

COMMISSION ON MEDICAL OXYGEN SECURITY

COUNTRY CASE STUDY

Malawi

Financing a medical oxygen system

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Case study focus

This case study focuses on the financing of medical oxygen in Malawi, following the COVID-19 pandemic. In 2021, Malawi produced its first National Oxygen Ecosystem Road Map, which included a fully costed plan for national scale-up of oxygen services. The costed plan was developed using Ministry of Health Planning Department costing guidelines and was estimated at approximately US\$76 million to cover gaps in equipment and supplies to meet the projected national demand. In this case study we aim to describe the extent to which the planned financing has been achieved, key barriers and successes in ensuring funding is allocated to oxygen, and understand the stakeholders involved in this process.

Key messages

- *Centralised decision-making structures in Malawi benefitted from having oxygen champions that had a history of working in this space – meaning the existing data on hypoxaemia burden and the importance of oxygen were already well known when COVID-19 hit.*
- *However, central coordinating bodies lacked local representation from districts and were subject to different stakeholder priorities.*
- *Systems for tracking equipment procurement and distribution are critical and need to include equipment donations that occur outside for formal Government procurement structures. Without this, planning for a national oxygen system is challenging.*
- *Disseminating the national oxygen roadmap amongst Ministers, District management, donors and the public has raised awareness and led to positive action, but key funding gaps still remain.*

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Country Context

Demography, economy, and epidemiology

Malawi is a nation of 20.4 million people located in southern Africa. Population growth is a modest 2.6% per year. Approximately 18% of the population, equating to 3.7 million people, are children under the age of five. Almost 82% of the population lives in rural areas, while only 14% of the population has access to electricity. Malawi is classified by the World Bank as a low-income country, with a per-capita GDP of US\$645. Annual GDP growth is relatively low at 0.9% for 2022.(1) The Malawian economy has been characterized by high inflation in recent years, averaging 21% in 2022 and reaching 33% in November 2023 at the time of writing.(2)

Total healthcare spending in Malawi was US\$44 per capita as of 2019, with 57% coming from external development assistance, 24% coming from government spending, and 18% coming from private/out-of-pocket spending.(3) This has translated into a life expectancy of 63 years (60 for males, 68 for females) in 2022, and an under-five mortality rate of 39 per 1,000 live births.(1)

The top five causes of mortality across all ages are: 1) HIV/AIDS; 2) neonatal disorders; 3) acute lower respiratory infections; 4) tuberculosis; 5) diarrheal diseases – the top causes all have oxygen needs.(4) Currently, the reported burden of chronic respiratory conditions such as COPD is low, accounting for 1.2% of annual deaths.(4) However, presence of abnormal lung function is as high as 40% in the general adult population, indicating a high undiagnosed burden of non-communicable respiratory morbidity.(5) Reliable data on the

number of surgeries is lacking, but there is evidence of a large unmet surgical need and therefore, oxygen needs for surgical care (both intra-operative and post-operative) and critical care patients should increase as surgical capacity expands.(6)

Health system

The health system in Malawi is organized at three levels – primary, secondary, and tertiary – which are linked by a referral system. These health services are delivered through a network of public, private-for-profit, and faith-based providers, as shown in Table 1.(7)

- The primary care level consists of (i) community healthcare workers (named Health Surveillance Assistants), who provide integrated community case management care for children under-five, and (ii) health centers, which are generally staffed by nurses and medical assistants and provide outpatient care. Respiratory care services at the primary care level focus on screening patients for referral to higher-level facilities and may also include basic oxygen delivery for maternal care. Functional pulse oximeters are inconsistently available at this level of care.
- Secondary care is delivered at district hospitals, which provide general inpatient care and limited high-dependency care. Oxygen services at this level should be available for limited paediatric and adult high-dependency units, surgery and maternal and newborn care.

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- Tertiary care is provided by four central hospitals that are distributed geographically throughout the country. Oxygen services at this level should be available for ICU and critical care, surgery, general wards, maternal and newborn care and chronic care.

	Primary health posts, dispensaries, health centres	Secondary referral hospitals	Tertiary referral hospitals	Total
Government/public	625	45	4	674
Christian Health Association of Malawi (CHAM)	136	51	0	187
Private for-profit	359	17	0	376
Other (mostly NGO)	173	7	0	180
Total	1293	120	4	1417

Table 1: Distribution of health facilities in Malawi

The government operates the largest number of health facilities nationwide, including all four tertiary referral hospitals. In government facilities, all health services – including oxygen delivery – are provided free of charge. The Christian Health Association of Malawi (CHAM), a faith-based non-profit organization, is the second largest individual healthcare provider. CHAM facilities complement public facilities and are partially subsidized by the Ministry of Health, which prioritizes funding for CHAM facilities located more than eight kilometers from the nearest public facility. Small user fees may be charged for oxygen services at these facilities.

Within these facilities, Malawi faces a healthcare workforce shortage, with 1.49 health workers per 1,000 population, compared to the WHO target of 4.45 per 1,000.⁽⁸⁾ Figure 1 shows the vacancy rates (i.e., workforce shortage rates) against Ministry of Health targets for specific health worker cadres.⁽⁸⁾ All cadres face a staffing shortage, with the most severe shortages for lab assistants, pharmacists, and pharmacy technicians and assistants. Notable in this figure is the absence of biomedical engineers as a cadre of the healthcare workforce.

