxygen System Planning Tool input. The additional data were provided by technical experts and the Malawi Oxygen Task Force. *Table 29* shows oxygen-production sources in Malawi.

Table 29. Oxygen-production sources in Malawi.

PSA plant name / facility name	Ownership	Operational status	District	Health zone	Region	Refilling capacity (Yes/No)	Plant capacity (Nm³/h)
Daeyang Luke Hospital	FBO	Operational	Lilongwe	Central West	Central	No	10
Mercy James	FBO	Operational	Blantyre	South West	Southern	No	12
Neno District Hospital	MOH	Operational	Neno	South West	Southern	Yes	1.38
Queen Elizabeth Central Hospital	MOH	Operational	Blantyre	South West	Southern	Yes	50
Nkhata Bay District Hospital	MOH	Operational	Nkhata Bay	North	Northern	Yes	4.83
Kamuzu Central Hospital	MOH	Operational	Lilongwe	Central West	Central	Yes	50
Afrox Lilongwe Depot	Private	Operational	Lilongwe	Central West	Central	Yes	10
Afrox Blantyre Depot	Private	Operational	Blantyre	South West	Southern	Yes	10
Nkhoma Mission Hospital	CHAM	Planned	Lilongwe	Central West	Central	Yes	21
Phalombe District Hospital	MOH	Operational	Phalombe	South East	Southern	Yes	49
Mzuzu Central Hospital	MOH	Planned	Mzuzu	North	Northern	Yes	50
Karonga District Hospital	MOH	Planned	Karonga	North	Northern	Yes	23.8
Lisungwi Community Hospital	MOH	Temporarily out of order	Neno	South West	Southern	Yes	6.9
Kasungu	MOH	Planned	Kasungu	Central East	Central	Yes	Unknown
Mangochi	MOH	Planned	Mangochi	South East	Southern	Yes	Unknown
Bwaila	MOH	Planned	Lilongwe	Central West	Central	Yes	Unknown
Zomba Central Hospital	MOH	Planned	Zomba	South East	Southern	Yes	50

Abbreviations: CHAM, Christian Health Association of Malawi; FBO, faith-based organization, MOH, Ministry of Health; Nm3/h, normal cubic meter per hour.

Malawi Facility Oxygen Survey

The Malawi Facility Oxygen Survey is an Excel-based assessment that PATH conducted in 2020 and that preceded the 2020 BMES. It covered 21 central, district, and community hospitals, which were surveyed for bed capacity, oxygen supply, oxygen production, and available equipment.[xxiii] The key data pulled from this assessment were ward bed counts within facilities.

District Health Information System 2 (DHIS2) data inputs

Malawi's DHIS2 database is a specific Health Management Information System (HMIS) and was a primary data source for the oxygen needs estimation. DHIS2 is a software system commonly used by health facilities to collect and track data on population health. These data elements are used to calculate health indicators, which summarize progress towards achieving the goals set in national health policy. For example, there are indicators related to immunization coverage, TB and malaria case management, and maternal and child health (among many others). *Table 30* lists which data elements were pulled from DHIS2 and what they were used to calculate for the UNICEF tool.

Table 30. Use of DHIS2 data elements for oxygen needs estimation.

Data element	Use in UNICEF tool
Bed capacity	Fill gaps in BMES bed data
HMIS total # of admissions (including maternity)	Estimate bed turnover rate
HMIS # of OPD attendance	Estimate annual OPD visits
HMIS total inpatient days	Estimate bed occupancy rate

Abbreviations: BMES, Biomedical Equipment Survey; DHIS2, District Health Information System 2; HMIS, Health Management Information System; OPD, outpatient department; UNICEF, United Nations Children's Fund.

These data elements were pulled for all health facility tiers except for central hospitals. This is because all other Malawi hospitals use HMIS15, while central hospitals use HMIS17. Confidence in the data quality was high since DHIS2 is a government database, and the data were pulled from 2015–2019 data, a longer time span to increase accuracy.

Calculations from DHIS2 data

The following are the calculations used for key elements:

- **Bed turnover rate** = (annual admissions) / (# of beds in facility);

  annual admissions = (average admission per month)*(12 months).

- **Annual outpatient department (OPD)** = average OPD per month*12 months.

- **Bed occupancy rate** = [(average number of beds occupied per day) / (number of beds total)] *100;

  average number of beds occupied per day = (average inpatient days across 6 months) / (30 days in a month)

[xxiii] The number of facilities surveyed and the equipment list were expanded in the 2020 BMES. Also important to note is that this assessment was conducted prior to the COVID-19 pandemic.

A8: Oxygen standards

Table 31 provides a comparison of oxygen purity standards.

Table 31. Comparison of global standards for oxygen purity.

