Federal Republic of Nigeria

NATIONAL STRATEGY FOR THE SCALE-UP OF MEDICAL OXYGEN IN HEALTH FACILITIES

2017 - 2022

Federal Ministry of Health

National Strategy for the Scale-up of Medical Oxygen in Health Facilities

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TABLE OF CONTENTS

ACKNOWLEDGEMENTS

The *National Strategy for the Scale-up of Medical Oxygen in Health Facilities in Nigeria* emerged as a Federal Ministry of Health led process, and was developed in consultation with stakeholders from a diversity of backgrounds and expertise in the public health arena. With the primary goal of reducing morbidity and mortality from limited hypoxaemia management in Nigeria in the next five years and beyond, these stakeholders have focused their attention on developing a strategy that will achieve the stated goal:

Federal Ministry of HealthState Ministries of Health: Anambra, Lagos

National Primary Health Care Development Agency

State Primary Health Care Board: Niger

National Hospital Abuja

Federal Medical Centre: Keffi

Bill and Melinda Gates Foundation

University College Hospital/University of Ibadan

Maiduguri University Teaching Hospital

University of Melbourne's Centre for International Child Health

Nigerian Association of Biomedical

Engineers and Technologists

Air Liquide

Air Separation

Pharmacists Council of Nigeria

Nigerian Medical Association

World Health Organisation

United Nations Children's Fund

Clinton Health Access Initiative

University of Abuja Teaching Hospital

Jos University Teaching Hospital

Hospital Management Boards: Bauchi, Kano, Lagos, Niger, Rivers

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ACRONYMS

CHAI	Health Access Initiative
COPD	Obstructive Pulmonary Disease
COREN	Council for the Regulation of Engineering in Nigeria
DHIS	District Health Information System
DRF	Drug Revolving Fund
EEL	Essential Equipment List
EFCC	Economic and Financial Crimes Commission
EWS	Early Warning Sign
FMoH	Federal Ministry of Health
GAPPD	Global Action Plan for Pneumonia and Diarrhoea
HCW	Heath Care Worker
HMB	Hospital Management Board
ICU	Intensive Care Unit
KPI	Key Performance Indicator
kPa	kilopascal
LGA	Local Government Area
LMIS	Logistics Management Information System
LPM	Litres per minute
LRS	Low Resource Settings
LWG	Logistics Working Group
MDAs	Ministries, Departments and Agencies
MoF	Ministry of Finance
NABET	Nigerian Association of Biomedical Engineers and Technologists
NPHCDA	National Primary Health Care Development Agency
NAFDAC	National Agency for Food and Drugs Administration and Control
NHIS	National Health Insurance Scheme
NHMIS	National Health Management Information System
NHSDP II	National Strategic Health Development Plan 2
NIMR	Nigerian Institute of Medical Research
NSO	National Standing Order
NSTG	National Standard Treatment Guidelines
O2	Oxygen
OPD	Out-Patient Department
OR	Operating Room
PHC	Primary Health Centre
PIPD	Paediatric Inpatient Department
POx	Pulse Oximeter
PPP	Public Private Partnership
PSA	Pressure Swing Adsorption
QIT	Quality Improvement Team
SDGs	Sustainable Development Goals
SHF	Secondary Health Facility
SMoH	Ministry of Health

SON	Standards Organization of Nigeria
SOPs	Standard Operating Procedures
SPHCMB	State Primary Health Care Management Board
SpO2	Arterial Haemoglobin Oxygen Saturation as measured by Pulse Oximetry
TEC	Evaluation Committee
THF	Tertiary Health Facility
TWG	Technical Working Group
UCH	University College Hospital
WHO	World Health Organization

FOREWORD

In Nigeria, more than half a million deaths annually are caused by 10 diseases associated with hypoxaemia. In children under five years of age, hypoxaemia is a major complication of pneumonia, and is responsible for 120,000 deaths per year. Yet, effective oxygen therapy in children can reduce mortality due to pneumonia by 35%, and is also essential for severely ill neonates, safe surgery, anaesthesia, and obstetric care.

Across the three tiers of health facilities in Nigeria, access to life-saving oxygen therapy is limited at best. Fragmented oxygen supply systems, irregular power supply, and limited maintenance of relevant equipment frustrate efforts to provide affordable and reliable oxygen therapy. Additionally, despite its importance in both acute and severe illnesses, hypoxaemia is often not well recognized or managed in health facilities in Nigeria. Pulse oximeters are in limited availability, or non-functional due to absence of spare parts, and are consequently not routinely used in facilities.

The Federal Ministry of Health recognizes these challenges, and in line with the National Strategic Health Development Plan 2, seeks an integrated approach to resolving the persistent bottlenecks to delivering adequate hypoxaemia management in Nigerian health facilities. More specifically, the National Strategy on the Scale-up of Medical Oxygen in Health Facilities in Nigeria will create an enabling environment for medical oxygen scale-up in the country and strengthen oxygen supply systems. Indeed, the strategy exemplifies the federal government's commitment to a multi-stakeholder approach to addressing head-on, challenges in the country's healthcare system.

To this effect, the strategy has identified five areas of intervention to drastically improve availability and access to adequate hypoxaemia management in the short –term: (i) policy and financing; (ii) availability of diagnostics and oxygen supply systems; (iii) clinical practice and equipment maintenance; (iv) patient acceptance and uptake of medical oxygen; and (v) data collection and use for hypoxaemia management. These intervention areas will be complemented by structural changes within Nigeria's health system.

Furthermore, the strategy provides an implementation framework for scaling up medical oxygen in health facilities. It is intended as a guide for resource mobilization towards these efforts, and for the development of implementation tools including standard operating procedures and technical specifications for devices and equipment, which will strengthen efforts to ensure that expanded access to medical oxygen is sustained beyond the short-term.

The Federal Ministry of Health enjoins partners to refer to this document as the blueprint for medical oxygen scale-up in Nigeria. FMoH will lead coordination and implementation of this strategy to save lives and improve the well-being of Nigerians.

Professor Isaac Adewole FAS, FRCOG, FSPSP, Dsc (Hons)
Honourable Minister of Health

EXECUTIVE SUMMARY

Globally, hypoxaemia is a major cause of morbidity and mortality, and in Nigeria, 625,000 deaths each year are attributable to ten disease conditions associated with hypoxaemia. These clinical conditions include asthma, chronic obstructive pulmonary disease (COPD), interstitial lung disease and pulmonary sarcoidosis, lower respiratory infections, and pneumoconiosis. Hypoxaemia is a major fatal complication of pneumonia in children, responsible for an estimated 120,000 deaths each year in Nigeria. To end these preventable deaths, prompt diagnosis and treatment of hypoxaemia should be available in all hospitals and medical units. The World Health Organization (WHO) recommends pulse oximetry as the most cost-effective method for detecting and monitoring hypoxaemia. Medical oxygen is the life-saving therapy for hypoxaemia, and can be supplied by concentrators, cylinders, or oxygen plants.

Currently, Nigerian clinicians rely heavily on clinical signs to diagnose pneumonia in Nigerian facilities and the use of pulse oximetry to diagnose hypoxaemia is minimal In addition, a multi-facility baseline assessment was conducted in 832 primary, secondary, and tertiary facilities across eight1 Nigerian states in 2016. Of secondary and tertiary health facilities assessed, only 55% provided functional oxygen therapy and 11% provided pulse oximeters. In PHCs, availability of oxygen and pulse oximetry was even lower. Access to safe and efficient oxygen is limited by a lack of clear policies and guidelines, adequate funding, limited availability of functional oxygen[1] supply systems, weak maintenance systems for equipment, and inadequate skills and expertise among health workers and technicians.

The National Strategy for the Scale-up of Medical Oxygen in Health Facilities aims to reduce mortality and morbidity from hypoxaemia in Nigeria by addressing these gaps in access. Specifically, the National Strategy will increase access to oxygen supply systems over the next five years by achieving the following objectives:

1. Create an enabling environment for management of hypoxaemia;
2. Improve availability of high-quality diagnostics and oxygen supply systems;
3. Improve clinical use of oxygen and maintenance of equipment by healthcare teams
4. Increase acceptance and uptake of affordable oxygen among patients with hypoxaemia and their caregivers; and
5. Strengthen collection, management, and use of high-quality data for hypoxaemia management

In line with the principles of the National Strategic Health Development Plan 2 , a set of interventions will be implemented across facility types and throughout different levels of the health system in Nigeria. Availability of oxygen will be addressed systematically, and the supply model needs will be supported by adequate maintenance, training, financing,

1.Functional oxygen is defined as having either a functioning concentrator and a nasal cannula or catheter available; or a completely or partially filled cylinder with a pressure gauge, regulator, flow meter, and humidifier attached. Additionally, the cylinder must be attached to a wheeled trolley and a nasal cannula or catheter available.

organization, and monitoring. Successful implementation will rely on strong leadership and coordination, broad stakeholder engagement, and dedicated resources.

Improving access to high-quality, appropriate, and functional oxygen supply systems has the potential to significantly reduce mortality from hypoxaemia in Nigeria. For children, improved oxygen access coupled with clinical training, supervision and improvements in broader patient care practices has demonstrated a reduction in mortality due to pneumonia by 35%. The Federal Ministry of Health of Nigeria is committed to working with state governments, health facilities, and relevant stakeholders to make oxygen access a key priority. The National Strategy for the Scale-up of Medical Oxygen in Health Facilities provides the framework to guide conception and roll out of improved access pulse oximetry and oxygen.

1. BACKGROUND

1.1 Hypoxaemia

Hypoxaemia, insufficient oxygen in the blood or low blood oxygen saturation, is a major cause of morbidity and mortality associated with acute and chronic lung disease in adults and can lead to death irrespective of age, sex, aetiology, geographic region or clinical presentation of a patient. In Nigeria, it is estimated that more than 625,000 deaths a year occur due to diseases associated with hypoxaemia, with the majority of these deaths caused by anaemias, congenital anomalies, and respiratory conditions including asthma, chronic obstructive pulmonary disease (COPD), interstitial lung disease and pulmonary sarcoidosis, lower respiratory infections (e.g. pneumonia, bronchiolitis), and pneumoconiosis[2]. From a surgical perspective, oxygen is critical in operating theatres and anaesthesia, as well as during recovery periods in intensive care units (ICUs).[3-4]

For children, hypoxaemia is a major fatal complication of pneumonia, the leading cause of under-five mortality in the country, responsible for approximately 120,000 deaths each year[5] .The risk of death from pneumonia increases with increasing severity of hypoxaemia. In a recent systematic review of more than 16,000 children with acute pneumonia or other lower respiratory tract infections worldwide, the median hypoxaemia prevalence of children with severe pneumonia requiring hospitalization was 13.3%[6]. Additionally, in secondary health facilities in Nigeria, 25% of neonates and approximately 12% of under-5 children admitted to hospital with pneumonia are hypoxaemic on admission[7].

The ability to quickly detect and treat hypoxaemia is therefore critical to patient care. While the gold standard for measuring oxygen saturation is blood gas analysis, it is invasive and expensive. Detection of hypoxaemia based on clinical signs is also suboptimal due to insufficient sensitivity and specificity[8,9]. The World Health Organization (WHO) advocates for pulse oximetry as the most cost-effective method for detecting and monitoring hypoxaemia (e.g., saturation level of <90%) in hospitals .[10]

Hypoxaemia is treated by administering oxygen, which is included on the WHO list of essential medicines - and by treatment of the underlying cause. WHO guidelines also emphasize the importance of oxygen within the necessary package of providing care for seriously ill children, and for emergency, anaesthesia and surgical services in district and provincial hospitals.

Despite the importance of oxygen supply systems across all types of acute and severe illnesses, effective diagnosis and management of hypoxaemia in Nigeria is limited by

2. Secondary analysis conducted by CHAI of Nigeria hypoxia-related deaths using the Global Disease Burden Study 2013, and other literature review
3. WHO. (2015, November). WHO Model List of Essential Medicines - 19th List (April 2015).
4. WHO. (2009). Implementation Manual WHO Surgical Safety Checklist 2009. Retrieved April 2017, from World Health Organization: http://apps.who.int/iris/bitstream/10665/44186/1/9789241598590_eng.pdf
5. UNICEF. A Promise Renewed Progress Report 2015. September 2015
6. Subhi R, et al. The prevalence of hypoxemia among ill children in developing countries. Lancet Infect Dis. 2009;9.
7. Unpublished data, Graham H, Falade A.G., May 2016
8. Weber M, et al. Predictors of hypoxemia in hospital admissions with acute lower respiratory tract infection in a developing country. Arch. Dis. Child. 1997; 76(4):310-314.
9. Lodha et al. Can clinical symptoms or signs accurately predict hypoxemia in children with acute lower respiratory tract infections? Indian Pediatrics, 2004, Volume 41, pp 129-135
10. WHO. Oxygen Therapy for Children. 2016.

limited access to effective diagnostic tools and medical oxygen, low use of diagnostics and of oxygen, as well as the absence of supportive clinical governance and equipment maintenance systems. Previous studies have shown that improved oxygen systems – including the use of pulse oximetry and oxygen by trained staff – have potential to reduce mortality from childhood pneumonia by 35%.[11]

1.2 Pulse Oximetry

There are four categories of pulse oximeters—benchtop, handheld, fingertip, and mobile device (see Figure 1). Both finger-tip and handheld oximeters are portable and the latter are more durable. Benchtop pulse oximeters are mostly used in operating theatres and intensive care units, though some models of handheld pulse oximeters have this functionality as well. When maintained in good condition, pulse oximeters can have a lifespan of up to eight years.[12] Components such as sensor probes and wiring are the most prone to damage and account for the high failure rate of pulse oximeters.[13]

Stationary/benchtop	Handheld	Fingertip	Mobile device
 Stationary, continuous operation/monitoring pulse oximeter.	 Hand-held portable device that can be used for both one-off readings (diagnostics & spot checks) or for continuous monitoring.	 Portable device used for one-off (diagnostics & spot checks) readings.	 Hand-held portable device used for one-off (diagnostics & spot-checks) readings.

