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Ministry of Health

MEDICAL OXYGEN IN KENYA

GUIDELINES ON PRODUCTION, DELIVERY, & MANAGEMENT

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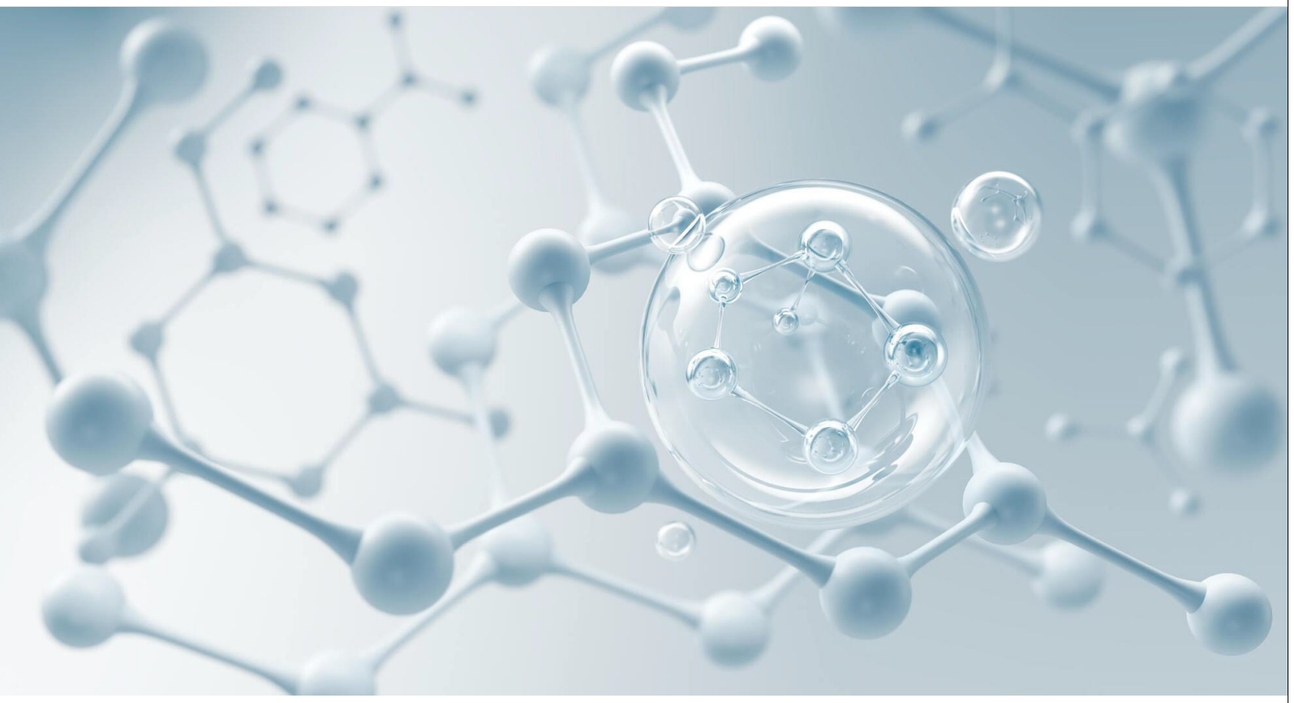

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FOREWORD

The Kenyan Health Sector plays a critical role in providing health care services in response to the population's needs in line with the aspiration of the Constitution of Kenya (2010) and the Kenya Health Policy, 2014-2030 goal of attaining the highest possible standard of health in a manner responsive to the needs of the population. Ensuring effective, safe, and affordable health products and technologies are available and rationally used, is pivotal to a functioning healthcare system that supports the UHC agenda.

Medical Oxygen is a critical component of healthcare service provision and is used in various medical settings to support patients with respiratory conditions or those who require oxygen therapy.

Regrettably, low and middle-income countries often experience significant inequities in quality medical oxygen supply and demand, with major impacts on preventable mortality. These inequities became particularly prominent during the global COVID19 pandemic, highlighting the need for additional investment and research into the best methods to utilize supplemental medical oxygen and ensure stable access to it.

In Kenya, the supply of medical oxygen faces challenges related to availability, quality, supply chain, storage, infrastructure, cost, distribution, regulatory oversight, equipment maintenance, human resource capacity, emergency preparedness, and environmental impact. Addressing these challenges requires concerted collaboration and investment to ensure consistent, safe, and affordable access to this vital healthcare resource.

To address the challenges highlighted above, the Ministry of Health recommended the development of guidelines and protocols as well as technical specifications for oxygen, oxygen generation and storage equipment, and related therapy devices.

This document will guide to ensure there is standardization of the quality, production, storage, and distribution of medical oxygen. When used together with the requisite Technical Specifications for Medical Oxygen, Oxygen Therapy Devices, and Equipment, it is expected that there will be a rational selection of medical Oxygen and the related equipment and devices.

The guidelines will direct decision-makers, managers, and healthcare workers in enhancing the quality of patient care, as well as improving consistency of care and outcomes through the provision of quality Medical Oxygen. Overall, Kenya's health system will be resilient and sustainable for emergency preparedness and response.

Dr. Patrick Amoth, EBS
Ag. Director General of Health
Ministry of Health

PREFACE

Kenya utilizes various medical gases in healthcare settings. These gases are essential for therapy, surgery, medical procedures, and other applications.

Among the medical gases, oxygen is the most widely used, mainly on patients with medical conditions requiring supplemental Oxygen for breathing support or therapy. Within health facilities in Kenya, the supply of medical oxygen is from cylinders filled with either liquid or gaseous oxygen, PSA plants, bulk liquid oxygen storage tanks, and Oxygen concentrators.

In Kenya, various assessments have revealed inadequacies in the quality and quantity of medical oxygen. Additionally, poor quality or inadequate infrastructure, facilities, and equipment for oxygen production and delivery were found in some health facilities. Funding for medical oxygen was inadequate, and so were the human resources needed to effectively manage the commodity. There were weak monitoring systems. Standards and guidelines were not available.

The Guidelines on Production, Delivery, and Management of Medical Oxygen in Kenya were developed to address the challenges above. The development process included extensive consultation with various technical experts and other stakeholders in the medical oxygen ecosystem.

The guidelines are divided into sections including an introduction that provides background information on medical oxygen. It outlines the scope and purpose of the guidelines, the rationale and context and objectives of the guidelines. Other sections outline production, storage, supply and delivery of medical oxygen; testing and commissioning of oxygen equipment; regulation and quality assurance; operational and risk management, as well as monitoring and reporting.

These guidelines are targeted at industrial and on-site producers (health facilities), distributors, handlers and users (health workers) of medical oxygen. They provide comprehensive guidance to ensure the availability of quality medical oxygen for the provision of healthcare services in the implementation of Universal Health Coverage.

Dr. Tom Menge
Directorate of Health Products and Technologies
Ministry of Health

ACKNOWLEDGEMENTS

The Ministry of Health acknowledges the support and contribution made by various stakeholders towards the development of these guidelines. The compilation of these guidelines on the production, delivery and management of medical oxygen in Kenya would not have been possible without the support, hard work, and endless efforts of a large number of individuals and institutions.

We appreciate the Technical Working Group members who steered the process as well as the editorial team that ensured that the content of this document is comprehensive, accurate, relevant and in line with the desired standards and current practices.

We acknowledge the invaluable inputs of all technical experts, drawn from the Ministry of Health, partners and Counties, who went out of their way to research, collate and compile the content for this document.

We greatly appreciate the financial and technical support from Jhpiego, through the USAID-funded RISE Project and Clinton Health Access Initiative (CHAI) in the development process of these guidelines.

Finally, we thank all those who participated in the preparation of these guidelines and whose diverse contributions made it a success.

LIST OF ABBREVIATIONS AND ACRONYMS

AE	Adverse Events
ASU	Air Separation Unit
ASME	American Society of Mechanical Engineers
BS	British Standard
cGMP	Current Good Manufacturing Practice
COVID-19	Coronavirus Disease - 2019
EN	European Standard (Europäische Norm)
GMP	Good Manufacturing Practice
HCW	Health Care Worker
HMT	Health Management Team
HPT	Health Products and Technologies
HRH	Human Resource for Health
ICH	International Council on Harmonization
ICT	Information, Communication and Technology
IPC	Infection Prevention Control
ISO	International Organization for Standardization
KEBS	Kenya Bureau of Standards
KEPH	Kenya Essential Package of Health
KHIS	Kenya Health Information System
KS	Kenya Standard
LPM	Liters per Minute
M&E	Monitoring and Evaluation
MOH	Ministry of Health
PPB	Pharmacy and Poisons Board
PSA	Pressure Swing Adsorption
SCHMT	Sub County Health Management Team
SOP	Standard Operating Procedure
UHC	Universal Health Coverage
WHO	World Health Organization

DEFINITION OF TERMS

Cylinder - A container, usually cylindrical suited for compressed, liquefied or dissolved gas, fitted with a device to regulate the spontaneous outflow of gas at atmospheric pressure and room temperature.

Gas - Any substance that is completely gaseous at 1.013 bar and +200C or has a vapor pressure exceeding 3 bar at +5000C.

Globally Harmonized System of Classification and Labeling of Chemicals (GHS) – A system for standardizing and harmonizing the classification and labeling of chemicals.

Good Manufacturing Practice (GMP) – That part of quality assurance that ensures that medical oxygen is consistently produced and controlled to the quality standards appropriate to their intended use and as required by the Marketing Authorization or Product Specification.

Hazard - Something with the potential to cause harm, injury, illness, disease or loss.

Hydrostatic pressure test - A test performed, as required by national or international regulations to ensure that pressure containers can withstand pressures up to the container's design pressure.

Liquefied gas - Gas which, when packaged for transport, is partially liquid (or solid) at a temperature above –50 to 146C.

Manifold - Equipment or an apparatus designed to enable one or more gas containers to be emptied and filled at the same time.

Manufacturer – Commercial entity, or individual engaging in the production of medical Oxygen.

Medical Gas - A gas that is manufactured and stored in a liquefied, non-liquefied, or cryogenic state, packaged, and intended for administration to a patient in anesthesia, therapy, or diagnosis; or used to operate medical equipment or for testing medical equipment. Any gas or mixture of gases intended to be administered to patients for therapeutic, diagnostic or prophylactic purposes using pharmacological action.

Non-return valve - A valve that permits flow in one direction only.