Parameters	ISO 10083	US Pharmacopeia XXII	European Pharmacopeia
Oxygen (O_2)	> 90%	90%–96%	90%–96%
Carbon monoxide (CO)	≤ 5 ppm % v/v	< 0.001%	≤ 5 ppm % v/v
Carbon dioxide (CO_2)	≤ 300 ppm % v/v	< 0.03%	< 300 ppm
Sulfur dioxide (SO_2)	≤ 1 ppm % v/v	-	< 1 ppm % v/v
Nitrous oxides (NO & NO_2)	≤ 2 ppm % v/v	-	< 2 ppm % v/v
Water vapor (H_2O)	≤ 67 vpm (–46°C)	-	≤ 67 vpm (–46°C)
Particles	0.01 micron	0.01 micron	0.01 micron
Oil concentration	≤ 0.1 mg/m^3	≤ 0.1 mg/m^3	≤ 0.1 mg/m^4
Dust particles	0.5 mg/m^3	0.5 mg/m^3	0.5 mg/m^3
Odor	None	None	None

Abbreviations: ISO, International Organization for Standardization; ppm, parts per million; vpm, volumes per million; v/v, volume per volume.

A9: Oxygen equipment and supplies costing methods

Costing overview

Cost estimates were created by estimating quantity of equipment and supplies required at a national level and then multiplying that by their per-unit pricing. Equipment quantities were generated using Malawi's official standard list of equipment, drafted in 2009.[42] The number of equipment pieces per general or intensive care unit (ICU) bed depends on the health facility type; higher-level ones have greater ratios of equipment to beds since they are likely to treat patients with higher rates of hypoxemia and, therefore, greater respiratory care needs (*Table 32*). Equipment-to-bed ratios were multiplied by total beds at each health system level to estimate total equipment pieces required across all health facilities in Malawi (*Table 33*).

Table 32. Ratios of equipment pieces to bed type.

Equipment type	General bed rate per facility type						ICU/OT bed rate
	Central hospital	District hospital	Mission hospital	Community hospital	Rural hospital	Health center	
Oxygen cylinder	0.03	0.03	0.03	0.12	0.12	0.16	2.0
Oxygen concentrator	0.03	0.03	0.03	0.14	0.14	0.08	1.0
Ventilator	0.00	0.00	0.00	0.00	0.00	0.00	0.5
Pulse oximeter	0.10	0.10	0.10	0.10	0.10	0.10	1.0
Patient monitor with ECG	0.00	0.00	0.00	0.02	0.02	0.00	1.0
Patient monitor without ECG	0.00	0.00	0.00	0.00	0.00	0.00	1.0
Suction (manual)	0.04	0.04	0.04	0.16	0.16	0.16	0.5
Suction (electric)	0.01	0.01	0.01	0.08	0.08	0.04	0.5
Resuscitation (adult)	0.02	0.02	0.02	0.14	0.14	0.12	1.0
Resuscitation (pediatric)	0.02	0.02	0.02	0.08	0.08	0.08	0

Abbreviations: ECG, electrocardiogram; ICU, intensive care unit; OT, occupational therapy.

Table 33. Estimated total equipment pieces for Malawi's health system.

Equipment type	Central hospital	District hospital	Mission hospital	Community hospital	Rural hospital	Health center	ICU/OT	TOTAL
Total facilities	**5**	**25**	**27**	**2**	**25**	**457**	**N/A**	**541**
Total beds	**3,683**	**6,608**	**4,483**	**154**	**1,339**	**6,753**	**145**	**23,165**
Oxygen cylinder	133	300	324	19	185	2,037	290	**3,288**
Oxygen concentrator	125	230	159	23	198	796	145	**1,676**
Ventilator	0	0	0	0	0	0	76	**76**
Pulse oximeter	371	667	455	16	141	878	145	**2,673**
Patient monitor with ECG	20	46	37	4	38	0	145	**290**
Patient monitor without ECG	0	0	0	0	0	0	145	**145**
Suction (manual)	143	263	182	25	226	1,349	76	**2,264**
Suction (electric)	38	74	58	13	118	530	76	**907**
Resuscitation (adult)	90	171	122	23	198	1,012	145	**1,761**
Resuscitation (pediatric)	90	171	122	13	118	796	0	**1,310**

Abbreviations: ECG, electrocardiogram; ICU, intensive care unit; OT, occupational therapy.

Equipment and supplies unit costs were sourced from the UNICEF Supply Catalogue and the World Health Organization's *Emergency Global Supply Chain System (COVID-19)* catalogue (*Table 34*).

Table 34. Estimated unit costs for equipment pieces.