Figure . Overview of Pulse Oximetry Options

1.3 Oxygen Supply Systems

There are three main sources of oxygen supply—cylinders, concentrators, and oxygen plants (see Figure 2). Cylinders serve as reservoirs for high purity oxygen compressed under high pressure and require refilling from a reliable source once depleted. Cylinders do

11. Duke T et al. Improved oxygen systems for childhood pneumonia: a multihospital effectiveness study in Papua New Guinea. Lancet 2008; 372(9646):1328-1333.
12. Burn SL et al. Peri-operative pulse oximetry in low-income countries: a cost–effectiveness analysis. Bulletin of the World Health Organization. 2014;92(12):858-867. doi:10.2471/BLT.14.137315.
13. Crede S. et al. Where do pulse oximeter probes break, Journal of Clinical Monitoring and Computing 2014, Volume 28, Issue 3, pp 309-314

not require electricity for oxygen delivery. Safe oxygen delivery via cylinder requires that they be used uniquely for medical-grade oxygen, and be properly fitted with the right components such as a compatible pressure gauge, regulator, and flow meter. (A humidifier may also be required but not for low flow oxygen delivered via nasal prongs, catheter or a mask). Although hardly conducted, maintenance of cylinders and their components, when required, is provided by the suppliers at the point of refill as the cylinders themselves are often leased from a centralized gas supplier. The need for frequent refilling of cylinders requires transportation which can be prohibitive from a logistical, cost, and even security perspective thereby introducing supply risks. Cylinders frequently leak 20-50% of their contents, due to faulty or poorly fitted regulators.

Oxygen concentrators are devices that concentrate oxygen from ambient air using pressure swing adsorption (PSA), most commonly. Concentrators are small and light enough to be wheeled around wards as needed, though are generally stationary at the bedside. Depending on the model, oxygen can be split between multiple patients at any given time. These devices are 100% reliant on electricity and also depend on quality and consistent preventative maintenance to ensure an acceptable oxygen output.

Oxygen cylinders	Oxygen concentrators	Central oxygen source / Oxygen plant
 High pressure O2 supplied via portable canisters/cylinders delivered to facilities.	 Oxygen enriched gas is supplied by entraining air from the environment and separating oxygen from nitrogen using pressure swing adsorption (PSA)	 Oxygen is provided via a large, on-site, central source and piped directly to terminal unit (point of use). Can be done cryogenically or by PSA.

Figure . Overview of Main Oxygen Supply Options

Oxygen plants can generate medical-grade oxygen in one of two ways—either using PSA or cryogenically to form bulk liquid oxygen. Oxygen plants are capital intensive, but their capacity and efficiency can be increased by setting up pipes to provide oxygen directly to wards. Excess capacities can be stored in cylinders and made available to neighbouring health facilities at a charge, thereby generating revenue for that facility. At scale, they are the most cost-effective of all oxygen supply systems – though depend on highly robust maintenance. Oxygen plants are designed to function 24 hours a day and can last up to 25 years if properly maintained. In the Nigerian context, PSA plants are preferred; large bulk liquid oxygen tanks can also be installed on-site and used as a filling station to fill cylinders for back up, but they require high technical knowledge and bear the greatest risk in settings with extreme temperature and humidity conditions. It may present as a safety issue where leakages arise as oxygen is a fire hazard.

Caution!

Oxygen supports combustion. Concentrated oxygen present near a fire greatly increases its intensity and can even support the combustion of materials which normally do not burn.

This is not a technical guidance document. The FMoH assumes no responsibility for the mishandling or otherwise inappropriate use of oxygen. Anyone having contact with oxygen, including, but not limited to, technicians and clinicians, shall undertake comprehensive trainings on the safe administration and handling of oxygen and related commodities, along with associated risks.

In facilities where power is unreliable, the choice for oxygen supply systems has tended strongly towards oxygen cylinders. Depending on the number of available hours of electricity, generators that also function as filling stations for oxygen cylinders can be used. Despite these challenges with concentrators, several countries – Malawi, Egypt, Papua New Guinea, Gambia and even now in the South-West of Nigeria – have successfully implemented their use in conjunction with dedicated solar power installations in health facilities.[14] New technologies are currently under field testing that store oxygen at low to medium pressure, resulting in substantial improvements in overall energy efficiency.

14. Schneider, G. Oxygen supply in rural Africa: a personal experience. The International Journal of Tuburculosis and Lung Disease, 2001 June; 5(6): 524-6.

2. SITUATION ANALYSIS

In Nigeria, facility-based studies have been conducted to better understand the current management of hypoxaemia, as well as availability and supply of oxygen supply systems in the country. As early as 2002, Mokuolu and Ajayi published an economic case for concentrators based on the use of an oxygen concentrator in the neonatal unit of the University of Ilorin Teaching Hospital.[15] An unpublished survey by Nuhu et al (2013) assessed anaesthesia workforce and infrastructure including oxygen and pulse oximeters in 14 public hospitals in Plateau state. Additionally, a case study of oxygen plants, oxygen supply, cost, and use in four tertiary hospitals was conducted in 2015.[16] The University of Ibadan/University College Hospital (UCH) Ibadan, in collaboration with the University of Melbourne, (Australia) also assessed the capacity of 12 secondary health facilities (SHFs) in four states of south-west Nigeria to provide oxygen to sick children.[17] In 2016, the Clinton Health Access Initiative (CHAI), in partnership with the government, conducted a multi-facility oxygen assessment in eight states to measure detection of hypoxaemia and availability of oxygen supply systems in selected facilities. In addition, a national supply and maintenance landscape assessment was conducted.[18]

2.1 Current Management of Hypoxaemia

Evidence suggests that reliance on clinical signs is common practice in Nigeria and the use of pulse oximetry in surveyed facilities to diagnose hypoxaemia is minimal. The study in southwest Nigeria found that hospitals did not routinely assess children using pulse oximetry and only three out of 12 hospitals assessed had pulse oximeters in paediatric areas. Most children who needed oxygen did not receive it – oxygen was administered to less than 20% of children with probable hypoxaemia, and oxygen was often ceased prematurely. Despite general under use of oxygen, it was still given to many children who probably did not need it.

This finding was corroborated in the multi-facility oxygen assessment in eight states where only a subset of PHCs (3%) and referral facilities (24%) had pulse oximeters. Among all the SHFs and THFs visited, 75% had paediatric inpatient departments (PIPD). Of these facility PIPDs, only 24% attested to having pulse oximeters; however, only 11% of these were functional (Figure 3). In addition, the assessment showed that up to 41% of outpatient cases with probable hypoxaemia were not admitted, implying that a large proportion of OPD cases with severe pneumonia are inappropriately treated on an outpatient basis.

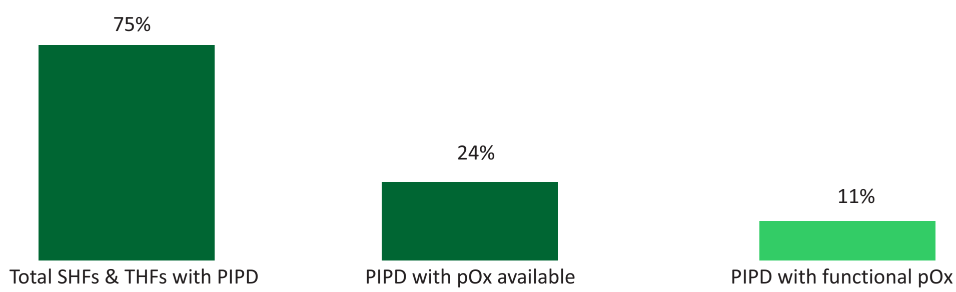


Figure 3. Availability of Pulse Oximeters in SHFs & THFs (n=181) (Source: CHAI Facility Audits, 2016)

15. Mokuolu O.A. and Ajayi O.A. Use of an oxygen concentrator in a Nigerian neonatal unit: economic implications and reliability. Annals of Tropical Medicine. 2002;22:209-2012.
16. Study conducted by Dr. Sanusi Ibrahim (University of Maiduguri Teaching Hospital). The tertiary facilities in the case study include Jos University Teaching Hospital, University of Port Harcourt Teaching Hospital, Lagos University Teaching Hospital, and University of Maiduguri Teaching Hospital.
17. Graham HR, et al. Oxygen for children and newborns in non-tertiary hospitals in South-west Nigeria: A needs assessment. African Journal of Medicine and Medical Sciences. 2016; 45: 31-39. States include Oyo, Ondo, Ogun, and Osun.
18. CHAI. Oxygen Supply and Maintenance Landscape, 2017. Based on data from facility audits carried out in 651 PHCs and 181 SHFs and THFs in eight states (Lagos, Kaduna, Kano, Niger, Rivers, Bauchi, Cross Rivers and Katsina).

2.2 Current Availability of Oxygen Delivery Systems

Current availability of oxygen delivery systems in surveyed facilities is also lower than desired levels. The study in the southwest found that while all hospitals had some access to oxygen cylinders and concentrators, this was limited by inadequate power supply and poor maintenance capacity. However, the vast majority of oxygen concentrators tested was found to be unsuitable for use – one-third was simply blowing out air. One hospital conducted preventative maintenance while four hospitals could attempt onsite repairs. Pulse oximeters were routinely used for paediatric cases in only one of the 12 hospitals. The study in Plateau state found no pulse oximeters or oxygen delivery systems in any of the 14 hospitals surveyed.

Similarly, the multi-facility oxygen assessment in eight states found that only 4% of PHCs assessed had functional oxygen equipment[19] in the form of cylinders and concentrators; 67% of PHCs providing oxygen therapy used cylinders as the primary source of oxygen. A wide variation in the frequency of refilling cylinders was observed with some facilities refilling fortnightly and others only once a quarter. For SHFs and THFs, 55% of facilities provided oxygen therapy; of these facilities, oxygen is provided using cylinders (80%), concentrators (47%), and plants (4%). Thirty-seven percent of these referral facilities rely on more than one source of oxygen delivery systems. Similar to pulse oximeters, oxygen supply was mainly available in operating theatres and maternity wards. However, neonatal units were most likely of the units in the public hospitals to have provided oxygen therapy to patients (93%). The oxygen supply mix across 96 facilities is provided in Figure 4.