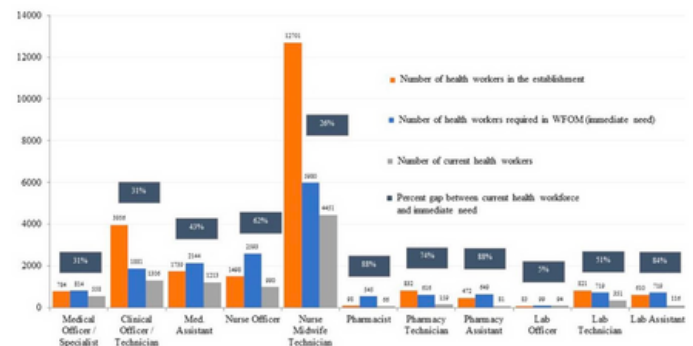


Figure 1: Current workforce, modelled workforce needs, and workforce targets set by MOH establishment (Berman et al 2022)⁸

COVID-19

Malawi registered its first case of COVID-19 on April 2, 2020. As of September 2022, Malawi had four waves of COVID-19 with 87,981 confirmed cases, resulting in 2,680 deaths (for a case fatality rate of 3.0%). The first wave of the pandemic began in April 2020 and caused a reported 6,039 cases. A second wave hit in mid-December 2020, causing a reported 28,807 cases. A third wave emerged in June 2021 and continued until the end of September 2021 and was responsible for a reported 27,129 cases. The fourth wave emerged in December 2021 with a reported 23,366 cases (Figure 2).⁽⁹⁾

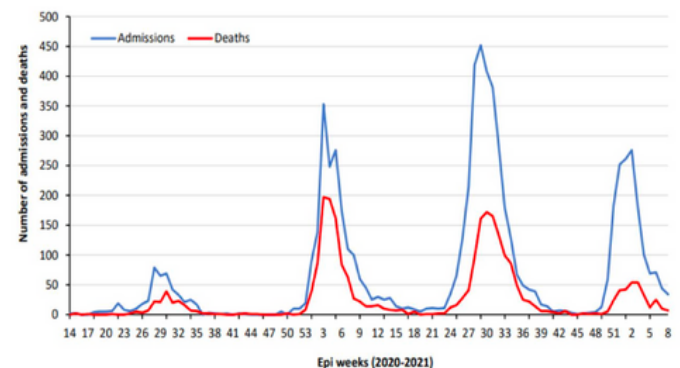


Figure 2: Hospital admissions and Deaths for COVID-19 in Malawi from April 2020 – December 2021 (PHIM surveillance unit).⁹

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The third wave saw the highest number of hospitalizations, while the second wave recorded the highest number of deaths from COVID-19. Admitted COVID-19 patients receiving oxygen varied by wave as well, with fewest requiring oxygen during the 4th Omicron wave (17% vs 62% in the third wave).(10) Deaths from COVID-19 affected males more than females (64.2% of those who died were male), and tended to occur in the older population groups, with a median age of 61 years.(9)

The government of Malawi's response to the COVID-19 pandemic included bolstering the healthcare workforce by recruiting an additional 5,622 health workers, including 179 medical doctors, 325 nursing officers, 86 clinical officers and 233 laboratory personnel. The government also declared a national emergency in March 2020 and again in January 2021, which limited individual travel and required schools to close in an attempt to curtail the spread of the virus but stopped short of enforcing a complete lockdown.

These states of emergency led to a reduction in access to essential health services and challenges in delivering routine care.(11) For HIV services, studies showed a significant reduction in demand for HIV testing, voluntary medical male circumcision, and pre-exposure prophylaxis.(12) For maternal, newborn and child health (MNCH) services, the COVID-19 response led to reductions in outpatient department consultations, institutional deliveries, and reductions in antenatal care visits.(13,14) A reduction in overall outpatient visits was also reported.(15)

Oxygen supply and clinical use landscape in Malawi

Oxygen supply and demand

As part of the 2021 National Oxygen Ecosystem Roadmap development, the Ministry of Health estimated the national oxygen need to be approximately 1.4 billion liters per year (Table 2). (16) This was estimated using the UNICEF Oxygen System Planning tool.(17)

Facility type	Number of health facilities	Number of hypoxicemic cases per year	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	4	100,579	16,942,200	2,492	206,130,000	30,313
Community hospital	2	1,107	181,350	27	2,206,500	324
District hospital	25	171,868	29,561,790	4,347	359,668,380	52,892
Health centre	457	618,396	39,472,350	5,805	480,246,900	70,625
Mission hospital	27	55,471	20,682,090	3,041	251,632,080	37,005
Rural hospital	25	59,497	8,316,270	1,223	101,181,420	14,880
Total	541	1,006,918	115,156,050	16,935	1,401,065,280	206,039

Table 2: Oxygen demand from the Medical Oxygen Ecosystem roadmap

These estimates represent a routine care scenario and do not factor in surges in oxygen need due to spikes in COVID-19 cases that were present at the time of planning, or surge needs that will occur in the future. These surges were significant enough to cause widespread oxygen shortages, especially during the second and third COVID-19 waves in Malawi.

Medical oxygen supply in Malawi comes in several forms. The primary bulk liquid oxygen supplier is AFROX Malawi, which has two liquid oxygen storage tanks in the central and southern region of Malawi. AFROX imports liquid oxygen from South Africa and converts to it to gas in country. Health facilities then buy oxygen cylinder refills, with procurement coordinated by individual facilities, who pay directly to AFROX based on the number of cylinders consumed.