Equipment	Unit cost (MK)	Unit cost (USD)	Source
Oxygen cylinder	$54,400.00	$68.00	Afrox
Oxygen concentrator (10 L), with accessories	$840,000.00	$1,050.00	UNICEF*
Ventilator, intensive care with breathing circuits and patient interface	$18,847,040.00	$23,558.80	WHO**
Pulse oximeter handheld (with cables and sensor)	$600,000.00	$750.00	WHO**
Pulse oximeter fingertip	$16,960.00	$21.20	WHO**
Pulse oximeter tabletop	$1,320,000.00	$1,650.00	WHO**
Patient monitor with ECG	$1,387,272.00	$1,734.09	WHO**
Patient monitor without ECG	$797,224.00	$996.53	WHO**
Suction-manual	$90,816.00	$113.52	UNICEF*
Suction-electric	$130,408.00	$163.01	UNICEF*
Resuscitation (adult)	$24,344.00	$30.43	UNICEF*
Resuscitation (pediatric)	$22,424.00	$28.03	UNICEF*

** UNICEF Supply Catalogue: https://supply.unicef.org/.*
*** WHO Emergency Global Supply Chain System (COVID-19) catalogue: https://www.who.int/publications/m/item/emergency-global-supply-chain-system-covid-19-catalogue.*
Abbreviations*: Afrox, African Oxygen; ECG, electrocardiogram; MK, Malawi Kwacha; UNICEF, United Nations Children's Fund; WHO, World Health Organization.*

A series of assumptions were employed for costing equipment and supplies. These are categorized in *Table 35*. Beside each assumption, a note has been added for "decision-maker utility." This describes how decision-makers in government or elsewhere can adjust these cost estimates to make them fit the current situation in Malawi or to observe how costs change when various factors are manipulated.

Table 35. Costing assumptions.

Assumption type	Assumption	Decision-maker utility
Base	Malawi's SEL includes a set of respiratory care durable devices. Some device types that are recommended for respiratory care are not included here.	Further expansion of the SEL for Malawi should be conducted by government decision-makers if other device types are identified as critical to procure. Additionally, the recommended ratio of equipment per bed, or per facility level, can be manipulated as decision-makers see fit.
Base	Minimum thresholds for equipment count per facility were set in cases where a facility's bed count times its equipment ratio results in a unit count below 1. Any decimal values for equipment counts were rounded up to the nearest whole number.	Minimum numbers of equipment per facility can be adjusted.
Base	Oxygen commodities, consumables, and accessories* are not included in budgeted equipment and supplies since they are heavily correlated with demand and oxygen equipment usage. This makes their need highly variable.	Decision-makers should track oxygen consumption and device usage to accurately anticipate demand for, budget for, and procure necessary supplies for such.
Base	Existing equipment pieces in health facilities are not accounted for. This may make the total (costed) equipment an overestimate.	To properly estimate the amount of equipment and supplies to procure, national-level gap assessments must be conducted. This requires quantifying equipment and supplies availability in all health facilities.
Base	Total costed equipment was based on the estimated number of existing beds in Malawi's health system. Over the next 5 years, Malawi's population will grow, and ideally the health system's bed capacity will grow, as well.	This increase in beds in the next 5 years is not accounted for but should be considered by decision-makers during future budgeting or budget adjustments.
CAPEX	Costs for improving power quality, availability, and infrastructure are not accounted for in this estimate, except for power-quality accessories for oxygen concentrators.** Other equipment types that use electricity may benefit from such accessories,*** and facilities with unreliable power may want to invest in uninterrupted power supply or backup generators.	Procuring equipment to improve power quality and availability would improve the infrastructure at facilities and allow facilities more options for oxygen production. Decision-makers should consider these investments when planning which oxygen source is best for a location.
OPEX	Electricity costs for devices were included in costing where power consumption of the device type was known (oxygen concentrators and pressure swing adsorption plants).	Energy costs can be refined by decision-makers if data are collected on estimated power consumption of device types.

CAPEX	"Installation" comprises installation and commissioning, plus initial training of personnel. It is estimated at 10% of the CAPEX of the device for type B devices (oxygen concentrator, ventilator, patient monitor, and suction device) and 5% for type C devices (resuscitation). Estimate and device type designation are based on guidance from *How to Plan and Budget for Your Healthcare Technology*.[43]	The cost of installing and commissioning the equipment and training personnel can be refined by decision-makers.
OPEX	"Maintenance (labor and spare parts)" is estimated as 10.00% of CAPEX per year for type B technologies (oxygen concentrator, ventilator, patient monitor, and suction device) and 4.25% for type C devices (resuscitation).	The cost of maintenance, labor, and spare parts can be refined by decision-makers.