Risk - The likelihood of harm, injury, illness or loss from a particular hazard. Risk reflects both the likelihood of occurrence and its severity of outcome, for example, through an unexpected event happening that may either cause harm or have an impact upon the organization’s patients, employees, contractors or visitors including the general public.

Risk Assessment - The process whereby hazards are identified and the level of risk identified is evaluated and control measures are implemented.

Tank - A static thermally insulated container designed for the storage of liquefied or cryogenic gas. They are also called “fixed cryogenic vessels”

Valve - A device for opening and closing containers.

Vent - To remove the residual gas from a container/system down to 1.013 bar by opening the container/system to the atmosphere.

1 INTRODUCTION

1.1 MEDICAL GASES FOR THE HEALTH SYSTEM

The provision of quality medical gases is essential to the health system. Medical gases are critical for patient management in medical, pediatric, surgical and obstetric emergencies. They are also used for laboratory diagnosis and operating surgical equipment in health facilities.

Types of Medical Gases

i.	Oxygen	**ii.**	Nitrous oxide	**iii.**	Nitrogen
iv.	Carbon dioxide	**v.**	Helium	**vi.**	Argon
vii.	Medical air	**viii.**	Surgical air	**ix.**	Compressed air
x.	Vacuum	**xi.**	Heliox	**xii.**	Entonox
xiii.	Krypton	**xiv.**	Neon	**xv.**	Carbon monoxide

Uses of Selected Medical Gases

1. **Oxygen** - hypoxemia
2. **Carbon dioxide** – invasive surgery, laparoscopy, cryotherapy, carrier for drug delivery, respiratory stimulant.
3. **Nitrogen** – laboratory freezers, pharmaceutical industry, powering surgical and other equipment, superconductive Magnetic Resonance Imaging.
4. **Nitrous Oxide** – Anesthetic
5. **Entonox (50% Nitrous Oxide and 50% Oxygen)** – short pain relief, calming anxiety during painful procedures, labor
6. **Helium** – For treatment of upper airway obstruction or increased airway resistance
7. **Heliox** – (79% Helium and 21% Oxygen) – Assist delivery of Oxygen to the lung
8. **Argon** – retinal detachment and retinal phototherapy, welding arteries during surgery and destroying tumors

1.2 SITUATION ANALYSIS AND OUTLINE OF THE PROBLEM

In Kenya, various assessments have revealed inadequacies in the quality and quantity of oxygen available for medical use, as well as in the delivery of the same.

From the Kenya Harmonized Health Facility Assessment 2018/2019, in terms of readiness to offer services for the management of cardiovascular disease (CVD), Oxygen had the lowest availability (16%) of the tracer items for CVD. There was a similar low availability of oxygen for management of chronic respiratory disease. On the other hand, for breathing emergency care, administration of Oxygen was the highest available intervention (78% of hospitals). Measurement of Pulse oximetry at triage units and the emergency units was available in only 58% of hospitals for both services.

In a study carried out in Level 2 and Level 3 facilities in 11 Counties in Kenya in December 2020 (Prof. Madara Ogot, Dr. Richard Ayah, Rita Muriuki and Prof. James Nyangaya. Oxygen Access and Affordability in Health Facilities in Kenya. UON. 2021), 65% facilities did not have any Oxygen at all while 35% of the facilities had Oxygen supply. Analysis by ownership revealed that 57% of private hospitals had Oxygen supply compared to 25% of public health facilities, and 25 % of faith-based hospitals.

A cross-sectional survey (2012) in 22 internship hospitals revealed that less than 50% had all the resources needed to provide Oxygen. (WHO. Availability and Use Oxygen in District Hospitals in Low- and Middle-Income Countries. 2017).

In the MOH facilities assessment, it was found that some equipment was underutilized while in some cases equipment such as a single concentrator was shared by up to eight patients yet designed for one. This was attributed to the lack of knowledge about the type of device by the HCW on duty, resources and demand mismatch. (Medical Devices Management Policy 2019-2030. Ministry of Health. 2019).

The challenges can thus be summed up as follows:

- **i.** Inadequate availability of medical oxygen
- **ii.** Poor quality medical oxygen
- **iii.** Unrecommended conversion of industrial oxygen for medical use
- **iv.** Poor quality or inadequate infrastructure, facilities and equipment for oxygen production and delivery
- **v.** Shortage or absence of trained staff
- **vi.** Inadequate guidelines, standards, and protocols for the production and delivery of medical oxygen
- **vii.** Weak logistics management
- **viii**. Ineffective or absent supportive supervision and mentorship
- **ix**. Inadequate information for decision-making
- **x.** Lack of adherence to existing regulations, standards and laws and poor enforcement of the same
- **xi.** Weak regulation in the production and delivery of medical oxygen
- **xii.** Inadequate quality assurance practices
- **xiii.** Donations whose specifications are not in line with Kenyan standards

Key issues to be addressed:

- **a.** Quality of medical oxygen produced
- **b.** Systems for the delivery of medical oxygen
- **c.** Operations management and maintenance
- **d.** Quality assurance and regulation
- **e.** Monitoring and reporting
- **f.** Environmentally safe disposal of waste
- **g.** Human resource capacity

1.3 SCOPE AND APPLICATION OF THE GUIDELINES

These guidelines apply to industrial and on-site producers (health facilities), distributors, handlers and HCWs of medical oxygen.

1.4 GOAL OF THE GUIDELINES

To ensure the availability and rational use of medical oxygen.

1.5 OBJECTIVES OF THE GUIDELINES

i. To ensure availability and utilization of quality and safe medical oxygen.
ii. Ensure adherence to the recommended standards and protocols in the cost-effective production, delivery and management of medical oxygen.
iii. Maximize the safety of medical oxygen through effective quality assurance, monitoring and reporting.

1.6 CONTEXT AND POLICY ENVIRONMENT

The Kenya Health Policy (2014-2030)

The Kenya Health Policy (KHP), 2014–2030 provides directions to ensure significant improvement in the overall status of health in Kenya in line with the Constitution of Kenya 2010, the country's long-term development agenda, Vision 2030 and global commitments. KHP has 8 policy orientations.

Policy Framework for Health: Orientations, Principles, Objectives, and Goal

Policy Orientation 3: Health Products and Technologies (HPT): "is geared towards ensuring that effective, safe, and affordable health products and technologies are available and appropriately used at all times while moving towards maintaining a strategic national health products and technologies (HPT) reserve.

Policy Objective 4: provision of essential healthcare: provision of health services with an emphasis on affordability, equity, access and quality of healthcare that is responsive to clients' needs. Key strategies are ensuring access to emergency care and provision of a quality KEPH as per norms, standards, and guidelines by the defined levels of care.

Kenya Health Sector Strategic Plan (2018–2023)

In the area of health service delivery, there is a key focus on increasing access to care that is equitable in terms of quality and availability of services at all levels, including emergency care.

Kenya Essential Medicines List (KEML)

Oxygen is listed in KEML emphasizing its importance as part of essential health products and technologies.

Medical oxygen should be available in all health facilities to reduce mortality arising from conditions that reduce the levels of oxygen in the blood (hypoxemia).

Kenya Essential Medical Supplies List (KEMSL)

Covers the Oxygen delivery equipment. They are listed as essential supplies

1.7 JUSTIFICATION FOR THE DEVELOPMENT OF THE GUIDELINES

Whereas oxygen therapy is recommended for the management of various hypoxemic conditions, health facilities have not been able to adequately provide it. The emergence of COVID-19 aggravated an already dire situation on medical oxygen access.

There are inadequate guidelines, standards and protocols for the production, storage and delivery of medical oxygen. Regulation and quality assurance in the production and delivery of medical oxygen is weak. There is a lack of data for decision-making and inadequate monitoring of products, processes and systems. Inadequate knowledge and skills among HCWs and technicians hamper the safe and effective use of medical oxygen systems and/or equipment.

The guideline is aligned to:

- The Constitution of Kenya (2010)
- Vision 2030
- Kenya Health Policy 2014-2030
- Universal Health Coverage (UHC) in attainment of the Bottom-Up Economic Transformation Agenda (BETA)
- The Health Act (No. 21 of 2017)
- Kenya Health Sector Strategic Plan 2023-2027
- The guidelines will provide policy guidance and standards for oxygen production and delivery for medical services in Kenya

1.8 DEVELOPMENT PROCESS

These guidelines were developed through an extensive consultative process.

i. A technical working group was appointed by the Principal Secretary to steer the process.
ii. The initial meetings to define the scope and content of the guidelines were held, followed by detailed background work.
iii. A workshop was convened to review and harmonize the process maps and to develop the content of the guidelines.
iv. The output from the workshop provided the basis for drafting the guidelines.
v. The outline and draft were presented to internal stakeholders for technical review and input.
vi. More workshops were held to engage counties and other stakeholders both internal and external as well as other technical experts.
vii. The final document was, thereafter, approved for dissemination and implementation.

2 PRODUCTION OF MEDICAL OXYGEN

2.1 MEDICAL OXYGEN PRODUCTION

The production of medical oxygen is done through various methods of concentration, possible because of air separation units (ASU), which separate nitrogen, oxygen, and sometimes inert gases such as argon. The methods for obtaining concentrated oxygen include:

i. Cryogenic fractional distillation - Utilizes an extremely cold (freezing, cryogenic) section to generate Liquid Oxygen (LOX)
ii. Pressure swing adsorption (PSA) generates medical oxygen (gaseous). Oxygen concentrators are used for producing low-volume oxygen. They use PSA technology (molecular sieve) and oxygen concentration should be above 90%
iii. Vacuum Swing Adsorption (VSA) - segregates gases from a gaseous mixture at near ambient pressure; the process then swings to a vacuum to regenerate the adsorbent material. It differs from other PSA techniques because it operates at near-ambient temperatures and pressures
iv. Vacuum pressure swing absorption (VPSA), is a mixed technology, which combines engineering systems of pressure variations from positive (pressure swing adsorption) to negative (vacuum swing adsorption) at different stages of the overall process to concentrate oxygen
v. Oxygen concentrators - used for producing low-volume oxygen suitable for one patient or for home use. They use PSA technology (molecular sieve) and oxygen concentration should be above 90%
vi. Chemical process - the reaction between hydrogen peroxide and water produces oxygen. However, it is difficult to utilize this process to produce large volumes. (American Society of Chemistry)

2.2 INDUSTRIAL / OFF-SITE PRODUCTION

Medical oxygen is manufactured, controlled, stored and distributed per the recommendations in prevailing relevant guidelines.