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Most cylinders found in public facilities have historically been procured via this method. A biomedical equipment survey conducted by PATH in 2021 found a low availability of cylinders in many facilities.(18) However, this is likely an underestimate of current availability, and doesn't necessarily reflect newer cylinder distribution models, given the numerous new procurements done during the COVID-19 pandemic.

Additional bulk oxygen capacity is available via Pressure Swing Adsorption (PSA) oxygen plants that have been installed in a number of public sector hospitals by the Ministry of Health and its partners. As of April 2023, ten active PSA plants are co-located at health facilities across the country, with nine more planned or awaiting procurement and installation. These PSA plants are located at mostly district hospitals and Central hospitals. Only one community hospital has a PSA plant on site. As these PSA plants become functional, a shift towards a 'hub and spoke' model coordinated by larger hospitals may occur. In terms of clinical use, most cylinders are used directly at the bedside of patients.

Oxygen concentrators also play a major role in oxygen delivery in Malawi, even in facilities that have other bulk oxygen production capacity. A biomedical equipment survey in 2022 reached 490 health facilities and documented the availability of oxygen concentrators (Table 3), and pulse oximeters (Table 4).(19) This report highlighted that availability of concentrators and pulse oximeters remains a major challenge, particularly at the lowest levels of the health system, and that even when equipment is available it is often non-functional.

A major challenge identified was facilities receiving devices from numerous sources, both before and during the COVID-19 pandemic, and as a result facilities end up managing multiple different brands and models of the same device type. For example, this survey identified 50 unique concentrator manufacturers and 49 pulse oximeter manufacturers;(19) many of these devices have specialized training needs but lack adequate documentation. Another challenge is that this equipment are often not equally distributed at a sub-national and sub-district level, resulting in inequitable access.(20)

Facility Type	Number of facilities included	Average number of concentrators per facility	Percent of concentrators that are functional	Percent of facilities with at least one functional concentrator	Average availability gap vs. MOH standards
Central Hospitals	4	167	74%	100%	34%
District Hospitals	24	26	71%	88%	74%
Rural/Community Hospitals	2	1.5	100%	50%	94%
Health Centres	460	0.7	86%	24%	85%
Total	490	1630	76%	28%	84%

Table 3: Availability of oxygen concentrators in public-sector facilities in Malawi¹⁹

Facility Type	Number of facilities included	Average number of oximeters per facility	Percent of oximeters that are functional	Percent of facilities with at least one functional oximeter	Average availability gap (% vs. MOH standards)
Central Hospitals	4	120.8	89%	100%	0%
District Hospitals	24	20.5	98%	83%	48%
Rural/Community Hospitals	2	0	--	0%	100%
Health Centres	460	1	97%	18%	68%
Totals	490	1434 units total	95%	21%	66%

Table 4: Availability of pulse oximeters in public-sector facilities in Malawi¹⁹

Clinical use of oxygen in Malawi

Regulation and oversight of medical oxygen lie primarily with the Pharmacy Medicines Regulatory Authority (PMRA). However, standards that regulate oxygen production and delivery exist only in draft form as of December 2023. The Ministry of Health, through its Directorate of Clinical Services, has been primarily responsible for developing clinical guidelines and training resources for healthcare workers.

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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.(21) 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. Previous studies have found the prevalence of hypoxia in this population to range from 8% to 28%.(22)

Among children under-five, hypoxemia is the primary fatal complication of pneumonia, affecting 13.3% of children with pneumonia according to the WHO.(23) The UN Inter-Agency Group on Child Mortality Estimates conclude that about 26,000 children died in Malawi in 2021; the Malawi Ministry of Health estimates that 11% (2,860) of these deaths were attributed to pneumonia.(24) A study by McCollum et al. in five hospitals found that 5.3% of hospitalized Malawian children under 15 years old were hypoxemic and, while there was more hypoxemia among children with respiratory illness, it was also spread across children with other diagnoses, such as malaria and sepsis.(25)

Pulse oximetry was not routinely used, and only 22.5% of children needing supplemental oxygen, as defined by WHO guidelines, were given oxygen.(25) A recent analysis in Malawi has also reported implementation of WHO guidelines without pulse oximetry will miss high risk cases of pneumonia, highlighting the need for routine pulse oximetry to improve outcomes.(26)

Oxygen is also used among surgical patients. Hypoxemia occurs in about 30% of all surgical cases in the early post-operative period, and it is recommended that all surgical cases receive supplemental oxygen, which has been demonstrated to reduce the incidence of postoperative hypoxemia. Data for this group in Malawi specifically was not found. Similarly, very few studies have estimated the prevalence of hypoxemia in the rest of the population in this setting. In a previous study in two hospitals, 4% of admitted adults were found to be hypoxemic, with only 11% receiving oxygen treatment at the time of assessment. (27)

A 2019 study reported that COPD prevalence was 0.9% in the population.(28) However, we found no published reports on oxygen use among this patient population outside the hospital, and lack of data about chronic respiratory disease in Malawi has been reported as a key gap previously.(29)

Financing an oxygen system

Organisation of the system

Governance of the Malawian health system has been nominally decentralized since the passage of the Local Government Act of 1998. Primary and secondary healthcare delivery are managed by Health Center Management Committees, who are in turn overseen by District Health Management Teams, and ultimately by District Councils and their leadership (Figure 3).(30)

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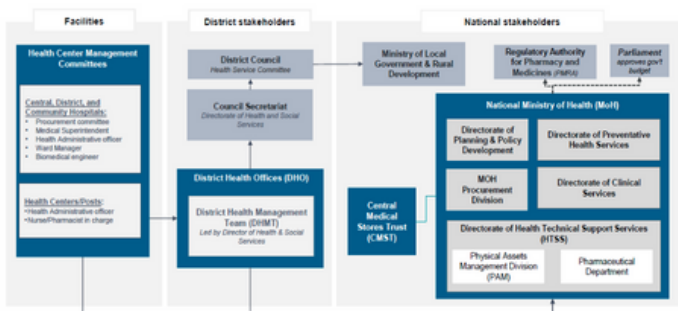


Figure 3: Public sector medical devices stakeholders in Malawi

In practice, however, these decentralization reforms were never fully implemented, and have been reversed in some cases. Local governments account for less than 5% of total government spending,⁽³¹⁾ so district health budgets are heavily dependent on central-level transfers, which often come earmarked and with little opportunity for district input.