** Masks of various types, tubing, cannula, prongs, flow meters, flow splitters.*
*** For oxygen concentrators, a voltage stabilizer and surge protector are included in the upfront capital expense.*
**** Improving power quality can prevent damage to electrical devices from adverse power events. This can increase device life span and save costs in the long term.*
Abbreviations: CAPEX, capital expenditure; OPEX, operating expenditure; SEL, standard equipment list.

Pulse oximetry costing

The cost estimate included reflects the cost to equip all health facilities (n = 541) with the recommended standard number of oxygen-monitoring devices for the five-year implementation period. It is important to note that pulse oximeters are chosen as the oxygen monitoring device of choice; however, some patient monitors have SpO_2 monitoring capabilities and can be procured as an alternative device type. Patient monitors are most important for ICU care due to their monitoring ability and should be prioritized in ICU wards over pulse oximeters when possible. Costing for pulse oximetry was done using the UNICEF Oxygen System Planning Tool.

Table 36 shows total estimated costs over five years to equip 541 health facilities with the recommended standard of equipment per bed.

Table 36. Pulse oximetry costing.

Cost categories	Year 1 (USD)	Year 2 (USD)	Year 3 (USD)	Year 4 (USD)	Year 5 (USD)	Total 5-year cost (USD)
Initial product cost	$729,790	$0	$0	$0	$0	$729,790
Accessories	$61,550	$0	$0	$0	$0	$61,550
Shipping	$79,134	$0	$0	$0	$0	$79,134
Distribution	$39,567	$0	$0	$0	$0	$39,567
Installation	$7,913	$0	$0	$0	$0	$7,913
Training (one-time cost)	$36,490	$0	$0	$0	$0	$36,490
Capital expenditure subtotal	**$954,444**	**$0**	**$0**	**$0**	**$0**	**$954,444**
Spare parts	$0	$143,450	$143,450	$143,450	$143,450	$573,800
Maintenance	$2,374	$2,374	$2,374	$2,374	$2,374	$11,870
Device replacement	$0	$0	$0	$0	$235,816	$235,816
Operating expenditure subtotal	**$2,374**	**$145,824**	**$145,824**	**$145,824**	**$381,640**	**$821,486**
Grand total	**$956,818**	**$145,824**	**$145,824**	**$145,824**	**$381,640**	**$1,775,930**

Table 37 lists the units of equipment that will be purchased in year 1, and total purchased units over five years, according to the cost estimate.

Table 37. Pulse oximetry and accessories units procured.

Pulse oximeter and accessories	Number up front	Estimated device replacement and spare part quantities during total 5 years
Main components		

Tabletop pulse oximeter	351	0
Handheld pulse oximeter	701	701
Adult tabletop pulse oximeter probe	682	2,728
Pediatric tabletop pulse oximeter probe	0	0
Neonatal tabletop pulse oximeter probe	0	0
Adult handheld pulse oximeter probe	556	5,004
Pediatric handheld pulse oximeter probe	625	5,625
Neonatal handheld pulse oximeter probe	599	5,391
Spare parts for 5 years		
Battery for tabletop		341
Battery for handheld		1,402

Pulse oximetry costing assumptions are as follows:

- Two types of pulse oximeters were costed: tabletop and handheld devices.
- The default price for a tabletop device was estimated to be US$1,500; a handheld device was estimated at $290.
- Tabletop devices have a longer life span, approximately seven years, while handheld devices have a life span of four years.
- The ratio of devices to beds depended on bed type; for instance, ICU beds and occupational therapy beds, which require high-pressure oxygen, are assumed to require constant monitoring. Thus, they are recommended to have one tabletop device per bed for continuous monitoring. All other bed types requiring spot checks are recommended to use handheld devices in a ratio of one device to ten beds.

Pressure swing adsorption (PSA) plant costing

The following describes how costs were estimated for PSA plants in two different scenarios.

Scenario 1: Baseline

This estimation assumes all current and planned plants will be the only PSA plant investments made within the five-year implementation period. Scenario 1 totals the following:

- Estimated capital costs (capital expenditure, or CAPEX) for installing planned plants.
- Estimated operational costs (operating expenditure, or OPEX) for existing and planned plants.

It is important to note that CAPEX for planned plants may not be applicable and/or may be an overestimate for some or all of the planned plants, given that many have existing funding from partner organizations. It is recommended, therefore, that stakeholders focus on the OPEX cost estimate and use the CAPEX estimate to respond to potential changes in available funding for planned plants. *Table 38* shows the tentative funding status of PSA plants in Malawi.

Table 38. Tentative funding status of Malawi pressure swing adsorption plants.