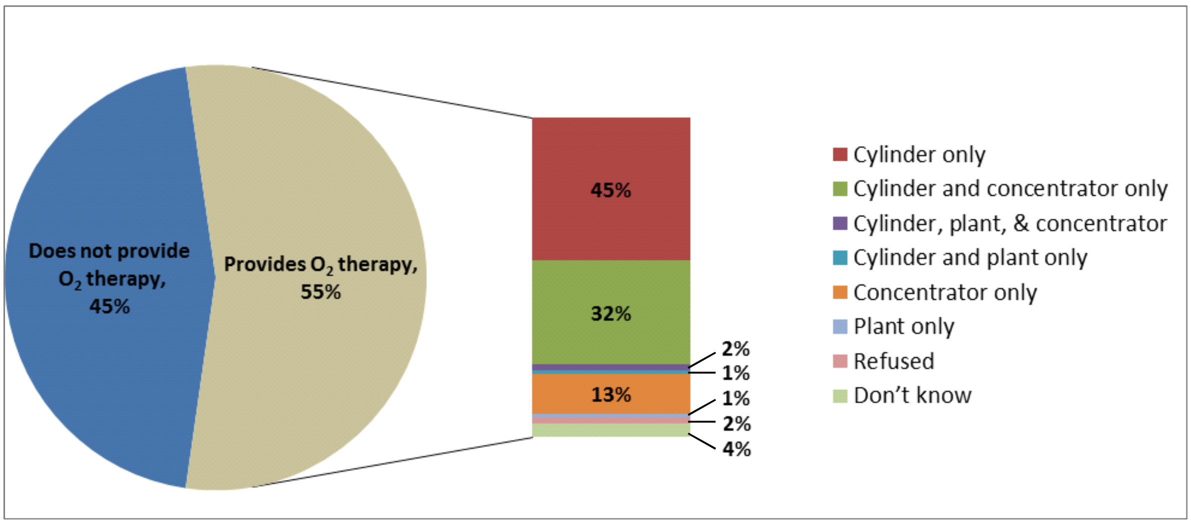


Figure 4. Oxygen Supply Mix in SHFs and THFs (n=96 facilities) (Source: CHAI Baseline Assessment, 2016)

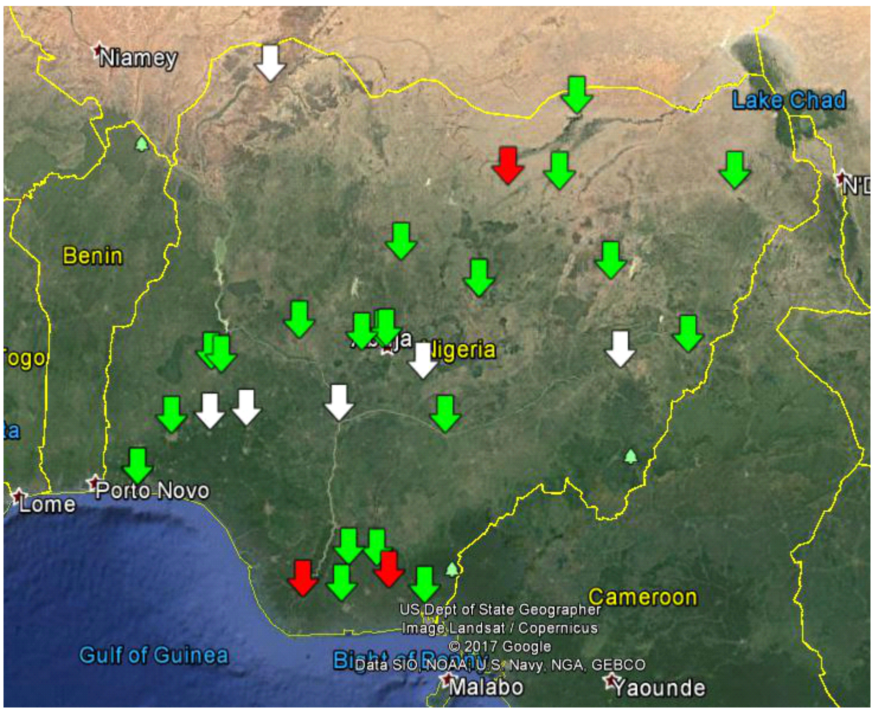
19. Refer to glossary for definition of functional oxygen

2.3 Supply and Maintenance Landscape

There is a range of oxygen products and brands on the Nigeria market.[20] In hospitals surveyed in the eight-state oxygen assessment, various desktop, handheld, and fingertip pulse oximeters were found. A wide variety of pulse oximeter brands across the different types are available on the market. At the time of the study (2016), the retail price of fingertip pulse oximeters ranged from N 8,000 to N 22,500 (median price of N10,000) and handheld pulse oximeters from N35,000 to N205,000. Outside the warranty of medical equipment, directly purchased, repair and maintenance of pulse oximeters in hospitals are often carried out by an in-house engineering/biomedical department when broken or functioning at a sub-optimal level.

For oxygen, cylinders are also widely used; empty cylinders can be rented for as little as N4,000 and refilled for N980 per cubic meter depending on the source and size of the cylinders.[21] The cost to patients ranges between N600 and N7,000 per hour; in some cases patients are charged a flat fee or costed per cylinder used. The University of Ibadan study revealed that oxygen cylinders were expensive, costing hospitals N96,000 to N2.2 million per year in refill costs alone. The cost to patients is also expensive, averaging from 1,000 per day to N2,000 per hour.[22]

Oxygen concentrators are also used in Nigeria; 18 brands of concentrators were found in facilities surveyed and as of 2016, could be purchased from various distributors in Nigeria at a range of N 180,000 to N 420,000. However, to operate at optimal capacity, concentrators require a 100% power supply and regular preventive maintenance and repair. With up to 96% of SHFs and THFs having limited access to in-house technicians to meet maintenance requirements, and lacking consistent supply of device-specific spare or



20. CHAI, Oxygen Supply and Maintenance Landscape Assessment, 2017.
21. BOC gases refill prices as provided by a BOC gases representative in Kaduna
22. Graham H. Oxygen: an update on latest research guidelines. Oxygen Implementation Project Nigeria.

replacement parts, increased downtime of the equipment remains a challenge. This contributes, immensely, to the supply gap of stable oxygen therapy.

Facility-based oxygen plants have remained limited in Nigerian hospitals due to initial high capital requirement. Additionally, the 2015 case study of 4 facility-based plants found that factors such as inadequate power supply and wear-and-tear on pipes delivering oxygen to hospitals wards are threats to optimising the use of such plants. There are three main oxygen plant developers in the country—OGSI, Airsep, and Oxymat—and two cryogenic plants owned and operated by BOC Gases Nigeria. Bas ed on currently available data, there are at least 30 plants, of varying capacity, established in the country; 21 of these plants are purportedly functioning, 6 are of an unknown status, and three are non-operational (see Figure 5). However, it is unknown which plants operate at full capacity. In addition, this landscape does not include plants in the private sector.

3. KEY BARRIERS TO ACCESS

Several barriers constrain access to safe and efficient oxygen delivery systems[23,24,25]. In February of 2016, the FMoH convened a meeting with key stakeholders—representing federal and state health agencies, health facilities, oxygen suppliers, clinicians, and biomedical engineers—and identified key barriers to oxygen access in Nigeria. These barriers cut across the eight priority areas for the National Strategic Health Development Plan 2 (NSHDP II), which underscores the complexity of challenges across the health system in addressing the low oxygen access issue in the country.

Policy and regulatory barriers

At the federal level, the National Standard Treatment Guidelines (NSTG), Essential Equipment List (EEL), and National Standing Orders (NSO) have been updated to recommend oxygen and pulse oximetry. These policies will need to be disseminated and adopted at the state level. While pulse oximeters and oxygen delivery systems are classified as medical devices by the National Agency for Food and Drug Administration and Control (NAFDAC), their regulatory status are not clearly defined. At a leadership level, strong clinical governance structures are needed to appropriately monitor and manage the administration of medical oxygen in health facilities.

Financial barriers

At the state level, limited funds have been allocated to support adequate and sustainable procurement and maintenance of oxygen delivery systems contributing to the low availability of oxygen in public health facilities. Owing to associated costs to refill and transport cylinders to their point of use, patients are sometimes required to bear the high costs of receiving medical oxygen. In some instances, oxygen is not administered until payments have been made by patients. As mentioned above, these costs could range between N600 and N7000 per hour across the different types of oxygen therapy.[26]

Facility/structural barriers

Only a handful of plants in the country are operating at optimal capacity due to inadequate maintenance and management structures. This is due to technical challenges, knowledge gaps in oxygen plant management, lack of efficient training of contractors and maintenance teams, management loggerheads and a high turnover of trained staff. Lack of adherence to planned preventive maintenance programs also contributes to the problem.

Procurement and maintenance need systems that go beyond individual health facilities. Currently, technical expertise at the facility and state level to support procurement, installation, and maintenance of oxygen delivery systems is insufficient. In addition, state budget funds are not enough to support on-going installation and essential preventative maintenance and procurement processes are non-existent or non-functional.

23. Graham H, et al. Oxygen for children and newborns in non- tertiary hospitals in South-west Nigeria : A needs assessment. Afr J Med Med Sci. 2016;45(June).
24. Graham H, et al. Providing oxygen to children in hospitals: a realist review. Bulletin of the World Health Organization. 2017; 95:288-302.
25. CHAI. Oxygen Supply and Maintenance Landscape Assessment. March 2017
26. CHAI Baseline Assessment, 2016

Weak referral systems

Referral networks from the community level to higher levels of care (PHCs, SHFs, and THFs) are generally weakened by institutional and organizational barriers. At the community level, low awareness about hypoxaemia and a lack of understanding about the need for referrals are primary reasons for delayed care-seeking and poor compliance with referrals. Poor perceptions of the quality of care delivered in referral facilities may also contribute to low follow-through with referrals. Additionally, the absence of established and functional emergency transport systems, high transportation costs, and difficult geographical terrains also pose barriers to care-seeking at health facilities.

At the facility level, low levels of knowledge and skills among healthcare workers to promptly diagnose hypoxaemia in patients, limit their ability to perform critical triaging and initiate timely referrals where necessary. The lack of standard operating procedures (SOPs) or clear protocols for referrals of hypoxaemic cases, which clearly delineate roles and responsibilities of all involved from the referring facility to referral facilities, constrains the effectiveness of referrals across the continuum of care. Most referral facilities are often not equipped and prepared to receive and manage referred cases. Referrals are often not included as a strong component of supportive supervision. In addition, facilities often lack the appropriate documents for referrals and existing M&E systems and reporting systems do not include the appropriate data for tracking and managing referrals between different levels.

Supply barriers

As mentioned above, there is a wide range of brands and models of pulse oximeters and oxygen sources in public health facilities in the country. This lack of uniformity results in procurement of sub-standard equipment and consumables as well as a lack of standardization of spares not only across manufacturers, but also models. In facilities where oxygen sources do exist, there is a lack of access to appropriate delivery and monitoring devices (e.g., nasal prongs, catheters, analysers, etc.). In addition, frequent interruptions in power supply force many facilities to rely on alternate and backup power sources, which can be expensive and incur recurring costs particularly when oxygen concentrators are used.

Supply stock-outs often occur due to administrative bureaucracies for the release of funds, supplier unreliability, and high transportation costs. Stock-outs can also occur when demand for oxygen supersedes available supply, which can be exacerbated by down time of equipment, poor quantification of needs, and delay and/or lack of coordination in refilling cylinders.

Within facilities, there is often a lack of strong distribution systems of produced oxygen from plants to patients in wards (e.g., no piping or manifolds). There are also no clear arrangements guiding the movement and transportation of filled or empty cylinders (between wards or hospital departments) or of empty cylinders from the respective ward to the plant.

Provider/Human Resources for Health barriers

A lack of knowledge among health providers about the clinical usage of oxygen and user-level maintenance of oxygen supply equipment contributes to low levels of utilization and the reduced lifespan of oxygen equipment, respectively. The use of pulse oximeters is critical for accurately diagnosing hypoxaemia, but many providers are not familiar with the equipment or do not have the skills to properly analyze and evaluate results. Moreover, in the presence of commodities, there remains a lack of adherence to best practice protocols and guidelines for diagnosis and management of hypoxaemia in health facilities.

Adequate maintenance and management is critical for fully functional mechanical devices; however, trained biomedical engineers and technicians to provide reliable equipment maintenance and repair are not always available and adherence to planned preventive maintenance programs is low. These challenges are largely due to knowledge gaps in oxygen plant management, availability and access to spare parts and limited motivation of technicians.

Caregiver barriers

Demand for oxygen remains low due to misconceptions of oxygen therapy in the community. For example, caregivers often perceive that medical oxygen kills and often associate it with terminal cases. Therefore, caregivers may be reluctant to place children on oxygen therapy without adequate counselling from the health provider. Oxygen therapy is not perceived as routine in the treatment of cases such as severe pneumonia in children. Where oxygen therapy is recommended, access to oxygen supply is often restricted as oxygen is prioritized in ICU and operating theatres compared to paediatric wards.