Since 2005, District Council leadership has been appointed by central-level entities (the Office of the President and Cabinet, and the Ministry for Local Government, Unity, and Culture) rather than by local elections which was the case between 1998 and 2005.^(32,33) For these reasons, de facto power and decision-making authority within the health system remains highly centralized, as depicted in the government stakeholder influence map in Figure 4.

For respiratory care equipment, the Ministry of Health's Physical Assets Management (PAM) Division, which sits within the Directorate of Health Technical Services (HTSS) has the broadest scope of responsibility and authority of any individual stakeholder. They are responsible for most aspects of medical device

management, including planning and conducting procurement, determining device allocation and arranging distribution, and overseeing maintenance and repair of devices. However, these responsibilities intersect with other Ministry of Health departments in important ways, leading to some overlap and an evolving division of roles between departments.

For example:

- While PAM prepares budget requests for medical device procurement and operation (based on compiled submissions from the DHMTs), final funding decisions and allocations are made by the MoH Planning Department.
- PAM must also work in coordination with the MoH Procurement Division for any procurements that they manage directly; the Procurement Division's mandate is to ensure adherence to key transparency and competitiveness regulations.
- PAM is also not the only agency who can conduct procurements; the Central Medical Stores Trust (CMST), which sits outside the MoH, has historically focused on pharmaceutical products, but has increasingly taken on procurement of medical device consumables and smaller medical devices. This leads to a blurring of lines between PAM's and CMST's procurement duties.
- While respiratory care devices are managed under PAM, oxygen as a drug, falls under the purview of the MoH Pharmacy Division as it is considered an essential medicine. Both divisions fall under the same directorate (HTSS), but this dynamic has the potential to complicate management decisions and information sharing related to oxygen delivery.

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- For example, the Pharmacy division has a robust supply chain management system for medicines, but that system has not been extended to medical devices in part because of the separation of roles between the two divisions.

In addition, there are a large number of private, non-profit, and donor organizations that play a role in oxygen and respiratory care delivery. A non-exhaustive list of key organisations, their relative power and interests are shown in Table 5. Malawi's stakeholder structure and political economy were a critical influence in shaping the government's response to COVID-19, the passage of the Oxygen Ecosystem Roadmap, and ultimately the financing of oxygen in general.

Engagement across this broader group of stakeholders occurs primarily through the National Oxygen Taskforce. At the height of the COVID-19 pandemic the Taskforce met bi-weekly to identify specific partner and health system needs, coordinate oxygen-related activities, and endorsing key policy documents. The Taskforce represented a critical venue for developing, revising, and championing the National Oxygen Ecosystem Roadmap, and had continued to meet (albeit less frequently) to address ongoing oxygen access challenges.

Centralized decision-making enabled oxygen champions

Prior to the COVID-19 pandemic, the Malawi Ministry of Health had already been involved in a variety of oxygen and respiratory care-related research, innovations, investments, and projects. For example:

- The Child Lung Health Program, funded by the International Union Against Tuberculosis

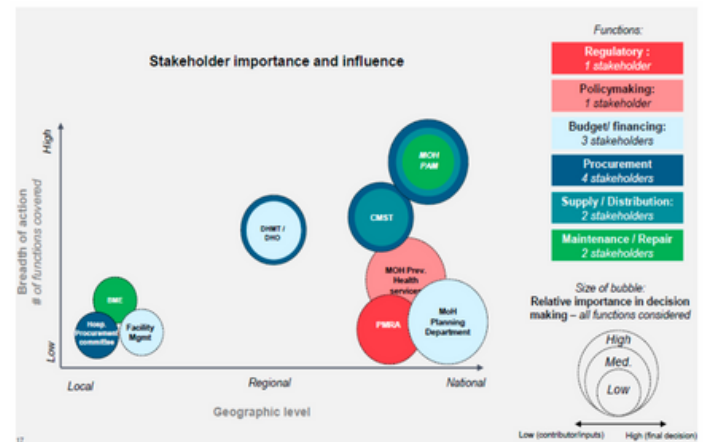


Figure 4: Malawi public sector stakeholder influence map

- and Lung Disease and the Gates Foundation, standardized inpatient case management for severe forms of pneumonia in children,(34) and provided oxygen concentrators to paediatric units in Malawi central and district hospitals between 2002 and 2004.(35)
- The set-up of oxygen for surgical care, with a nationwide implementation of tailored anaesthetic systems was first done in the 1980's and roll-out of pulse oximeters with Lifebox in 2014.(36–38)
- Queen Elizabeth Central Hospital was one of the original partners involved in developing and testing the Pumani bubble CPAP device in 2012.(39) Queen Elizabeth Central Hospital, Kamuzu Central Hospital and the University of Malawi College of Medicine have all led a variety of CPAP research in subsequent years. This research also involved international institutions like Rice University, Baylor University, Johns Hopkins University, University College London, and University Medical Centre Utrecht in the Netherlands. (39–41)

