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MINISTRY OF HEALTH - ETHIOPIA

MEDICAL OXYGEN AND OXYGEN THERAPY DEVICES SUPPLY CHAIN MANAGEMENT GUIDELINE

October, 2023

Ethiopia

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Foreword

Strengthening the national medical oxygen and device procurement and supply chain management system is crucial to ensuring equitable access to quality and cost-effective oxygen therapy. In light of the existing supply chain management challenges, the national medical oxygen roadmap II (2022-2027) emphasized the need to ensure the availability of robust systems in place for the efficient and effective procurement, placement, management, logistics, and supply chain of medical oxygen systems at all levels of the health system. This national medical oxygen and oxygen therapy devices supply chain management guideline was developed to ensure a reliable oxygen supply chain management system to meet the growing demand.

A broad group of stakeholders and experts were involved in the development process. I believe that this guideline will help health facilities, administrative bodies, and other stakeholders in establishing and strengthening medical oxygen and therapy device supply chain management and ensuring a secure oxygen therapy service for those who need it mostly.

Thus, I would like to express my deepest appreciation to those who are involved in and support the development, and similarly, I believe all stakeholders will actively engage in the implementation of the guidelines to achieve the objectives through collaborative and coordinated efforts.

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Acknowledgement

The Ethiopian Ministry of Health would like to acknowledge the crucial role of various experts and technical assistants from the MOH, and implementing partners for their unreserved effort and contributions in finalizing this guideline.

Special thanks to the lead technical teams that invested their full effort during the process. The Ministry would also like to express its appreciation to the Clinton Health Access Initiative (CHAI), JHPIEGO's USAID, Reaching Impact, Saturation, and Epidemic Control (RISE) and Korea Foundation for International Healthcare (KOFIH) project for their technical and financial support in development of the national medical oxygen & devices supply chain management guideline.

The contributions of the following individuals in the drafting and review processes for the document are also duly acknowledged.

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Acronym

ASU	Air separating Unit
BiBAP	Bilevel Positive Airway Pressure
CPAP	Continuous Positive Airway Pressure
EPSS	Ethiopian Pharmaceuticals Supply Service
HFNC	high-flow nasal cannula
HUCSH	Hawassa University Comprehensive Specialized Hospital
IFRR	Internal Facility Report and Resupply
IPLS	Integrated Pharmaceuticals Logistics System
ISO	International Organization for Standardization
LMIS	Logistics Management Information System
LMIS	logistics management information system
LOX	Liquid Oxygen
LPM	Liter per minute
LTA	Long Term Agreement
MEMIS	Medical Equipment Management Information System
MO	Medical Oxygen
MOH	Ministry of Health
NICU	Neonatal Intensive Care Units
PSA	Pressure Swing Adsorption
SCM	Supply Chain Management
SPHMMC	St Paul Hospital Millennium Medical College
VEN	Vital, Essential, non/less essential
WHO	World Health Organization

Key Definitions

Medical Oxygen: is oxygen of a distinct quality intended for use in patients and is produced, distributed and stored according to the applicable health regulatory requirements for patient use. Medicinal oxygen and medical oxygen are used interchangeably.

Oxygen Ecosystem: The oxygen ecosystem refers to holistic efforts, initiatives, and resources across health systems that are required for an optimal and sustainable implementation of oxygen systems. The long-term sustainability of oxygen systems requires a holistic approach and a resource ecosystem focused not only on oxygen production but also on distribution and delivery, ongoing maintenance and upkeep.

Supply Chain: is a set of interlinked players and processes – including assessment, planning, procurement, shipping, goods clearance, warehousing and inventory management, in-country distribution, information management, and monitoring and evaluation – that ensure that the right quantities of the right supplies are delivered to the right locations at the right time, to meet the needs of the end users in the most efficient manner possible.

Forecasting: The process of estimating the quantities and costs of products required to meet the demand for a particular time frame. It uses consumption, service, demographic, and morbidity data, assumption on programmatic scale-up, service capacity, and related factors to estimate the requirements.

Supply planning: The process of determining which health products should be procured, the amount to be procured, the time at which they should be delivered, and the financial costs to be incurred. It requires data on forecasted quantity, stock on hand, stock on order, lead times, wastage, and logistics costs, and minimum and maximum stock levels to estimate the requirements.

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CHAPTER ONE

INTRODUCTION

1.1. Background

Medical oxygen is an essential medicine with no substitution and it is administered to patients as an inhalation gas. Medical oxygen is essential for the prevention and treatment of hypoxaemia-a condition where the oxygen level in the blood is lower than normal which can also lead to serious complications and death. It is used for treating life-threatening hypoxemic conditions of most leading causes of mortality in under 5 children, obstetric complications at delivery, surgical procedures and trauma.

Globally 35% of possible reduction in risk of death from childhood pneumonia could be prevented with introduction of improved oxygen delivery systems and 15% pregnant women in Low- and Middle-Income Countries who develop life-threatening complications could have been treated with oxygen therapy.

World Health Organization (WHO) included oxygen in its Model List of Essential Medicines (EML) and List of Essential Medicines for Children (EMLc), identifying oxygen as a medicine essential for the management of hypoxemia.

Despite being an essential medicine, oxygen is a complex product. It needs to be produced by a medical device or industrial plant and requires a whole system to safely reach patients. Medical oxygen supply systems basically consist of oxygen source, distribution, delivery, and patient monitoring devises. Due to its complexity, access to oxygen faces many challenges on availability, quality, affordability, management, supply, human resources capacity and safety. The following diagram illustrates all the components of an oxygen system.

Cognizant of oxygen’s vitality and pivotal role in quality health care service, the government has given due attention in improving the medical oxygen ecosystem by implementing national medical oxygen roadmap, allocating and mobilizing resources towards scaling up the national medical oxygen production, supply and rational use.

Despite tremendous government and stakeholders’ efforts, there is still huge unmet need and limited access to medical oxygen. Ethiopia's fragile oxygen production and supply system could not meet the growing demands, which imposed a great deal of strain on health facilities. There is a need for organizing efficient and systematic quantification, procurement, distribution

management system, including devising oxygen consumption & oxygen devises inventory tracking mechanism/ information system.

1.2. Rationale

Oxygen therapy is an essential part of ending preventable deaths among children and adults. However, reliable access to oxygen remains inadequate across many health facilities in the country. Oxygen access has been a long-neglected element of health services. Advent of COVID-19 pandemic has created wakeup call for investment in oxygen. Scaling up access to oxygen is one of the most effective and critical actions decision-makers can take to improve health outcomes and save lives.

The findings of oxygen roadmap end-term evaluation revealed a considerable challenge in the medical oxygen supply chain management. The salient challenges identified include shortage of oxygen; insufficient capacity and training on the management of medical oxygen; inadequate documentation of oxygen cylinder consumption; inadequate availability of spare parts and tools for maintaining and repairing oxygen devices which significantly hamper the continuum of care.

Lack of oxygen devices, limited supply chain awareness, lack of data for demand forecasts, weak supply chain monitoring and information systems, geographic barriers, and limited capacity building activities are also barriers that hinder the availability of oxygen.

Furthermore, despite the huge capital spent by health facilities to avail medical oxygen, the SCM system of medical oxygen is still inefficient where there is low operating capacity of existing oxygen plants, poor procurement and supply management practises, and inadequate coordination among stakeholders.

Therefore, it is found to be important to develop a medical oxygen SCM guideline that helps to support the implementation of reliable oxygen SCM system. The guideline addresses basic concepts on oxygen medical devices system, selection of medical oxygen and its devices, the need for organizing efficient and systematic demand forecasting, supply planning, procurement, distribution management system, storage & inventory management, information system, monitoring and evaluation of the oxygen SCM system.

1.3. Purpose

To provide guidance on medical oxygen and oxygen devices, supply chain management, and rational use to ensure equitable access to quality, and cost-effective oxygen therapy at all levels of health facilities.

1.4. Objectives

- To provide guidance on appropriate medical oxygen & devices selection, quantification, procurement, distribution, storage, inventory management, and logistics management information system (LMIS).
- To promote safe and rational use of medical oxygen in health facilities.
- To enable medical oxygen supply chain management monitoring and evaluation at all levels of health system.

1.5. Scope

This guideline covers medical oxygen & devices supply chain management including selection, quantification, procurement, distribution, storage, inventory management, and LMIS. This guideline also addresses safety and quality assurance issues across the relevant supply chain components. The guide does not address medical oxygen devices engineering aspects such as design, installation, testing, commissioning, maintenance, and detail devices operational management systems.

The document is expected to provide guidance to health program supply chain managers, pharmacists, biomedical engineers, and other health care providers involved in medical oxygen & devices supply chain management. Detail areas with regards to installation, preventive maintenance, and oxygen clinical therapy are addressed separately in other national MOH documents.

CHAPTER TWO

MEDICAL OXYGEN SYSTEM DEVICES

2.1. Medical Oxygen System

The oxygen systems for medical use include, but are not limited to, oxygen production, storage, distribution and delivery supplies, as well as various items for flow regulation, conditioning, quality assurance (QA), quality control (QC) and safety, that are embedded into the dynamics of the oxygen ecosystem. The long-term sustainability of oxygen systems requires a holistic approach and a resource ecosystem focused not only on oxygen production but also on distribution and delivery, ongoing maintenance and upkeep.

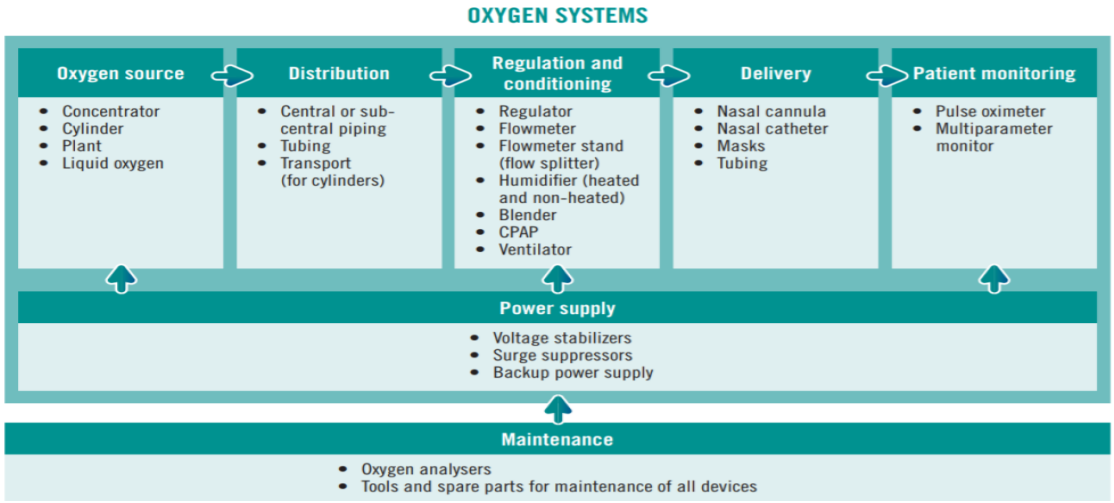

Figure 1: Components of oxygen system

To enable access to high-quality, safe and continuous oxygen systems the following are required:

- ✓ Sustained financial resources;
- ✓ Appropriate policy and regulatory frameworks;
- ✓ Regular needs and feasibility assessment;
- ✓ Available, appropriate, trained clinical and technical workforce;
- ✓ Available, appropriate, affordable and well-maintained source, storage, distribution and delivery systems; and
- ✓ System monitoring: reporting and tracking key performance indicators (KPI).

The appropriate choice of oxygen system device is multifactorial. It is based on the need-gap assessment and the absorptive capacity of the health facility, which includes available technical workforce, infrastructure, reliability of power supply, access to maintenance services and spare parts, among others. Unfortunately, an important standard procedure of preparing backup plans to ensure continuous access to oxygen, even in case of emergency, is often disregarded due to budget availability and structural design.

Medical oxygen supply system shall comprise of primary supply, secondary supply and in some cases, reserve supply sources. There is no one oxygen strategy that is the best for all health facilities or regions. It is important when developing a resilient oxygen strategy to consider equipment redundancy. All equipment, however well maintained, can and will fail from time to time. For severely ill hypoxemic patients, even a brief time without oxygen can be fatal. All facilities should have a backup plan. Large facilities with critical care beds should have fully redundant oxygen supply.

Primary Supply: The primary source of supply shall be permanently connected and shall be the main source of supply to the medical oxygen supply system. It can be either an oxygen concentrator, which produces oxygen from ambient air by using a process called pressure swing adsorption (PSA), or a liquid oxygen tank, which stores oxygen in a cryogenic form and gasifies it when needed.

As a minimum, the primary supply should have usable quantity of product to meet expected usage between scheduled product deliveries.

Secondary supply: This is the backup source of supply that is automatically activated when the primary source fails or runs out of oxygen. It can be either a bank of oxygen cylinders, which store oxygen in a compressed form, or another concentrator or liquid oxygen tank. The secondary source should have enough quantity of oxygen to meet the demand until the primary source is restored

Reserve supply: This is the emergency source of supply that is used when both the primary and secondary sources are unavailable or insufficient. It can be either a portable oxygen cylinder, which can be moved to the patient's bedside, or an independent reserve supply system, which consists of a separate pipeline and outlets for critical care areas or remote wards.As a minimum, the reserve supply should have usable quantity of product to meet critical patient care between a request for product delivery and the delivery of the product.

2.2. Medical oxygen devices

Medical oxygen devices are devices that are used to deliver safe and quality-assured medical oxygen to patients and to ensure its sustainable supply in health facilities. These devices can be categorized primarily as oxygen quality monitoring devices, flow regulation devices, medical oxygen monitoring devices, and conditioning devices.