4. CURRENT GOVERNMENT AND PARTNERS' EFFORTS

The Federal Ministry of Health (FMoH) and several partners are already supporting efforts to improve access to oxygen delivery systems in the country, including in the areas described below:

Partner	Area(s) of intervention
FMoH and NPHCDA	NSTGs and NSOs have already been revised to include oxygen and pulse oximeters for use at health facilities. Revisions to the Essential Equipment List to include oxygen and pulse oximeters will be completed in 2017.
WHO	Providing technical guidance on oxygen therapy in health facilities including through documents such as the 'oxygen therapy for children: a manual for health workers' (2016), and 'technical specifications for oxygen concentrators' (2015). Leading advocacy efforts through the integrated Global Action Plan for Pneumonia and Diarrhoea (GAPPD).
UNICEF	Co-launched GAPPD with WHO in 2009 to develop a multi-sectoral approach to protect, prevent, and treat childhood pneumonia and diarrhoea in a coordinated manner.
CHAI	Improving availability of pulse oximeters and oxygen by accelerating policy change, translation, and implementation in three states (Kano, Kaduna, and Niger).
Engineering World Health (EWH) and Duke University	Training Nigerian facility-based biomedical technicians to repair and service biomedical equipment in facilities. This is a GE Foundation funded project.
Lifebox	Facilitating the transfer of pulse oximeters and probes, manufactured in Taiwan, to hospitals globally, including Nigeria.
Malaria Consortium	Testing community case management of chest in-drawing pneumonia in children in Niger (Lapai and Paikoro LGAs).
Maternal Child Survival Program (MCSP)	Supporting selected SHFs and THFs in three states (Kogi, Cross River, and Ebonyi) to improve oxygen therapy for newborn care—part of the "sick newborn corner" total care package—through clinical trainings, remote mentoring, and procurements.
Maternal, Newborn, & Child Health Programme (MNCH2)	Working in six high burden states in Northern Nigeria to improve the quality and delivery of MNCH services in this region. Supporting state government by improving availability of pulse oximeters and oxygen by procurement of relevant equipment.
University of Ibadan/ University College Hospital and University of Melbourne	Scaling up a comprehensive oxygen system in 12 secondary hospitals in four states of southwest Nigeria (Oyo, Ondo, Ogun, Osun).
Funding partners	The Bill & Melinda Gates Foundation funds the work implemented by CHAI and by the UI/UCH/UniMelb consortium. USAID supports work on MCSP. DFID funds the MNCH2 programme in Nigeria.
Private sector	Key private sector players are currently and/or have the capacity to manufacture and distribute medical grade oxygen as part of their core business, including Air Separation Nigeria Ltd, Air Liquide, BOC gases, and United Gases.

5. STRATEGIC FRAMEWORK

Vision

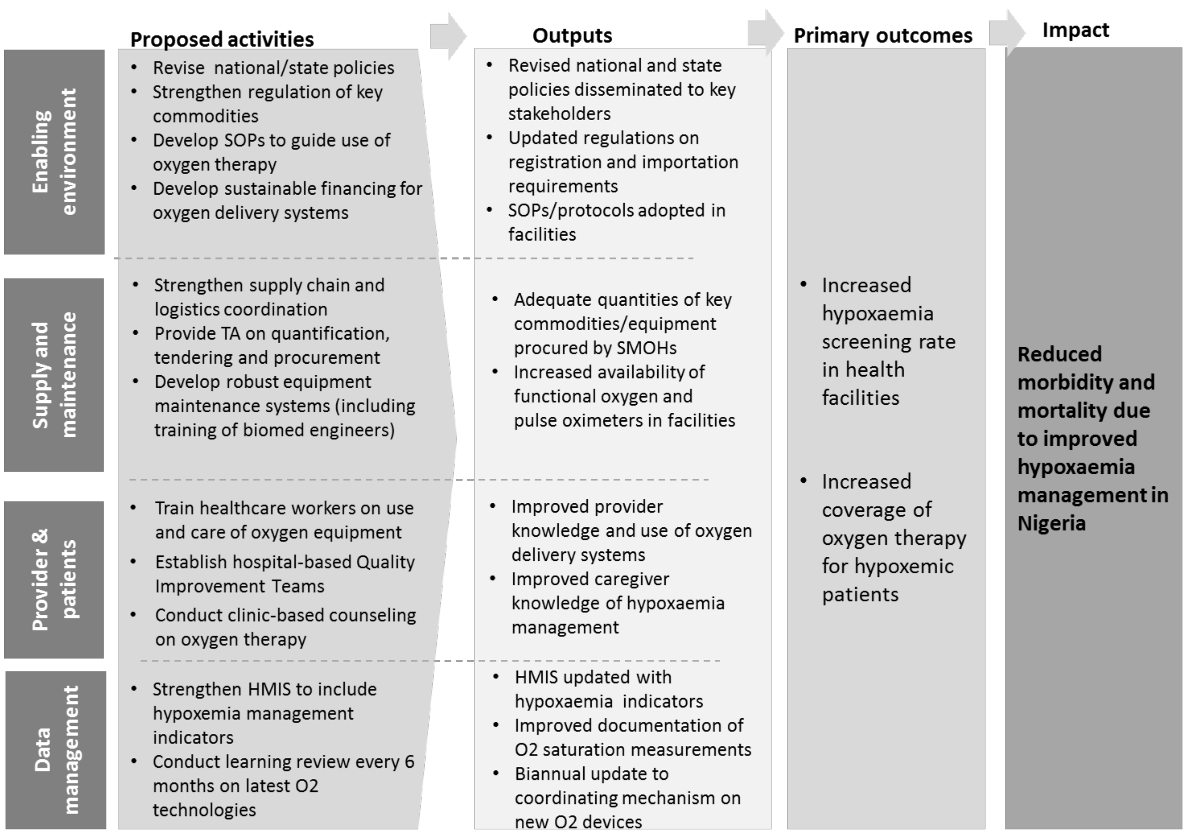
The vision of the National Strategy for the Scale-up of Medical Oxygen is to ensure that no patient admitted to health facilities in Nigeria dies from hypoxaemia. The overall goal is to reduce morbidity and mortality due to hypoxaemia in Nigeria by addressing the key barriers limiting access to diagnostics and oxygen delivery systems in health facilities. The National Strategy provides a framework for all major actors—government, facilities, implementing partners, and private sector—involved in the planning and implementation of diagnostics and oxygen delivery systems.

Objectives

To reach this goal, the National Strategy aims to achieve the following objectives by 2022 (see Figure 6):

1. Create an enabling environment for management of hypoxaemia;
2. Improve availability of high-quality diagnostics and oxygen delivery systems;
3. Improve clinical use of oxygen and maintenance of equipment by healthcare teams
4. Increase acceptance and uptake of affordable oxygen among patients with hypoxaemia and their caregivers; and

Strengthen collection, management, and use of high-quality data for hypoxaemia management



6. IMPLEMENTATION STRATEGIES

The National Strategy will be implemented under the overarching framework of the National Strategic Health Development Plan 2 (NSHDP 2), which aims to strengthen the national health system to vastly improve the health status of Nigerians. The NSHDP 2 articulates the following strategic pillars for improving healthcare delivery in Nigeria:

- Enabled environment for attainment of sector outcomes: the National Strategy should create the right framework and environment to ultimately improve patient outcomes and save lives;
- Increase utilization of essential package of health care services: the Strategy should encourage appropriate use of oxygen therapy services among patients;
- Strengthened health system for delivery of package of essential health care services: the Strategy should articulate interventions that strengthen the Nigerian health system;
- Protection from health emergencies and risks: the Strategy design should incorporate emergency planning for all relevant health sector components; and
- Predictable financing and risk protection: the Strategy should outline steps for sustainably financing scale-up interventions and for ensuring oxygen therapy is prioritized for health insurance.

Following the above principles of the NSHDP 2, the following section outlines a set of interventions to strengthen the health system to effectively deliver quality services for patients with hypoxaemia. Specifically, these interventions will address key barriers limiting widespread and sustainable access to oxygen delivery across facility types and throughout different levels of the health system in Nigeria. This section includes an overview of requirements and considerations for implementing an efficient and sustainable model as well as roles and responsibilities of relevant stakeholders to ensure smooth implementation. For such a system to be implemented, availability of oxygen needs to be addressed systemically, and the supply model needs to be supported by adequate maintenance, training, financing, organization, and monitoring.

Objective 1:
Create an enabling environment formanagement of hypoxaemia

Intervention 1: Revise national/state policies to recommend the use of oxygen and pulse oximeters

The FMoH and NPHCDA will work with key professional associations, civil society, relevant parastatals, and partners to identify relevant national and state policies and guidelines for revision, and develop new guidelines for oxygen commodities for the different facility levels. Specific policies that have already been revised to include oxygen and pulse oximeters include the NSTG and the NSO. Revisions will need to be disseminated at national level and adopted at state and LGA levels through the relevant departments, agencies, and other implementing partners.

Health facilities can be accredited for achieving certain standards of practice. Led by relevant agencies including COREN and NABET, a systematic institutionalised training program for hospital technicians, will also be implemented.

Intervention 2: Create coordinating mechanisms for oxygen scale-up at national and state level

Led by FMOH and SMOH respectively, national and state coordinating mechanisms for oxygen scale-up, will be instrumental to ensuring effective implementation of the National Strategy, with continuous feedback established among state and national teams. Details of the reporting structure for these mechanisms are provided in Section 7 Coordination and Management of the National Strategy.

Intervention 3: Develop sustainable financing for oxygen delivery systems

The Government will garner strong political will to ensure the prioritization of efficient oxygen delivery systems in health facilities. States and health facilities should explore sustainable funding mechanisms—such as inclusion in facility drug revolving fund schemes (DRFs), annual operational budgets, and other functional state-funded free MNCH services programmes—to reduce the financial burden on patients and improve the value chain for oxygen delivery. These can also be linked to clearly defined mechanisms which will play a key role in ensuring sustainability and affordability to patients. The feasibility of including oxygen therapy as a covered service under the National Health Insurance Scheme (NHIS), a public sector insurance scheme which covers nearly 7 million Nigerians, will also be explored.

Federal and state governments will also assess opportunities to establish or strengthen relationships with the private sector, which will be critical for ensuring sustained improvements for oxygen generation and systems maintenance. For example, public private partnerships (PPP) may be explored to identify cost-effective and sustainable models for expanding oxygen delivery systems (e.g. for oxygen plant ownership, operations and maintenance).

Objective 2:
Improve availability of high-quality diagnostics and oxygen delivery systems

Intervention 4: Implement quality assurance and quality control measures for the procurement of oxygen delivery equipment and pulse oximeters

NAFDAC and the Standards Organization of Nigeria (SON) will be engaged to provide specific guidance on registration and regulation for imported diagnostics and treatment equipment that should meet current good manufacturing practice, as well as to adopt device specifications such as those indicated in Annex C and ensure that these remain current. These agencies will ensure registration of quality assured oxygen delivery solutions, including control of local supply availability.

State procurement policies will be reviewed and updated on a regular basis, and should include the latest minimum specifications for medical devices under procurement, outlined by the relevant regulatory agencies. (See Annex C for the latest specifications as at the time of publication of the National Strategy).

Intervention 5: Strengthen quantification, tendering, and procurement processes
Robust quantification and forecasting of facility-level oxygen needs are necessary to ensure a reliable and adequate supply of oxygen. In particular, federal and state governments will adopt best practices for quantification, forecasting, developing requisite budgets, and commodities' procurement. FMoH will disseminate to states key tools and considerations necessary to facilitate the selection and procurement of high-quality oxygen equipment and diagnostics. Supply coordination committees, established and strengthened by federal and state governments, will also ensure accountability for the quantification and forecasting processes.

For state-level planning, state government tenders will be continuously updated to incorporate oxygen equipment that best meets current specifications (see Annex C) and takes into consideration, environmental context. For example, a process for evaluation and selection of suppliers should be based on pre-defined criteria and procurement best practices to ensure a fair and transparent process for selecting high-quality and the most cost-effective equipment from available options. Partners and relevant stakeholders will provide required technical support to state governments to strengthen related operational planning and budget activities on an annual basis. Oxygen equipment, spares parts, and other relevant supplies will be included in budget planning. Transparency between government partners and manufacturers or suppliers should be maintained so as to ensure supply of both of high-quality oxygen equipment with uniformity in standards and to facilitate suitable price negotiations.

Intervention 6: Improve oxygen supply logistics and coordination
A well-functioning oxygen supply system will rely on an effective Logistics Management Information System (LMIS), including: inventory control system; adequate production capacity; financing; human resources; and strong supply chain capacity. Additional activities include improving the supply base, procurement of adequate and appropriate quantities, establishing and/or bolstering systems for restock (including the refilling cylinders), and overarching supply-related information management. FMoH will work with states and partners to integrate oxygen and diagnostics commodities into the current LMIS in order to maintain availability at service delivery points.

FMOH and where necessary, SMOHs, will develop clear SOPs for oxygen-related supply chain processes including forecasting, ordering, and distribution. SOPs will be executed consistently throughout the supply chain, and managers will be assigned to monitor process quality and to optimize it as needed.

Intervention 7: Select and implement optimal oxygen delivery models
The decision to guide the selection and implementation of the appropriate oxygen equipment mix for a given facility – cylinders, concentrators and/or generators/plants– is driven by a combination of factors, including, but not limited to: facility size; current

availability of oxygen supply commodities; estimated oxygen demand; proximity to existing oxygen production infrastructure; technical capacity to maintain oxygen equipment; and facility power supply.

Decisions regarding the selection of optimal oxygen supply systems can be taken at various administrative levels - at the facility level or at the level of the SMOH/FMOH and the key decision makers influencing these will vary accordingly. Facility administrators, SPHCMBs, HMBs and frontline health care staff – including BMEs have a significant role to play in the planning and selection process at the facility level. SMOHs, through their relevant MDAs (e.g. HMB, SPHCMB, Department of Medical Services and Department of Pharmaceutical services) will also play an important role in the selection of oxygen delivery models by providing a broader approach to assessing and addressing needs.