The quality system should incorporate the principles of GMP and good distribution practice which should be applied to the life cycle stages of medical oxygen. This includes steps such as the receipt of raw materials, manufacturing, filling, testing, release, distribution and container return after the use of medical oxygen.

2.3 ON-SITE PRODUCTION

This includes the manufacturing of medical oxygen in hospitals, or at home for personal use.

The principles for industrial production may be applied in those instances to ensure that oxygen generated at hospitals or homes is suitable for their intended use and meets the appropriate quality standards (as per current KEBS standards and WHO references).

2.4 REGULATION OF PRODUCTION

In pursuit of patient safety and risk minimization at production, the following regulations apply.

a. Medical oxygen requires current good manufacturing practices (cGMP) that ensure drug safety, identity, strength, quality, and purity
b. Both air separation units (ASUs) that produce liquid oxygen and other gases in bulk quantities for medical applications, and transfillers that take bulk oxygen (liquid or gas) and transfer it to a smaller container must be regulated.
c. Oxygen concentrators, by contrast, are not considered to be medical gas manufacturing equipment and are instead regulated as medical devices.
d. A firm involved in production, packaging and labeling shall ensure that related accessories of medical products comply with established standards (KS 10651-5:2006)
e. No manufacturer, distributor, importer or exporter shall sell a medical gas unless it has been produced, packaged/labeled, tested, and stored per Pharmacy and Poisons Board (PPB) requirements contained in the Guidelines for Inspection of Manufacturers of Medical Gasses (Pharmacy and Poisons Board, February 2022).

2.5 QUALITY STANDARDS FOR MEDICAL OXYGEN

Medical Oxygen must comply with standard as described in Table 1 and Table 2 below:

Table 1: Oxygen Purity as defined in KEBS Standard KS –2170-1:2009

Purity of medical Oxygen (at STP)	Oxygen purity ≥ 99.5% v/v as per KEBS standard KS 2170-1:2009	
Impurity limits (at STP)	As per KEBS standard KS 2170-1:2009 for Medical Oxygen	
	Carbon monoxide ppm v/v	≤ 5
	Carbon dioxide ppm v/v	≤ 300
	Water ppm v/v	≤60
	Oil mg/m3	≤ 0.1

The test method is also described in the standard.

The quality of Oxygen produced on-site by PSA/VSA/VPSA technologies shall be as per the European Pharmacopoeia as described in Table 2.

Table 2: Purity of Medical Oxygen as defined in the Monograph 'Oxygen 93% 04/2011:2455 European Pharmacopoeia 7.1'

Purpose	To continually produce medical grade Oxygen, 93 (Oxygen 93) at STP from ambient air
Purity of medical Oxygen produced (At STP)	Oxygen 93% ± 3% as per *PhEur. 7.1, No. 04/2011: 2455*

Impurity limits (At STP)	As per *PhEur. 7.1, No. 04/2011: 2455*	
	Carbon monoxide ppm v/v	≤ 5
	Carbon dioxide ppm v/v	≤ 300
	Water ppm v/v	≤67
	Oil mg/m^3	≤ 0.1
	Nitrogen Monoxide and Nitrogen dioxide ppm v/v	≤ 2
	Sulfur dioxide ppm v/v	≤ 1

3 STORAGE OF MEDICAL OXYGEN

3.0 STORAGE OF MEDICAL OXYGEN

Storage of medical oxygen shall be as per regulations and standards.

i. Storage equipment must be appropriate for medical oxygen.
ii. Materials used shall be non-toxic, non-reactive to medical oxygen, and corrosion-resistant.
iii. The construction of containers for storage must comply with relevant approved international standards.

3.1 CONTAINERS FOR MEDICAL OXYGEN

There are two types of containers for storage of medical oxygen. Cylinders and bulk tanks.

Cylinders

Cylinders are constructed from steel, aluminum/alloy, carbon fiber, or other composite material (as per relevant international standards).

a. Cylinders are constructed from steel, aluminum/alloy, carbon fiber, or other composite material (as per relevant international standards).
b. Cylinders should be painted and cleaned.
c. The cylinder shall be marked and colored for the specific gas as per ***KS ISO 32:1977*** as follows.

— Name of gas
— Name and address of the manufacturer
— Purity of the gas
— Batch number
— Date of filling
— Filling pressure

d. The cylinder must have precautionary labels as per KEBS standards KS ISO 7225
e. The chemical formula must be indicated
f. The cylinders shall be fitted with a valve or tap which shall not be lubricated with oil or grease. Valve fittings should comply with relevant international standards
g. The complete regulator (with flow meter) shall be fixed as recommended by the manufacturer and following the in-country protocols
h. All cylinders should be fitted with valve caps or valve guards designed as per ***KS ISO 11117:1998***
i. Medical gas cylinders generally require no maintenance other than the periodic tests for quality assurance;

— All medical Oxygen cylinders should be serviced at recommended intervals and checked to ensure safety in storage, use and transportation

— All medical Oxygen cylinders must be certified every five years

- Regulators and flow meters shall be inspected and calibrated following the manufacturer's instructions by a certified biomedical engineer at annual intervals, and records kept within the health facilities.

Cryogenic Tanks/Bulk Liquid Oxygen Tanks

This is a static thermally insulated container designed for the storage of liquefied or cryogenic medical oxygen. It is constructed from steel, aluminum/alloy, carbon fiber or other composite material as per relevant international standards.

3.2 STORAGE

Compressed Medical Oxygen

- Compressed medical oxygen shall be stored in cylinders
- All medical oxygen cylinders shall be stored in demarcated areas that are properly labeled. The demarcated areas are in three types: Filled, empty and faulty
- Broken or damaged cylinders that can no longer be used should be withdrawn from usable stock
- Where applicable, disposal shall be done as per the provisions of the relevant Public Procurement and Asset Disposal Act

Liquid Medical Oxygen

- Tanks shall be installed at a suitable and accessible location away from other installations e.g., incinerators, kitchens, power generators, vehicle parking, fuel stations, electrical lines, etc.
- Tanks should be secured (caged) with controlled access by authorized personnel only

3.3 STORAGE AREAS

i. The storage area for compressed medical oxygen cylinders shall be divided into three zones i.e., full, empty and faulty

ii. Storage areas should be appropriately designed, constructed and maintained

— Size – The store should have adequate space for storage and navigation

— Walling – Materials used are stone or steel whereby the wall occupies half the height. Adequate lighting, open ventilation for the remaining half of the height

— Height – Minimum 3M

— Floor – Must have a foundation plinth constructed from concrete and raised in such a way that drainage/ rainwater cannot spill into the system. Standard concrete floor finished with terrazzo or equivalent

— Roofing – Iron sheets, concrete slab, tiles or equivalent

— Entrance- Minimum of 2.4m (Width) by 2.0m (Height) to allow movement. A ramp for trolleys and vehicle access (for loading and unloading)

— All facilities shall be equipped with a system that will provide suitable protection against theft

— The store should have firefighting equipment

iii. They should be kept clean and dry. A written cleaning program should be available indicating the frequency of cleaning and the methods to be used to clean the storage areas.

iv. The location of the storage area should be away from other installations, water, sewer, drainage and electrical lines

v. Safety distances should be complied with

3.4 STORAGE CONDITIONS

a. All cylinders must be stored in the designated area (s)

b. Cylinders must be stored vertically and they should be restrained

c. Conditions for storage should be such that they prevent alterations purity of oxygen

d. Where special storage conditions are required, these should be provided, controlled, monitored and recorded

e. There should be a written program for pest control

f. For quality control, pressure and purity should be monitored and recorded monthly

g. Periodic cylinder stock reconciliation should be performed at defined intervals by comparing the actual and recorded stocks. Discrepancies should be identified and investigated. The appropriate corrective action should be taken.

3.5 INVENTORY MANAGEMENT

All facilities shall use inventory management and control systems that:

- Track production
- Monitor quality
- Facilitate tracking of consumption of oxygen
- Track the movement of cylinders, equipment and accessories
- Facilitate decision making including quantification of facility oxygen needs and associated production costs
- Monitoring wastage, damage and obsolescence should be done routinely

4 SUPPLY AND DELIVERY OF MEDICAL OXYGEN

4.1 SUPPLY OF MEDICAL OXYGEN

Health Facility Oxygen Supply Systems

Oxygen can be supplied to health facilities through a variety of methods, such as tanks for compressed liquid Oxygen (LOX), compressed gas cylinders, on-site pressure swing adsorption (PSA/VSA/VPSA) plants and Oxygen concentrators

- Infrastructure, skilled healthcare workforce, risk management and available financing should inform the most appropriate option
- Ensure the availability of appropriate accessories
- A health facility may have one or more sources of Oxygen supply

The supply system should consist of a reliable primary source that serves as the main supply to most areas where Oxygen is required in the health facility, a secondary supply to serve as a backup in case of failure of the primary one and a tertiary supply in case there is failure of the primary and secondary supplies.

I. Primary supply

- The primary supply should have a usable quantity of medical Oxygen to meet expected usage between scheduled deliveries.

II. Secondary supply

- The secondary source is the backup supply in the event of failure of the primary supply
- As a minimum, the secondary supply should have a usable quantity of medical Oxygen to meet the expected demand between the time of request and the time of delivery

III. Tertiary supply

- Should be reserved for emergency use

Piping and manifold system for medical Oxygen

The purpose of this system is to distribute medical oxygen from a source to the end-user (patient)

i. Description

It consists of a network of medical-grade interconnected pipes, control systems, terminal units (bed units) and manifolds (designed and installed as per ISO 7396-1:2016 - Medical gas pipeline systems - Part 1: Pipeline systems for compressed medical gases and vacuum). The source of medical Oxygen can be a PSA plant, bulk liquid storage tank or a bank of cylinders or a combination of one or more of the above.

ii. Considerations

The pressure of medical oxygen at terminal units must be at 4 bar

Purity must be maintained throughout the piping system

Installation must be as per guidelines (Health Technical Memorandum 02-01: Medical gas pipeline systems)

Transportation

I. Bulk transportation

- When transporting liquid Oxygen, it shall comply with the relevant standards and guidelines
- Cylinders should be transported in compliance with the relevant standards and guidelines

II. Health facilities

- For transportation to or out of the health facility, a designated vehicle purposely built (in compliance with KEBS standards and PPB guidelines) for transportation of Oxygen gas cylinders
- Ambulances should only carry Oxygen cylinder(s) (size D and F) intended for the patient that they will be transporting
- Within the health facility, cylinders should be transported on designated trolleys
- Cylinders should be secured to wall brackets at the point of use

4.2 DELIVERY SYSTEMS FOR MEDICAL OXYGEN

Description

Delivery systems are classified into low and high-flow delivery systems.