2.2.1. Medical Oxygen Source

Medical Oxygen is a complex product which is produced in an industrial process following good manufacturing practices (GMP) or is generated on-site using medical oxygen concentrators.

The three most common sources of medical oxygen in health care facilities are: compressed gas cylinders, oxygen concentrators and oxygen plants.

Medical oxygen is a complex product that is produced in an industrial process following good manufacturing practices (GMP) or generated on-site using medical oxygen concentrators. Oxygen plants and medical oxygen concentrators are two common sources of oxygen used in health facilities. A cylinder is the most commonly used type of medical oxygen storage in healthcare settings.

A. Medical Oxygen plants

Oxygen plants are assemblies of different equipment to produce medical oxygen. The plants produce different flow rates depending on the capacity of the air compressor. The plants produce concentrated oxygen in gas form, which will be distributed directly to where it is needed through the medical gas pipeline system or through a high-pressure gas cylinder filled at a cylinder filling station. The two types of medical oxygen plants used in Ethiopia are pressure swing adsorption (PSA) and cryogenic/liquid.

i. Pressure Swing Adsorption (PSA) oxygen plant

This medical oxygen plant is an onsite oxygen-generating system using pressure swing adsorption (PSA) technology, which supplies high-pressure oxygen throughout a facility via a central pipeline system or via cylinders refilled by the plant. PSA adsorption technology produces medical oxygen with a concentration of 93%±3% from ambient air. It serves as a large, central source of oxygen generation that can be located on-site at health facilities. It requires significant maintenance of the production and piping systems by trained technicians and engineers.

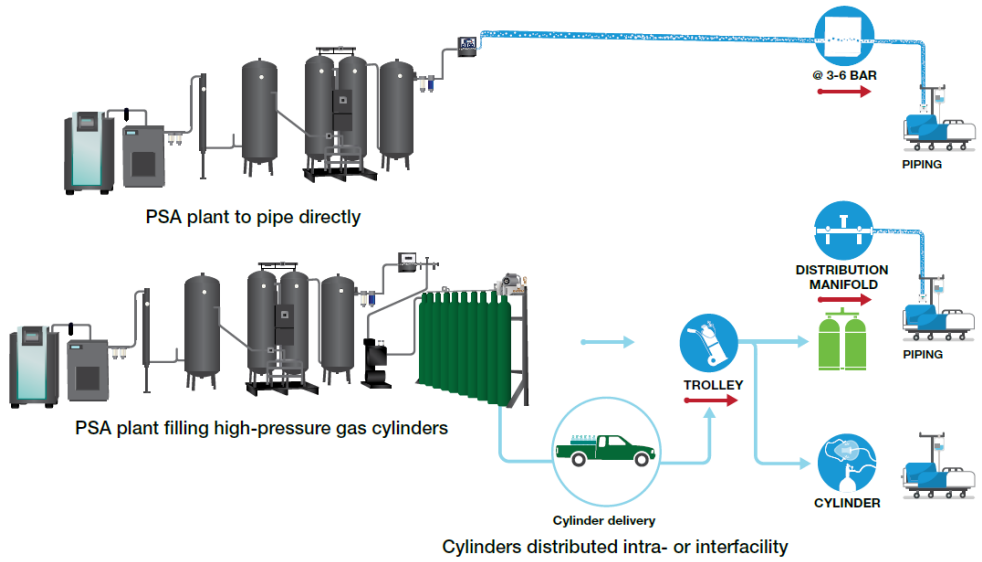

Figure 2: Distribution of oxygen produced by PSA plant:

Source: World Health Organization (2023). Foundations of medical oxygen systems, 17 February 2023

ii. Cryogenic/liquid oxygen plant

A cryogenic or liquid oxygen plant produces bulk liquid oxygen through cryogenic distillation and stores it in a large tank. Air separation is based on the cryogenic rectification process, in which the air is cooled down to the required very low temperature of negative 183 degrees Celsius and then liquefied. When rectification is carried out, the individual components of air are separated from each other due to their varying boiling points. Medical oxygen produced by air liquefaction contains an oxygen concentration not less than 99.5% V/V.

B. Liquid oxygen tank

In a liquid oxygen plant, medical oxygen is bulk liquid oxygen stored in a large tank and distributed to service-provider points throughout a health facility's central pipeline system or filled in medical oxygen cylinders by self-vaporization. The liquid oxygen tank supplies a centrally piped system throughout the health facility or is filled in cylinders by self-vaporization.

C. Medical Oxygen Concentrators

A medical oxygen concentrator is a self-contained, electrically powered medical device designed to concentrate oxygen from ambient air. The concentrator delivers low-flow, continuous, clean, and concentrated oxygen (> 82%) from room air (21%).

These concentrators are portable and can be moved between clinical areas or wards, but they are also often set up to be stationary fixtures in patient areas. Concentrators designed for portable medical support are available in models that can deliver maximum flow rates of between 5 and 10 L/min. When used with a flowmeter stand for splitting flow, concentrators can provide a continuous supply of oxygen to multiple patients at the same time. Concentrators can provide a safe and cost-effective source of medical oxygen, but they require a source of continuous and reliable power and regular preventive maintenance to ensure proper functioning.

Figure 3: Oxygen concentrator

D. Medical Oxygen Cylinders

Medical oxygen gas can be compressed and stored in cylinders. These cylinders are filled at a gas manufacturing plant, either via cryogenic distillation or via a PSA plant. Cylinders can be used by installing them directly within patient areas or by connecting them to sub-central manifold systems (groups of cylinders linked in parallel) at the facility. Thus, medical oxygen can be piped to specific areas of the health facility, even at the ward level.

Once filled, cylinders do not require electricity, but they do require several accessories and fittings to deliver oxygen, such as pressure gauges, regulators, flowmeters, caps, and, in some cases, humidifiers. Cylinders also require periodic maintenance, commonly provided by gas suppliers at the point of refilling. In the event that all available oxygen sources fail and in normal circumstances, a backup medical oxygen cylinder is essential to ensure continuity of oxygen treatment.

Figure 4: Oxygen cylinders

E. Manifold system

A manifold system is an oxygen piping system where cylinders are connected or linked in parallel to deliver medical oxygen to different units or wards of health facilities. In health facilities, the manifold oxygen distribution system enables centralized control, greater efficiency, increased safety, and accurate flow management. Manifold system can be manual and automatic. They differ in terms of their operation and control mechanisms.

Figure 5: Manifold system

Note: - The colour of the cylinders used in the figure above is not Ethiopian standard but used for demonstration purpose only.

2.2.2. Medical oxygen monitoring, regulation, conditioning and delivery devices

Medical oxygen monitoring, regulation and condition devices play an important role in providing safe and effective oxygen therapy to patients, ensuring the patient receives the correct amount of oxygen at the correct quality, flow, and humidity. They also help to prevent complications from oxygen therapy, such as hypoxia (low oxygen levels in the blood) and hyperoxia (high oxygen levels in the blood). There are various devices that are used to monitor, regulate, and condition medical oxygen for optimal delivery to patients.

These devices can be categorized primarily as oxygen quality monitoring, flow regulation, medical oxygen monitoring, and conditioning devices.

s.n	Medical oxygen monitoring, regulation, and conditioning devices category	Example/s
1	Quality monitoring	Analyzer
2	Flow regulation	Flow meters, Flow-splitting devices
3	Medical oxygen monitoring	Pulse oximeter, Pulse oximeter probes
4	Conditioning devices	CPAP, BiBAP, mechanical ventilator, Humidifier
5	Delivery Devices	Nasal cannula, nasal catheter, face mask

A. Oxygen analyzers

Oxygen analyzers are devices that measure and display the concentration of oxygen in patient breathing circuits, medical gas supply lines, compressed gas cylinders, and oxygen concentrators. They are also used to check and adjust devices used to administer oxygen to patients. Oxygen analyzers can also be built into ventilators or anesthesia units, where the oxygen sensor is automatically enabled when the system is in use (an alarm is needed in this case). Other analyzers are intended to perform routine oxygen spot checks either at the oxygen source (e.g., an oxygen concentrator), in the environment (e.g., an oxygen hood), or during equipment maintenance (no alarm is needed).

Oxygen analyzers use different sensing technologies for testing oxygen purity. Three common sensor technologies are electrochemical (involving galvanic cells), ultrasonic, and paramagnetic.

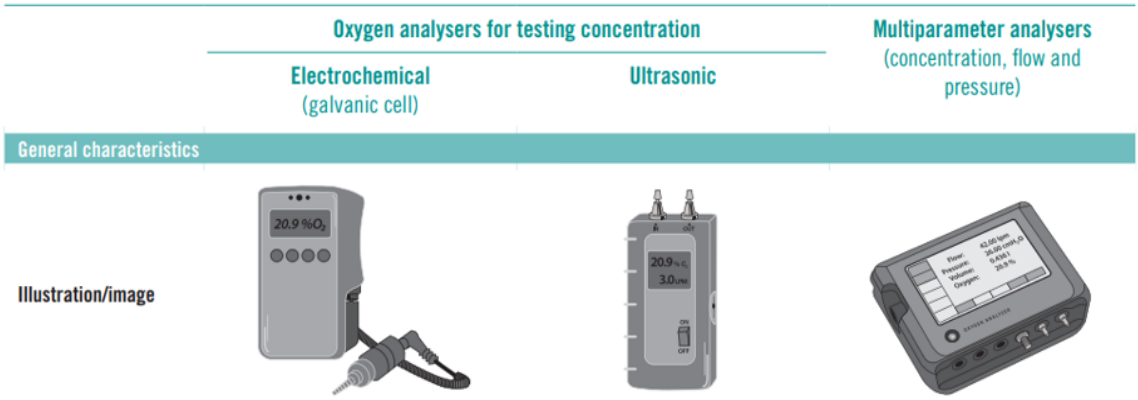

Figure 6: Oxygen analyzers

B. Medical Oxygen Flow Regulators

Medical oxygen flow regulators are devices that control the flow and pressure of oxygen from a compressed gas cylinder or tank to a patient who requires oxygen therapy. They are essential for ensuring that the patient receives the correct amount of oxygen at the required or prescribed pressure.

This category includes flow meters and flow-splitting devices.

i. Flowmeters

Flowmeters are devices that measure and control the rate of oxygen flow to a patient, from either a concentrator, or a high-pressure cylinder, or a terminal unit of a piped system. There are different types of flowmeters and the commonly used flow meters in Ethiopia are: Thorpe tube and Bourdon gauge. They come in various flow ranges and types.

ii. Thorpe tube flowmeter

Also known as a rotameter, is a device used to directly measure the flow rate of a gas in medical instruments. It consists of a connection to a gas source, a distal valve to control gas flow rate, an upright clear tube containing a float (which rises and falls in relation to gas flow) and an outlet port. The outlet port, commonly a Diameter Index Safety System (DISS) connector (could be male or female), can be connected to a barbed conical connector for oxygen tubing to a delivery device such as nasal prongs, or a humidifier.

Thorpe tube flowmeters are calibrated to a specific medical gas (e.g., oxygen or medical air) and come in dedicated flow rate ranges appropriate for different patient groups (e.g., neonate, infant, child, adult).

Figure 7: Thorpe tube flowmeter

iii. Bourdon gauge

A Bourdon gauge is a double gauge that consists of inlet and outlet ports, and a pressure gauge that reads as flow rate. One on the cylinder side to indicate the contents of pressure (could be male or female connector) and the other on the delivery side to indicate the outlet. They are calibrated to a specific medical gas and have a dedicated flow rate range. An advantage of bourdon gauge flowmeters is that they are unaffected by gravity and can operate at any angle. This makes them ideal for emergency medicine and transport.

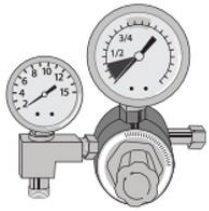

Figure 8: Bourdon gauge

iv. Flow-splitting devices

A flow-splitting device can provide an effective and efficient means of administering medical oxygen to multiple patients from a single source when supply permits. Flow-splitting devices may be used with concentrators, cylinders, and centralized systems for neonates, pediatric and adult patients. The two main devices for splitting oxygen flow discussed here are the flowmeter stand and the dual flowmeter.

v. Flowmeter stand

A flowmeter stand, also referred to as flowmeter station or assembly, is a device that distributes medical oxygen, in a controlled manner, from a single source to multiple (up to five) outlets through independent flowmeters, to meet individual patient needs. It is most commonly used with concentrators or in settings where there are few oxygen sources.

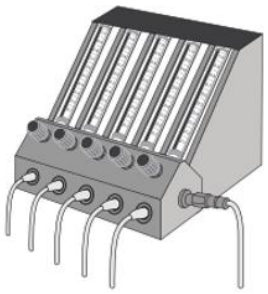

Figure 9: Flowmeter stand

vi. Dual flowmeter

This is a twin configuration of a Thorpe tube flowmeter to allow for an independent gas supply to two patients from a single gas source. This device is most suitable for connection to a terminal unit oxygen source.

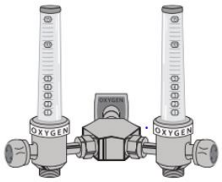

Figure 10: Dual flowmeter

vii. Plastic flow splitter

There are also plastic flow splitters that distribute medical oxygen from a single source to multiple outlets. For example, Y connectors divide flow into two outlets. These devices, however, are not recommended to be used alone because the flow may not be divided equally and there is no indicator of actual flow from each outlet.

C. Oxygen Monitoring Device

An oxygen monitoring device is a device that can measure the level of oxygen in the patient blood. Oxygen saturation (SpO2) can be measured using pulse oximeter and patient monitor device.

i. Pulse oximetry

It is a simple and non-invasive method to indirectly measure the oxygen saturation of haemoglobin in arterial blood (SpO_2). Pulse oximeters are the accepted global standard for detecting and monitoring hypoxemia, which is an abnormally low level of oxygen in the blood.