The first step in selecting any model would be a thorough assessment and inventory of current equipment to show current functionality and existing infrastructure. An up-to-date inventory of existing infrastructure is a pre-requisite for effective planning. A thorough evaluation of all other factors and considerations should complement this and guide decision-making for allocation of resources towards oxygen scale-up at facility and regional levels. Buy-in from all stakeholders involved across board, including health facilities and state governments will help ensure efficient and cost-effective implementation of oxygen supply systems.

A more detailed assessment of existing oxygen plants and infrastructure at the state level will also be conducted to better understand gaps that could be potentially filled with the installation (or rehabilitation) of new and existing medical grade oxygen plants in selected referral facilities.

Objective 3:
Improve clinical use of oxygen and maintenance of relevant equipment

Intervention 8: Develop standard operating procedures and protocols for oxygen use in health facilities

The FMoH will work closely with key stakeholders to develop guidelines for various facility levels, including SOPs to guide effective and efficient use of oxygen therapy—both for diagnostics and oxygen administration as well as appropriate referral. The provision of appropriate two-way referral forms at all levels of care will also support effective referrals and improve patient outcomes. This will include working with relevant stakeholders on strategies to ensure wide adoption of pulse oximetry at facility level. SOPs for biomedical engineering personnel relating to equipment management and maintenance will also be developed.

FMoH and NPHCDA will also develop guidance for the implementation procedures for different oxygen delivery methods based on the determined supply mix (see preliminary considerations, annex D).

Intervention 9: Establish management systems for maintenance of equipment and spare parts

Supported by state-level oxygen coordinating mechanisms, facilities will ensure that spare parts and accessories are readily available at each facility according to basic needs and technical capacity for planned preventative maintenance and general repairs. Manuals and protocols on the use and maintenance of oxygen equipment should be available within the facilities, including those unique to products. In addition to technical presence at each facility, expert technical capacity at state-level should be made rapidly available to support facilities with more complex repairs or troubleshooting if/when required. A properly coordinated mechanism as such will help to avoid long delays relating to maintenance.

Governments at all levels will be required to allocate on-going funds to retain an adequate supply of spare parts as well as for human resources that can carry out requisite preventative maintenance by including these items in their budget lines. A culture of maintenance of oxygen diagnostics and supplies, including preventative work, as well as the use of maintenance log books will be fostered in health facilities.

To maintain high functional capacities of oxygen plants where they exist, it is important that these plants run autonomously, have their own management team, and generate their own fund by supplying to neighbouring facilities. Health facility personnel, specifically biomedical engineers, as such, should be resident in facilities and be responsible for ensuring that plants are maintained as required for assurance of continuity of oxygen supply.

Intervention 10: Build capacity of relevant healthcare teams on the clinical use of oxygen and maintenance of equipment

FMoH, along with its partners and agencies, will develop standardized training modules and sensitization guides for use at the facility level. These materials will be designed to train doctors, nurses, and other health providers on the use of pulse oximetry and oxygen therapy for different age groups and medical conditions. Training and capacity building packages will also focus on appropriate and critical triaging of the hypoxemic patient, referral initiation and completion along the continuum of care. Targeted messages should be developed for the relevant cadre of health workers implementing oxygen therapy in the health facilities. Job aids will be designed, developed and tested for effective delivery of information. This also includes proper documentation of all patient care related to oxygen use, SpO2 readings at appropriate intervals, flow of oxygen, wean plan and final patient outcome.

Additionally, in order to ensure durability of equipment and effective utilization of available equipment, relevant members of the health team will be trained on the clinical use of oxygen, and the day-to-day appropriate use and care of oxygen equipment. Trainings will be integrated into all health training institution curricula and at Continuing Medical Education (CME) sessions. Also required with this is the assurance of an effective communication system to ensure that all devices are working at all times at all locations.

Intervention 11: Strengthen multi-disciplinary quality improvement teams in hospitals

To improve practices and uptake of oxygen in facilities, a multidisciplinary team comprised of biomedical engineering experts, clinical, and administrative personnel, will be established to ensure consistent management of oxygen supply and equipment in facilities. This team will leverage on the existing Quality Improvement Team (QIT) within the facility, or where not in place, will function as such. The QIT will be responsible for developing and coordinating quality improvement plans at the facility level to improve health outcomes. It will also ensure that the national guidelines are implemented at facility level, and will promote adherence to evidence-based clinical guidelines and protocols as contained in national guidelines. Additionally, the team will review progress against Key Performance Indicators (KPIs) and coordinate quality improvement plans to address identified gaps.

Objective 4:
Increase acceptance and uptake of affordable oxygen therapy among patients with hypoxaemia and their caregivers

Intervention 12: Improve care-seeking for hypoxaemia, and knowledge of oxygen and pulse oximeters among patients with hypoxaemia and their caregivers

Anecdotal evidence from clinicians indicates low awareness among patients about oxygen and reticence among caregivers to have oxygen administered to their wards. Indeed, low awareness about a product among end-users can lead to low acceptability of the product. In light of this, research will be conducted to better understand current knowledge, attitudes, and practices (KAP) of caregivers towards oxygen therapy. Results of the KAP study will inform the messages and high-impact channels that will be used to reach caregivers. Messages could potentially include information on how to identify both the symptoms and danger signs of hypoxaemia. Additionally, health providers will also provide adequate counselling to caregivers on the use and benefits of oxygen therapy for severely ill children to dispel the misconception that oxygen is only associated with terminal cases.

Objective 5:
Strengthen collection, management, and use of high-quality data for hypoxaemia management

Intervention 13: Strengthen health facility tools and their use for collection of high-quality data

To improve hypoxaemia management in health facilities, relevant data must be collected and reviewed systematically. To avoid creating parallel data collection systems, current templates for patient records should be reviewed and strengthened to include relevant fields for oxygen therapy that can be fed into quality improvement team review meetings for immediate action, and eventually into state-level reporting dashboards. For example, this could include developing a standardized chart for recording relevant observations. However, successful data tracking requires facility-level stewardship starting with the frontline workers attending to patients. Considerations such as the administrative burden posed by additional paperwork should be considered in re-designing health information system healthcare workers should own and use the data to improve service quality to patients.

Intervention 14: Improve data visibility for use in decision-making

Facility-level accountability should be complemented by state- and national-level accountability for key hypoxaemia management indicators that will help galvanise action across the country to improve and accelerate the scale-up of medical oxygen therapy. To this end, the National Health Management Information System (NHMIS) will also be revised to include a component on oxygen use and pulse oximetry, for example by adding appropriate indicators that can be tracked and analysed through regular reviews of data. This will help to identify and address drivers of poor data quality.

Intervention 15: Create and maintain an open-access research repository for hypoxaemia management

Given the evolving landscape of pulse oximeters and oxygen delivery systems, there will be on-going efforts to evaluate the product landscape to assess ongoing suitability identify improved equipment or devices. In addition, a research repository will be created to gather information on implementation. Partners will coordinate with academic and government institutions to maintain a list of relevant on-going and completed studies in Nigeria. A call for abstracts and presentation on study findings will occur on a regular basis.

7. COORDINATION AND MANAGEMENT

7.1 Governance and Coordination

Coordination of partner efforts to scale-up access to medical oxygen will be critical for achieving successful and efficient implementation of the National Strategy. The FMoH will explore existing mechanisms that may be leveraged to drive progress on implementation. If one does not exist, a new national coordination mechanism will be established to provide oversight and accountability for implementation. The coordinating mechanism will include technical working groups to drive progress in specific areas such as supply and distribution, clinical governance and equipment maintenance, and policy and financing in order to anchor multi-stakeholder engagement on partner strengths and expertise. A terms-of-reference will be developed for each working group in line with the objectives of the National Strategy.

To complete these efforts, it will also be critical to establish oxygen teams at each level (national, state, local, and facility) to ensure effective implementation, with continuous multilateral feedback established among teams.

7.2 Management Responsibilities

The FMoH and NPHCDA will provide overall leadership at the national level to ensure progress towards implementation of the National Strategy. The FMoH and NPHCDA will be responsible for updating national policies, clinical guidelines, regulations, and other standards, and disseminating them to relevant stakeholders for implementation. Additionally, FMoH has created an oxygen desk within the ministry to lead the activities of the national coordinating mechanism for the scale-up of oxygen therapy in the country. The coordinating mechanism will comprise of a multi-disciplinary team consisting of a minimum of biomedical engineers or technicians, pharmacists, nurses, and doctors from the public and private sector, academia, and development partners.

SMoH and relevant agencies (SPHCB, HMB) will work with respective facilities levels (THF, SHF, PHC) to adopt national guidelines and policies and oversee the delivery of pulse oximetry and appropriate oxygen delivery systems in health facilities. This will include procurement and planning, allocation of state resources, development of maintenance and technical support systems, and training and supervision for health providers, technicians, and Quality Improvement Teams (QITs). These QITs will be multi-disciplinary, and accountable to the CMAC for tertiary facilities; HMB for state run secondary facilities; or Medical Officer -in-charge at primary healthcare centres. The multi-disciplinary state coordinating mechanism for oxygen therapy scale-up will be led by the oxygen desk at SMoH.

Further information on various partner roles and responsibilities, including those for implementing partners and the private sector is provided in detail in Section 8. Implementation Plan.

8. IMPLEMENTATION PLAN

The following implementation plan spans across the five years of the National Strategy—2018 to 2022—outlining the timeframe and activities for each objective. . Leads and co-leads for each activity are also listed.

		Responsible	2018	2019	2020	2021	2022
OBJECTIVE 1: Create an enabling environment for management of hypoxemia							
Intervention 1: Revise national/state policies to recommend use of oxygen and pulse oximeters							
Activity 1.0	Revise/disseminate national policies (NSO, NSTG, EEL)	FMOH, SMOH, NPHCDA	■				
Activity 1.1	Develop and disseminate clinical guidelines for oxygen therapy	FMOH, SMOH, NPHCDA	■				
Intervention 2: Create oxygen coordinating mechanisms for oxygen scale-up at national and state level							
Activity 2.0	Establish national coordinating mechanism for oxygen therapy scale-up	FMOH	■				
Activity 2.1	Establish state coordinating mechanism for oxygen therapy scale-up	SMOH	■				
Intervention 3: Develop sustainable financing for oxygen delivery systems							
Activity 3.0	Advocate for expanding NHIS and CBHIS to cover oxygen therapy	FMOH, NHIS, MOF	■	■	■		
Activity 3.1	Allocate budgets for procuring oxygen commodities and equipment	SMOH	■	■	■	■	■
OBJECTIVE 2: Improve availability of high-quality diagnostics and oxygen delivery systems							
Intervention 4: Conduct quality assurance and implement quality control measures for the procurement of oxygen delivery equipment and pulse oximeters							
Activity 4.0	Develop minimum standards for products to meet int'l standards	FMOH, SON, NAFDAC	■				
Activity 4.1	Develop guidance for registration/importation of equipment	NAFDAC, SON	■				
Activity 4.2	Establish maintenance and technical support systems at regional level	FMOH, SMOH	■	■			
Intervention 5: Strengthen quantification, tendering, and procurement processes							
Activity 5.0	Create/expand quantification/supply coordination committee	SMOH	■				
Activity 5.1	Develop robust quantifications of oxygen need	SMOH	■		■		■
Activity 5.2	Update tenders to reflect minimum standards	SMOH		■	■	■	■
Activity 5.3	Develop list of MOH preferred products (for pooled procurements and maintenance and repairs)	FMOH, SMOH	■	■	■	■	■
Intervention 6: Improve oxygen supply logistics and coordination							
Activity 6.0	Map existing supply chain for oxygen delivery systems in states	FMOH, SMOH	■				
Activity 6.1	Integrate equipment into existing commodity supply chains	FMOH, SMOH	■	■			
Activity 6.2	Monitor supply chain and logistics through LMIS	FMOH, SMOH	■	■	■	■	■
Activity 6.3	Revise/develop SOPs for oxygen supply chain processes	FMOH, SMOH	■		■		■
Intervention 7: Select and implement optimal oxygen delivery models							
Activity 7.0	Develop facility-level models for optimal oxygen delivery systems	FMOH, SMOH, SPHCBM, HMB	■	■			
Activity 7.1	Establish and monitor appropriate models in facilities	FMOH, SMOH, SPHCBM, HMB	■	■	■	■	■
OBJECTIVE 3: Improve clinical use of oxygen and maintenance of equipment by health care team							
Intervention 8: Develop standard operating procedures and protocols for oxygen use in health facilities							
Activity 8.0	Develop SOP/protocol for pulse oximetry services and oxygen administration	FMOH, NPHCDA, SMOH, SPHCMB, HMB	■	■			