Facility/plant name	Status	Funder	Included in estimate
Mercy James	Active	Funded (unknown)	OPEX
Neno District Hospital	Active	Partners In Health	OPEX
Lisungwi Community Hospital	Active	Partners In Health	OPEX
Nkhata Bay District Hospital	Awaiting final spare parts	GOM / Last Mile Health	OPEX
Daeyang Luke Hospital	Active		OPEX
Queen Elizabeth Central Hospital	Active	GOM/FCDO/UNICEF	OPEX
Kamuzu Central Hospital	Active	GOM/FCDO/UNICEF/Gavi	OPEX
Lilongwe	Expected August 2021	German Agency for International Cooperation	Not included due to insufficient costing data
Afrox Lilongwe	Active	N/A	Not included, private industry
Afrox Blantyre	Active	N/A	Not included, private industry
Nkhoma Mission Hospital	Planned		OPEX, CAPEX
Phalombe District Hospital	Handed over		OPEX
Mzuzu Central Hospital	Planned		OPEX, CAPEX
Kasungu	Planned	The Global Fund	OPEX, CAPEX
Karonga District Hospital	Planned		OPEX, CAPEX
Zomba Central Hospital	Planned		OPEX, CAPEX
Mangochi	Planned	The Global Fund	OPEX, CAPEX
Bwaila	Planned	The Global Fund	OPEX, CAPEX

Abbreviations: CAPEX, capital expenditure; FCDO, UK Foreign, Commonwealth & Development Office; GOM, Government of Malawi; OPEX, operating expenditure.

Table 39 shows the estimated costs for installing and operating a single PSA plant.

Table 39. Cost to install and operate a single pressure swing adsorption plant.

Cost categories	Year 1 (USD)	Year 2 (USD)	Year 3 (USD)	Year 4 (USD)	Year 5 (USD)	Total 5-year cost (USD)
Initial costs of equipment, spare parts and accessories (*Free Carrier*)	$300,000	$0	$0	$0	$0	$300,000
Shipping and delivery	$10,000	$0	$0	$0	$0	$10,000
Installation, testing, and initial training costs	$35,000	$0	$0	$0	$0	$35,000
Capital expenditure subtotal	**$345,000**	**$0**	**$0**	**$0**	**$0**	**$345,000**
Energy	$17,523	$17,523	$17,523	$17,523	$17,523	$87,615
After-sales service*	$40,000	$0	$40,000	$0	$40,000	$120,000
Operating expenditure subtotal	**$57,523**	**$17,523**	**$57,523**	**$17,523**	**$57,523**	**$207,615**
Grand total for scenario 1	**$402,523**	**$17,523**	**$57,523**	**$17,523**	**$57,523**	**$552,615**

**After-sales service cost assumes installed plants will receive after-sales service and preventative maintenance at the point of purchase to avoid complexity in contracting for such. Packages for 2 years of quarterly visits can be expected to cost in the region of US$40,000. For simplicity, all plants (newly installed and operational) are estimated to cost the same.*

Table 40 shows the estimated costs for scenario 1, where Malawi installs the five currently planned PSA plants and operates these plants in addition to existing plants for the next five years.

Table 40. Pressure swing adsorption plant costing for scenario 1.

Cost categories	Year 1 (USD)	Year 2 (USD)	Year 3 (USD)	Year 4 (USD)	Year 5 (USD)	Total 5-year cost (USD)
Initial costs of equipment, spare parts and accessories (*Free Carrier*)	$300,000	$0	$0	$0	$0	$300,000
Shipping and delivery	$10,000	$0	$0	$0	$0	$10,000
Installation, testing, and initial training costs	$35,000	$0	$0	$0	$0	$35,000
Number of planned plants (multiplier of above line items)	5	N/A	N/A	N/A	N/A	N/A
Capital expenditure subtotal	**$1,725,000**	**$0**	**$0**	**$0**	**$0**	**$1,725,000**
Energy	$17,523	$17,523	$17,523	$17,523	$17,523	$87,615
After-sales service*	$40,000	$0	$40,000	$0	$40,000	$120,000
Number of planned and existing plants (multiplier of above line items)	13	N/A	N/A	N/A	N/A	N/A
Operating expenditure subtotal	**$747,798**	**$227,798**	**$747,798**	**$227,798**	**$747,798**	**$2,698,990**
Grand total for scenario 1	**$2,472,798**	**$227,798**	**$747,798**	**$227,798**	**$747,798**	**$4,423,990**

**After-sales service cost assumes installed plants will receive after-sales service and preventative maintenance at the point of purchase to avoid complexity in contracting for such. Packages for 2 years of quarterly visits can be expected to cost in the region of US$40,000. For simplicity, all plants (newly installed and operational) are estimated to cost the same.*

Scenario 2: PSA plant installations at all district hospitals in Malawi

This estimation assumes that all district hospitals will have an installed PSA plant within the five-year implementation period (*Table 41*). Scenario 2 totals the following:

- Estimated capital costs (CAPEX) for installing 25 PSA plants, including the 5 currently planned plants (see *Table 38* above) and 20 new plant installations at district hospitals.[xxiv]
- Estimated operational costs (OPEX) for all existing and planned plants (33 plants in total).