It uses the principle of differential light absorption to determine SpO_2. A sensor (also called a probe) is applied to an area of the body (e.g. a finger, toe or earlobe) and transmits different wavelengths of light from light-emitting diodes (LEDs) through the skin and into the tissue. These devices can serve as either a spot checking device or can be used for continuous monitoring:

- A spot check is a single SpO_2 reading that is taken to detect if a patient is hypoxemic and therefore qualifies for oxygen therapy.
- For continuous monitoring, the probe remains fixed to the patient and a continuous reading of SpO_2 is provided by the device.

Based on application and design sophistication, pulse oximeters fall into three distinct groups: Self-contained fingertip or finger clip oximeter, Portable handheld oximeter and Tabletop or stand-alone oximeter.

ii. Pulse oximeter probes

Probes for pulse oximetry devices represent a significant ongoing cost. Their cables and connectors are fragile and susceptible to wear and tear, requiring frequent replacement. Both disposable (single patient) and reusable probes are available. There are also multiple pulse oximeter cable connector types, many of which are proprietary to the make and model of pulse oximeter.

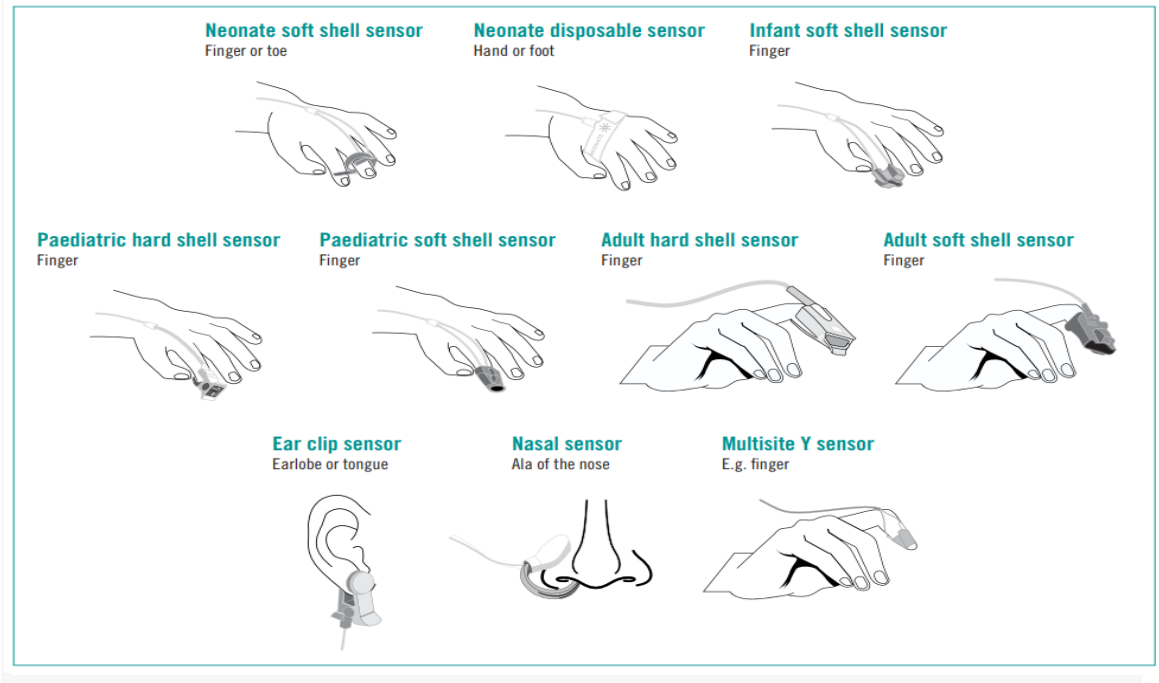

Figure 11: Pulse oximeter probes

iii. Patient monitor

In addition to displaying and tracking vital signs such as heart rate, blood pressure, respiratory rate and temperature, patient monitor device also measures Oxygen Saturation (SpO2).

Patient monitors typically have a screen display that shows real-time measurements of the monitored parameters. They may also include alarms and alerts to notify healthcare providers of abnormal readings or changes in the patient's condition. The data collected by patient monitors can be stored electronically for documentation, analysis, and review.

It is important to note that patient monitors come in various configurations and capabilities, ranging from bedside monitors to portable handheld devices. The specific features and parameters monitored may vary depending on the monitor model and the intended use in different clinical settings.

Figure 12: Patient monitor

D. Medical oxygen conditioning devices

An oxygen conditioning device is a device that regulates and modifies the oxygen flow and temperature for medical purposes.

iv. Mechanical ventilator

A mechanical ventilator, also known as a ventilation machine or ventilator, is a medical device used to assist or replace a patient's spontaneous breathing. These machines are typically employed in intensive care units (ICUs), operating rooms, and other clinical settings where patients require respiratory support. Mechanical ventilators deliver controlled amounts of air or oxygen to the patient's lungs, helping to maintain adequate oxygenation and ventilation.

Mechanical ventilators are complex devices that require skilled healthcare professionals to set up, monitor, and manage. The selection of a specific ventilation mode and settings depends on the patient's condition, underlying respiratory pathology, and the expertise of the healthcare team.

Figure 13: Mechanical ventilator

v. Continuous Positive Airway Pressure (CPAP)

CPAP is a device that delivers a continuous and steady flow of air pressure to keep the airways open during sleep. A CPAP machine consists of a mask or nasal interface that covers the nose or both the nose and mouth, and it is connected to a device that generates the pressurized air. The continuous positive pressure from the CPAP machine helps prevent the airway from collapsing, allowing for normal breathing patterns and reducing sleep apnea symptoms.

vi. Bilevel Positive Airway Pressure (BiPAP)

BiPAP, also known as non-invasive positive pressure ventilation (NPPV), is a respiratory support device that delivers two different levels of air pressure: a higher inspiratory positive airway pressure (IPAP) and a lower expiratory positive airway pressure (EPAP). BiPAP is commonly used in the treatment of respiratory failure, particularly when there is impaired ventilation or difficulty removing carbon dioxide from the body. The IPAP provides support during inhalation, while the EPAP maintains positive pressure during exhalation, helping to keep the airways open and improving the exchange of oxygen and carbon dioxide. BiPAP machines also utilize a mask or nasal interface for delivering the pressurized air.

NB: Both CPAP and BiPAP are considered non-invasive because they do not require the insertion of tubes or invasive procedures. They can be used in various healthcare settings, including hospitals, sleep clinics, and home care, to provide effective respiratory support and improve breathing for patients with specific respiratory conditions. The selection of CPAP or BiPAP therapy depends on the individual patient's needs, the underlying respiratory condition, and the recommendation of healthcare professionals.

Figure 14: CPAP and BiBAP

vii. Oxygen Humidifiers

Medical oxygen humidifiers are used to add moisture to dry oxygen before it is delivered to a patient. These are medical devices that can be integrated into oxygen delivery systems to humidify supplemental oxygen.

viii. Non-heated bubble humidifiers

Non-heated bubble humidifiers are simple, low-cost devices that add water to oxygen gas by bubbling the gas through water at room temperature. They are appropriate to use if a nasopharyngeal catheter is used to deliver oxygen or if a higher-than-standard flow is used.

Bubble humidifiers can be reusable bottles or single-use bottles that come either empty or pre-filled with distilled water. Reusable bottles introduce a risk of bacterial contamination if the water in the bottle is not changed regularly, whereas single-use bottles reduce this risk. Bubble humidifiers are less efficient than heated humidifiers because unheated gas is less able to hold water vapor.

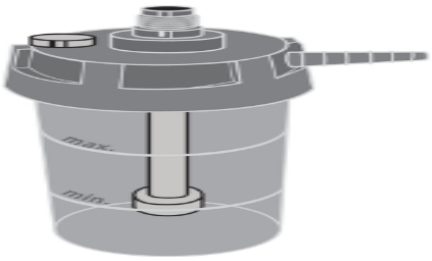

Figure 15: Non-heated bubble humidifiers

Source: UNICEF Supply Division. 2018. Supply Catalogue.

ix. Heated humidifiers

Heated humidifiers consist of a heat source and a humidification chamber (a refillable transparent container). The built-in heater warms the water in the chamber to add moisture to the airstream as it passes over the water surface. The heat is adjustable for more or less moisture. Heated humidification is needed for CPAP and for high-flow nasal cannula (HFNC) oxygen therapy. (Note that some CPAP devices have built-in humidification.)

Heated humidifiers are more effective at humidifying gas than non-heated ones. However, heated humidifiers are moderately expensive compared with non-heated humidifiers and require a continuous power supply. Heated humidification is needed for CPAP and for High flow nasal cannula (HFNC) oxygen therapy

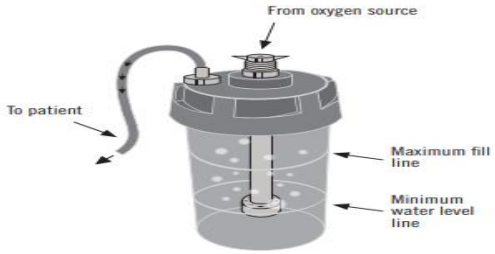

Figure 16: Heated humidifier

E. Medical Oxygen Delivery Devices

These are devices that connect an oxygen source to a patient, for the delivery of oxygen therapy and they can be used regardless of what source of oxygen is used (cylinder, concentrator, or piped system). Devices for oxygen delivery differ in cost, efficiency of oxygen use, and ability to provide the requisite fraction of inspired oxygen. The choice of appropriate delivery device will thus depend on clinical needs and device capabilities.

i. Non-invasive methods

Non-invasive methods of oxygen delivery include head boxes/ incubators face masks (simple, partial rebreathing and non-rebreathing), tents and nasal cannula. With these methods, the fraction of inspired oxygen can be determined more precisely by an oxygen analyzer placed near the patient's mouth. For neonates, infants and children, however, the use of head boxes, face masks, incubators and tents to deliver oxygen is generally discouraged, as they are wasteful of oxygen and potentially harmful due to the risk of carbon dioxide accumulation.

Head boxes/ incubators

An oxyhood, also known as a hood or oxygen hood, is a transparent enclosure that fits over an infant's head to deliver oxygen therapy. It is commonly used in neonatal intensive care units (NICUs) to provide oxygen support to premature babies or infants with respiratory distress. The oxyhood creates an oxygen-rich environment around the baby's head while allowing healthcare providers to monitor the baby's condition.

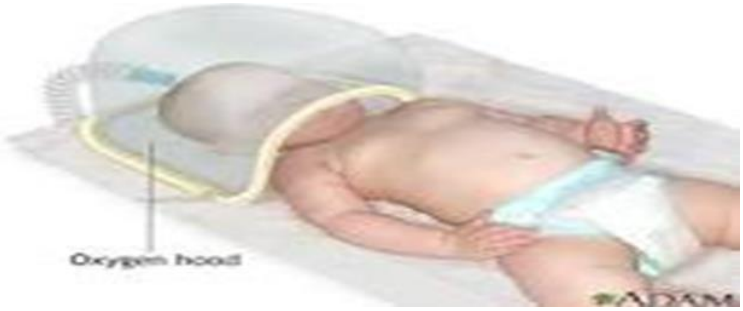

Figure 17: Head boxes/ incubators

Oxygen Face Masks

Oxygen face masks are devices used to deliver oxygen directly to a patient's airways. These masks cover the nose and mouth and are connected to an oxygen source through humidifier. They are commonly used in medical settings to administer supplemental oxygen to patients with respiratory conditions or those in need of oxygen therapy. Oxygen face masks come in various types, including simple face masks, partial rebreather masks, non-rebreather masks, and venturi masks. The specific type of mask used depends on patient's condition.

Figure 18: Simple Oxygen face mask

Figure 19: Non-rebreather face mask

Nasal cannula (nasal prongs)

Nasal cannula are the preferred method for delivering oxygen to infants and children under 5 years of age with hypoxemia. Nasal cannula consist of plastic tubes that end in two short tapered prongs that are placed in the nostrils. When delivering standard flow rates with this delivery method, the flow of oxygen typically does not meet the patient's full inspiratory demand so that ambient air mixes with the delivered oxygen. The prongs should not fill the nostrils completely to allow ambient room air in around the prongs, thus different sizes are available to meet the needs of different patient groups – typically neonate, infant, child, and adult.

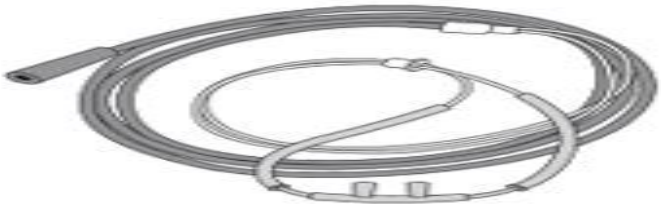

Figure 20: Nasal cannula (nasal prongs)

ii. Invasive methods

Nasal catheter

This is a thin, flexible tube that is passed into the nose and ends with its tip in the nasal cavity. Catheters are sized according to the French gauge system (Fr), also known as Charrière (Ch), where the gauge is three times the external tubing diameter. Nasal catheters are less costly than nasal cannulae and are recommended as an alternative where nasal cannulae are not available.

Nasal catheters are usually well tolerated, and they are unlikely to be dislodged. Both nasal cannulae and nasal catheters provide an optimal balance between safety, efficacy and efficiency.