Low-flow Delivery System

Low-flow systems provide oxygen at flow rates that are lower than patients' inspiratory demands. The standard flow meters are calibrated to oxygen flow rates of up to 15 L/min.

(*Reference: https://www.ahajournals.org/doi/10.1161/01.STR.0000185387.51425.f9;

https://opencriticalcare.org/encyclopedia/overview-of-oxygen-delivery-devices/).)

Devices for low-flow delivery systems are as follows:

— Low Flow Nasal Cannula
— Simple Facemask
— Facemask with reservoir (non-rebreather)
— Facemask with reservoir (partial rebreather)
— Bubble CPAP
— Nebulizer mask
— Bag Valve Mask (BVM)
— Oxygen concentrators

High-flow Delivery System

High-flow systems provide a constant FiO2 (Fraction of Inspired Oxygen) by delivering the gas at flow rates that exceed the patient's peak inspiratory flow rate and by using devices that entrain a fixed proportion of room air.

(*Reference: https://www.ahajournals.org/doi/10.1161/01.STR.0000185387.51425.f9

https://opencriticalcare.org/encyclopedia/overview-of-oxygen-delivery-devices/)

Devices for high-flow delivery systems:

- High-flow nasal cannulas
- Air entrainment Mask (i.e. Venturi Mask)
- Anesthetic machines
- Ventilators Invasive and Non-Invasive

5 TESTING AND COMMISSIONING

5.0 TESTING AND COMMISSIONING

This chapter covers the testing of medical Oxygen, calibration of equipment and commissioning of the Medical Oxygen supply system(s) as well as training of personnel. The importance of testing Medical Oxygen is that it assures the quality and safety of the product available for use.

Calibration of equipment gives an assurance of the accuracy of the equipment required to provide the critical measurements necessary for the performance of the systems.

Commissioning is essential to guarantee that the system will work as it was designed to. It is also to train personnel who will produce, use or handle Medical Oxygen.

Testing of Medical Oxygen

The concentration of medical Oxygen is determined as a percentage by volume using a suitable paramagnetic analyzer. The analyzer should have a suitable readable range with readability of 0.1% or better. [ref: KEBS KS 2170-1:2009, KS 2170-2:2008]

For Oxygen 99.5%, the acceptance criteria is not less than 99.0% of Oxygen by volume. The limits for impurities are: Carbon dioxide maximum of 300 ppm V/V, Carbon monoxide maximum of 5 ppm V/V, Water vapor maximum of 67 ppm V/V, Oil of 0.1mg/m3 [ref: BP 2019, KEBS KS 2170-1:2009]

Testing for Health Facilities Generating Medical Oxygen (93±3%) and Filling Cylinders:

i. Oxygen purity - calibrated Oxygen analyzer
ii. Should not be less than 90%
iii. Impurities - periodically submit samples to KEBS for further analysis
iv. These tests also apply for Oxygen concentrators

Testing of Medical Oxygen Storage and Delivery Systems

I. Tests on the pipeline

The following are tests that should be performed on the pipeline;

i. Visual check of the pipeline labeling, marking and sleeving and support
ii. Leakage test
iii. Test for cross-connection

II. Tests after complete installation of the pipeline system

The following tests should be carried out after the complete installation of the pipeline system

a. Tests for leakage
b. Tests of Area Valve Service Units (AVSUs) for closure, correct service and control of the terminal units in the zone: checks for correct labeling of AVSUs for zone reference and identity of terminal units controlled and flow direction indication
c. Tests of Line Valve Assemblies (LVAs) for closure and identification
d. Tests for cross-connection, flow, pressure drop, mechanical function and correct identity of the terminal units: checks for correct labeling and association with AVSUs (this is only required when, within a specific area, there are separate circuits for the same service, for example dual/ split circuits)
e. Tests for mechanical function and identity of Non-Interchangeable Screw Threaded (NIST) connectors
f. Performance tests of the pipeline system
g. Functional tests of all supply systems
h. Checks of safety valve certification
i. Tests of warning systems
j. Tests for particulate contamination/odor/taste: these may be carried out immediately after installation, using medical air, or after purging and filling with the specified gases.

5.1 CALIBRATION

i. Instruments must be calibrated at regular intervals. The calibration certificates/records for the functional as well as quality instrumentation should be available indicating the status of calibration and the intervals
ii. Personnel who carry out calibration and preventive maintenance should have appropriate qualifications and training.
iii. A calibration program should be available and should provide information such as calibration standards and limits, responsible persons, records and actions to be taken when problems are identified.
iv. There should be traceability to standards (e.g., national, regional or international standards) used in the calibration.
v. When the equipment, instruments and other devices have not been used for a certain period, their function and calibration status should be verified and shown to be satisfactory before use.

Reference: WHO TRS 937 ANNEX 4, HTM-02

Commissioning

Commissioning is the setting up, adjustment and testing of equipment or a system to ensure that all safety and performance requirements have been met as per the user specifications and capacities specified by the designer or developer. The commissioning procedures are required for new installations, additions to existing installations and modifications of existing installations. These should be carried out by qualified personnel before the system is ready for use.

Technical training

- The personnel involved in the production, labeling, packaging, storing and administration of the medical oxygen must have the appropriate training.
- A training program for the personnel should be developed and regularly reviewed.
- Refresher training and reassessment of personnel should be carried out at regular intervals.

6 REGULATION AND QUALITY ASSURANCE FOR MEDICAL OXYGEN

6.1 REGULATION OF MANUFACTURE

The guidelines for regulation and quality assurance of medical oxygen consist of applicable principles and practices that are internationally acceptable and that should facilitate compliance with Good Manufacturing Practices for firms that are involved in the production, control, packaging or labeling, storage and distribution of medical oxygen.

Among the major highlights of the guideline include:

a. **Quality management system:** Companies that are involved in the manufacture, control, storage and distribution of medical oxygen should document, implement and maintain a comprehensively designed and clearly defined quality management system
b. **Quality risk management:** The manufacturer has a systematic process for assessing, controlling, communicating and reviewing risks to the quality of medical oxygen across the production lifecycle
c. **Good Manufacturing Practices for medical oxygen:** The manufacturer ensures that medical oxygen is consistently produced and controlled according to the quality standards appropriate to the intended use
d. **The Premises** where medical oxygen is manufactured should be located, designed, constructed and maintained to suit the operations to be carried out
e. **The Equipment and Utilities** used for the production of medical oxygen are suitable and permit effective cleaning and maintenance and minimize the risk of contamination
f. **The personnel** involved in the manufacture, control, certification or release of a batch, storage and distribution of medical oxygen should possess adequate qualifications, scientific education and practical experience
g. **The manufacturer** maintains a high level of sanitation and hygiene
h. **The manufacturer conducts an annual quality review** of all the medical oxygen manufactured within that period to verify the consistency of the existing processes
i. **Self-inspections** should be carried out according to a written, authorized procedure. The objective should be to detect any shortcomings in the implementation of GMP and to recommend the necessary corrective actions
j. **There are systems in place to handle market complaints and recalls**
k. **Documentation system** should be established and implemented such as specifications, SOPs and related documents, as appropriate for the manufacture, control, storage, and distribution of medical gases
l. **Quality control:** To ensure the necessary tests are carried out and that materials are not released for use nor products released for sale or supply until their quality has been confirmed to be compliant
m. **Product life cycle and continuous improvement:** These principles should be applied in the relevant areas of the facility, equipment, instrument, utility, product and processes

n. **Storage areas** should be appropriately designed, constructed and maintained. They should be kept clean and dry and there should be sufficient space and ventilation

o. **The scope and extent of qualification and validation** should be determined based on risk management principles. Authorized procedures, protocols and records should be maintained.

The detailed guidelines on regulation and quality assurance of medical gases (including oxygen) can be obtained at www.pharmacyboardkenya.org.

Any person/entity interested in setting up a new manufacturing facility for medical oxygen in Kenya should follow the procedure as outlined in the guidelines for setting up a new manufacturing facility in Kenya for health products and technologies available on the **PPB** website. www.pharmacyboardkenya.org, and **Ministry of Health**: www.health.go.ke

6.2 QUALITY ASSURANCE

Inspection Strategy

- **Routine surveillance inspections**: Routine surveillance inspections document and evaluate Medical Oxygen manufacturing establishment compliance with the cGMP requirements. It is a requirement that all the manufacturers of medical oxygen should comply with the laid down cGMP requirements.
- **Compliance Inspections**: Compliance inspections evaluate or verify firms' implementation of corrective actions and preventive actions to address deficiencies arising from previous inspections.

— **For-cause inspections:** The regulator shall carry out for-cause inspections to investigate specific problems or to evaluate specific aspects of a manufacturing operation. For-cause inspections may be initiated from consumer complaints, recall notices, etc.

- **The frequency of inspections** for manufacturers of medical oxygen shall be determined by; the risk classification of the manufacturer as per previous inspection results, adverse events, and reports of mix-ups, injuries, deaths, or contamination.
- **The national regulatory authority** shall make an annual schedule for the inspection of medical oxygen manufacturers.
- **Inspection teams** shall comprise experts from the national and county level.
- **Inspectional approaches:** Inspections of medical oxyegn manufacturers are to be performed under either full or abbreviated inspections using the systems strategy outlined below;

— **Full Inspections** include coverage of at least four systems

— **Abbreviated Inspections** include coverage of two systems plus a set of questions that cover key aspects of medical gas manufacturing, drawn from all of the systems. Abbreviated Inspections are recommended for Oxygen-only transfillers with a satisfactory record of cGMP compliance and for other medical gas firms as described in this program

- **Initial manufacturers** of Medical Oxygen should be given priority for inspection.

7 OPERATIONAL MANAGEMENT

7.1 CLASSIFICATION OF GASES

Classification of gases by physical type

I. Permanent gases

These are gases that remain in the gaseous state in the cylinders at normal temperatures. The volume of the contents of the cylinder is directly related to the pressure of the gas; for example, at a quarter of the filled pressure, the cylinder is a quarter full. Such gases include oxygen and medical air.

II. Liquefiable gases

These are gases that are supplied as a liquid at normal temperatures (for example nitrous oxide and carbon dioxide) or gases supplied as a liquid at a cryogenic temperature, that is, below –40°C (for example liquid nitrogen and liquid oxygen).