Intervention 9: Establish management systems for maintenance of equipment and spare parts		
Activity 9.0	Develop SOPs for equipment maintenance	FMOH, SMOH, HMB, SPHCMB
Activity 9.1	Establish equipment maintenance protocols for personnel at all levels	FMOH, SMOH
Intervention 10: Build capacity of relevant health care teams on the clinical use of oxygen and maintenance of pulse oximeters		
Activity 10.0	Develop health provider training modules and job aides	FMOH, SMOH, HMB, SPHCMB
Activity 10.1	Train clinicians and health providers on clinical use	FMOH, SMOH, HMB, SPHCMB
Activity 10.2	Train biomedical engineers on maintenance and repairs	FMOH, SMOH, SPHCMB, HMB, NABET
Intervention 11: Strengthen multi-disciplinary quality improvement teams in hospitals		
Activity 11.0	Establish/expand TORs for QIT	SMOH, HMB
Activity 11.1	Review clinical and patient satisfaction KPIs related to oxygen therapy	SMOH, HMB, SPHCMB
Activity 11.2	Leverage state-level HMB/CMAC/MO-in-charge meetings to report on KPI progress	SMOH, HMB, CMAC, SPHCMB
Activity 11.3	Support monthly PHC LGA review meetings to report on KPIs	SMOH, SPHCMB
OBJECTIVE 4: Increase acceptance and uptake of affordable oxygen therapy among patients with hypoxaemia and their caregivers		
Intervention 12: Improve care-seeking for hypoxaemia, and knowledge of oxygen and pulse oximeters among patients with hypoxaemia and their caregivers		
Activity 12.0	Conduct KAP study on patients and caregivers in hospitals and in the community	FMOH, SMOH, NIMR
Activity 12.1	Identify channels and develop key messages to address misconceptions uncovered by research	SMOH, HMB, SPHCMB
OBJECTIVE 5: Strengthen collection, management, and use of high-quality data for hypoxaemia management		
Intervention 13: Strengthen health facility tools and their use for collection of high-quality data		
Activity 13.0	Develop facility-level performance indicators for hypoxaemia management	FMOH, SMOH, HMB, SPHCMB
Activity 13.1	Create/endorse template for nursing observation charts for PHC, SHF, and THF levels	FMOH, SMOH, HMB, SPHCMB
Activity 13.2	Train data collectors (medical records officers) on how to collect data for performance indicators	SMOH, HMB, SPHCMB
Activity 13.3	Integrate data collection process into existing HRH strategies	FMOH, SMOH, HMB
Intervention 14: Improve data visibility for use in decision-making		
Activity 14.0	Revise national M&E tools (e.g. HMIS, DHIS) to include relevant hypoxaemia indicators	FMOH, SMOH
Activity 14.1	Conduct facility-level data quality assessment (through QITs)	Health facilities, HMB
Activity 14.2	Analyze data to inform decision-making at facility, regional, and national levels	Health facilities, HMB, SMOH, FMOH
Intervention 15: Create and maintain an open-access research repository for hypoxaemia management		
Activity 15.0	Create research repository for appropriate products	FMOH, SMOH
Activity 15.1	Conduct learning review every 12 months (collect data and review trends)	FMOH, NAFDAC, SON, Private sector
Activity 15.2	Support testing of oxygen technologies and dissemination of results	FMOH
Coordination		
Intervention 16: Federal, state, and local government level coordination		
Activity 16.0	Create oxygen desk to lead coordination efforts	FMOH
Activity 16.1	Co-lead state-level coordination of oxygen scale-up through multi-disciplinary technical group	SMOH, SPHCMB

8.1 Roles and Responsibilities

The success of the implementation of the National Strategy relies on contributions from both the public and private sector and is contingent on each stakeholder group having a clear understanding of its role. The following presents a brief description of the main contributions that identified stakeholders will make in order to successfully scale-up oxygen therapy in Nigeria.

Federal Ministry of Health

- Disseminate national guidelines (EML, EEL, NSTG), clinical guidelines, regulations and National Strategy for oxygen delivery systems to relevant stakeholders for implementation
- Work with regulatory agencies (NAFDAC, SON) to update regulations to clarify registration and importation requirements for oxygen supply equipment and diagnostics meeting international standards (e.g., WHO specifications)
- Establish oxygen desk and assign officer to lead national multi-stakeholder coordinating mechanism on oxygen therapy scale-up
- Lead fundraising efforts for the strategy and galvanise funding commitments from other MDAs including revenue generating agencies and funds recovery agencies such as EFCC
- Facilitate annual review planning meetings in convening national coordinating mechanism meetings
- Enforce standards for quality clinical practice

National Primary Health Care Development Agency

- Disseminate relevant national guidelines (NSOs) to State Primary Healthcare Board and Agencies for dissemination to PHCs in the states
- Contribute to national coordinating mechanism for oxygen therapy scale-up

State Ministry of Health

- Conduct training and provide technical support for planning, implementation and monitoring oxygen plan and proper oxygen delivery system at the LGAs and PHCs.
- Allocate state resources to promote adequate supply and distribution of optimal key oxygen commodities to health facilities as well as reliable power supply
- Depending on oxygen supply mix, SMOHs should ensure that requisite power supply and dependability is reflected in the design and decision making process. Consideration should be given towards achieving reliable power supply e.g. grid/mains tariffs, back-up generator and fuel, solar power systems, etc.
- Strengthen referral network between different levels of facilities (Communities, PHCs, SHFs, THFs and the private sector)
- Organise and lead state coordinating mechanism for oxygen
- Lead fundraising efforts at the state-level for scale-up interventions

State Primary Health Care Board

- Implement appropriate IEC strategies to reach communities and caregivers with information on hypoxaemia and use of oxygen to enhance awareness and understanding
- Integrate oxygen use into supportive supervision platforms to PHCs in the state to improve provider capacity for diagnostics, triaging and referrals initiation
- Dissemination of relevant national guidelines (NSOs) and appropriate SOPs across all PHCs in the state

Hospital Management Boards

- Provide oversight for the development and strengthening of quality improvement teams in hospitals
- Track performance of hospitals against key performance indicators related to hypoxaemia detection and treatment
- Identify and address barriers and constraints to data use in hospitals

Primary Healthcare Facilities (Comprehensive Centres and Clinics)

- Appropriately test patients for hypoxaemia according to clinical guidelines
- Refer confirmed cases of hypoxaemia to SHFs

Secondary and Tertiary Health Facilities

- Conduct training and retraining of health personnel on oxygen therapy
- Ensure dissemination of and compliance to clinical guidelines on hypoxaemia detection and treatment
- Assist in laboratory diagnosis and effective case management using standardized management guidelines
- Facilitate monitoring and evaluation activities to measure progress in achieving the objectives and goals of oxygen delivery system.
- Foster a strong and functioning culture of maintenance of oxygen devices, including the use of maintenance records. Develop and strengthen clinical governance through the establishment and strengthening of quality improvement teams

Implementing Partners

- Provide the required technical support required for the implementation of the National Strategy.
- Mobilize additional resources to support the implementation of efficient oxygen delivery systems at national and state levels.

Private Sector

- Oxygen equipment suppliers to work with government to devise mechanisms for

equipment maintenance through provisions such as maintenance contracts and training of technicians and biomedical engineers
- Contribute sustainable funding mechanisms and funding for supply of oxygen equipment and spare parts

Private Medical Facilities and Not-for–profit Mission Hospitals – NMA, APGMPN, GMD

- Relevant private sector structures and associations such as the Association of Private and General Medical Practitioners of Nigeria (APGMPN), Guild of Medical Directors (GMD) will support Continuing Professional Development (CPDs) and trainings of health personnel on oxygen therapy
- Support dissemination of and compliance to clinical guidelines on hypoxaemia detection and treatment
- Ensure appropriate referrals to next level facilities and establish linkages with public facilities and relevant SMoH structures
- Foster a strong and functioning culture of maintenance of oxygen devices, including the use of maintenance records
- Improve Monitoring and Evaluation by strengthening reporting to relevant state HMIS platforms that collect information on hypoxaemia and oxygen use

9. ESTIMATED BUDGET FOR A MODEL STATE

As mentioned above, there is wide variability in oxygen needs by facility and by state, which make it difficult to estimate five-year costs for implementation the National Strategy across all 36 states of Nigeria. Specifically, each state will need to assess characteristics across all facilities (THFs, SHFs, and PHCs) and needs for oxygen to determine the most appropriate equipment supply mix and other costs required to roll out a comprehensive and functioning oxygen delivery system.

However, an estimated budget is provided below for a 'model state' to help illustrate key costs required for implementation as well as other factors for consideration. Specifically, this budget estimates the costs required to implement the National Strategy at state-level across a five year period, from 2018-2022. The health system in the 'model' state assumes four THFs, 33 SHFs, and 254 PHCs. The budget combines supply costs of oxygen equipment (CAPEX and OPEX) necessary to meet the estimated oxygen need for hypoxemic patients across these health facilities as well as the costs for implementing key interventions required to ensure appropriate use and maintenance of the equipment.

Key assumptions for calculating supply costs in the health facilities include the following:

- Oxygen source is supplied from concentrators, plants, and cylinders (cylinder size: 7.5 m3). The pulse oximeters applied into model were the handheld type.
- Power availability was fixed at 3 of 24 hours a day (or 13%) across all health facilities. However all costs associated with achieving reliable power depending on the Oxygen supply mix (e.g. grid/mains tariffs, back-up generator and fuel, solar power systems, etc.) should be incorporated into the costing process
- Other infrastructure requirements for introducing commodities such as electrical re-wiring, construction of plant-room etc., were not included.
- The model state budget does not account for population growth (e.g., number of new facilities/beds) across the forecasted 5-year period.
- The model state budget does not account for existing infrastructure which could be leveraged off of in determining supply mix.
- The model also does not account for future facility wide infrastructural updates

In this 'model state', the total cost for oxygen supply and implementation amounted to ~N5.78b. The cost of oxygen delivery systems (e.g., equipment, spare parts, and consumables) accounts for 97% (N5.58b) of this total cost. The remaining 3% (N193m) is required to roll out interventions to ensure the equipment is properly rolled out, maintained, and used in the system—including policy and planning support, procurement, distribution, trainings, and outreach to patients with hypoxaemia.

Annex F provides a sample budget worksheet that can be used to estimate the cost of oxygen scale-up in a state, where fiscal responsibility for most of the health facilities (especially PHCs and SHFs) lies with the state government. Annex G details a sample budget for a tertiary facility, for which fiscal responsibility in Nigeria often lies with the federal government.

5-Year State Model Costing for Oxygen Implementation

Intervention	2018 (Year 1)	2019 (Year 2)	2020 (Year 3)	2021 (Year 4)	2022 (Year 5)	Total (2018-2022)
Objective 1: Create an enabling environment and mobilize funding for hypoxemia management	₦ 13,400,000	₦ 7,835,000	₦ 10,595,000	₦ 7,835,000	₦ 10,595,000	₦ 50,260,000
Objective 2: Improve availability of high-quality diagnostics and oxygen delivery systems	₦ 844,050,00	₦ 1,190,632,000	₦ 1,190,632,000	₦ 1,190,632,000	₦ 1,190,632,00	₦ 5,646,578,000
Objective 3: Improve clinical use and maintenance of equipment among health providers and personnel	₦ 33,962,900	₦ 13,380,000	₦ 22,605,000	₦ 23,771,900	₦ 22,605,000	₦ 78,308,800
Objective 4. Increase use of oxygen among hypoxemic patients	₦ 3,920,000	₦ 0	₦ 0	₦ 0	₦ 0	₦ 3,920,000
Objective 5. Strengthen data management to track performance on hypoxemia diagnosis and management	₦ 889,600	₦ 0	₦ 0	₦ 889,600	₦ 0	₦ 1,779,200
			Total costs of implementation, 5 years (₦)			₦ 5,780,846,000
			Total costs of implementation, 5 years (USD, $)			$ 18,151,856
			CAPEX/OPEX as % of total			97%

Exchange Rate:

NGN/USD	0.00314

10. MONITORING & EVALUATION

Participatory Review and Annual Planning

At the national level, an annual planning exercise will be led by the FMoH to review progress on the targets set for the scale-up strategy and identify interventions in the strategy where to appropriately allocate funds. More specifically, the planning exercise of the national coordinating mechanism will consist of a review of the impact of mobilised funds on the scale-up of medical oxygen, based on the key performance indicators outlined in the performance indicator framework below. Data from states and their health facilities will constitute the subject of the review of progress against the scale-up targets.

Reporting

The FMoH will submit a yearly report to the National Council on Health and to the President of Nigeria on the implementation status of the oxygen strategy. An interim progress report will be submitted to the governors of all 36 states at the end of the first 2.5 years of the five-year strategy. A final report to the President, the National Assembly, and National Council on Health will be submitted at the end of the 5-year implementation period.

Key Performance Indicator Framework

The suggested core indicators for the national scale-up strategy for medical oxygen are presented in the figures below, and will be reviewed by the national coordinating mechanism to review indicator baselines, targets, and priority rankings, as more data become available on the oxygen supply, distribution, and use landscape across facilities in Nigeria.