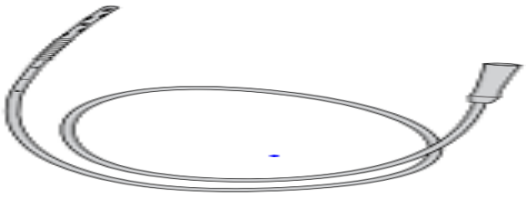

Figure 21: Nasal catheter

Endotracheal Tube

An endotracheal tube is a flexible tube that is placed in the trachea (windpipe) through the mouth or nose. The usual route for inserting an endotracheal tube is through the mouth. This is called an oral endotracheal tube. Less frequently, the endotracheal tube is inserted through the nose. This is called a nasal endotracheal tube.

It can be used to assist with breathing during surgery or to support breathing in people with lung disease, chest trauma, or airway obstruction.

An endotracheal tube is often used during surgery and in emergency situations; when a person is unconscious or unable to breathe on their own . If it is done while a person is conscious, medications can be used to help ease anxiety and prevent nausea. The placement of the tube is called endotracheal intubation. Endotracheal tubes come in different sizes. The bigger tubes are used for larger adults and the smallest ones are used for premature babies.

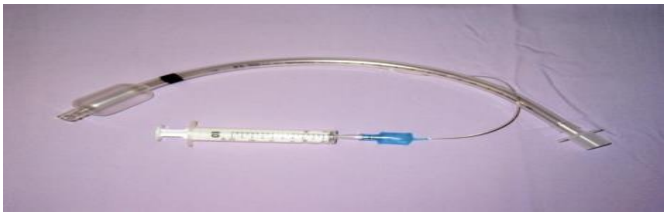

Figure 22: An Endotracheal Tube

Table 1: summary of some of the advantages and disadvantages of different oxygen delivery devices:

Oxygen delivery device	Advantages	Disadvantages
Nasal cannula	- Comfortable and easy to use - Allows eating, drinking, and talking - Suitable for mild to moderate hypoxaemia	- Low concentration of oxygen (24–44%) - Variable concentration of oxygen depending on breathing pattern - Risk of nasal dryness and irritation
Simple face mask	- Easy to use - Higher concentration of oxygen (35–60%) than nasal cannula - Suitable for moderate hypoxaemia	- Variable concentration of oxygen depending on breathing pattern - Risk of rebreathing carbon dioxide - Interferes with eating, drinking, and talking
Non-rebreather mask	- High concentration of oxygen (60–90%) - Minimal rebreathing of carbon dioxide - Suitable for severe hypoxaemia	- Requires high flow rate of oxygen (10–15 L/min) - Risk of suffocation if valves malfunction - Interferes with eating, drinking, and talking
Venturi mask	- Fixed concentration of oxygen (24–60%) regardless of breathing pattern - Allows precise titration of oxygen therapy - Suitable for patients with chronic lung disease	- Requires high flow rate of oxygen (4–15 L/min) - Requires different sized valves for different concentrations - Interferes with eating, drinking, and talking
High-flow nasal cannula	- High concentration of oxygen (21–100%) regardless of breathing pattern - Provides humidified and heated oxygen - Provides positive airway pressure - Suitable for patients with acute respiratory failure	- Requires specialized equipment and electricity - Expensive and difficult to maintain - Risk of aerosol generation and transmission of infection

iii. Devices for quality power supply

In oxygen therapy products, poor power conditions can significantly harm electrically powered oxygen concentrators, as well as pulse oximeters that require power directly from a main source or require recharging from a mains source. While ISO-compliant concentrators include basic power protection, repeated exposure to such poor-quality power can cause shut down, underperformance or permanent damage that requires repair by a skilled technician earlier than expected.

Two key devices that can help protect medical equipment from poor power are voltage stabilizers and surge suppressors. In fact, for oxygen concentrators, WHO recommends that both are used, as a minimum, to counter the poor-quality power that causes cumulative damage to devices over time

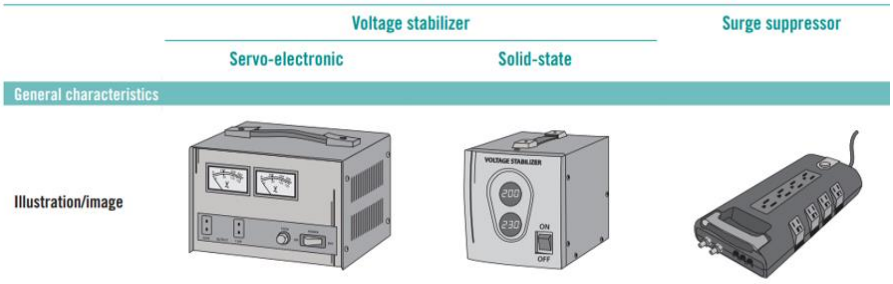

Figure 23: Devices for quality power supply

CHAPTER THREE

SELECTION OF MEDICAL OXYGEN AND OXYGEN THERAPY DEVICES

3.1. Introduction to medical oxygen and oxygen therapy devices selection

Selection, in this context, is the process of choosing the most appropriate medical oxygen devices for a specific patient or health facility. It is an important step in ensuring adequate oxygen therapy and improving outcomes for patients with hypoxemia.

Medical oxygen and its devices are considered as vital and necessary components of health care that should be available, accessible, affordable, and of assured quality for the population. Therefore, including them in the health facility's essential medicine and medical devices list is a crucial to improve access and availability of these life-saving resources in health care settings. The World Health Organization (WHO) has recognized the importance of medical oxygen and related medical devices by including them in the lists of

- The WHO Model List of Essential Medicines and the WHO Model List of Essential Medicines for Children
- The WHO Model Lists of Priority Medical Devices for General and Specialized Health Care Facilities and
- The WHO Model List of Priority Medical Devices for COVID-19 Case Management.

In addition to being listed on the WHO's model list of essential medicines, oxygen is also included on national medicine list. "Selection of oxygen" in this guideline refers to its inclusion on the medicine list. Health facilities are required to include oxygen on their list of facility-specific medicines, and they are also obliged to employ the proper quality-checking tools to assess the oxygen's suitability for medical usage.

By including medical oxygen and related medical devices in these lists, the WHO aims to increase awareness, advocacy, and action to ensure that every patient who needs oxygen therapy can receive it. These lists are intended to assist countries in developing their own national lists of essential medicines and medical devices, as well as in planning, budgeting, procuring, and managing these resources. They also serve as a reference for donors, manufacturers, and other stakeholders involved in the supply chain of medical oxygen and related medical devices.

3.2. Steps to be followed in selection of medical oxygen and oxygen therapy devices

To select medical oxygen and its related devices in health facility specific medicine and medical devices list here are some steps should be followed:

- Review the national lists of essential medicines and medical devices for medical oxygen and its devices.
- Assess the health needs and priorities of your health facility, especially regarding the prevalence and burden of hypoxaemia and respiratory infections among your patients.
- Evaluate the availability and quality of medical oxygen and its devices in your health facility, as well as the gaps and challenges in their supply chain.
- Consider factors such as the source, production capacity, storage capacity, infrastructure, distribution network, transportation suitability and cost, budget, human skill, maintenance, and safety of medical oxygen therapy devices.
- Consult with relevant expertise within the health facilities.

3.3. Selection of Medical oxygen devices

Medical oxygen devices are devices that are used to deliver safe and quality-assured medical oxygen to patients and to ensure its sustainable supply in health facilities. These devices can be categorized primarily as oxygen quality monitoring devices, flow regulation devices, medical oxygen monitoring devices, and conditioning devices.

Selection of oxygen sources

The appropriate choice of oxygen source depends on many factors. These factors can vary widely across different health care settings and contexts, and therefore there is no one-size-fits-all solution for oxygen supply. Each health care setting should conduct a thorough assessment of its oxygen needs and available resources; select the optimal mix of oxygen sources and delivery devices that can ensure the continuity and quality of oxygen therapy for patients.

It should be noted that the selection of oxygen sources for different HF levels should align with existing national policies and strategies.

Criteria to be considered for selecting the most appropriate oxygen source for a given setting are:

- The amount of oxygen needed per health facility, based on the epidemiological situation, the health facility capacity, the patient profile, and the clinical guidelines for oxygen therapy.
- The availability, reliability, and quality of different oxygen sources in the local market, oxygen plants, oxygen cylinders, oxygen concentrators, etc.
- The cost and benefit of each oxygen source, considering the initial investment, operational expenses, maintenance and spare parts requirements, and environmental impact.
- The infrastructure and power requirements including the backup generator for each oxygen source, and how feasible they are in the health facility.
- The safety and quality standards for each oxygen source, and how they can be ensured and monitored
- The training and supervision need for the staff that will operate and maintain each oxygen source.

Table 2: Comparison of the different medical oxygen source devices

	Cylinders	**Concentrators**	**Oxygen plant**	**Liquid Oxygen Tanker**
Description	A refillable cylindrical storage vessel used to store and transport oxygen in compressed gas form. Cylinders are refilled at a gas generating plant and thus require transportation to and from the plant	A self-contained, electrically powered medical device designed to concentrate oxygen from ambient air, using PSA technology	An onsite oxygen generating system using PSA/cryogenic technology, which supplies high-pressure oxygen throughout a facility via a central pipeline system, or via cylinders refilled by the plant	Bulk liquid oxygen generated offsite and stored in a large tank and supplied throughout a health facility pipeline system. Tank requires refilling by liquid oxygen supplier.

	Cylinders	Concentrators	Oxygen plant	Liquid Oxygen Tanker
Clinical application and/or use case	Can be used for all oxygen needs, including high-pressure supply and in facilities where power supply is intermittent or unreliable. Also used for ambulatory service or patient transport. Used as a backup for other systems	Used to deliver oxygen at the bedside or within close proximity to patient areas. A single concentrator can service several beds with the use of a flow splitter	Can be used for all oxygen needs, including high-pressure supply/high flow need	Can be used for all oxygen needs, including high-pressure supply and in facilities where power supply is intermittent or unreliable
Distribution mechanism	Connected to manifold of central/sub-central pipeline distribution system, or directly connected to patient with flow meter and tubing	Direct to patient with tubing or through a flow meter stand	Central/ sub-central pipeline distribution system, or can be used to refill cylinders that can be connected to manifold systems in the facility	Central pipeline distribution system or can be used to refill cylinders that can be connected to manifold systems in the facility
Electricity requirement	No	Yes	Yes	No (electricity is needed for pumping)
Initial costs	Moderate; cylinder, regulator, flowmeter, installation, training	Moderate; concentrator, spares, installation, Training	High; plant and pipeline distribution system, installation, training	Can be high; tank, pipeline Installation, training
Ongoing operating costs	High; cylinder deposit and leasing fees, refill costs,	Low; electricity and maintenance	Low/moderate; electricity and maintenance	Moderate (can be high if

	Cylinders	Concentrators	Oxygen plant	Liquid Oxygen Tanker
	transportation from refilling station to health facility	(spare parts and labour)	(spare parts and labour). May require additional staff to operate/manage if not operated by third party.	tank is leased); refill costs, maintenance
Maintenance requirement	Limited maintenance required by trained technicians.	Moderate maintenance required by trained technicians, who could be in-house.	Significant maintenance of system and piping required by highly trained technicians and engineers can be provided as part of contract.	Significant maintenance of system and piping required by highly trained technicians and engineers can be provided as part of contract.
User care	Moderate; regular checks of fittings and connections, regular checks of oxygen levels, cleaning exterior.	Moderate; cleaning of filters and device exterior.	Minimal; at terminal unit only.	Minimal; at terminal unit only.
Merits	No power source	Continuous oxygen supply (if power available) at low running cost. − Output flow can be split among multiple patients.	Can be cost-effective for large facilities. Can provide continuous oxygen supply.	99% oxygen obtained. High oxygen output for small space requirement
Drawbacks	Requires transport/ supply chain. Exhaustible supply. Highly reliant upon supplier.	Low pressure output, usually not suitable for CPAP or ventilators.	High capital investments. Requires Uninterrupted power.	Requires transport/ supply chain. Exhaustible supply. High maintenance for piping.

	Cylinders	Concentrators	Oxygen plant	Liquid Oxygen Tanker
	Risk of gas leakage. Risk of unwanted relocation.	Requires uninterrupted power. Requires backup cylinder supply. Requires maintenance.	Needs adequate infrastructure. High maintenance for piping. Requires backup cylinder supply. Risk of gas leakage from piping system.	Needs adequate infrastructure. Requires backup cylinder supply. Risk of gas leakage from piping system.

Even though the health facilities can select their source of medical oxygen by considering the above merits and drawbacks of each sources, the MOH national medical oxygen & devises quantification team comprised of multidisciplinary, recommend the sources for health facilities based on their level as indicated in the following table.

3.4. Medical oxygen monitoring, regulation, and conditioning and delivery devices

There are various devices that are used to monitor, regulate, condition and delivery medical oxygen for optimal delivery to patients. These devices can be categorized primarily as oxygen quality monitoring, flow regulation, medical oxygen monitoring, conditioning and delivery devices.

Oxygen delivery devices are the devices that deliver oxygen from the oxygen source to the patient's airway. They can be classified into two main categories: low-flow devices and high-flow devices.

The selection of the appropriate medical oxygen device depends on several factors, such as:

- The health facilities service level and service type
- The availability and compatibility of oxygen sources and delivery devices
- The cost, infrastructure and maintenance of oxygen delivery devices
- Availability of skilled health care workers
- Availability of spare parts, accessories and consumables
- Suitability with operating environment

CHAPTER FOUR

QUANTIFICATION

Quantification is the process of estimating quantities and costs of health products required for a specific period and determining when shipments of the products should be delivered to ensure an optimal and uninterrupted supply of the products. It includes both the forecasting and supply planning activities.

Oxygen, like other essential medicines, should be properly quantified to ensure its availability in health facilities. Its continuous availability depends on proper quantification of the oxygen therapy devices. Evidence based forecasting and supply planning at facility-levels are necessary to ensure a reliable, cost effective and adequate supply of oxygen and oxygen devices.