The most common gases, grouped as above, likely to be used in health buildings are shown below:

Table 3: Common Gases Used in Healthcare Settings

Group Classification of gas cylinder contents	Medical Gas	Non-medical gases
1. Flammable (red diamond label)		Acetylene LPG (for example propane, butane) Synthetic Town Gas (STG) Methane Natural Gas Hydrogen
2. Oxidizing and/or supports combustion (yellow diamond label)	Oxygen Nitrous oxide Oxygen/nitrous oxide Oxygen/Carbon dioxide Oxygen/helium mixtures	Oxygen Nitrous oxide Oxygen/nitrous, oxide mixtures
3. Toxic and corrosive		

3.1 Toxic and/or corrosive and flammable		Ammonia Ethylene oxide (C2H4O) Carbon monoxide Ethylene oxide/carbon dioxide measures >6% C2H4O
3.2 Toxic and/or corrosive and oxidizing		Nitric oxide measures Sulfur dioxide Chlorine
3.3 Toxic and/or corrosive only		Ethylene oxide/halocarbon mixtures <15% C2H4O (certain conditions only) Ethylene oxide /carbon dioxide mixtures <6% C2H4O
4. Others including inert, but excluding toxic or corrosive gases (green diamond on the label)	Carbon dioxide Helium Medical Nitric oxide 1000vpm (volume parts per million) in nitrogen	Compressed air Carbon dioxide Nitrogen Argon Helium/Halocarbon Refrigerants

Classification of gas cylinders

Gas cylinders are classified into two main categories: medical and non-medical. Cylinders from these two categories should never be mixed, either in storage or in use.

Gas cylinders are subdivided into groups, depending on the major risk associated with the cylinder contents as follows:

- **Group 1** – flammable
- **Group 2** – oxidizing
- **Group 3** – toxic or corrosive (the contents may also be flammable or oxidizing)
- **Group 4** – others (including inert gases).

Labeling/marking of cylinders

Cylinders should be color-coded and marked as per KS ISO 32, Gas cylinders for medical use — Marking for identification of content and KS ISO 7225, Gas cylinders — pre-cautionary labels

Each cylinder should have:

a. A batch label to include a unique batch number, filling branch code, cylinder code and product and expiry date;

b. A product identification label which includes:

— the product license number;
— the name and chemical symbol of the gas or gas mixture contained in the cylinder. Additionally, in the case of gas mixtures, the proportion of constituent gases should be shown;
— a hazard warning sign;
— a substance identification number;
— specific product and cylinder handling precautions;
— particular instructions to the user where necessary;
— safety information;

c. A serial number;

d. test mark, year and quarter of test.

Cylinders, pressure-reducing regulators and pressure gauges should be conspicuously marked “use no oil, grease or hand creams, etc.” or with the appropriate symbol. Cylinder yokes, pressure-reducing regulators and pressure gauges should be clearly and indelibly marked with the designation of the gas or gas mixture for which they are intended.

Pressure gauges should be as per KS 2170.

Cylinder color codes

Cylinder colors are detailed in the safety data sheets provided by the cylinder gas suppliers.

Cylinder sizing and naming

Cylinder sizes and names are detailed in the safety data sheets provided by the cylinder gas suppliers.

7.2 HANDLING OF CYLINDERS

Cylinder Management

Medical gases are medicines and, as such, it is recommended that, regardless of operational infrastructure, the Chief Pharmacist should take an active role in the management of medical gas cylinders. Risk assessments must be carried out as part of the cylinder management process.

Sound cylinder management includes consideration on;

i. Storage and handling of cylinders
ii. Access to storage area
iii. Store temperature
iv. Transport of oxygen cylinders
v. Preparation of cylinders for use
vi. Operating cylinder valves

NOTE: ***Standard Operating Procedures (SOPs) shall be developed for the various processes***

Cylinder safety

The main hazards associated with gas cylinders are:

i. Careless storage, handling, dropping or impact that can cause physical or personal injury
ii. Leakage of gas
iii. Fire outbreak

These hazards should be minimized by:

i. Correct design, location and construction of cylinder storage areas

ii. Provision of suitable storage and handling equipment
iii. Adoption of safe operating practices through prohibition of smoking, ignition sources and naked flames near storage areas
iv. Ensuring oil-free handling of oxygen cylinders (risk of explosions)
v. Compliance with the Occupational Safety and Health (OSHA) Act, 2007
vi. Proper training and supervision of all staff working in medical gas cylinder storage and handling areas

7.3 MINIMUM REQUIREMENTS (FOR EACH LEVEL)

All staff working in this area must be properly trained and supervised in handling medical oxygen

The minimum requirement for each health facility by KEPH level of care is summarized below:

Table 4: Minimum Requirements For Each Facility Level

Health facility level	Services	Number of Beds	Medical gas supply requirements	Accessories	Comments
Level 2 (Dispensary)	Outpatient	N/A	Oxygen cylinders – 2 (capacity 1,360 to 6,800 Liters) Oxygen concentrators – 1 (Single, 5LPM) Ambulance cylinders - 2 (capacity 1,360 Liters)	1. Oxygen Trolleys (at least 2) 2. Oxygen regulators (at least 4) 3. Oxygen flow meters (at least 4) 4. Humidifier bottles (at least 4) 5. Wall bracket 6. Splitters	
Level 3 (Health center)	Outpatient Inpatient Maternity Surgical procedures	16 -24	Manifold and piping (Manifold 3x2) – 3 for use and 3 as standby Oxygen cylinders - 8 (2 per ward) (6.8 to 8.5m3 /6,800 to 8,500 L) Oxygen concentrators, single, 5LPM Ambulance cylinders- 4 (capacity 1.36m3) Nitrous Oxide cylinders - 2 (capacity 8.5m3) and regulators (at least 3)	1. Oxygen regulators (at least 6) 2. Oxygen flow meters - cylinder and wall type (at least 12) 3. Humidifier bottles (at least 12) 4. Oxygen Trolleys (at least 6) 5. wall cylinder brackets (at every bed)	2-3 Oxygen terminal outlets per ward & 1-2 concentrators
				6. Splitters	
Level 4 (Hospital)	Outpatient Inpatient Maternity Theatres	150 plus 2 operating theatre beds	Liquid Oxygen tank (3,000 to 10,000 L) PSA plant (capacity 250 LPM) Manifold of 8 x 2 (minimum) Minimum quantity of 30 cylinders (capacity 8.5 cubic meters) 15 Oxygen concentrators Ambulance cylinders- 8 (capacity 1360 Liters)	Minimum of 30 complete Oxygen regulators with flowmeters At least 50 wall flow meters Each ward, Theatre and critical area should have twin wall brackets for cylinders At least 10 Oxygen trolleys Splitters Humidifier bottles, at least 50	The estimated Oxygen requirement is 250 LPM Level 4 hospitals should have a minimum of two sources of Oxygen
Level 5 (Referral hospital)	Outpatient Inpatient Maternity Theatre	400 plus 4 operating theatre beds and 4 intensive care unit beds	Liquid Oxygen tank (10,000 to 20,000 L) PSA plant (capacity 500 LPM, duplex) A Manifold of 12 x 2 (total 24 of capacity 6.3-8.5m3) Minimum quantity of 30 cylinders (capacity 8.5 cubic meters) 15 Oxygen concentrators 10 small ambulance cylinders (capacity 1.36 m3) 5 medium cylinders (capacity 3.4m3) Medical/Surgical air: Dual system compressors produce 4 bar of medical air and 7 bar of surgical air. Manifold backup system of 12 cylinders of 6.3m3 or 8.5m3 each Nitrous Oxide: Manifold of cylinders 8.5 m3 Entonox cylinders	Minimum of 50 complete Oxygen regulators with flowmeters At least 300 wall flow meters Each ward, Theatre, and critical areas should have twin wall brackets for cylinders At least 20 Oxygen trolleys Splitters Humidifier bottles, at least 300	The estimated Oxygen requirement is 500 LPM Level 5 hospitals should have a minimum of two sources of Oxygen

			Heliox cylinders Helium cylinders Nitrogen – Dewar tanks Carbon dioxide cylinders (between 5 – 10 kg) Argon cylinders Vacuum – vacuum dual pump Scavenging system for theatre (dual system)		

Table 5: Various Oxygen Cylinder Capacity / Sizes

Cylinder size (kg)	Oxygen capacity in L
1.84 kg (Ambulance)	1360 liters
4.6 kg	3400 liters
9.2 kg	6800 liters
11.5kg	8500 liters

Storage and transportation requirements

I. Level 2 Facility

- **Storage space-** A well-ventilated storage area should be available. Should be a cool dry place free from any corrosive material with medical gas cylinders upright and secured with a chain to prevent toppling (refer to the section on storage)
- **Trolleys –** A trolley is required to ferry medical gas cylinders. The trolley should have a safety chain/belt to secure the cylinder (refer to the section on transportation of cylinders)

II. Level 3 Facility

- **Storage space -** For small facilities, similar requirements to those of level 2 facilities will suffice
- For Level 3 facilities, a cage that is well-ventilated and roofed. Safety warning signs must be indicated as recommended for cylinders and the manifold
- Trolleys are required to ferry medical gas cylinders. They should have a safety chain/belt to secure the cylinder (refer to the section on transportation of cylinders)

III. Level 4 facilities and above

- **Well-ventilated and roofed cages for cylinder storage.** Safety warning signs must be indicated as recommended for cylinders and the manifold
- **Trolleys are required to ferry medical gas cylinders.** They should have a safety chain/belt to secure the cylinder (refer to the section on transportation of cylinders)

7.4 DETERMINATION OF QUANTITIES OF MEDICAL OXYGEN

Each facility should carry out a quantification of the Oxygen need depending on the number of cases of patients requiring oxygen.

A documented procedure for quantification should be prepared and made accessible

- **For lower-level facilities** such as levels 2 and 3 it is recommended that a cylinder of Oxygen be availed with a buffer to deal with any medical, obstetric and pediatric emergencies pending referral to the next level within its Primary Care Network.
- **For higher-level facilities** (Levels 4-6) general formula for quantification at a facility is;

for Outpatient Requirements:-

Reported cases of condition * X Oxygen flow rate (L/min) for condition * X Average duration of treatment (min) ***

for Inpatient Requirements:-

No. of beds** X Average bed occupancy rate X Average Oxygen flow rate used when the bed is occupied (L/min) X Period of quantification

Notes:

	* For determination of outpatient requirements, the formula is applied to each specific condition (e.g., severe malaria, pneumonia, sepsis, asthma, meningitis and other emergencies) and the totals are summed up.
	** If a facility has more than one category of bed e.g., General beds, Added Services beds, High dependency unit and intensive care unit beds then the formula must be applied to each category and the total summed up. care must be taken to apply the appropriate oxygen flow rate for each category
	*** For duration and period, these must be converted to minutes to allow for calculation

*Reference: The Oxygen Delivery Toolkit by PATH

7.5 HUMAN RESOURCE FOR HEALTH - TRAINING OF HCWS, ROLES AND RESPONSIBILITIES

HRH Requirements

I. Level 2 Facility

HRH capacity - Health care workers at the facility should have the capacity (knowledge) on the safety and handling of medical gas cylinders as well as how to prescribe and administer the said gases to patients.