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Stakeholder	Type	Power and Interest
Health Center Management Committees – Central District and Community Hospitals*	Public sector	Have authority within health facility and the catchment areas. Can advocate for more resources to area, but also distribute resources towards oxygen within their budget allocation.
National Ministry of Health – Directorate of Clinical Services*	Public Sector	Responsible for providing leadership in all hospital-based care. Advocates for oxygen needs, can aggregate demand for oxygen, can advocate for more financing towards oxygen allocation.
National Ministry of Health – Directorate of Health Technical Support Services (HTSS)*	Public Sector	Responsible for equipment procurement guidance, maintenance of equipment, service contract management, supply chain of diagnostics and other drugs. Can advocate for more procurement of oxygen equipment.
PATH*	NGO	Technical partner with broader visibility in oxygen ecosystem, expertise of development of roadmaps, costing and developing implementation arrangements. Strong advocacy skills to lobby for more oxygen resources.
FHI 360*	NGO	Supporting MoH in implementation of liquid oxygen in country.
Clinton Health Access Initiative (CHAI)*	NGO	Supporting MoH in implementation of liquid oxygen in country.
Catholic Relief Services (CRS)*	NGO	Supports training of HCWs in COVID-19 case management and oxygen delivery.
Medecins Sans Frontiers*	NGO	Supports in training, testing of COVID and maintenance of medical equipment.
Build Health International*	NGO	Supporting maintenance and training of BMEs in PSA plants.
NEST 360	NGO	Technology partner supporting neonatal care. Donates and trains medical engineers and end users of technologies in patient care.
Right to Care	NGO	Supports donations of oxygen equipment and training of HCW.
BMGF	Donor	Major donor of respiratory care and oxygen interventions.
USAID*	Donor	Major donor of respiratory care and oxygen interventions especially investments in liquid oxygen.
USG	Donor	Major donor of respiratory care and oxygen interventions especially liquid oxygen.
UNICEF*	Donor, multilateral	Supports training of HCW, and supply chain of RCE commodities. Supporting procurement of a PSA plant.
World Bank	Donor	Finance institution that provides loans and grant support for health care goods and services; provided emergency investments during the pandemic to support response efforts.
WHO*	Donor, multilateral	Provides technical support for clinical management and health systems.
Afrox	Private company	Private supplier of medical oxygen. Holds majority share of private market for medical oxygen.
Mission Pharma	Private company	Private supplier of medical equipment and consumables. Offers training, installation, and maintenance/repair services in Malawi.
Pulse Medics Equipment	Private company	Private supplier of Airsep concentrators, Airsep PSA plants, and installers of medical gas piping systems.

Table 5: Oxygen-specific stakeholders in Malawi. *Regular participants in the Malawi Oxygen Taskforce. NGO = non-governmental organization.

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- In 2015, The Paediatric and Child Health Association of Malawi partnered with the Ministry of Health to develop an extensive Care of Infants and Newborns training curriculum, which included substantial focus on oxygen.(42)
- The NEST360o partnership has also been operating in Malawi since 2019, introducing a package of newborn respiratory care technologies and supporting pre-service and in-service education for clinicians and biomedical engineers.

These prior investments related to oxygen access ensured that key leaders within the Ministry of Health and clinicians in the largest teaching hospitals were knowledgeable about critical oxygen gaps and needs, had positioned themselves as champions for those needs, and had developed effective working relationships with local and international academic and policy organizations. When the COVID-19 pandemic hit, these champions already had well-established credibility and experience engaging with external partners and donors.

The government's centralized power structure also played a key role in amplifying these champions' voices during the COVID-19 pandemic. As noted above, despite a nominal push for decentralization, de facto decision-making power remains concentrated among a few national-level stakeholders. For oxygen, this core decision-making group included most of the champions from earlier research and investment, and their voices and views carried outsized influence because there were so few other stakeholders involved.

The Oxygen Taskforce, which was established during the pandemic and was critical to organizing the COVID-19 response and passing the Oxygen Ecosystem Roadmap, was a key manifestation of this centralized power structure. The Taskforce served as a central forum to map out and coordinate various partner interventions, and for those partners to identify strategic, mutually beneficial areas of collaboration.

For example, PATH, UNICEF, and Partners in Health were able to use the Taskforce to coordinate the launch of both the Oxygen Ecosystem Roadmap and the complementary Emergency and Critical Care Strategy. The Taskforce also served as an accountability mechanism for all stakeholders involved. For example, the Roadmap's implementation framework identified specific actions, responsible organizations, and timelines for completion that were revisited frequently during Taskforce meetings. Finally, the Taskforce served as a forum for reinforcing and building deep and personal working relationships across key stakeholder organizations, ensuring more effective communication and collaboration.

However, despite its overall effectiveness there are some downsides to Malawi's centralized decision-making structure. While key experts and champions had influential voices, the centralization of power led to a very top-down approach to implementing key interventions, with less-than-ideal involvement of healthcare workers and leaders. For example, although district leaders and district hospital staff are part of the Oxygen Taskforce and were invited to all of the meetings, attendance among sub-national participants was much

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lower, due in large part to the high workload during the COVID-19 pandemic. As a result, the ideas and concerns of local-level staff may not have been captured reliably for key Taskforce decisions.