Principles of good quantification practices encompasses: -

- Evidence based feasible and cost-effective approaches
- Participatory and consultative manner with multi-disciplinary quantification team
- Iterative and periodic process
- Utilization of appropriate method of quantification based on resources and available data
- Use of standardized quantification tool

General guidance for quantification of medical oxygen and oxygen therapy devices in health facilities:

- The health facilities should start and finalize the quantification in time to avail the results for the next round of budgeting; and considering this, the quantification process shall be started at the beginning of Megabit (መጋቢት) and be finalized by mid of Miaziya (ሚያዚያ).
- The medical oxygen and its related devices are quantified together with other pharmaceuticals using the national quantification tool.

4.1. Process of quantification

The process of quantification in public health facilities shall encompass preparation, forecasting, supply planning, validation of the quantification result, and reconciliation of the need with available budget.

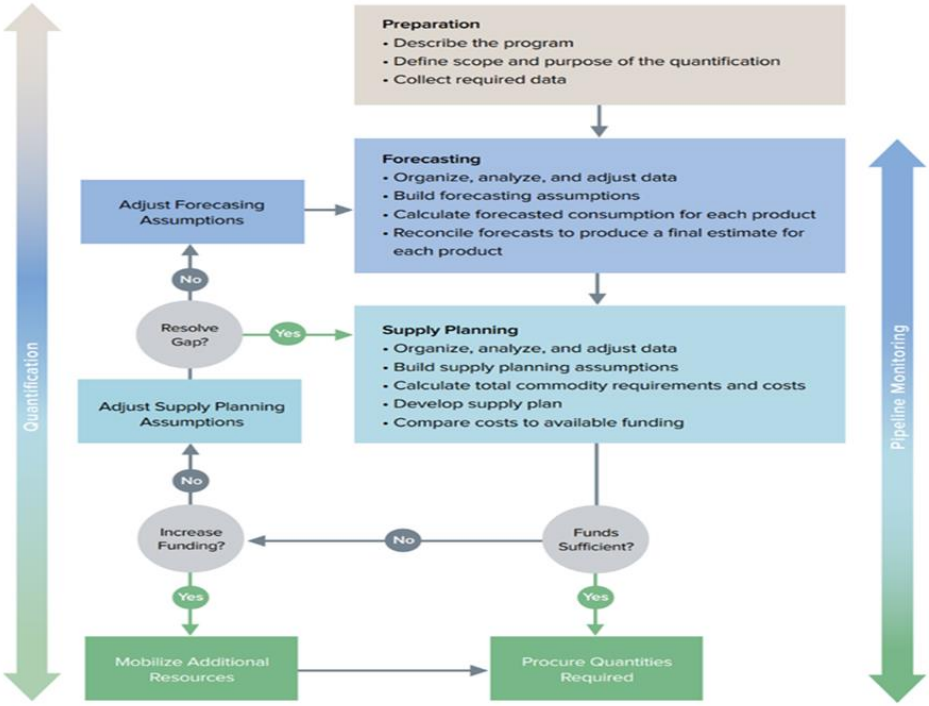

Figure 24: Process of quantification

4.1.1. Preparation

For proper planning and preparation, the following key points should be taken into account.

- Establish a multidisciplinary team of experts that will be assigned by the facility head
    - The quantification team should be organized with the right-mix that must at least include pharmacists, biomedical professionals, clinicians, procurement officers, warehouse managers, and other relevant experts as necessary.
- Develop an action plan that defines scope, the program's purpose, detailed activities, responsible bodies, and timeliness
- Share responsibilities to team members
- Review the previous quantification
- Define the method in consultation with health facility management and/or DTC/MEMC
- Identify required data with respective sources and collect the data

4.1.2. Forecasting of Medical oxygen and its device

Forecasting of medical oxygen and its related device involves four basic steps

i. Organizing, analyzing, and adjusting data

ii. Building and obtaining consensus on the forecasting assumptions

- Most often, if there are few or no data or complete data are not available.
- Assumptions may include issues such as a change in standard treatment guidelines, program strategies, priorities, expansion plans, or service capacity, client awareness to access and services, timing and amount of funding commitments for procurement, seasonality, or geographical differences in disease incidence and prevalence.
- Document the sources of data, information, input from key informants clearly and specifically which assumptions were made, and on what basis.

Two kinds of assumptions need to be made during the forecasting step:

- Assumptions on adjustments made to historical program data when data are missing, unreliable, outdated, or incomplete
- Assumptions on future program performance based on factors influencing demand for services and commodities.

Note: - the assumptions used for forecasts and supply plan should be revised throughout the quantification cycle.

iii. Calculating the forecasted quantity for each product

iv. Comparing and reconciling result of different forecasts, if other methods were employed.

Quantifying oxygen demand and its related devices is determined by the following forecasting methods.

A. **Consumption method**: uses records of past consumption of products to project future needs. To be reliable, the consumption data should come from a stable supply systems with a relatively uninterrupted supply.

B. **Morbidity method**: quantifies the theoretical quantity needed for the treatment of specific diseases. This method should require reliable data on morbidity and patient attendances (visits to health facilities) and uses standard treatment guidelines to project the product needs. Nevertheless, this method is often useful for new and expanding programs and may be the most convincing approach for justifying a budget request.

C. **Mixed** (consumption and morbidity method):

This is important when the quantification of the products is unable to do with the options of each of the above two methods.

Data requirement for forecasting medical oxygen

The following data should be used to quantify medical oxygen & its delivery devices while using different forecasting methods.

A. Consumption method:

S/N	Data type	Data source
1.	Beginning and ending balance in m^3 from total cylinders and oxygen tank; concentrator and oxygen plant production capacity.	Bin card, Inventory data
2.	Quantity of received during the period	Bin card and model 19 health
3.	Adjustments	Bin card, inventory data and consumption registration
4.	Stock out days	Bin card, registration at SDU
5.	Expired and Damaged quantity	Bin card, physical inventory
6.	Oxygen consumption from all sources during specific period	Oxygen consumption registration book

B. Morbidity method:

S/N	Data type	Data source
1.	Number of hypoxemia case per service delivery units	DHIS2 patient registration book
2.	Number of annual OPD visit and inpatient admissions by HFs in a year	DHIS2 report
3.	Total number of beds by HFs in the reporting year	DHIS2 report
4.	Number of HFs beds by type (OPD, general, adult, Paediatric, Neonatal, ICU, OT, ER)	Liaison office record
5.	Bed turnover rate (BTR) (no of discharges (including deaths) in the given time period / No of bed in the hospital during that time period.)	DHIS2 report
6.	Bed Occupancy Rate (BOR)	DHIS2 report
7.	Hypoxemia Prevalence	Survey report

C. In particular to medical equipment factors that should consider by users are:

- Functionality rate
- Life span
- Stock on hand
- Capital expense and operational expense
- Assumptions for accessories

Medical oxygen and Devices quantification tools

Health facilities should use the developed quantification tool, as indicated in the following.

A. Quantification tool for Consumption method

Table 3: Sample oxygen quantification tool using consumption method

Consumption Calculation Template															
SN	Product category	Product description	Unit	Unit price	Relevance (VEN)	Beginning Balance	Qty Received	Positive Adjustment	Negative Adjustment	Ending Balance	Stock Out Days	Expired & Damaged Qty	Calculated Consumption	aAMC	Wastage Rate
						A	B	C	D	E	F	G	**H=A+B+C-D-E**	**I= H/(3-(F/30.5))**	**J = G/(A+B+C)**

NB: Adjusted average monthly consumption (aAMC) is to take in to consideration stock out days and calculated every three months. In this calculation 30.5 indicates the number of days in a month.

B. Quantification tool for Morbidity method

Medical Oxygen Demand Calculation Formula

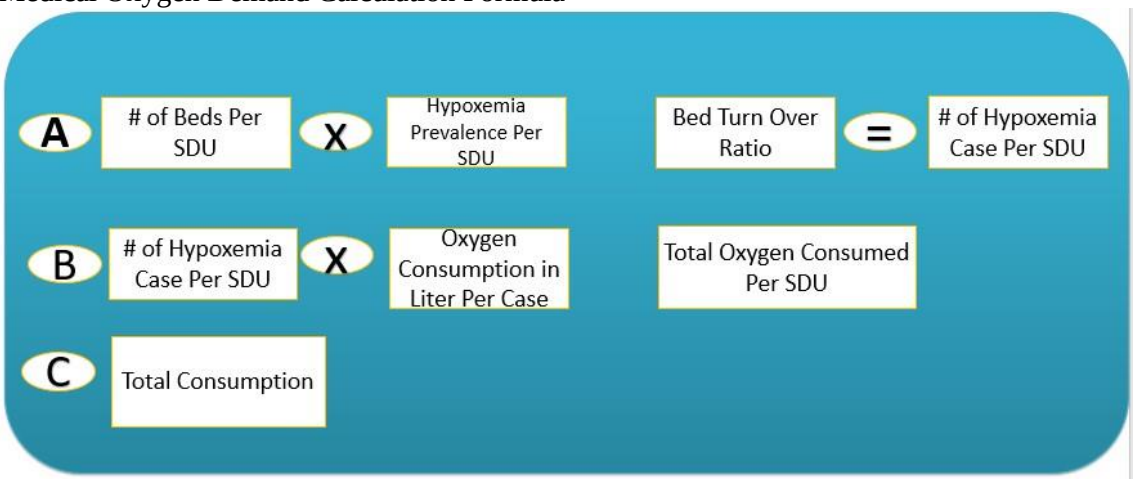

Figure 25: sample quantification tool using morbidity method (Taken from UNICEF OSPT)

A. *Estimation of the number of hypoxemic cases per year. → Used to quantify consumables (e.g. flow splitters, High flow (Venturi mask, non-rebreather mask) and low flow nasal oxygen accessories (nasal cannula, oxygen face mask, nasal catheter, cylinder accessories (flow meters, regulators, humidifiers) since these devices are for single patient use.*

B. *Daily oxygen demand (liters per day): → Used to estimate the number of cylinder refills required*

C. *Instantaneous oxygen demand (Litter per minute- LPM): → Used to inform number ofcylinders, concentrators and plant sizing that should meet the health facility demand.*

Parameters Influencing Oxygen Demand Calculations

The following table indicates given assumptions to calculate parameters influencing oxygen demand using morbidity method.

Table 4: Parameters Influencing Oxygen Demand Calculations by Bed Types (UNICEF Global Data)

SDU type	Hypoxemia prevalence (%)	Typical oxygen flow rate (LPM)	Duration of oxygen therapy (hours)	Bed type requires high-pressure oxygen. (Yes/No)
OPD	1%	5	1	**No**
General	6%	5	72	**No**
Adult	6%	6	144	**No**
Pediatric	10%	2	72	**No**
Neonatal	20%	1	72	**No**
ICU	100%	6	96	**Yes**
OR	100%	8	6	**Yes**
ER	**30%**	**6**	**16**	**No**

4.2. Supply Planning

Supply planning is process of determining which health products should be procured, the amount to be procured, the time at which they should be delivered, and the financial costs to be incurred. It requires data on forecasted quantity, stock on hand, stock on order, lead times, wastage, and logistics costs, and minimum and maximum stock levels to estimate the requirements.

Supply planning should be revised periodically toaccommodate changes in actual consumption trend, stock on hand, delivery schedules, expiries,transfers and other supply chain parameters.

As medical oxygen is vital for service provision at health facilities, continuous monitoring of stock levels and supply planning should be conducted. Unlike other medicines, most of the health facilities may procure medical oxygen every week or biweekly; hence, supply planning of medical oxygen should be regularly updated and followed to avoid shortage and stock out at health facilities. The following steps should be followed in supply planning;

1. Organize, analyse, and adjust data
2. Build supply planning assumptions

3. Calculate total commodity requirements and costs
4. Develop supply plan
5. Compare costs to available funding

Step 1: Organize, Analyse, and Adjust data

Forecasted consumption or demand of each product for the quantification period is the major output of the forecasting step, and is the key input data to the supply planning step. Data for the supply planning can be collected at the same time during preparation phase. To determine the total actual quantities to procure for the established procurement period, other data must be used, which should now be organized and analyzed. Type of data required supply planning includes:

- **Stock on hand**: preferably from physical inventory of each product to be quantified including losses and adjustments
- **Expiry dates**: for consumables products in stock to assess whether they will be used before expiry /Lifespan for equipment's
- **Pipeline products quantities**: products in shipment / transport already ordered, but not yet received
- **Established shipment/ transport intervals and current shipment delivery schedule**
- **Established national/ program /facility inventory level**: min-max stock levels for consumables
- **Product information -** national registration, availability in national standard treatment guideline or essential medicine list, product specific characteristics (formulations, dosages, number of units per pack size, unit cost, and others) accessories, spare parts, bundling issues etc
- **Supplier information** – prices, packaging, lead times, shipping & handling costs
- **Funding information** –Available funding sources, time commitments, funding disbursement schedules to determine when funding will be available for procurement from each source
- **Procurement information –** All procurement mechanisms e.g., National competitive bidding, donor procurement, direct or local procurement for all products to be quantified, procurement lead time for each procurement mechanism
- **Distribution information**
- **Installation, training, commissioning, maintenance costs etc**

Step 2: Build supply planning assumptions

As with the forecasting step, where data are unavailable, missed, incomplete, unreliable, or outdated, assumptions must be made. Most critical point in the assumptions-building process is:

- To document clearly and specifically the sources of information and the key informant inputs on the assumptions.
- Consensus on introduction of new products and utilization of existing stocks, the timing of available funds, supplier lead times, exact amounts of funding available, and estimates on arrival dates of supplies.
- Make assumptions on maximum and minimum stock at facility level if not available.