A designated porter - should be present at the facility to handle and transport pressurized gas cylinders safely.

II. Level 3 Facility

HRH capacity – Should be the same as that of Level 2 facilities

III. Level 4 facilities and above

HRH capacity – in addition to the requirements for level 2&3 facilities, these facilities must have adequate numbers of competent staff responsible for the management of medical oxygen:

a. Biomedical Engineer/Technologist to handle more maintenance responsibilities
b. Clinicians to prescribe medical gases
c. Nurse to administer and monitor the patients
d. Pharmacist to report and manage inventory
e. Supply chain officers to coordinate procurement of medical oxygen and accessories

Key Personnel in operations management and their responsibilities

1. Pharmacist

i. Ordering/Resupply
ii. Stock management
iii. Issues
iv. Forecasting and Quantification
v. Return of cylinders to stores
vi. Receipt of cylinders into stock

Note:

Cylinders that do not conform to the following requirements will not be accepted:

Each cylinder should have:

— a product identity label;
— a batch label.

Cylinders should be clean and free from rust and scale, and the paintwork should be in a condition enabling easy identification from the color-code chart

There should be a tamper-evident seal over the valve outlet.

2. Nursing Officer (County/Sub-county/Hospital)

i. On receipt of the cylinders on the ward/unit the nursing officer in charge must check the cylinder is full, expiry date and check the cylinder valve and regulator valve for function
ii. If the cylinder is not full or any discrepancy is noted then the Pharmacy must be informed immediately. The cylinder should not be accepted onto the ward however if this is unavoidable and temporary storage is necessary then the cylinder must be clearly labeled as not for use and a description of the fault/issue identified
iii. Handle, move, and where relevant, store medical gas cylinders safely
iv. Prepare a medical gas cylinder for use, connect it to a piece of medical equipment and, when empty, take the cylinder out of use, with due regard to any relevant local labeling requirements
v. Identify a faulty cylinder and take appropriate action
vi. Identify medical gas pipeline terminal units and flexible, color-coded hoses
vii. Safely and carefully use terminal units, their probes and flexible hose assemblies
viii. Prevent pollution of piped medical vacuum systems
ix. Cope with and prevent medical gas emergencies

3. Biomedical Engineer (County/Sub-county/Hospital)

i. Connect and disconnect safely pressurized gas cylinders from plant, manifolds and user equipment
ii. Respond to pressurized system alarms, hazards and emergencies, and observe local reporting procedures
iii. Replenish and operate (where required) emergency reserve supply systems following local estate directives
iv. Maintain medical oxygen inventories under supervision

4. Designated Porter

i. Identify a range of medical gas cylinders by color code, size and other labeling, and select cylinders by the needs of clinical/medical/engineering staff
ii. Handle and transport pressurized oxygen gas cylinders safely
iii. Identify a range of patient-connected equipment requiring pipeline and/or cylinder supplies of gas

Duties and Responsibilities

- This applies to all officers handling and using medical oxygen
- The officers handling and using medical gases must comply with all statutory obligations spelled out in this document and any other in the country

Consideration should be given to the following: -

— They all must be trained and operate at their levels of training. They should also be authorized to perform the duties as per levels of training
— Visual check medical gas equipment before they are used
— Remove defective equipment from use immediately, label it as faulty, decontaminate and send it for repair
— The safety of the officers at work is maintained at all times, using the appropriate Personal Protective Equipment (PPE) and manual handling equipment
— All officers must report all accidents or incidents, adverse events and near misses to the administration
— Maintain medical oxygen inventory records relevant to their designated departments

1. Chief Executive Responsibilities

i. Shall be responsible for the provision of health and safety
ii. Assure the board of management
iii. Ensure that the institution complies with the medical oxygen guidelines
iv. Ensure implementation of safe medical gas handling practices through appropriate delegation of duties and supervisory tasks
v. Ensure the availability of funds to procure adequate gases in time.

2. Managers and Heads of Units

i. Ensure the provision and implementation of specific procedures relating to medical oxygen
ii. Put in place processes that lead to monitoring and reviewing risk assessments and risk registers
iii. Ensure that all operators are duly licensed to practice
iv. Ensure that all the procedures and protocols that are developed reflect site-specific systems and processes used in their premises detailing all staff who are involved with the use, handling, and storage of medical gases
v. Identifying staff involved with the use, storage and handling of medical gas by way of a risk assessment outlining the hazards
vi. Ensuring protocols are developed for safely transporting medical gases, both on and off-site.
vii. Advise on the policy implementation and review
viii. Ensure adequate budgeting is done
ix. Compile data for all units under them

3. Nursing Officers, Team Leaders, Ward/Departmental Managers' Responsibilities

i. Provide suitable and sufficient specialist training to enable competence that is appropriate to their level of operation
ii. Avail personal protective equipment (PPE) and cylinder trolleys, and maintain them to a serviceable condition
iii. Make sure that all staff are aware of and use and implement the medical oxygen guidelines
iv. Make sure all staff are adequately trained considering their needs
v. Make sure all local storage areas are protected
vi. Ensure adequate quantification of needs
vii. Ensure timely ordering
viii. Continuously monitor stock levels
ix. Ensure that all documentation is done

4. Biomedical Engineering

i. Repair, maintain, calibrate and supply regulators, flowmeters, suction units, hoses and high-pressure systems connected to medical devices
ii. Provide technical advice to the facility for the procurement of any medical equipment that will be connected to the medical oxygen pipeline system
iii. Supervisory functions to all service units

5. Recognized Medical Oxygen Contractors

i. Ensure that they have qualified personnel for their operations
ii. Comply with all the regulatory requirements
iii. Ensure the right equipment for the production of medical gases
iv. Ensure that all equipment used are well serviced and maintained

6. Medical Oxygen Committees/Sub-committees

i. Provision of framework to enable the organizations to comply with regulations and guidelines for medical oxygen
ii. Ensure cost-effective gas availability
iii. Ensure training for employees is done to enable them to work within their competency levels
iv. Monitor incidents and take action to ensure compliance with the policy
v. Collect and maintain incident data for future reference
vi. Monitor implementation of specific operational guidelines for medical oxygen for each hospital

8 MONITORING AND REPORTING

8.1 INTRODUCTION

Monitoring and evaluation processes are essential functions to ensure that the priority health actions outlined are implemented as planned against stated objectives and desired results. They serve various purposes, including assessing progress, managing risks, making data-driven decisions, promoting transparency, and driving continuous improvement. Monitoring helps organizations track progress, identify issues early, and mitigate risks, while reporting keeps stakeholders informed and accountable.

Monitoring involves the collection of routine data that measure progress toward achieving program objectives. It is used to track changes in program performance over time with the purpose being to permit stakeholders to make informed decisions regarding the effectiveness of programs and the efficient use of resources.

Monitoring is sometimes referred to as process evaluation because it serves as a crucial component of assessing how well processes and activities are performing in the implementation process and asks key questions:

1. How well has the program been implemented?
2. How much does implementation vary from site to site?
3. Did the program benefit the intended people? At what cost?

For purposes of this guideline, this chapter outlines mechanisms to be used to measure process implementation, use, and achievement of targets outlined for the production and delivery of oxygen for medical services. To implement this guideline effectively, the health sector will continue addressing structural bottlenecks and enhance capacity building within itself, engage all the stakeholders for their contribution and promote innovativeness, creativity and professionalism towards the realization of the guideline.

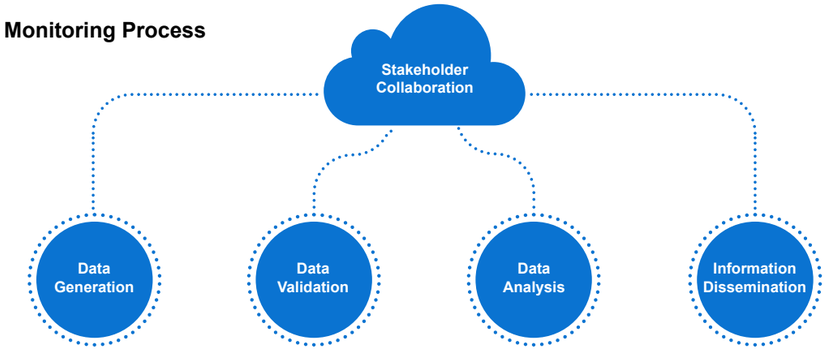
The evidence gathered through Monitoring and Evaluation (M&E) processes plays a vital role in improving the effectiveness, efficiency, and accountability of medical oxygen. This evidence will be used in various ways to inform decision-making, enhance performance, and drive positive change. The evidence gathered through M&E processes will be used to:

i. Guide decision-making in oxygen production and use by characterizing the implications of progress (or lack of it) being made.
ii. Guide implementation of the guidelines by providing information on progress and results.
iii. Guide the information dissemination and use in theoxygen production and use industry by the stakeholders.
iv. Provide a unified approach to monitoring progress by all stakeholders involved in oxygen production and use.
v. The M&E system will respond to meet the growing interest and demand for quality data for decision-making, measurement, learning, accountability and policy dialogue.

To achieve a robust monitoring system, effective policies, tools, processes and systems should be in place and adequately disseminated. The collection, tracking and analysis of data will make implementation effective to guide decision-making. The critical elements to be monitored are resources (inputs); service

statistics; service coverage/outcomes; investment outputs; access to services; and impact assessment. The key monitoring processes as outlined in Figure 1 will involve:

Figure 1: Monitoring Process



Data Generation

Various types of data will be collected from different sources to monitor the implementation progress. The data will be collected through routine methods, surveys, and periodic assessments, among others.

Routine activity data will be generated using the existing mechanisms

Data flow from the primary source through the levels of aggregation to the national level will be guided by reporting guidelines and reach the Ministry of Health (MOH) by the agreed timelines for all levels.

Data Validation

Data validation is a fundamental step in data management that ensures data accuracy, consistency, and reliability, contributing to better decision-making, regulatory compliance, and overall data quality.