Output indicators:
See the Output Indicators table below for the list of indicators corresponding to the 5 objectives of the National Strategy

↓

Outcome indicators:
- Increased hypoxaemia screening rate in health facilities
- Increased coverage of oxygen therapy for hypoxaemic patients

↓

Impact indicators:
- Reduced morbidity among patients due to improved hypoxaemia management
- Reduced mortality among patients due to improved hypoxaemia management

Output Indicators

1. Policy	2. Availability	3. Practice	4. Use	5. Data
1.1 National EEL updated with O2 1.2 State EELs updated with O2 1.3 National clinical guidelines for O2 developed 1.4 Number of facilities that have received national clinical guidelines 1.5 NHIS entitlement expanded to include oxygen therapy	2.1 Minimum standards developed for O2 equipment and Pox 2.2 Number of registered products that meet minimum standards 2.3 Number of states that have adopted global practices for forecasting and budgeting 2.4 O2 delivery systems included in budget and AOP 2.5 State-level multi-stakeholder supply and logistics committee instituted and meeting regularly 2.6 SOPs for oxygen supply chain produced and disseminated 2.7 % of facilities with managers assigned to updated supply chain SOPs 2.8 % of facilities that experience a stock-out of O2 2.9 % of facilities with appropriate and functional oxygen delivery mode	3.1 Health provider training modules on hypoxaemia diagnosis and management developed 3.2 SOP and job aides for pulse oximetry services developed and disseminated to health facilities 3.3 SOP and job aides for O2 administration developed and disseminated to health facilities 3.4 Hypoxaemia KPIs reported during PHC LGA review meetings 3.5 Hypoxaemia KPIs reported during HMB meetings 3.6 Number of clinicians and healthcare workers trained on O2 and Pox 3.7 Number of biomedical engineers/technicians trained on O2 and POx repairs 3.8 Facility maintenance log book to capture all O2-related devices and device specific details of planned preventative maintenance 3.9 Troubleshooting conducted time stipulated in training manual 3.10 Repairs conducted within time stipulated in maintenance manual 3.10 Repairs conducted within time stipulated in maintenance manual	4.1 % of caregivers who mention benefits of O2 therapy 4.2 % of caregivers who have heard of POx before 4.3 Proportion of patients who reject oxygen in the ward	5.1 M&E and research sub-group established in national coordinating mechanism 5.2 Chart templates and HMIS reporting forms include hypoxaemia detection and oxygen therapy 5.3 Number of facilities with POx included in patient charts 5.4 Repository of studies developed and consolidated 5.5 Repository of studies updated biannually

ANNEXES

Annex A. Overview of Oxygen Delivery Systems

	Oxygen cylinders	Oxygen concentrators	Central oxygen source / Oxygen plant
Current usage	Prevalent in many Hospitals but transport and filling fees are a limiting factor. Lower availability in PHCs.	Prevalent in many hospitals, but usage often affected by lack of power. Many brands and models available in Nigeria.	In-hospital PSA plants can be found throughout the country and main, centralized private cryogenic plans also exist.
Initial costs	Moderate: costs of cylinders and accessories (regulator & flowmeter)	Moderate: cost of concentrators and spares, installation, commissioning and training.	Significant: cost of all plant components including compressors and oxygen generation technologies, as well as pipeline distribution system.
Operational costs	High: (1) cylinder lease and/or handling/inspection fees, (2) filling and (3) transportation all required for each fill.	Low: Costs associated with electricity as well as spares over a period of time.	Low to moderate: Costs associated with electricity as well as spares over a period of time (with a possibility of cost-recovering from filling/selling cylinders externally if plant located in a facility). Staffing requirements.
Additional equipment required	· Regulator, gauges, flowmeter · Oxygen delivery materials (nasal prongs/catheter) Cylinder key	· Oxygen delivery materials (nasal prongs/catheter) Power source: e.g. solar power, Generator & UPS/voltage protection	· Oxygen delivery materials (nasal prongs/catheter) · Cylinders and their required additional equipment. Power source: e.g. solar power, Generator & UPS/voltage protection
Advantages	+ No need for electricity + Low maintenance needs	+ Can ensure continuous supply at low running cost + One concentrator can supply up to 5 children (flow requirements permitting).	+ Most cost effective for larger facilities + Can ensure continuous supply at all pressures.
Disadvantages	— High cost of transport — Highly dependent on supplier availability — Highly sensitive to leakage Cylinders to be handled with care (potential fire hazard and explosions.	— Max flow rate 5 L / min (concentrators are typically not recommended for use in surgeries, however, there are anaesthetic machines that are connected to concentrators) — Requires access to uninterrupted power (unless used with an oxygen storage system) Service and supply of spare parts needed.	— High capital investment — Need for adequate infrastructure — Requires access to reliable and sufficient power source — System is potential for fire hazard – must be managed with care.

Annex B. Overview of Pulse Oximeters

	Stationary/benchtop	Handheld	Fingertip	Mobile device
Monitoring Parameters	SpO_2 HR Optional: Blood pressure ECG Temperature $ETCO_2$	SpO_2 HR (*some have additional features such as $ETCO_2$)	SpO_2 HR	SpO_2 HR
Use-case	· Continuous monitoring Diagnostic/ spot-check	Diagnostic/ spot-check	Diagnostic/Spot-check	Diagnostic/Spot-check
Additional equipment required	· Age-specific probes should be purchased. Probes need replacing after +/- 1 year.	· Age-specific probes should be purchased. · Probes need replacing after +/- 1 year. Replacement batteries.	· Device itself is age-specific, multiple will be needed. Replacement batteries.	· Age-specific probes should be purchased. Probes need replacing after +/- 1 year.
Additional information for decision making	· Greatest accuracy, most comprehensive type. · Need for mains (though internal emerg. battery for some autonomy) · More durable Not portable unless on trolley	· More alarms and internal memory than fingertip devices · Some devices have rechargeable batteries, others disposable · More durable Portable	· No internal memory · Basic requirements met · Some devices have rechargeable batteries, others disposable · Less durable · Portable	· No need for electricity · Runs off of mobile device battery Measurements and data can be shared via email Portable

Annex C. Specifications for pulse oximeters, oxygen concentrators and relevant accessories

Disclaimer: This National Strategy for the Scale-up of Medical Oxygen in Health Facilities is intended to provide states/facilities with overall high-level guidance in developing their strategy for scale-up. Specifications for pulse oximeters, oxygen concentrators and relevant commodities provided herein are to serve as a reference only and are based on current globally accepted standards. Therefore, the specifications in the strategy are intended to guide the identification and evaluation of potential high-quality equipment for procurement. Decisions on the selection of specific brands and devices will be left to states during their own tendering and procurement processes.

PULSE OXIMETERS

In the absence of globally accepted specifications for pulse oximeter devices, information contained herein draws from the Global Pulse Oximetry Project[27] (a WHO initiative, 2008) as well as relevant WHO and ISO specifications. It is to serve as a guide, providing a targeted list of considerations for product verification and/or selection. This guide starts with general criteria, listing features that all pulse oximeter devices must have, followed by desirable criteria that should be in place, but that are not mandatory for functionality. Criteria for specific device types, as presented in Annex B, are listed in the table below general criteria.

ALL pulse oximeters must:

- Meet all relevant ISO 80601-2-61:2011 criteria (former ISO 9919)
- Carry a CE mark and/or FDA approval
- Have audible* and visual display alarms for low oxygen saturation and battery levels.
- Be pre-programmed to measure arterial oxygen saturation (SpO_2) between clinically relevant limits (e.g. of 70-100%) with an accuracy of within ± 2% of saturation.
- Be pre-programmed to measure pulse rates between clinically relevant limits (e.g. between 20-200 beats per min, bpm) with an accuracy of ± 3 bpm.
- Display pulse rates numerically and with a plethysmograph** (in waveform and/or bar graph)
- Are reusable and/or have reusable sensors/ probes sized for adults, children and neonates.
- Have power adaptor to be Type-B AC (British standard) and operate at 240 V, 50 Hz.
- Work reliably at temperatures up to 40°C and ≤ 95% relative humidity.
- Have a minimum 1 year warranty on the equipment provided in detail.

In addition, it would be desirable for the pulse oximeter to:

- Have an IPX1 ingress protection rating, as a minimum, according to IEC (e.g. in the

27. Global Pulse Oximetry Project – First International Consultation Meeting WHO Headquarters, Geneva, Switzerland 29th and 30th October 2008. Background Document. http://www.who.int/patientsafety/events/08/1st_pulse_oximetry_meeting_background_doc.pdf

case of bodily fluid spills and for regular cleaning).

- Be simple and intuitive to use.
- Have back-lit screen with large readouts on the display screen that are visible in dim lighting.
- Have robust probes and sturdy wiring in order to withstand heavy use.
- Have differential alarm if it takes longer than 30 secs to detect next pulse value.

Additional specifications for pulse oximeter types:

Type	Additional specifications
Benchtop	· Must have 3 hours operational capacity on rechargeable built-in battery, and take no more than 7 hours to charge. Ideally have internal memory to store at least 99 IDs with up to 200 records/ID, and a port for downloading and/or printing.
Handheld	· Must have ⩾ 6 hours operational capacity on rechargeable built-in battery and take no more than 10 hours to charge or use standard size disposable batteries. · Ideally be portable (⩽300 g) and easily hand-held. Ideally have internal memory to store at least 99 IDs with up to 200 records/ID, and a port for downloading and/or printing.
Fingertip	Must use standard sized rechargeable or disposable batteries (e.g. AAA).
Mobile device	Must be compatible with various mobile device operating systems (iOS, Android).

* Audible not necessary on fingertip pulse oximeters

** Plethysmograph not necessary on fingertip pulse oximeters

OXYGEN CONCENTRATORS[28]

- Declaration of conformity to ISO 80601-2-69:2014 (or adhere to the three-year transition period from ISO 8359:1996)
- Carry a CE mark and/or FDA 510k clearance.
- Be capable of delivering a continuous flow of oxygen at a concentration ⩾85% (±3%)
- Be equipped with at least one built in flowmeter with flow rate control capable of delivering 0.5 LPM as a minimum, and be able to increase by 0.5 LPM increments to a 5 LPM (or higher) maximum-rated flow.
- Provide a flow rate from the device that must not exceed the maximum rated flow rate, and be capable of generating oxygen at 55 kPa at all flows.
- Context specific environmental requirements: capable of delivering and maintaining the minimum oxygen concentration at the specified maximum flow rate of the concentrator at 40°C and 95% relative humidity (RH).
- Have alarms indicating when

28. WHO. (2015). WHO Medical Device Technical Series. Technical Specifications for Oxygen Concentrators. Geneva, Switzerland.

  - Oxygen concentration falls below 82%
  - Low flow
  - High or low pressure
  - Power supply failure
  - High temperature
- Have removable particle filters incorporated to prevent dust ingress.
- Produce no more than 50 dB(A) of noise when in operation.
- Have a power efficiency of not more than 70 W/LPM, and have a Type-B AC (British standard) power plug (or include an adapter) and operate at 240 V, 50 Hz B (or include a converter).
- Have a meter (digital or analogue) that displays cumulative hours of device operations.
- Have (option for) 5 year manufacturer's warranty

FLOWMETER ASSEMBLY [29]

A flowmeter (flow splitter or flow station) assembly should be considered for sharing oxygen from one concentrator, along individual lines, between multiple neonatal or paediatric patients. These should consist of:

- Up to 5x 0-2L/min flowmeters
- Ability to titrate to 0.1L/min, ±5% of full scale.

OXYGEN ANALYZER[30]

- Battery operated, hand-held device
- Works reliably at temperatures up to 40°C and ≤ 95% RH.
- Must measure and display clearly: Oxygen purity: 21%-95.6% ± 1.5%,
- Compatible for use with oxygen concentrator device listed in tender and include necessary attachments/tubes.
- The device should have a 2 year warranty provided in detail on both analyzer and sensor.

Desirable:

- Oxygen flowrate: 0-10 LPM ±0.2%
- Patient output pressure: 5-350 kPa

29. As per required purpose and based on existing product availability
30. As per required purpose and based on concentrator specifications

CYLINDERS

- Complies with the current European Pharmacopoeia monograph (0417) or equivalent
- Nominal valve outlet pressure: 137 bar
- White shoulder as a minimum or all-white tank.
- Compatible pressure regulator and gauges (inlet/outlet)
- Compatible flow meter and gauge
- Compatible humidifier
- All components must be rated for use with oxygen.

Annex D. Additional considerations to appropriately fit a facility with oxygen concentrators [31]

Procurement of commodities alone will not directly solve the issue of lack of oxygen supply. And doing so flippantly could result in an unprecedented waste of resources. A comprehensive assessment of structural, technical and clinical barriers is required prior to the installation of oxygen concentrators, at the outset of an investment.