Step 3: Calculate total commodity requirements and costs

The estimate of the total commodity requirements for the forecast period is the sum of

1) Quantities required as determined by the forecast,

2) Additional quantities needed to cover procurement and supplier lead times and buffer stocks, etc,

3) Any significant quantities that will be removed from inventory due to expiry before usage,

And then subtracting

a) Quantity of each product already in stock (stock on hand) and

b) Any quantities that have been ordered but not yet received (quantity on order).

c) Production capacity for medical equipment likes O2 concentrator, PSA Plants, etc…

In order to identify the produced amount of oxygen and use for quantification, health facilities should determine the total supply volume of oxygen for their oxygen devices based on the following formula.

- **Oxygen concentrator**

Annual Expected Output (m3) = ((# of available concentrators * Production capacity (LPM) * Effective working hours per day * Functionality rate (%)) * 60 * 365) / 1000

- **Oxygen plant**

Annual Expected Output (m3) = ((# of available oxygen Plant * Production capacity (m^3/hr.) * Effective working hours per day * Functionality rate (%)) * 365)

- **LOX Tank**

Annual Expected Output (m3) = ((# of available LOX tank * 861* Liquid volume (L) * Functionality rate (%)) / 1000

Oxygen cylinder to empty time determination

Oxygen cylinder to empty time determination is the process of estimating how long an oxygen cylinder will last based on its size, pressure, and flow rate. There are different formulas and methods for calculating the duration of an oxygen tank, depending on the type and size of the cylinder. Some of the factors that affect the duration of an oxygen tank are:

- Cylinder size: The larger the cylinder, the more oxygen it can hold and the longer it will last.
- Cylinder pressure: The higher the pressure, the more oxygen there is in the tank and the longer it will last.
- Gas flow: The higher the flow rate, the faster the oxygen is delivered to the patient and the faster the tank will run out.

One of the common formulas for estimating oxygen tank duration is:

$$\text{Duration (minutes)} = \frac{(Cylinder\ pressure\ (psi) - 200)\ x\ Cylinder\ volume\ (liter)}{Flow\ rate\ (LPM)}$$

Meter cube (m^3) to cylinder conversion

Water capacity of cylinder 47L = 0.047m^3 at 1Bar (at standard temperature and pressure); NB: 1bar~14.5037psi and 1bar =100kpa

Since the cylinder is filled at 150Bar then the capacity will be 0.047x150 = 7m^3 Therefore, 47L cylinder = 7m^3 oxygen at the filling pressure of 150Bar

The production capacity in number of cylinders will be: 720m^3/day divided by 7m^3 = 102 cylinders/day. Hence, the daily production will be 102 cylinder/day.

Step 4: Develop supply plan

In developing the supply plan should consider the following

- Schedule the delivery to arrive at the time when the stock level reaches at the minimum stock level
- The quantity of product to order should bring the months of stock (MOS) back up to the established maximum stock level
- Round the quantity to order up to the nearest whole unit of supplier packaging

The next step is to estimate the cost of the total commodity requirements

Updated sources of information on product prices and supplier rates are needed to estimate the cost of the quantities of products to be ordered.

Total Cost of Ownership should include costs such as product cost, insurance, freight, in land transport, customs clearance and duties, bank service, operation costs, in-country storage and distribution, installation, training, commissioning, supply of accessories and spare parts, and warranty.

Flexible procurement contracts with suppliers are recommended so that shipment quantities can be adjusted to respond to an uptake in services, and fluctuations in patient demand, existing stock levels, and rates of consumption.

Step 5: Compare costs to available funding

The final decision on the quantities to procure will be determined by the amount of funding available for procurement. If resources are insufficient and there is a funding gap, it is critical that the required reduction in quantities be calculated after revisiting and adjusting the forecasted quantities.

After adjusting the assumptions, the quantification team will need to repeat the steps in the quantification process by calculating the forecasted monthly consumption of each product to the final calculation of the actual quantities of each product to procure, or by adjusting the supply plan to reconcile the results of the quantification with the funding constraints.

The final decision on the quantities to procure is based on the amount of funding available. If sufficient funding is available, the final quantity to procure for each product will be the same as the quantity to order that was determined during the quantification.

Funding gap analysis and appropriate actions to be followed is described below in the figure.

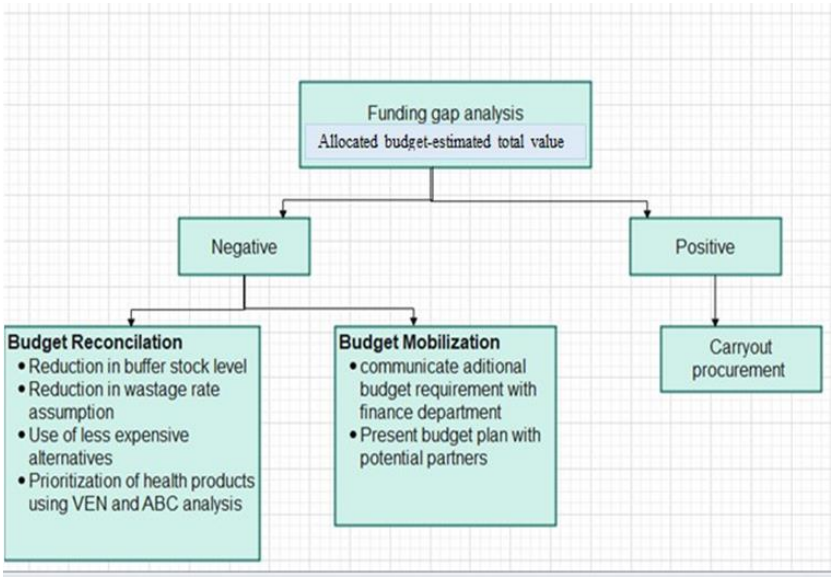

Figure 26: Funding Gap Analysis and Strategies

4.3. Budget Reconciliation

Budget reconciliation deals with determining the final quantities to procure based on the amount of funding allocated for procurement. In particular to oxygen delivery devices, the adjustment of quantification result to the available budget should be done through systematic review and categorization of the result using ABC analysis and VEN classification with other pharmaceuticals.

NB: It should be noted that medical oxygen is one of the vital medicines in health facilities where medical oxygen service is provided. Hence, priority should be given at all times to ensure availability of medical oxygen and its vital oxygen devices that are necessary for proper functioning of medical oxygen service.

CHAPTER FIVE

PROCUREMENT OF MEDICAL OXYGEN & DEVICES

5.1. Basics of procurement

Procurement follows quantification and is the process of acquiring goods and services an organization needs for its operations. Procurement has multiple steps which includes sourcing and tendering, award of contract, contract preparation, contract administration (including monitoring and evaluation), and delivery of the goods or services, close of contract. Procurement covers acquiring through purchasing, donation, renting, leasing, etc.

With respect to medical oxygen, the procurement follows the overall health sector goods procurement processes, policies and procedures. This plays an important role in ensuring that a cost-effective and efficient selection and award process is conducted to obtain appropriate and sustainable oxygen and its devices. For the procurement process to achieve this objective, an integrated approach, one that engages key actors in the appropriate planning and procurement activities should be followed.

To ensure the availability oxygen in a sustainable manner, a number of factors should be considered while procuring.

According to Federal Public Procurement Directive 2010, the following general principles must receive due consideration when undertaking all procurement activities related with medical oxygen and its devices:

1. Value for money
2. Non-discriminatory
3. Efficiency, Effectiveness, & Economy
4. Transparency & fairness
5. Accountability
6. Encourage local producers through preferential treatments

5.2. Procurement Methods

Whenever a procuring health facility procures oxygen and related medical devices, it is needed to decide upon the most appropriate procurement method and the types of suppliers to approach. According to the Federal Public Procurement Directive of Ethiopia, the possible procurement methods are listed below:

- Open bidding
- Restricted bidding
- Request for quotations
- Single source/ direct procurement
- Request for proposal, and
- Two stage bidding

The federal public procurement directive encourages the procurement entities to use the open bidding method. However, one can also use the single sourcing/direct procurement method provided that there are situations that necessitate such method as indicated in the directive, and approved by the head of the procuring entity.

5.3. Procurement Process

The procurement process includes most of the decisions and actions that determine the specific medicine quantities obtained, prices paid, and quality of medicines received. There are three phases of procurement:

Program planning: it covers activities from defining the procurement need until initiating the procurement requisition, which includes defining the medical oxygen and its devices, preparing specification, assessment of procurement options and budget, funding, & procurement requisition.

Tender process: this process starts from procurement requisition up to contracts signing, which includes procurement planning, developing bidding documents and involving offers, selecting suppliers and contract signing

Contract management: a step in which supplier performance monitoring and receiving of the products or services is conducted, which includes contract performance and monitoring and delivery of goods.

The below **flowchart** provides a multi-step procurement process that is generally followed when planning for and procuring medical equipment, including oxygen delivery devices. It highlights that a multidisciplinary team should be established that develops a detailed work plan and ensures its implementation. Some of the critical activities include refining the actual procurement need based on the quantification made earlier; finalizing the bidding document by including all the necessary requirements; conducting technical, financial and supplier evaluations against the bidding document and the need of the health facility; ensuring of site preparation for the upcoming products; inspection of the products and receiving; conduct supplier performance monitoring to make sure that the supplier has delivered all the agreed-upon products and services satisfactorily as per the and the agreement entered between the buyer and the supplier. The facility may develop a tool or checklist to conduct the supplier performance evaluation efficiently.

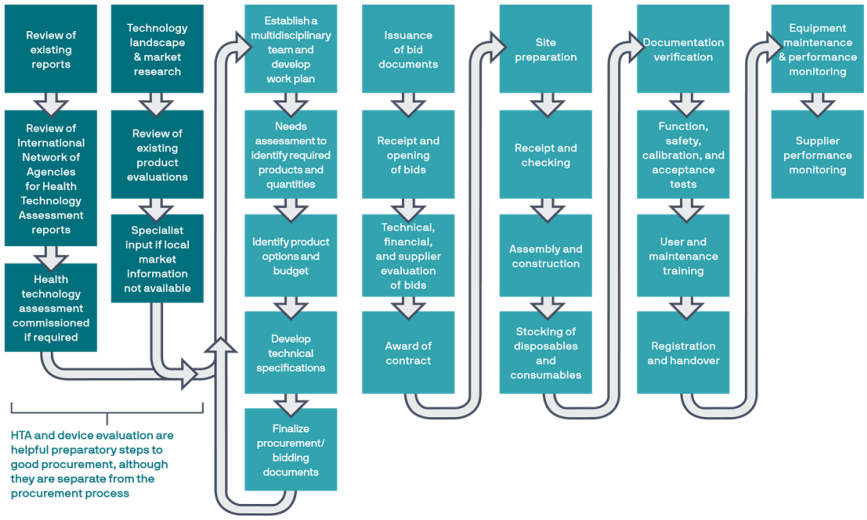

Figure 27: Summary flowchart of integrated procurement process

5.4. Procurement Planning

The supply plan, which is the final output from the quantification exercise, provides critical inputs to the procurement plan. In addition, a procurement plan includes the identification of the procurement method to be used, a list of the key steps in the procurement process (such as advertise bid, open bid, evaluate bid, award contract, disburse payments, etc.), and a timeline with estimated dates for completing each step of the process, including the names of the responsible parties. Part of the plan should clearly state timelines, dates, and responsibilities assigned for each activity. Dates for completion should be set for all activities; but they must be realistic, based on experience and current capacity.

Key Considerations

- Some medical oxygen devices have low direct procurement cost but high running/operational costs which is not seen as face value of the devices. Hence, in selecting oxygen delivery devices, in addition to the safety, quality and effectiveness parameters, the procurement methods should consider the total cost of ownership, including the hidden costs which include the direct purchase cost, transportation and other related costs, the maintenance cost, cost of disposal, spare parts cost etc.
- To effectively implement procurement activities, it is important to engage a multidisciplinary team in the procurement process.
- Standard bidding documents should be used and all the necessary components of the documents should be carefully filled.
- Bidding documents and/or procurement agreements for medical oxygen procurement should clearly define/indicate the technical specifications and service requirements, the logistics aspects, etc. Some of them include:
    - Quantities, unit, specifications, and quality assurance requirements of the desired products
    - Delivery dates and required destination of the shipment
    - Mode of transport and who handles the transportation
    - Regulations, procedures, and timing for responding to the bid
    - Selection criteria that will be used to evaluate and select suppliers
    - Installation requirement for the medical oxygen and related devices.
    - Warranty time needed to be included

- Access to spare parts and for how long the service is needed
- Capacity building describing the type of trainings required
- The amount and type of bid security
- The amount and type of performance guarantee

Through a public-private partnership modality, health facilities might work with medical oxygen devices manufacturers or suppliers in an arrangement to allow the manufacturer/supplier to use their premises to provide services (e.g. provide oxygen service) to the health facility's patients/clients with an agreed upon service fee. An outsourcing agreement can also be reached with a private service healthcare provider to refer the health facility's patients/clients to get oxygen related services for a fixed service fee.

5.5. Monitor contract performance

The step is to ensure that the established contract is adhered to and that supplies are received, as planned. Establishing a contract performance monitoring system and implementing it early in the contract process ensures that problems are identified and resolved early, before they become bigger problems. In monitoring performances, the health facilities are required to check and verify that the product or service is delivered as per the agreement with respect to timeliness of the delivery, quality of the product or service, and other aspects that are included in the bidding document and the agreements.

5.6. Delivery

The last step in the procurement process is to ensure delivery and receipt of the goods at the required destination. Products must also meet any special requirements included in the contract. After inspection, if no problems are detected, products can be accepted into the warehouse, get registered and added to the usable inventory for use.