Additionally, a centralized power structure for oxygen in Malawi has proven challenging to maintain in a global health landscape, given diverse interests and priorities (often driven by other competing centralized decision structures) from within the Oxygen Taskforce membership. For example, the Oxygen Roadmap did not originally contain plans to invest in liquid oxygen within the first five years, due to a lack of piping and absorptive capacity in health facilities and the lack of a liquid oxygen production facility within Malawi (and the associated supply risks of importing liquid oxygen from a neighbouring country). Nevertheless, liquid oxygen investments are underway, because of available funding through a broader, multi-country liquid oxygen initiative. Such divergent priorities will likely continue to crop up, putting pressure on the government's centralized structure and plans.

Pre-existing data enabled rapid decision-making, but systems are needed for planning

The large body of local oxygen-related research mentioned above also provided the Ministry of Health with a variety of useful data at the outset of the pandemic, and in many cases the Ministry of Health was able to turn that data into quick decisions and actions. For example, clinical research in hypoxemia prevalence impact of oxygen treatments in pneumonia patients, and value of pulse oximetry was critical to helping to advocate for the importance of oxygen, using evidence-

based research.(43–46) The fact that Malawian Ministry of Health officials comprised many of the research co-authors only improved how quickly the research could be put into action.

In addition, PATH had conducted a biomedical equipment survey for oxygen equipment in January of 2020 (the activity was part of a multi-country effort that was planned prior to the pandemic) and updated that initial data with a rapid assessment in June of 2020.(18) Other equipment-focused assessments included: the Malawi Service Provision Assessments from 2014;(47) NEST360's initial facility evaluations focused on availability of oxygen equipment in district hospital NICUs; and the Malawi Emergency and Critical Care (MECC) survey.(48)

Together, these data sources helped the government quickly understand where there were supply gaps in oxygen equipment and convey the need to donor agencies. This is reflected in funding applications like the government's application to the Global Fund COVID-19 Response Mechanism.

On the other hand, routine monitoring and reporting systems were not already in place, and the government faced challenges in managing data flow and took time to establish reporting systems. One particularly acute challenge arose around tracking equipment donations. Public health facilities could receive donations directly from private parties, and the government did not have a system in place to track what was being donated where. As a result, the Ministry of Health could not effectively allocate incoming equipment because it couldn't update its initial equipment gap assessments with information about new

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donations. Additionally, for oxygen specifically, there was a high occurrence of well-meaning donors buying and donating industrial oxygen cylinders, which cannot be used in a medical setting. Had there been a proper system in place for coordination and tracking of donations, there could have been stronger messaging on proper cylinder specifications – and could have allowed the Ministry of Health to advocate for its oxygen priorities more effectively.

Another data challenge was the continued prevalence of paper-based clinical record systems. Handwritten patient records are difficult to read, aggregate, and analyse in real time. As a result, only basic statistics were recorded and reported to the central level, such as the total number of patient admissions per week or per month. Detailed records about COVID-19 patient outcomes weren't being used to assess what was happening at the patient level. These data and reporting challenges were amplified by shifts in the broader government power and funding structure resulting from the COVID-19 pandemic response.

Once a national disaster was declared the Department of Disaster Management Affairs took charge of coordinating pandemic response and routing large financial donations from both the Government and external donor agencies.⁽⁴⁹⁾ A National COVID-19 taskforce was also formed, with each participating Ministry (including Health) responsible for developing their own activities to support COVID-19 response. While this was a sensible COVID-19 response framework, it led to new and additional steps in the data and decision-making flow for key leaders in the Ministry of Health, especially the technical working groups that were traditionally responsible for things like

clinical policy or budgeting/financing. In part due to these new reporting and decision-making structures, it was hard to track and manage spending from donors like the IMF and World Bank,⁽⁵⁰⁾ and difficult for MoH leaders to secure typical resources needed to distribute donated or newly purchased goods from the central level to the health facilities.

Catalyzing oxygen investment through policy action

The launch and dissemination of the National Oxygen Roadmap offers important lessons on the use of policy action to stimulate investment. First, as part of the launch process, the MoH planned an extensive advocacy campaign using several dissemination channels:

- Invited the Chair of the Health Committee of Parliament to review the roadmap and give the keynote speech at the Roadmap launch event itself.
- Engaged the World Health Organization, a key dissemination partner in planning the main launch event.
- Presented the Roadmap and costed implementation plan to a consortium of the main health donors in Malawi.
- Engaged news media, including an article printed in Nyasa Times, a prominent local online news platform.
- Travelled to the Districts to disseminate the roadmap and implementation plan; timed visits to coincide with district implementation plans and budget requests; also created template implementation plans to enable their quick completion.
- Included printed copies of the Roadmap with each respiratory care equipment delivery.

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- Engaged the Global Fund's principal recipient throughout the roadmap development as part of the oxygen taskforce; scheduled advocacy meetings once there was detailed information on key respiratory care access gaps and fundable activities in the implementation plan.

These launch and dissemination efforts created several advantages in stimulating oxygen investment. First and perhaps most importantly, the specific, delineated implementation plan and associated cost estimates made it easy for partners and donors to identify investment opportunities that aligned with their mission and funding situations. For example, the Global Fund and World Bank saw and responded to the need for additional bulk oxygen production; once the PSA plants they funded are operational, Malawi is expected to sufficient bulk oxygen production to meet the needs estimated in the Roadmap.