Data validation through regular data quality assessment to verify the reported progress from source to aggregated values to ensure that data are of the highest quality. Annual and quarterly data quality audits will be carried out, to review the data across all the indicators.

Data Analysis

Data analysis is the process of inspecting, cleaning, transforming, and interpreting data to discover useful information, draw conclusions, and support decision-making. This step ensures the transformation of data into information that can be used for decision-making at all levels.

It requires a team with strong analytic skills to make sense of the presented data.

The analysis will be done during the quarterly and annual performance reviews, where achievements will be compared against set targets.

Information Dissemination

Information dissemination is a fundamental process for sharing information, knowledge, and messages with various audiences through multiple channels and methods. Effective dissemination ensures that information reaches its intended recipients and serves its intended purpose, whether it's raising awareness, educating, informing, or promoting change.

Information products, for example, annual performance review reports, will be routinely disseminated to key sector stakeholders and the public as part of the quarterly and annual reviews and feedback on the progress and plan provided.

Stakeholders' collaboration

This is a versatile and valuable approach used to achieve a wide range of goals, from project management and decision-making to innovation, problem-solving, and social change. It leverages the collective wisdom and resources of diverse stakeholders to address complex challenges and create positive outcomes.

Effective engagement of other relevant Departments and Agencies in the health sector M&E process is key. Each of these stakeholders generates and requires specific information related to their functions and responsibilities.

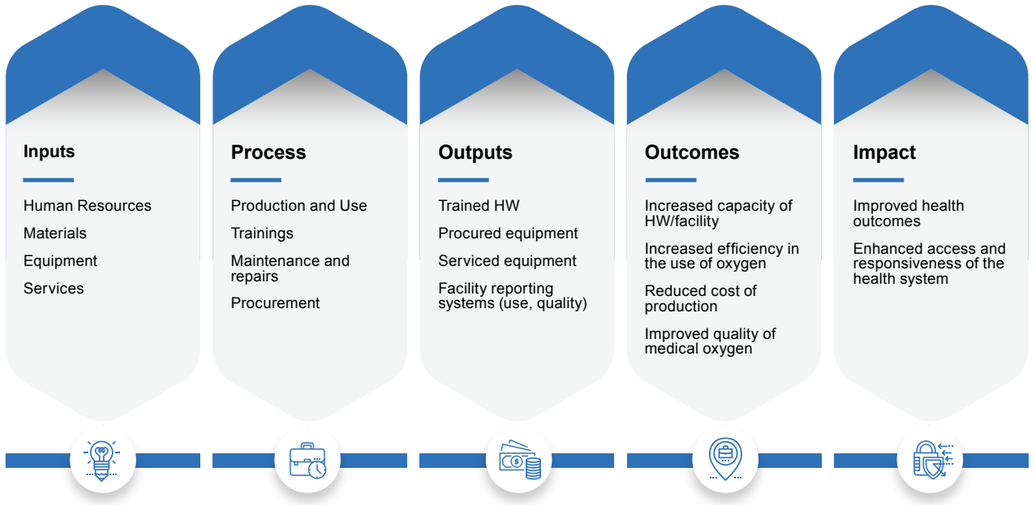
The information generated by all these stakeholders is collectively required for the overall assessment of performance.

8.2 LOGIC MODEL

A clear framework is essential to guide monitoring and reporting. The framework in the Figure below explains how the program is supposed to work by laying out the components of the initiative and the order or the steps needed to achieve the desired results. This will increase the understanding of the program's goals and objectives, as well as define the relationships between factors key to implementation; and articulate the internal and external elements that could affect the program's success.

The logic model as outlined looks at what it takes to achieve intended results, thus linking the results expected, with the strategies, output and input, for a shared understanding of the relationships between the results expected, activities conducted, and resources required.

Figure 2: Monitoring and Evaluation Logical framework



8.3 INDICATORS FOR OXYGEN PRODUCTION AND USE

The indicators are based on the respective domain areas. Counties will be required to develop specific implementation plans with clear targets for the indicators.

Below is a table of indicators to be monitored:

Table 6: **Monitoring and Evaluation Matrix**

Description	Indicator	Indicator definition	Data source	Frequency of data collection	Responsibility	Reporting (next level reported to)
Production	The proportion of Oxygen supplied with a purity of at least 99.5% for cryogenic, >95% for PSA and >90% for concentrators Disaggregation: Equipment type, facility.	Numerator: Volume of Oxygen supplied with recommended purity as per the method of production in m3 Denominator: Total volume of Oxygen supplied in m3	Commodity management registers	x	Biomedical Engineer	In-Charge/ HMT
	Total number of officers working at the Oxygen plant Disaggregation: Sex, facility type, designation	The total number of officers working at the Oxygen plant	Facility training matrix	Bi-Annual	Facility In charge	SCHMIDT
	Number of officers with training and skills to work at the Oxygen plant Disaggregation: Sex, facility type	The total number of officers trained in the management of Oxygen plants	Facility training matrix	Bi-Annual	Facility In charge	SCHMT
	The proportion of technical staff working at the Oxygen plants trained in Oxygen systems operation and maintenance	Numerator: number of technical staff working at the Oxygen plant trained in Oxygen systems operation and maintenance Denominator: the total number of staff working at the Oxygen plant.	Facility training matrix	Bi-Annual	Facility In charge	SCHMT
	Flow rate of Oxygen (L/Min)	The measured flow rate of Oxygen in Liters per Minute	Flow rate monitoring chart	Daily	Biomedical Engineer	In-Charge/ HMT
	Pressure output from the PSA plant	The pressure at the outlet of the PSA plant measured in Pascals (Pa)	Pressure monitoring chart	Daily	Biomedical Engineer	In-Charge/ HMT
	The proportion of supportive supervision visits conducted at sites/ facilities with Oxygen plants.	Numerator: Number of facilities with Oxygen plants that received at least one supervision visit during the reporting period.	Support supervision reports	Quarterly	HMT	SCHMT
	Disaggregation: Facility type/level	Denominator: Total number of sites with an Oxygen plant during the reporting quarter				
	The volume of Oxygen produced/ supplied per day in m3 Disaggregation: Facility type, Oxygen generation equipment type	The total volume of Oxygen produced by the Oxygen plant in a day in m3	Commodity management registers	Monthly	Biomedical Engineer	In-Charge/ HMT
	The volume of Oxygen in m3 consumed/used per day Disaggregation: Facility type	Total volume of Oxygen consumed/used in a day at the facility.	Commodity management registers	Monthly	Biomedical Engineer	In-Charge / HMT
	Number of IPC assessments done in a year Disaggregation: Facility Type	The number of IPC assessments carried out in one year	Service delivery registers/ Assessment reports	Bi-Annual	IPC committee	In-Charge/ HMT
	IPC Scores attained in percentage during IPC assessment (Note: The recommendation is to set a standard, e.g., by saying the proportion of facilities with an IPC score ≥ 85%. The numerator could then be: The number of Oxygen-served sites with an IPC score ≥ 85%. Denominator: Total number of Oxygen-served sites that received IPC assessment)	Record of the IPC scores attained in percentages from the assessments done	Service delivery registers/ Assessment reports	Quarterly	IPC committee	KHIS/HMT
	The proportion of facilities with an IPC score ≥ 85%	Numerator: Number of Oxygen- served sites with an IPC score ≥85% Denominator: Total number of sites with Oxygen plants that received an IPC assessment	Service delivery registers/ Assessment reports	Quarterly	IPC committee	KHIS/HMT

	The proportion of Oxygen plants maintained within the recommended period Disaggregation: Oxygen plant type	Numerator: The Number of Oxygen plants maintained within the recommended period. Denominator: Total number of Oxygen plants	Maintenance register	Bi-Annual	Biomedical Engineer/facility in charge	KHIS/ Maintenance Inventory
	Number of maintenance schedules done as per the manufacturer's recommendations	Numerator: number of times Oxygen plants were maintained. Denominator: number of maintenance schedules recommended by the manufacturer	Maintenance register	Bi-Annual	Biomedical Engineer/facility in charge	KHIS/ Maintenance Inventory
Storage	The proportion of Oxygen plants controlled for entry by unauthorized persons	Numerator: number of Oxygen plants with controlled access measures in place. Denominator: Total number of Oxygen plants	Entry register	Monthly	Biomedical Engineer/In charge	In-Charge/ HMT
	Capacity of Oxygen storage within the facility	Total available capacity for storage of Oxygen cylinders within the facility	Commodity management registers	Monthly	Biomedical Engineer/ Pharmacist	In-Charge/ HMT
	The proportion of Oxygen stored per day compared to the daily Oxygen consumption	Numerator: Total volume of Oxygen stored in a day. Denominator: Volume of Oxygen consumed in a day	Service delivery registers	Monthly	Biomedical Engineer/ Pharmacist	In-Charge/ HMT
	Number of liters of Oxygen produced and stored per day	The total volume of Oxygen produced and stored within the facility in a day	Commodity management registers	Monthly	Biomedical Engineer	In-Charge/ HMT
	Number of cylinders with different quantities of medical gases Disaggregation Type, number	Number of cylinders with different quantities of medical gases	Commodity management registers	Monthly	Biomedical Engineer	In-Charge/ HMT

Availability	The proportion of health facilities with at least one Oxygen source available (compressed liquid Oxygen (LOX), compressed gas cylinders, on-site pressure swing adsorption (PSA) plants, and Oxygen concentrators) Disaggregation: By type, number	Numerator: Number of health facilities with Oxygen available Denominator: Total number of health facilities	Routine/Oxygen management system/ KHIS	Monthly	CHMT	MOH/KHIS
	The proportion of useable beds equipped with a functional Oxygen supply in Oxygen-served facilities. Disaggregation: Facility, unit/ department	Numerator: The number of useable beds equipped with a functional Oxygen supply in Oxygen-served facilities. Denominator: Total number of useable beds in Oxygen-served facilities.	Non-routine/ Oxygen management system/ KHIS	Quarterly	CHMT	MOH/KHIS
	The proportion of functional Oxygen monitoring equipment available. Disaggregation: Facility, Facility Level, Equipment type, unit/ department	Numerator: The number of functional Oxygen monitoring equipment available. Denominator: Total Oxygen monitoring equipment (functional and non-functioning)	Non-routine/ Oxygen management system/ KHIS	Quarterly	CHMT	MOH/KHIS
	Proportion of functional Oxygen delivery equipment available. Disaggregation: Facility, facility type, equipment type, unit/ department	Numerator: The number of functional Oxygen delivery equipment available. Denominator:Total Oxygen delivery equipment (functional and non-functioning)	Non-routine/ Oxygen management system/ KHIS	Quarterly	CHMT	MOH/KHIS
Functionality	Number of health facilities with functional liquid Oxygen system	Number of HFs with a functional liquid Oxygen system	Routine/Oxygen management system/ KHIS	Monthly	CHMT	MOH/KHIS
	Number of health facilities with functional on-site pressure swing adsorption (PSA) plants	Number of health facilities with functional on-site pressure swing adsorption (PSA) plants	Routine/Oxygen management system/ KHIS	Monthly	CHMT	MOH/KHIS