It is important to note that scenario 2 assumes all plant installations occurring in year 1. This is not a feasible scenario but has been done in this way to show decision-makers the upper bound of potential costs. All costing assumptions are the same as for scenario 1.

Table 41. Pressure swing adsorption plant costing for scenario 2.

Cost categories	Year 1 (USD)	Year 2 (USD)	Year 3 (USD)	Year 4 (USD)	Year 5 (USD)	Total 5-year cost (USD)
Initial costs of equipment, spare parts and accessories (*Free Carrier*)	$300,000	$0	$0	$0	$0	$300,000
Shipping and delivery	$10,000	$0	$0	$0	$0	$10,000
Installation, testing, and initial training costs	$35,000	$0	$0	$0	$0	$35,000
Number of planned plants (multiplier of above line items)	25	N/A	N/A	N/A	N/A	N/A
Capital expenditure subtotal	**$8,625,000**	**$0**	**$0**	**$0**	**$0**	**$8,625,000**
Energy	$17,523	$17,523	$17,523	$17,523	$17,523	$87,615
After-sales service*	$40,000	$0	$40,000	$0	$40,000	$120,000
Number of planned and existing plants (multiplier of above line items)	33	N/A	N/A	N/A	N/A	N/A
Operating expenditure subtotal	**$1,898,256**	**$578,256**	**$1,898,256**	**$578,256**	**$1,898,256**	**$6,851,282**
Grand total for scenario 2	**$10,523,256**	**$578,256**	**$1,898,256**	**$578,256**	**$1,898,256**	**$15,476,282**

**After-sales service cost assumes installed plants will receive after-sales service and preventative maintenance at the point of purchase to avoid complexity in contracting for such. Packages for 2 years of quarterly visits can be expected to cost in the region of US$40,000. For simplicity, all plants (newly installed and operational) are estimated to cost the same.*

[xxiv] Five plants are already located or planned at district hospitals (Nkhata Bay, Phalombe, Kasunga, Neno, and Karonga). This leaves 20 district hospitals without plants.

PSA costing assumptions are as follows:

- Initial costs of equipment, spare parts, and accessories (Free Carrier): CAPEX costs are estimated for a containerized, "medium-sized" plant of approximately 21 normal cubic meters per hour (10,280 L/hr. plant capacity) and filing station.[xxv] CAPEX costs could be lower if purchasing a skid-mounted plant and could be higher or lower if purchasing a differently sized plant. CAPEX also includes required accessories, manifolds, cylinders, and a spare parts kit for two years. Costs could be higher depending on the complexity of the installation site.
- Shipping & delivery: Cost is estimated between $7,000 and $10,000 for delivery to location of a skid-mounted or containerized plant. Costs could be significantly higher in hard-to-reach locations. The high end of this range was chosen for the cost estimate, based on the location of planned plants and likely distance from a PSA plant supplier.
- Installation, testing, and initial training costs: A comprehensive installation and testing package, including on-site training of technicians, is required and can be expected to cost in the region of $25,000 to $45,0000 per site. A midrange estimate of $35,000 was chosen, assuming training for 12 persons over two weeks.
- After-sales service: This cost assumes installed plants will receive after-sales service and preventive maintenance at the point of purchase to avoid complexity in contracting for such. Packages for two years of quarterly visits can be expected to cost in the region of $40,000. For simplicity, all plants (newly installed and operational) are estimated to cost the same.
- Energy: The cost of electricity is presented as an annual cost and based on the assumption that a plant runs for 16 hours per day, every day of the year. The energy requirement of a midsized PSA plant (approx. 10,000 L/hr.) is 17.65 kilowatts, and the cost of electricity in Malawi is approximately $0.17 per kilowatt hour.[44] Plant operation hours and size of plant will influence costing.

Oxygen cylinder costing

Costing for oxygen cylinders includes two components; total cost to meet estimated oxygen needs with size J (6800L) cylinders, and the total costs to equip ambulance and health facilities with size F (1360L) cylinders for patient transport.

This first component of this estimate describes the potential cost to Malawi's health system if the entire annual oxygen demand was filled by size J (6800L) oxygen cylinders sourced from a Malawi-based supplier (*Table 42*). This excludes the oxygen demand from facilities with PSA plants that are assumed to cover their own oxygen needs.