The Roadmap also helped implementing partners demonstrate to their donors how individual projects mapped back to the overarching goals of improving oxygen access. This approach of using a national strategic plan to direct coordinated action has previous success stories in Malawi.(51)

Additionally, the presence of Ministry of Health leaders who can speak to the Roadmap in detail has begun to drive important changes to internal policies and procedures. The PAM Directorate, for example, was able to successfully expand staffing for biomedical engineers to ensure that they would be stationed in all hospitals slated to receive PSA plants in the Roadmap. The Clinical Services

Directorate has made significant progress in securing expansion of oxygen services at the health clinic level.

That said, funding for oxygen in Malawi remains a work in progress. As of June 2023, only about 30% of the Roadmap had been fully financed, leading to many concerning gaps. For example, while capital investments such as PSA plant procurements have been covered by the World Bank and Global Fund, the on-going and consumable costs, such as maintenance of those PSA plants is not well funded after their current service contracts expire. Additionally, some oxygen funding went to uses outside of the initial Roadmap implementation plan, in many cases driven by divergent organizational interests. The liquid oxygen example mentioned above, for example, as well as PSA plants installed in smaller facilities not on the Roadmap's list of facilities.

A midline assessment of the Roadmap, will be a key opportunity to track progress toward implementation, and adapt the approach based on evolving priorities, new assessments, and the experiences and lessons described above. The goal of this assessment is to refocus government, donor, and partner attention on the most important gaps and priorities, and in doing so accelerate the path to greater financing for oxygen needs.

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Additional methods information

The information in this case study was assembled in two phases – firstly for an internal report conducted by PATH in 2022 which involved academic and grey literature searches and key informant interviews. This was then complemented with a narrow rapid review of academic literature on the political economy of oxygen.

Desk-based review

An initial literature search used Google, Google Scholar, and PubMed to identify relevant academic and grey literature in several categories:

1. Academic literature documenting the long **history of respiratory care research in Malawi** by the Ministry of Health, universities, and teaching hospitals. Key search terms included “Malawi” + [“respiratory distress” or “hypoxemia” or “pneumonia” or “respiratory care” or “oxygen” or “oxygen access” or “bubble CPAP” or “ventilation” or “pulse oximetry”].
2. Academic or grey literature focused on the **COVID-19 pandemic and the government’s response effort**, specifically the impact on respiratory care systems. Key search terms included “Malawi” + [“COVID-19” or “coronavirus” or “pandemic”] + [“impact” or “response” or “preparedness”].
3. Academic or grey literature focused specifically on **analyzing health sector stakeholder influence in Malawi**. Key search terms included “Malawi” + [“health” or “health sector”] + [“influence mapping” or “political economy analysis” or

“decentralization”]. Almost all resulting literature focused on political decentralization in Malawi, and its impact on various sectors including healthcare.

4. Official **government strategy and policy documents** outlining broad, “on-paper” stakeholder responsibilities.
5. Academic and grey literature **assessments of individual health sector functions** in Malawi, such as health financing or procurement. Key search terms included “Malawi” + [“health” or “health sector”] + [“financing” or “procurement” or “supply chain” or “management”]

Key informant interviews

For the stakeholder importance and influence mapping, PATH conducted a series of key informant interviews from January to May of 2022 with administrative and technical leaders whose roles span key aspects of oxygen and medical device management (e.g., supply and distribution, financing, procurement, service delivery, and maintenance). Key informant interviews lasted between 30 minutes and one hour, and focused on several general topic areas within each interviewee’s domain of expertise:

- What are the typical processes within that domain (e.g., financing, procurement, maintenance) and how do they apply to medical device management?
- Who are the key stakeholders they interact with on a regular basis with respect to medical device management, and what are those interactions like?
- How would they characterize the power dynamics and incentives for each of these key stakeholders?

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Position and Organization	Relevance
Chief Procurement Officer, Ministry of Health	Highlight MOH role in medical device procurement
Procurement Officer, Central Medical Stores Trust	Role of CMST in medical device and oxygen procurement; relationship with PAM
Director, JM Diagnostics	Private sector distributor perspective on medical device supply and relationships with public sector stakeholders
Chief Operations Officer, Medical Consultants Africa Ltd	Private sector distributor perspective on medical device supply and relationships with public sector stakeholders
Deputy Director, Physical Assets Management Division, MOH	Detail PAM role in oxygen and medical device financing, procurement, and maintenance
Acting Head, Department of Emergency and Clinical Services, MOH	Illustrate the MOH Pharmacy division's role in oxygen management, and relationship with other MOH entities
Medical Council of Malawi	General overview of medical device stakeholders; role of civil society organizations
Pediatric and Child Health Association	General overview of medical device stakeholders; role of civil society organizations
Chief Economist, Planning Department, MOH	Detail the strategic role of MOH Planning Department; interaction with Ministry of Finance
Principal Economist, Planning Department, MOH	Detail tactical role of MOH Planning Department; interactions with PAM and other operational stakeholders
Principal Economist, Planning Department, MOH	Detail tactical role of MOH Planning Department; interactions with PAM and other operational stakeholders
Regional Management Unit engineer, PAM, MOH	General overview of medical device and oxygen management at subnational level; role of stakeholders in financing and directing device maintenance
Regional Management Unit engineer, PAM, MOH	General overview of medical device and oxygen management at subnational level; role of stakeholders in financing and directing device maintenance
Director of Programs, CHAM	CHAMS offers 40% of health services in Malawi and trains 80% of health workforce.
Marketing Manager, AFROX	Largest/Majority private supplier of medical oxygen in Malawi.

Table 6: Key informant interview participants

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Rapid scoping review

A more formal rapid scoping review was also conducted, using a standardized approach across the case studies - the results of the search are presented in the Prisma diagram below.