5.7. Procurement of Medical Oxygen Plant

The Procurement of medical oxygen plants requires special considerations because it is a highly resource intensive investment. Preliminary activities entail close communication with the end user from the beginning of the process. These activities include oxygen need-gap assessment, site evaluation and preparation (e.g. evaluation of readiness in terms of human resources, electrical power supply and infrastructure) and the definition of long-term service requirements and financial capability and warranty.

The lifespan of a medical oxygen plant should be guaranteed for 10 years by the manufacturer. Likewise, all medical oxygen plants should have at least a 3-year warranty period, starting from the date of commissioning, to prove quality performance in the specific setting.

5.8. Medical oxygen device Donation

This should align with the National Medical Devices Donation Directive which outlines the conditions for accepting donated medical devices at health facilities. Donated medical oxygen plant and device must be in good working order, needed by the hospital, and compatible .Instruction manuals, supplies, consumables, and spare parts should be provided, and expertise for maintenance and repair should be available in Ethiopia. The donor should provide training and follow-up support, and customs clearance responsibilities must be agreed upon. All donations must be reviewed and approved by the hospital management before acceptance.

5.9. Procurement Optimization

The acquisition system of medical oxygen devices can be improved by introducing different innovative globally proven best procurement practices including:

- Standardizing and strengthening healthcare technology assessment and selection,
- Establishing or using already established pooled procurement mechanisms,
- Establishment of proper contract management, post procurement and installation warranty period follow up systems,
- Service Level Agreements (SLA) to ensure long term availability of accessories and spare parts and after sales services by placing long term agreement procurement systems on the medical oxygen device.

CHAPTER SIX

DISTRIBUTION

Distribution refers to the process of delivering goods or resources from a source to a destination or end-user through various channels and networks. The goal of distribution is to ensure that products or services are available to customers in the right quantity, at the right time, and in the right place**.**

6.1. Distribution of medical oxygen

Medical oxygen distribution requires careful planning, logistics management, and coordination among various stakeholders involved in the distribution process**.**

Medical oxygen can be delivered to a health facility through the central piping system, manifold system, and cylinders filled from private or public owned medial oxygen producing plants.

Within the health facility, the distribution of medical oxygen cylinders from the storage to departments/wards should be based on the demand and schedule set.

6.1.1. Distribution within health facility

Centralized piping system

Centralized piping systems are widely utilized for the distribution of medical oxygen in hospitals which have medical oxygen plants or liquid oxygen tank. These systems are regarded as cost-effective for numerous reasons as it avoids the need for handling and transporting heavy cylinders between hospital wards since this distribution system does not need cylinders, it saves space, no risk of damage of floors, minimizes leakage of gas and the operation is easy and friendly. Centralized systems provide better control and monitoring of oxygen distribution. Zonal valves, flow meters, oxygen sensors and other control devices can be centralized, allowing for easier monitoring and adjustment of flow rates, pressures, and other parameters. This centralized control enhances efficiency and reduces wastage.

Centralized piping system supply oxygen using the oxygen generated either from PSA or cryogenic/ liquid oxygen plants. In PSA plants, after oxygen is being produced, it is piped directly to terminal units/wards within patient areas. In case of liquid oxygen, after vaporizers convert the liquid oxygen into a gaseous state, oxygen is piped in a similar way with PSA plants. However, the high cost and complexity of installing centralized oxygen sources

with copper pipelines and the associated specialized maintenance required for this make pipeline systems less accessible for health facilities in the country.

The following considerations must be made when using a central piping system.

- A dedicated biomedical engineer or mechanical engineer should be assigned to closely monitor the operation.
- To ensure safe and efficient operation, oxygen levels, pressures, and other relevant factors should be measured and monitored using sensors, gauges, and alarms.
- For the proper functioning of the centralized piped oxygen system, regular maintenance, inspection through routine checks of the equipment, periodic calibration of instruments, and adherence to safety guidelines and regulations is needed.
- Continuous electric power and backup generators should be available.
- For in case of any interruption, manifold system or cylinder choices should be accessible as a backup.

Manifold system

Cylinders that are filled at a gas manufacturing plant, either via a cryogenic distillation or pressure swing adsorption (PSA) or liquid tank and transported to health facilities are connected or linked in parallel to form a manifold systems that are piped to different units/wards of the health facility.

In health facilities, the manifold oxygen distribution system enables centralized control, greater efficiency, increased safety, and accurate flow management. These benefits contribute to improved patient care, more efficient operations, and cost savings for healthcare facilities. Manifold system can be manual and automatic.

Things to be considered in manifold distribution system:

- Consider integrating the manifold system to other building systems like as the electrical system, emergency power supply, and building management system to enable system coordination, remote monitoring, and continuous communication.
- Consider the predicted oxygen demand in the facility, taking into account factors such as the number of patients, the types of medical procedures done, and the expected flow rates to determine the capacity and sizing needs of the manifold system.
- Determine the flow rates and pressure levels required for various places of usage, such as patient rooms, operating rooms, and diagnostic regions by taking into account the

specific oxygen therapy requirements as well as the medical equipment that will be linked to the manifold system.

- To mitigate the risk of system failure and ensures continuous oxygen availability, consider backup cylinders oxygen bank.
- Put a “No Smoking” sign near oxygen sources/manifold system in the hospital

Directly from cylinder

Medical oxygen can be directly supplied using the cylinder tank at bed side.

During moving oxygen cylinder within the health facility, the following key procedures should be considered.

- Use a cart designed to move cylinders
- Use smooth surface which is suitable and easy for transport
- Ensure the cylinder valve is in the fully closed position
- Never drop the cylinders or allow things to bang into them
- Ensure that the cylinder contents are clearly labeled
- Cylinders should be placed only on flat floors or platforms
- Transporting cylinders in an upright position is always preferred

Figure 28: Moving medical oxygen cylinder within health facility

Source: mariumoxygen.com.

Safety should always be the top priority to prevent accidents, ensure the integrity of the cylinders, and protect the well-being of individuals involved in transportation and the public.

6.2. Transportation of medical oxygen

6.2.1. Transportation of liquid oxygen

Transporting oxygen using the tanks and storing it as a liquid takes less space and is less expensive than moving and storing it as a gas under high pressure.

Transporting liquid medical oxygen requires careful attention to safety considerations due to the unique properties and hazards associated with cryogenic liquids. Careful handling is required due to the possibility of accidentally rupturing the pressurized tank, which could lead to safety risks such as cold burns and a source of ignition for fires.

Figure 29: Liquid medical oxygen transportation

Source: www.alibaba.com

Here are some key issues to consider during the transportation of liquid medical oxygen:

- Make sure that liquid medical oxygen meets international and national standards.
- Liquid oxygen should be transported and stored at extremely low temperatures, typically around -183 degrees Celsius (-297 degrees Fahrenheit).
- Specialized cryogenic containers, such as vacuum-insulated Dewar flasks or tank trucks, are used to transport liquid oxygen. Ensure that the containers are designed and maintained to withstand the low temperatures, high pressure and prevent the loss of oxygen through evaporation.
- Liquid medical oxygen containers should be securely fastened within the transport vehicle to prevent shifting or falling during transit. Use appropriate restraints, such as straps or brackets, to secure the containers in place.
- Liquid oxygen containers must be properly packaged and insulated to minimize heat transfer and maintain the low temperature.

- Approved packaging materials and techniques should be used to prevent damage to the containers.
- Containers should be properly vented to release any buildup of gaseous oxygen, which can result from the natural evaporation and expansion of the liquid.
- Liquid oxygen should be transported separately from flammable materials to minimize the risk of fire or explosion.
- Maintain adequate distance from flammable materials during loading, unloading, and transportation.
- During shipping, appropriate safety equipment such as fire extinguishers, spill kits, and personal protective equipment should be carried.
- Personnel involved in the transportation of liquid medical oxygen should be trained in safe loading, unloading, and moving, and emergency response procedure.
- Properly label and mark the liquid oxygen and associated transport liquid oxygen tank with the required hazard labels, warning signs, and identification codes.
- Ensure that all parties are aware of the transportation schedule, any specific requirements, and emergency contact information. Communicate any changes or issues promptly to maintain a coordinated and safe transportation process.

Quality assurance and control in distribution of liquid oxygen

Quality practices will be required for the final transfer of liquid oxygen to the facility storage vessel(s), which remain the responsibility of the supplier. In addition to the safety points listed above:

- The transport tank will be pressurized slightly higher than the recipient vessel(s) and a non-return valve will be located downstream of the transfer pump. Both features serve to ensure that no oxygen back-flows from the on-site storage vessel into the tank truck.
- A certificate of analysis for the liquid oxygen in the tank shall be handed over from the driver to the recipient health facility. A formal acceptance process must take place prior to trans filling the facility storage vessel(s).
- No vehicles shall block the entrance or exit of the liquid oxygen tank truck.
- Only authorized persons shall be allowed near the tank truck or vacuum insulated evaporator (VIE) tank; to avoid oxygen enrichment, personnel involved in the process shall not stand near oxygen vents.
- Trans filling shall not take place over, under, or through anything.

- The operator responsible for trans filling shall wear appropriate PPE.

6.2.2. Transportation of oxygen cylinders from source

Medical oxygen filled into cylinders either from cryogenic source or PSA plant is transported to the health facilities. Because of the possible hazards involved with compressed gases, transporting oxygen cylinders requires special attention to safety precautions.

Figure 30: Transporting medical oxygen cylinders

(Note: this is just for demonstration and doesn't show country's cylinder color coding standard)

Important considerations when transporting oxygen cylinders

- Use valve protection caps prior to moving the cylinders.
- To avoid injury, use safe handling techniques such as cylinder dollies and appropriate lifting equipment when loading or unloading oxygen cylinders.
- Oxygen cylinders should be securely packaged and protected during transport to prevent damage or leakage.
- Use appropriate packaging materials, for instance racks, to minimize the risk of cylinder movement or impact during transit.
- Oxygen cylinders should be transported in an upright position to prevent the release of gas and to maintain the integrity of the cylinder valve.
- Properly secure oxygen cylinders during transportation to prevent shifting or tipping.
- Ensure adequate ventilation during transport, especially when transporting a large number of cylinders to dissipate any leaked gases and reduces the risk of oxygen concentration buildup, which can increase the flammability of the surroundings.
- An open vehicle is preferred for cylinders transport.

- Oxygen cylinders should be transported separately from flammable materials to reduce the risk of fire or explosion.
- Never drop the cylinders or allow things to bang into them.
- Personnel involved in the transportation of medical oxygen cylinders should be trained in safe loading, unloading, and moving, and emergency response procedures.
- During shipping, appropriate safety equipment such as fire extinguishers, spill kits, and personal protective equipment should be carried.
- Properly label and mark the oxygen cylinders and associated transport containers with the required hazard labels, warning signs, and identification codes.
- Maintain proper documentation of the cylinders being transported, including cylinder serial numbers, contents, and pertinent safety information.

Distribution of oxygen from oxygen producing hospital to nearby health facilities:

Many tertiary and general hospitals in the country are installing oxygen production plants. Although there may be hospitals, which consume all the produced oxygen by themselves, many hospitals have surplus after fulfilling their oxygen need. The host hospital after fulfilling its oxygen need is expected to supply the surplus oxygen to the nearby health facilities through hub and spoke model. The oxygen producing hospital is the "hub" and those receiving the excess are the "spoke".

The distribution of the surplus oxygen from the oxygen producing hospital to the receiving health facility could be done in one of the following ways:-

- The hospital owned oxygen plant can distribute medical oxygen directly to the buyer health institution.
- The buyer health institution can receive oxygen from the hospital owned oxygen plant.
- The hospital owned oxygen plant may, in the distribution of medical oxygen, sub contract the carriage of the medical oxygen to a third party.

Quality assurance and control in distribution of medical oxygen

Quality should be kept during distribution of medical oxygen. The followings are some of the considerations in ensuring quality and safety of medical oxygen distribution.

All vehicles transporting oxygen shall have:

- A vehicle reverse alarm feature

- A secondary locking device to prevent rolling when parked (such as wheel chocks)
- A charged fire extinguisher in the driver's cab
- "No smoking" signs in the cab and on the back of the vehicle
- A vehicle safety equipment kit, comprising two safety cones (pylons), a torch/flashlight, and a reflective jacket
- A first-aid kit

The vehicle engine must be turned off during loading/off-loading and must be kept clean.

Vehicle loading:

- Lifting devices shall be used where available (e.g., hydraulic liftgate, forklift); otherwise, a ramp shall be used with a trolly.
- Vehicle payload capacity shall never be exceeded. Consider the weight of empty cylinders being returned – do not overload with empty cylinders.
- Imbalances should always be avoided as they could pose a risk during transport.
- Cylinders shall be upright and restrained so they cannot move during transport.
- Vents shall never be blocked by cylinders, trollies, or any other ancillary equipment.
- Cylinders shall always be transported with valve protection (e.g., valve cap or valve guard) in place to ensure that the integrity of the valve and valve stem remains intact.
- Unrelated items shall never be loaded on vehicles transporting oxygen. If a spare tire is in the vehicle, it must be in a separate compartment.
- Never transport people with the loaded cylinder - not staff, not civilians.

6.3. Distribution of oxygen therapy devices

Distribution of oxygen related devices, accessories and consumables can be done and managed in similar way of other medical equipment distribution. Oxygen therapy devices that help to deliver, regulate, condition, and monitor medical oxygen should follow the same system of pharmaceuticals and medical devices distribution. The health facility should implement internal facility report and resupply system to ensure rational distribution within health facilities.