Stakeholders should consider this scenario as an upper bound cost estimate for cylinders. In reality, the oxygen need should be filled by a mix of oxygen-production sources, just one of which is cylinders. It is also important to keep in mind that what is being costed in this scenario is the cost to refill cylinders, which, in total, would provide the annual bulk oxygen need. The actual number of cylinders in distribution and their frequency of refill is not considered here.

Table 42. Estimated oxygen cylinder costs to fill annual need.

Cost categories	Year 1 (USD)	Year 2 (USD)	Year 3 (USD)	Year 4 (USD)	Year 5 (USD)	Total 5-year cost (USD)
Cylinder size "J" (6,800 L)*	$12,379,317	$12,379,317	$12,379,317	$12,379,317	$12,379,317	$61,896,583
Grand total						$61,896,583

[xxv] For reference, a 10,280 L/hr. plant is comparable to the existing plant at Daeyang Luke Hospital, if operating at capacity.

* Includes cost of cylinder, distribution, and refill (does not include cylinder accessories).

Oxygen cylinder costing assumptions are as follows:

- To estimate the number of total cylinders needed per year, the oxygen need of facilities with PSA plants was first subtracted from the estimated national annual oxygen need. This number (1,228,686,696 L) was then divided by 6,800, the approximate liters of oxygen per cylinder.
- The total number of cylinders needed per year was multiplied by the estimated price per cylinder.
- The price of contracting a 6,800 L cylinder in Malawi is estimated at Malawi Kwacha (MK) 54809.32.
- A conversion rate of 1 USD to MK 800 was used to convert total cost.[xxvi]
- It is assumed in this estimate that PSA plants are not distributing oxygen to nearby facilities.

The second component of costing for oxygen cylinders considers the cost to equip ambulances and health facilities with size F (1360L) cylinders for patient transport. *Table 43* shows the total costs for oxygen cylinders, from both components of the estimate.

Table 43. Total oxygen cylinder costs.

Cost categories	Year 1 (USD)	Year 2 (USD)	Year 3 (USD)	Year 4 (USD)	Year 5 (USD)	Total 5 Year cost (USD)
Cylinder size J (6800L)*	$12,379,317	$12,379,317	$12,379,317	$12,379,317	$12,379,317	$61,896,583
Cylinder size F (1360)	$122,554	$122,554	$122,554	$122,554	$122,554	$612,768
Grand total	**$12,501,870**	**$12,501,870**	**$12,501,870**	**$12,501,870**	**$12,501,870**	**$62,509,351**

Oxygen cylinder costing assumptions are as follows:

- For costing size F cylinders (1360L) for ambulances and patient transport within facilities, we scaled down the unit cost from the 6800 L size J cylinders, to end up with an estimated unit cost of 10961.864 MK per cylinder. Additional data collection should be done to identify the true cost of size F cylinders.
- Next, we assumed that every district hospital (26) in Malawi is equipped with an ambulance for patient transport.
- We assumed every ambulance would be stocked with two size F cylinders.
- We assumed every district hospital (26) and every central hospital (4) would have 4 size F cylinders stocked for patient transport between wards in the facility.
- Lastly, we assumed bi-weekly refills of all cylinders to arrive at annual costs, which are the same for each year.

Additional detail on equipment and supplies costing

Tables 44 through *48* show the costing for other equipment and supplies.

[xxvi] Conversion rate on July 14, 2021.

Table 43. Oxygen concentrators costing for 1,676 devices.

Cost categories	Year 1 (USD)	Year 2 (USD)	Year 3 (USD)	Year 4 (USD)	Year 5 (USD)	Total 5-year cost (USD)
Oxygen concentrator size 10 LPM, with accessories*	$1,759,800	$0	$0	$0	$0	$1,759,800
Installation**	$175,980	$0	$0	$0	$0	$175,980
Capital expenditure subtotal	**$1,935,780**	**$0**	**$0**	**$0**	**$0**	**$1,935,780**
Energy	$521	$521	$521	$521	$521	$2,606
Maintenance (labor and spare parts)***	$175,980	$175,980	$175,980	$175,980	$175,980	$879,900
Operating expenditure subtotal	**$176,501**	**$176,501**	**$176,501**	**$176,501**	**$176,501**	**$882,506**
Grand total	**$2,112,281**	**$176,501**	**$176,501**	**$176,501**	**$176,501**	**$2,818,286**

**Accessories include flow splitter, voltage stabilizer, surge suppressor, and oxygen analyzer (for biomedical engineers).*
***Includes installation and commissioning, plus initial training of personnel (10% of capital expenditure of device).*
****Spare parts cost and maintenance estimated to cost 10% of capital expenditure per year.*
Abbreviation: LPM, liters per minute.

Table 44. Ventilators costing for 76 devices.