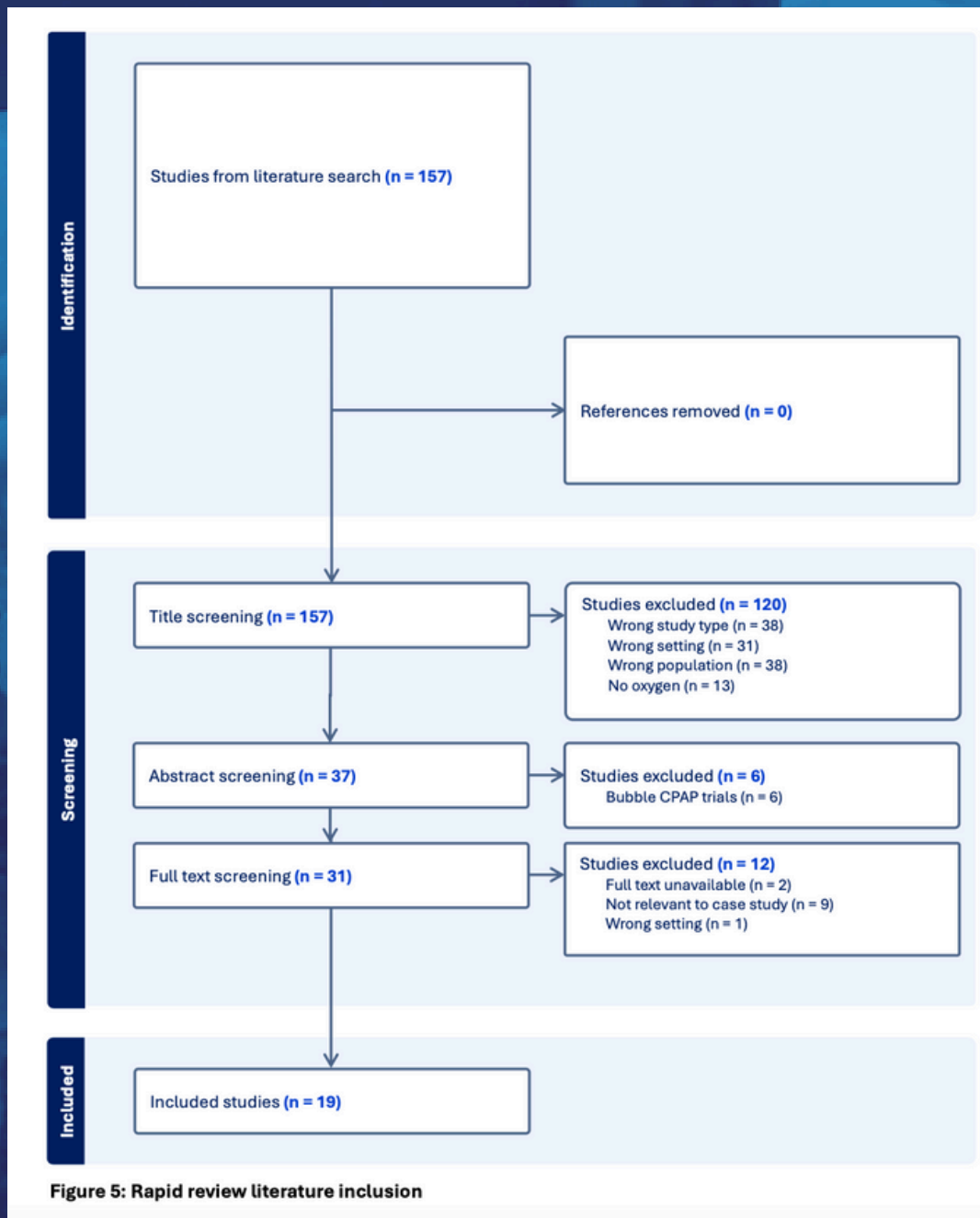


Figure 5: Rapid review literature inclusion

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ABOUT THE COMMISSION

Announced in September 2022, *The Lancet Global Health* Commission on Medical Oxygen Security provides a thorough exploration of medical oxygen coverage gaps, with recommendations to ensure that no patient dies for lack of access to this essential medicine, including during public health emergencies like COVID-19.

The Commission was led by 18 Commissioners - multi-disciplinary academics with clinical, economic, engineering, epidemiological, and public policy expertise - representing all regions of the world. Forty Advisors representing United Nations and global health agencies, donors, academic institutions, and non-governmental organizations provided guidance. A large global network of Oxygen Access Collaborators provided constant input to the Commission and included representatives from industry and Ministries of Health. Special consultations were conducted with patients, caregivers, and clinicians to ensure that their voices and experiences shaped the Commission's recommendations.

An Executive Committee coordinated the work of the Commission and included representatives from **Makerere University**, Uganda; **International Centre for Diarrheal Disease Research (icddr,b)**, Bangladesh; **Murdoch Children's Research Institute (MCRI)**, Australia; **Karolinska Institutet**, Sweden; and **Every Breath Counts Coalition**, USA.

You can find the Commission report [here](#) and the advocacy package [here](#), including:

- **Report with Comments**
- **Policy Brief (English, French, Spanish, Arabic, Chinese, and Russian)**
- **Spotlight Brief: Access to Medical Oxygen Scorecard (ATMO₂S)**
- **Spotlight Brief: Patient and Caregiver Testimonials**
- **Spotlight Brief: 10 Oxygen Coverage Indicators**
- **Spotlight Brief: 20 Priority Areas for Oxygen Innovation**
- **Country Case Studies**



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