Installation of concentrators should factor in the existing ward structure, power supply, capacity of generators, in-patient flow, presence of biomedical engineers versus technicians, where patients on oxygen will be situated, review of power outlets, cabling required, change-over switches etc. Specifically:

1. Engaging facility health workers and management to identify right team; prepare the hospital team on the goals of the program.
   A core oxygen team should be made up and consist of an installation and clinical team: Doctors, Heads of Department of relevant units/wards e.g. Head of Records, Children's unit, Electrician etc.
2. Identifying the ideal location of the concentrators in the applicable wards
3. Identifying the length/type of cabling, tubing and trunking to be used.
4. The location of nursing stations. Beds serviced with oxygen, and flow splitters are usually positioned close to the nursing stations.
5. Availability of power – consider a hybrid system of power generation using at least two sources (e.g. generator, grid power, solar/battery).
6. Location of generator – generator should be one with copper coils as previous experience showed that those with aluminum coils were not able to successfully power the concentrators.
7. Carry out a pre-installation survey; the current layout of the facility may need to be changed; buy-in from heads of facilities is necessary.
8. Capacity of generator bearing in mind the induction charge of concentrator of choice. This has to be considered when procuring alternative power sources that will power more than one concentrator.
9. Oxygen delivery piping across the ward

31. As per CHAI experience as well as with input from Oxygen Implementation Project in SW Nigeria.

Annex E. Suggested Reading for Health Administrators and Other Stakeholders

Clinical Use of Oxygen in Hospitals
(Source: WHO, 2012)
Guidelines for health-care workers, hospital engineers and managers on the clinical use of oxygen in hospitals with limited resources. Key information provided around hypoxemia, giving oxygen, oxygen systems in hospitals, diagnosis of hypoxemia, humidification, and principles of managing a national or regional oxygen program.
http://video.rch.org.au/cich/The_Clinical_Use_of_Oxygen_November_2011.pdf

Oxygen Therapy for Children
(Source: WHO, 2016)
A practical bedside manual for health workers to guide the provision of oxygen therapy for children supporting improved use and availability in low resource settings. Focused around appropriate detection of hypoxemia and use of pulse oximetry, oxygen delivery systems and monitoring of patients on oxygen therapy. Additionally, the manual addresses practical use of pulse oximetry, and oxygen concentrators and cylinders.
http://apps.who.int/iris/bitstream/10665/204584/1/9789241549554_eng.pdf

Technical Specifications for Oxygen Concentrators
(Source: WHO, 2015)
A WHO-produced guidance document for the appropriate selection, procurement, utilization and maintenance of oxygen concentrations and necessary accessories. Efforts in doing so holistically are to increase the availability, management and quality of oxygen concentrators for an overall improvement in health outcomes in LRS.
http://apps.who.int/medicinedocs/documents/s22194en/s22194en.pdf

Annex F. 5-Year State Model Costing for Oxygen Implementation

The following is a template for a five-year costing for scaling up medical oxygen in a model state. "Sample Actvities" provide details on considerations for each item of the budget.

Intervention	Item	2018 (Year 1)	2019 (Year 2)	2020 (Year 3)	2021 (Year 4)	2022 (Year 5)	Total (5 years)	Sample Activities
Objective 1: Create an enabling environment and mobilize funding for hypoxaemia management								
Intervention 1	Adapt, print, and disseminate national policies and clinical guidelines							Review meetings, stakeholder dissemination meeting, printing of policies
Intervention 2	State-level coordination							Quarterly meetings/ secretariat functions
Intervention 2	AOP development and review							Annual AOP development and review meetings
Objective 2: Improve availability of high-quality diagnostics and oxygen delivery systems								
Intervention 5	Quantification, tendering, and procurement support							TEC and LWG meetings, consultant support
Intervention 5	Map existing supply chain and integrate equipment							TWG meetings, consultant support
Intervention 6	Develop SOPs for oxygen supply chain processes							TWG meetings, consultant support
Intervention 6	Monitor process quality and optimize processes							TWG meetings/consultant support/field visits
Intervention 7	Select optimal mix of oxygen delivery systems							Planning meetings
Intervention 7	Implement appropriate model (CAPEX costs)							Mix of oxygen equipment, oximeters & power supply for all facilities in state[32]
Intervention 7	Implement appropriate model (OPEX costs - ongoing technical expenses)							Oximeter replacement, spares, & plant power, operations and maintenance). In year 1, all breakages recovered in warranty of equipment.
Intervention 7	Implement appropriate model (OPEX costs - ongoing operational expenses)							Cylinder transport, cylinder servicing, power requirements for concentrators, concentrator servicing)
Intervention 7	Implement appropriate model (Conduct pre-installation assessments)							Installation cost of ₦ 160,000 per 10 facilities
Intervention 7	Implement appropriate model (Installation of equipment)							Consultant support
Objective 3: Improve clinical use and maintenance of equipment among health providers and personnel								
Intervention 8	Develop SOP/protocol for pulse oximetry and oxygen administration in health facilities							Review meetings, printing and dissemination, consultant support
Intervention 9	Develop SOP/protocol for maintenance							Review meetings, printing and dissemination, consultant support

32. E.g., cylinders and regulators, concentrators and their voltage surge protectors, oxygen plant & piping

Intervention 10	Develop provider training manuals and job aids							2 review meetings, consultant support, printing and dissemination
Intervention 10	Trainings for clinicians/HCWs							2 trainings per facility, facilitation fees, training materials
Intervention 10	Supportive supervision for trained health care providers							Quarterly visits, Integrate into and leverage existing SS platforms - RI/etc
Intervention 10	Dissemination through professional associations							Dissemination through 5 professional associations: Dissemination meetings, materials, facilitation
Intervention 10	Develop, print, and disseminate training manuals and job aids for biomedical engineers							Consultant support, review meetings, printing
Intervention 10	Trainings for biomedical engineers							3-day training for biomed engineers
Intervention 11	Develop/strengthen QIT teams							Monthly meetings in all SHFs, monthly meetings and data collection
Intervention 11	Support monthly PHC LGA review meetings to report on KPIs							Monthly PHC LGA meetings in all LGAs, monthly meetings and data collection
Objective 4. Increase use of oxygen among hypoxaemic patients								
Intervention 12	Conduct Knowledge, Attitude and Practice (KAP) study							Consultant support for development of questionnaires/ field testing/survey and analysis
Intervention 12	Train providers to counsel caregivers on oxygen diagnostics and use							1 training per facility
Intervention 12	Disseminate messages through other high-impact channels							IEC Materials development, consultant support for content development, cost for dissemination
Objective 5. Strengthen data management to track performance on hypoxemia diagnosis and management								
Intervention 13	Revise reporting forms to include hypoxemia indicators							Consultant support, review/printing and dissemination to all facilities in the state; phased approach for PHCs. May not touch health posts.
Intervention 13	Train Medical Records Officers on use of updated reporting systems							Training of MROs from SHFs/THFs
				Total costs of implementation, 5 years (₦) Total costs of implementation, 5 years (USD, $) CAPEX/OPEX as % of total				

Exchange Rate:	
NGN/USD	

Annex G. 5-Year Costing for Oxygen Therapy Scale-up in a Model Tertiary Facility

The following is a sample budget for a model tertiary facility, provided here for illustrative purposes. The budget assumes and uses similar oxygen supply characteristics for facilities outlined in *Section 9. Estimated Budget for a Model State.*

5-Year Cost for Oxygen Therapy Scale-up in a Model Tertiary Facility						
Intervention	2018 (Year 1)	2019 (Year 2)	2020 (Year 3)	2021 (Year 4)	2022 (Year 5)	Total (2018-2022)
Objective 1: Create an enabling environment and mobilize funding for hypoxemia management	NGN 817,500	NGN 290,000	NGN 817,500	NGN 290,000	NGN 817,500	NGN 3,032,500
Objective 2: Improve availability of high-quality diagnostics and oxygen delivery systems	NGN 64,400,045	NGN 73,099,653	NGN 73,099,653	NGN 73,099,653	NGN 73,099,653	NGN 356,798,656
Objective 3: Improve clinical use and maintenance of equipment among health providers and personnel	NGN 2,734,000	NGN 1,321,500	NGN 1,371,500	NGN 2,684,000	NGN 1,371,500	NGN 9,482,500
Objective 4. Increase use of oxygen among hypoxemic patients	NGN 350,000	NGN 0	NGN 0	NGN 0	NGN 0	NGN 350,000
Objective 5. Strengthen data management to track performance on hypoxemia diagnosis and management	NGN 680,000	NGN 550,000	NGN 550,000	NGN 680,000	NGN 550,000	NGN 3,010,000
					Total costs of implementation, 5 years (NGN)	NGN 372,673,656
					Total costs of implementation, 5 years (USD)[33]	USD 1,170,195
					CAPEX/OPEX as % of total	93%

Exchange rate: NGN:USD 0.00314

Annex H. Key Indicators and Data Sources

Outcome indicators and proposed data sources

ID	Outcome	Indicator(s)	Data source
A	Increased hypoxaemia screening rate in health facilities	Hypoxaemia screening rate: Proportion of patients who received pulse oximetry on admission	Patient charts, Health facility survey, DHIS/ updated NHMIS
B	Increased coverage of oxygen therapy for hypoxaemic patients	Oxygen coverage: % of hypoxaemic patients who received oxygen therapy upon admission	Patient charts, Health facility survey

Intermediate outcomes (1-5), output indicators and their proposed data sources

Output	Indicator(s)	Data source
Intermediate Outcome 1. Enabling environment created for hypoxaemia management		
National and state policies revised to recommend the use of oxygen and pulse oximeters	National EEL updated with O_2 State EELs updated with O_2	FMOH (EEL) SMOH (EEL)
Clinical guidelines developed and disseminated to all healthcare facilities	National clinical guidelines for O_2 developed Number of facilities that have received national clinical guidelines	FMOH Clinical Guidelines TBD
Sustainable financing developed for oxygen delivery systems	NHIS entitlement expanded to include oxygen therapy	NHIS policy document
Intermediate Outcome 2. Improved availability of high-quality diagnostics and oxygen delivery systems		
Minimum standards/ specifications developed for oxygen delivery equipment and pulse oximeters for procurement	Minimum standards developed for O_2 equipment and POx Number of registered products that meet minimum standards	NAFDAC policy document /SON
Quantification, tendering, and procurement processes strengthened	Number of states that have adopted global practices for forecasting and budgeting O_2 delivery systems included in budget and AOP	State AOP Report State budget
Oxygen supply integrated into current LMIS	State-level multi-stakeholder supply and logistics committee instituted and meeting regularly SOPs for oxygen supply chain produced and disseminated % of facilities with managers assigned to updated supply chain SOPs % of facilities that experience a stock-out of O_2	TBD

Optimal oxygen delivery models selected and implemented	% of facilities with appropriate and functional oxygen delivery mode	TBD
Intermediate Outcome 3. Improved clinical use of oxygen and maintenance of equipment among healthcare teams		
Procedures and protocols for oxygen use in health facilities developed according to clinical guidelines and disseminated	Health provider training modules on hypoxaemia diagnosis and management developed SOP and job aides for pulse oximetry services developed and disseminated to health facilities SOP and job aides for O_2 administration developed and disseminated to health facilities	TBD
Regional level management systems established for clinical governance of oxygen therapy	Hypoxaemia KPIs reported during PHC LGA review meetings Hypoxaemia KPIs reported during HMB meetings	PHC LGA and HMB meeting reports
Capacity of healthcare providers on the clinical use of oxygen and pulse oximeters built	Number of clinicians and healthcare workers trained on O_2 and Pox Number of biomedical engineers/technicians trained on O_2 and POx repairs	Health facility survey
Management systems established for maintenance of equipment and spare parts	Facility maintenance log book to capture all O2-related devices and device specific details of: Planned preventative maintenance Troubleshooting conducted time stipulated in training manual Repairs conducted within time stipulated in maintenance manual	Health facility medical device logbook
Multi-disciplinary quality improvement teams in hospitals strengthened	# of facilities with functional QITs that review and report on hypoxaemia diagnosis and management	Facility report to HMB/SMOH
Intermediate Outcome 4. Increased use of oxygen among hypoxemic patients		
Caregiver knowledge of oxygen therapy and pulse oximeter use improved	% of caregivers who mention benefits of O_2 therapy % of caregivers who have heard of Pox before	Health facility survey
Decreased rejection of oxygen therapy among caregivers	Proportion of patients who reject oxygen in the ward	Health facility survey
Intermediate Outcome 5. Data management to improve quality of hypoxaemia care strengthened		
Facility-level health information systems strengthened to capture relevant clinical data	M&E and research sub-group established in national coordinating mechanism Chart templates and HMIS reporting forms include hypoxaemia detection and oxygen therapy Number of facilities with POx included in patient charts	FMOH (Coordinating Mechanism Report) NHMIS Form Patient charts

Research repository created for appropriate products for hypoxaemia diagnosis and treatment	Repository of studies developed and consolidated Repository of studies updated biannually	FMOH (learning Review Report)