Cost categories	Year 1 (USD)	Year 2 (USD)	Year 3 (USD)	Year 4 (USD)	Year 5 (USD)	Total 5-year cost (USD)
Ventilator, intensive care with breathing circuits and patient interface	$1,790,469	$0	$0	$0	$0	$1,790,469
Installation*	$179,047	$0	$0	$0	$0	$179,047
Capital expenditure subtotal	**$1,969,516**	**$0**	**$0**	**$0**	**$0**	**$1,969,516**
Maintenance (labor and spare parts)**	$179,047	$179,047	$179,047	$179,047	$179,047	$895,234
Operating expenditure subtotal	**$179,047**	**$179,047**	**$179,047**	**$179,047**	**$179,047**	**$895,234**
Grand total	**$2,148,563**	**$179,047**	**$179,047**	**$179,047**	**$179,047**	**$2,864,750**

**Includes installation and commissioning, plus initial training of personnel (10% of capital expenditure of device).*
***Spare parts cost and maintenance estimated to cost 10% of capital expenditure per year.*

Table 45. Suction devices costing for 2,264 manual and 907 electrical devices.

Cost categories	Year 1 (USD)	Year 2 (USD)	Year 3 (USD)	Year 4 (USD)	Year 5 (USD)	Total 5-year cost (USD)
Suction device (manual)	$257,009	$0	$0	$0	$0	$257,009
Suction device (electric)	$147,850	$0	$0	$0	$0	$147,850
Installation*	$40,486	$0	$0	$0	$0	$40,486
Capital expenditure subtotal	**$445,345**	**$0**	**$0**	**$0**	**$0**	**$445,345**
Maintenance (labor and spare parts)**	$40,486	$34,813	$34,813	$34,813	$34,813	$179,739
Operating expenditure subtotal	**$40,486**	**$34,813**	**$34,813**	**$34,813**	**$34,813**	**$179,739**
Grand total	**$485,831**	**$34,813**	**$34,813**	**$34,813**	**$34,813**	**$625,085**

**Includes installation and commissioning, plus initial training of personnel (10% of capital expenditure of device).*
***Spare parts cost and maintenance estimated to cost 10% of capital expenditure per year.*

Table 46. Patient monitors costing for 290 devices with ECG and 145 devices without ECG.

Cost categories	Year 1 (USD)	Year 2 (USD)	Year 3 (USD)	Year 4 (USD)	Year 5 (USD)	Total 5-year cost (USD)
Patient monitor with ECG	$502,886	$0	$0	$0	$0	$502,886
Patient monitor without ECG	$144,497	$0	$0	$0	$0	$144,497
Installation*	$64,738	$0	$0	$0	$0	$64,738
Capital expenditure subtotal	**$712,121**	**$0**	**$0**	**$0**	**$0**	**$712,121**
Maintenance (labor and spare parts)**	$64,738	$64,738	$64,738	$64,738	$64,738	$323,691
Operating expenditure subtotal	**$64,738**	**$64,738**	**$64,738**	**$64,738**	**$64,738**	**$323,691**
Grand total	**$776,860**	**$64,738**	**$64,738**	**$64,738**	**$64,738**	**$1,035,813**

**Includes installation and commissioning, plus initial training of personnel (10% of capital expenditure of device).*
***Spare parts cost and maintenance estimated to cost 10% of capital expenditure per year.*
Abbreviation: ECG, electrocardiogram.

Table 47. Resuscitation devices costing for 1,761 adult and 1,310 pediatric devices.

Cost categories	Year 1 (USD)	Year 2 (USD)	Year 3 (USD)	Year 4 (USD)	Year 5 (USD)	Total 5-year cost (USD)
Resuscitation/ambu bag (adult)	$53,587	$0	$0	$0	$0	$53,587
Resuscitation/ambu bag (pediatric)	$36,719	$0	$0	$0	$0	$36,719
Installation*	$4,515	$0	$0	$0	$0	$4,515
Capital expenditure subtotal	**$94,822**	**$0**	**$0**	**$0**	**$0**	**$94,822**
Maintenance (labor and spare parts)**	$3,838	$3,838	$3,838	$3,838	$3,838	$19,190
Operating expenditure subtotal	**$3,838**	**$3,838**	**$3,838**	**$3,838**	**$3,838**	**$19,190**
Grand total	**$98,660**	**$3,838**	**$3,838**	**$3,838**	**$3,838**	**$114,012**

**Includes installation, commissioning, plus initial training of personnel (5% of capital expenditure of device).*
***Spare parts cost and maintenance estimated to cost 4.25% of capital expenditure per year.*

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Contact address: Ministry of Health, Lilongwe 3, P. O. Box 30377, Lilongwe, Malawi. Telephone: (+265) 1 789 400, 1 788 849, 1 789 195 Fax: (+265) 1 789 431

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