	Proportion of functional Oxygen source equipment. Disaggregation: by facility, equipment type (Liquid Oxygen, PSA, concentrators, cylinders), number	Numerator: Number of functional Oxygen source equipment Denominator: Total number of Oxygen source equipment	Routine/Oxygen management system/ KHIS	Monthly	CHMT	MOH/KHIS
Technical capacity	Number of HCWs trained on Oxygen system Disaggregation: cadre, department	Number of HCWs trained on Oxygen system	Non-routine/ Oxygen management system/ KHIS	Quarterly	Facility in charge	SCHMT
	The proportion of clinical staff working in Oxygen-served facilities trained in Oxygen therapy. Disaggregation: By Sex, type of facility, unit/ department	Numerator: The total number of clinical staff trained on Oxygen therapy in Oxygen-served sites/facilities. Denominator: Total number of clinical staff in Oxygen-served sites/facilities.	Facility training matrix	Quarterly	Facility in Charge	SCHMT
Needs assessment	Proportion of health facilities with functional pulse oximetry Disaggregation: Facility, sub-county, county, number, unit/ department	Numerator: Number of health facilities with functional pulse oximetry. Denominator: Total number of facilities	Routine/Oxygen management system/ KHIS	Monthly	SCHMT	CHMT
	Proportion of Oxygen supplied to the health facility Disaggregation: By equipment supply type (PSA, liquid tank, concentrators, cylinders)	Numerator: Quantity (in m3) of Oxygen supplied to the health facility by equipment supply type (Liquid tank, PSA, concentrators, cylinders) Denominator: Total Oxygen (m3) supplied to the facility	Routine/Oxygen management system/ KHIS	Monthly	Facility in charge/ biomedical engineer	SCHMT
	Quantity of Oxygen remaining at the facility at the end reporting period (liters)	Quantity of Oxygen remaining at the facility at the end reporting period (liters)	Routine/Oxygen management system/ KHIS	Monthly	Biomedical engineer/ facility in charge	SCHMT
	Proportion of Oxygen wastage at the health facility at the end of the reporting period (liters)	Proportion of Oxygen wastage at the health facility at the end of the reporting period (liters)	Routine/Oxygen management system/ KHIS	Monthly	Biomedical engineer/ facility in charge	SCHMT
	Numerator: Quantity of Oxygen wastage Denominator: Total quantity of Oxygen generated/ received					
Monitoring	Facility Oxygen consumption in m3/ Liters (L)	Oxygen consumption expressed in m3/ Liters (L)	Routine/Oxygen management system/ KHIS	Monthly	Facility in charge	SCHMT
	The proportion of patients screened for hypoxemia at the facility entry point. Disaggregation: by facility, unit, diagnosis.	Numerator: Number of patients screened for hypoxemia using the pulse oximetry at entry point. Denominator: Number of patients that accessed health services.	Facility screening registers	Monthly	HCWs	In-Charge
	The proportion of hypoxemic patients who accessed supplementary Oxygen. Disaggregation: By Facility, Facility Type, Disease diagnosis	Numerator: Number of patients that received supplementary Oxygen (both deceased and released) Denominator: Number of patients diagnosed with hypoxemia	Routine/Oxygen management system/ KHIS	Monthly	Facility in charge	SCHMT
Improved data, information use, and monitoring	The proportion of health facilities reporting on Oxygen in OMIS/KHIS	Numerator: Number of health facilities reporting on Oxygen in OMIS/KHIS Denominator: Number of health facilities providing Oxygen services	Routine/Oxygen management system/ KHIS	Monthly	SCHMT	CHMT
	Proportion of facilities that are conducting monthly Oxygen data review sessions/ meetings	Numerator: Number of facilities conducting monthly Oxygen data review sessions/meetings	Routine/Oxygen management system/ KHIS	Monthly	SCHMT	CHMT

		Denominator: Number of facilities reporting on Oxygen data in OMIS/KHIS				
Quality management System and Good Manufacturing Practices (GMP) for medical gases	The proportion of health facilities reporting production of Oxygen from PSA plants in compliance with purity standard; For cryogenic >99.5%, for PSA 95% ±3% and concentrator > 90 %	Numerator: Number of health facilities reporting production of Oxygen from PSA plants meeting the purity standard Denominator: Total number of health facilities producing Oxygen from PSA plants	KHIS/registers	Monthly	CHMT	MOH/KHIS
	Number of facilities (refilling Oxygen) adhering to Good Manufacturing Practices (GMP)	Number of facilities (refilling Oxygen) adhering to Good Manufacturing Practices (GMP)	Assessment reports	Annual	PPB	MOH/DHPT, facility in-charges & County director for for health
Personnel involved in production (must be certified by the relevant regulatory body)	Proportion of certified personnel involved in Oxygen production	Numerator: Number of certified personnel involved in the production of Oxygen Denominator: Total number of personnel involved in the production of Oxygen	Assessment/ surveys	Quarterly	health facility management	SCHMT
Establish SOP on Oxygen production, quality and storage	The proportion of health facilities adhering to the SOP on Oxygen production, quality and storage	Numerator: Number of facilities adhering to the SOP on Oxygen production, quality and storage Denominator: Number of health facilities producing Oxygen	Assessment/ Supportive supervision	Quarterly	CHMT	DHPT
	Number of SOPs on Oxygen production, quality and storage developed	Number of SOPs on Oxygen production, quality and storage developed	SOPs files	Annual	Oxygen TWG	DHPT
Existence of applied risk mitigation measures	Proportion of facilities with functional risk mitigation team	Numerator: Number of health facilities with functional risk mitigation team Denominator: Number of health facilities	Minutes/ Audit reports	Quarterly	SCHMT	CHMT
	The proportion of facilities with an Oxygen-focal point person	Numerator: Number of Oxygen-served facilities with an Oxygen focal point person. Denominator: Total number of Oxygen-served facilities.	Minutes/ Audit reports	Quarterly	SCHMT	CHMT
	Proportion of facilities with risk mitigation measures in place	Numerator: Number of health facilities with risk mitigation measures in place Denominator: Number of health facilities	Minutes/ Audit reports	Quarterly	SCHMT	CHMT
	Proportion of facilities that have conducted safety audits (in the quarter)	Numerator: Number of health facilities that have conducted safety audits in the reporting period?? Denominator: Number of health facilities	Minutes/ Audit reports	Quarterly	SCHMT	CHMT
Lifespan guarantee of production quality	The proportion of facilities with a written 2-year warranty and guarantee for spares for a minimum of 10 years	Numerator: Number of health facilities with a written 2-year warranty and guarantee for spares minimum of 10 years for PSA plants Denominator: Number of health facilities with installed PSA plants	Service contracts	Annual	Biomedical Engineer/ SCHMT	CHMT
	Proportion of facilities with maintenance agreement/plan	Numerator: Number of Oxygen-served health facilities with maintenance agreement/plan Denominator: Total number of Oxygen-served health facilities	Maintenance contract/ Maintenance plan	Annual	Biomedical Engineer/ SCHMT	CHMT
	The proportion of the budget allocated towards respiratory care. Disaggregation: by facility, sub-county, county	Numerator: Value of budget allocated toward respiratory care Denominator: Total budget value	Accounting documents	Annually	HMT, SCHMT	SCHMT, CHMT, MOH

9 RISK MANAGEMENT

9.1 RISK MANAGEMENT

These guidelines are prone to be influenced by external factors that may not necessarily be related to the health sector. It is therefore crucial that a deliberate effort is made to foresee these and identify mitigation measures early enough to ensure that implementation continues smoothly. Risk mitigation refers to the process of planning and developing methods and options to reduce threats—or risks—to project objectives. Risk mitigation progress monitoring includes tracking identified risks, identifying new risks, and evaluating risk process effectiveness throughout the implementation.

The identified risks and mitigating measures are summarized in the table below.

Table xx: Risks and Mitigationin Implementing the Guidelines

Type	Risk	Mitigation
Political	The country currently faces a high political commitment to delivering quality healthcare services to its citizens in line with the 2010 Constitution, thereby fostering an enabling environment for the implementation of health policies. The implementation of health services is devolved. The implementation might be affected if; — Country leadership after the election is not committed — Insufficient continuous buy-in/commitment by the county leadership	Continuously involve county leadership in decision-making and implementation of the guidelines.
Economic	Implementation of the guidelines requires sufficient and sustainable financial resources. However, economic growth is currently not commensurate to the investment in the health sector.	Conduct an annual review of the funding gap to track progress and inform resource mobilization strategies. Advocacy for resources at county levels.
Social	The Kenya Health Policy has emphasized a people-centered approach to healthcare. Lack of stakeholder involvement may lead to the implementation of policies/strategies/guidelines that may not necessarily respond to the needs	Promote social accountability at all levels to increase demand creation for health care services. Stakeholders' involvement in the development and implementation of the guidelines. Repositioning of strategic commodities and supplies to ensure continuity in the provision of health care services
Technological	Connectivity, lack of enhanced use of the e-health system, and weak ICT infrastructure. The country has not adopted uniform Electronic Medical Records and Telemedicine to facilitate real-time data.	Provide adequate infrastructure for ICT to improve access e.g. computers, telephone, M-health services Train on the use of ICT and preventive maintenance Design standardized electronic medical records that will be adopted and used in all public health facilities for real-time data and information exchange
Environmental	Globalization and global climate change (emerging and re-emerging diseases), unexpected floods in some parts of the country pose significant implications for public health Country preparedness and response to new and emerging pandemics such as COVID-19	Set aside adequate resources for emergency preparedness and response.
Legal	Poor implementation of health sector reforms. Prioritization of Healthcare resources has not been well embraced at the county level.	Enhance the implementation of the health sector reforms through consultation and mutual accountability Amendment of the Public Finance Management (PFM) Act 2012 to allow ring-fencing of the health resources allocated.

10 ANNEXES

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