CHAPTER SEVEN

STORAGE AND INVENTORY MANAGEMENT

Proper storage and efficient inventory management are necessary to ensure timely availability of oxygen devices to healthcare facilities and individuals who rely on them. In terms of storage, oxygen devices need to be kept in a controlled environment that follows appropriate safety guidelines. This includes storing oxygen cylinders, concentrators, and other related equipment in a well-ventilated and secure area. The storage space should be free from potential hazards such as open flames, flammable materials, and extreme temperatures. Additionally, adequate space should be allocated to accommodate the quantity of oxygen devices based on demand forecasts.

Inventory management involves closely monitoring the stock levels of various oxygen devices and maintaining an optimal quantity to meet customer requirements. Effective inventory management involves tracking the inflow and outflow of oxygen devices, related consumables their condition, and shelf life. This helps in preventing stock outs, minimizing excess inventory, and reducing the risk of obsolescence. There are different inventory management tools that can be used to manage the inventory of oxygen devices and consumables.

7.1. Storage of medical oxygen therapy devices

Proper storage management of medical oxygen, related devices and consumables are essential to ensure the safety and effectiveness of this life-sustaining product. Here are some general guidelines for good storage practices of oxygen devices and cylinders:

7.1.1. Receiving:

- During unloading, ensure proper handling of cylinder and other oxygen devices as per the manufacturer recommendation
- During receiving, properly inspect all incoming oxygen devices and cylinders for damages, leaks, or signs of tampering.
- Conduct acceptance test for oxygen therapy devices if applicable while receiving.
- Each incoming delivery should be checked against the relevant documentation, to ensure that the correct product is delivered from the correct supplier. This may include, the purchase order, containers, label description, batch number, expiry date, product and quantity.

- Receiving areas should be of sufficient size to allow the physical inspection, medical oxygen purity and pressure checking of incoming medical oxygen devices and cylinders.
- Select a random number of medical oxygen cylinders to check purity using oxygen analyzers.
- Broken or damaged items should be quarantined from received usable stock.
- Check the pressure gauge on each cylinder to ensure that the cylinder is full and it is in the acceptable range (above 2000 psi).
- The store manager should receive using model 19/health after checking all received oxygen and related devices.
- The health facility committee assigned for hand-over should involve bio-medical engineers/technicians, pharmacist, and medical oxygen porters in the process of receiving.

7.1.2. Good storage practices:

- Ensure storage areas are appropriately designed, constructed and maintained.
- Store oxygen devices and cylinders in a well-ventilated and sufficient space that is clean, dry, and free from exposure to heat sources, direct sunlight, and flammable or combustible substances.
- Oxygen cylinders should be kept at least 20 feet away from flammable items.
- Ensure that oxygen cylinders are placed in an upright position and properly secured in a storage rack or stand to prevent them from falling or rolling.
- To ensure the safety and effectiveness of oxygen cylinder operations, head caps should be in place for cylinders valve protection whenever the cylinder is not in use.
- Ensure storage areas maintained within acceptable and specified temperature limits.
- Where the labels show special storage conditions are required (e.g. temperature, relative humidity), these should be provided, controlled, monitored and recorded accordingly.
- Precautions should be taken to prevent unauthorized persons from entering storage areas.
- Follow a "first-in, first-out" method to use older oxygen cylinders first to prevent pressure reduction.
- Ensure that there is a written sanitation program available indicating the frequency of cleaning and the methods to be used to clean premises and storage areas.

- Stores must verify that the oxygen devices and cylinders meet the required quality standards during storage. They may include checking for any defects or damages that may affect the functionality or safety of the medical oxygen devices.
- Empty and full cylinders should be separately stored with clear labeling.
- The storage container for liquid oxygen better to be designed and constructed specifically for low-temperature storage that ensures adequate insulation to minimize heat transfer.
- To prevent the buildup of excessive pressure, the liquid oxygen storage container should be equipped with pressure relief devices to protect the container from rupturing or exploding in case of a pressure increase.
- Ensure liquid oxygen stored in a well-insulated container with temperature control to keep the temperature below -183 °C (-297 °F) to maintain the liquid state.
- Avoid storing or placing any objects on top of cylinders and other oxygen devices.
- Maintain accurate and comprehensive records of all oxygen cylinders, including the date of receipt, usage, and inspections.

Figure 31: proper cylinder positioning

Note: The diagram is intended to show how to store medical oxygen cylinder and the colour of the oxygen cylinder doesn't represent Ethiopian cylinder coding

7.1.3. Labels and coding:

- Clearly label all oxygen cylinders and devices with their contents, such as "oxygen" or "medical oxygen" or "Liquid Oxygen" or "LOX". This helps to identify and differentiate them from other gases easily.

- The cylinder should carry appropriate hazard warning labels or symbols indicating that it contains a hazardous substance. The below figure is an example of a typical label.

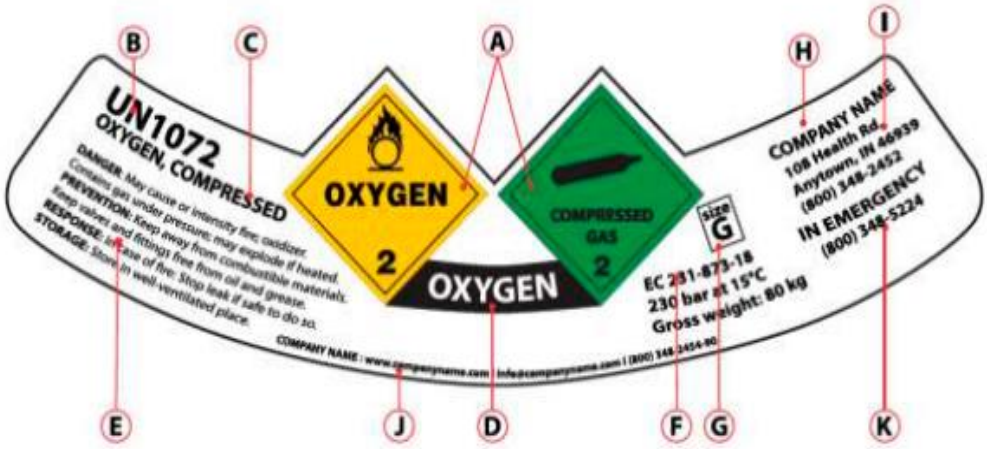

Figure 32: oxygen cylinder labeling

A. Diamond hazard label: displaying the primary hazard with additional hazard labels displaying any subsidiary hazards. These labels will display the dangerous goods classification number.

B. UN number: proceeded by the letters UN. The UN number is a number assigned by the United Nations Committee of Experts on the Transport of Dangerous Goods. The UN number for compressed oxygen is UN 1072.

C. Proper shipping name.

D. Product name (may be omitted if the proper shipping name is identical).

E. Signal word, hazard and precautionary statements.

F. EC number (if applicable).

G. Package size and pressure.

H. Company name.

I. Address of the gas company.

J. Additional company information.

K. Contact telephone number.

- Ethiopia adopted the ISO standard and should be coded accordingly
- Mark or label them as "Empty cylinder", if the cylinder is empty and other devices, oxygen concentrator if functional/nonfunctional, should be label.
- Do not use a cylinder that is not identified or if the label is not legible.

Gas	U.S. Color Code	ISO Color Code
Carbon Dioxide	Grey	Grey
He-O_2	Brown and Green	Brown and White
Instrument Air	Red (USA Only)	
Medical Air	Yellow	Black and White
Nitrogen	Black	Black
Nitrous Oxide	Blue	Blue
O_2-He	Green and Brown	White and Brown
Oxygen	Green	White
Vacuum (Suction)	White	Yellow
WAGD (Evac)	Purple	Purple

Figure 33: color coding of cylinders

7.1.4. Handling:

- Train personnel on proper handling techniques when moving or transporting oxygen cylinders.
- Never leave any unattended oxygen cylinder standing up.
- Use appropriate personal protective equipment such as gloves and safety glasses during moving cylinders.
- Do not drag, drop, or roll cylinders during transport.

Figure 34: Transportation of oxygen cylinders

7.1.5. Fire Safety:

- Ensure the availability of fire extinguishers specifically rated for oxygen fires in the storage area and regularly inspect, test, and maintain them.
- Ensure that all employees or personnel in the vicinity of the oxygen storage area are trained in fire safety procedures, including the use of fire extinguishers.

- Clearly mark the storage area to alert individuals to the presence of oxygen. Use "No Smoking" and "Flammable Gas" signs to reinforce the importance of fire safety.
- Have a clearly laid-out plan for responding to fire emergencies.
- Avoid using electrical equipment, switches or outlets in the direct vicinity of oxygen storage. If unavoidable, ensure that all electrical equipment installed in the area is explosion-proof and regularly inspected for any damages or faults.

Figure 35: Fire extinguisher

7.1.6. Inspections:

- Regularly inspect all oxygen devices and cylinders for damages, leaks, or signs of deterioration.
- Perform pressure tests as per manufacturer recommendations.
- Remove any defective medical oxygen devices from service immediately.
- Report the inspection result to the relevant personnel and management.
- Document inspections results/performances properly.
- Follow national guidelines and regulations.

7.2. Inventory Management

Inventory management is the overall strategy to ensure health facilities have the right amount of products at the right time and in the right place. Managing an inventory is aimed at satisfying customer requirements while minimizing total operational costs. It determines when to order products and in what quantities.

Inventory control system

Generally, the purpose of an inventory control system includes: -

- To determine when stock should be ordered/issued

- To determine how much stock should be ordered/issued
- To maintain an appropriate stock level of all products, avoiding shortages and oversupply

Proper inventory management is crucial for medical oxygen and related supplies. The driving factors to hold inventory are:-

- Uncertainty in demand
- Unpredictable or late deliveries from suppliers
- Lead time
- Delivery costs

To maintain adequate stock levels, it is necessary to establish the maximum and minimum months of stock and an emergency order point of medical oxygen and related consumables for each health facility in the system.

Maximum stock level - The maximum months of stock is the largest amount of the products a facility should hold at any one time.

- If a facility has more than the maximum, it is overstocked and the risk of having stocks expire before they are used is probable.
- Maximum stock level can be calculated as:

$$\boldsymbol{Max.stock\ level = max.weeks\ of\ stock \times Aver.weekly\ Consumption}$$

Where,

$$AWC = \frac{Total\ consumptions}{weeks\ of\ supply - (\frac{DOS}{7})}$$

Minimum stock level is the level of stock at which actions to replenish inventory should occur under normal conditions.

- It can be calculated as:

$$Min.Stock\ level = min.weeks\ of\ stock \times AWC$$

Emergency stock level is the level where the risk of stock out of the products is likely, and an emergency order should be placed immediately. It can be calculated as:

$$Emergency\ stock\ level = EOP \times AWC$$

Reorder level is the level of the stock of a particular item, held by the firm, when an order is needed to be placed for avoiding the risk of being out of stock. It is based on the average time taken by the supplier for replenishment, maximum usage of the item during the replenishment time, safety stock requirement, and storage capacity. It gives a signal regarding when to place a new order. The main risk factor in reorder level is being out of stock and related foregone sales.

Special considerations to maintain appropriate stock level of medical oxygen

- Ethiopia IPLS system uses forced ordering min-max inventory control system. The same can be applied for oxygen delivery devices and other related supplies.
- But for medical oxygen continuous review of min-max inventory control system would be ideal inventory control system because the stock status is always known by immediately updating after each transaction.
- The trigger for ordering is when the facility reaches the minimum level and where emergency orders are avoided. In the case of continues review there is no fixed review period, the order is made when the product reaches a min point.
- Recognizing different factors including need of expensive transportation for medical oxygen, consumption variation across facilities at different levels, transport cost associated with frequent purchase, and others it is recommended to fix minimum stock level.
- With all the consideration two-week minimum stock level (0.5months of stock) is set for which facilities has to undertake some mandatory activities for its implementation. To comply with this operation facilities are expected to do the following activities to comply with the set two-week min and 4 weeks max inventory control system.
- Accurate tracking of their consumption for at least four weeks to know the average medical oxygen weekly consumption.
- Quantify the actual medical oxygen cylinder required to hold the medical oxygen required for one month or AMC quantity.
- Count the total oxygen cylinder the facility owned.
- If the number of medical oxygen cylinders the facility owned is greater than or equal to the number the facility required to hold monthly inventory, it is possible to implement the above recommendation immediately. But if the number of medical oxygen cylinder is below the number required to hold monthly medical oxygen the facility is expected

to plan for additional cylinders acquisition for future to implement inventory holding policy and normalize medical oxygen supply system.

- It is possible for a facility to hold more than max stock level with the consideration of available number of empty cylinders, transportation capacity, and storage space availability.

The above steps are important to implement continues review period recommended that enables strict follow up of medical oxygen inventory control system and avoid stock out.

Physical Inventory

Stocktaking serves to identify any differences between stock records and physical inventory. Errors between inventory records and the available physical stock can lead to service interruptions, distort the replenishment cycle, and in extreme cases closure of the services.

Thus, the health facility should maintain stock and keep track of correct inventory information for medical oxygen, oxygen therapy devices, and other related devices.

Hence facilities should have the following regular system

- Conduct physical inventory of medical oxygen devices, accessories, and spare parts quarterly.
- Assign a unique number for each piece of medical oxygen device.
- Review the physical count of filled and empty medical oxygen cylinder continuously.
- Update medical oxygen devices inventory during every transactions (new acquisition, transfer to other site, end of life).
- Implement proper medical equipment management information system (MEMIS).

CHAPTER EIGHT

DECOMMISSIONING AND DISPOSAL

Decommissioning is the removals of medical devices from their originally intended uses in health care facilities to an alternative use or disposal. It involves the following steps:

- Decontaminating
- Disposition
    - Reuse (Donate, sold, refurbish, reprocess, trading or reassign internally)
    - Disposal

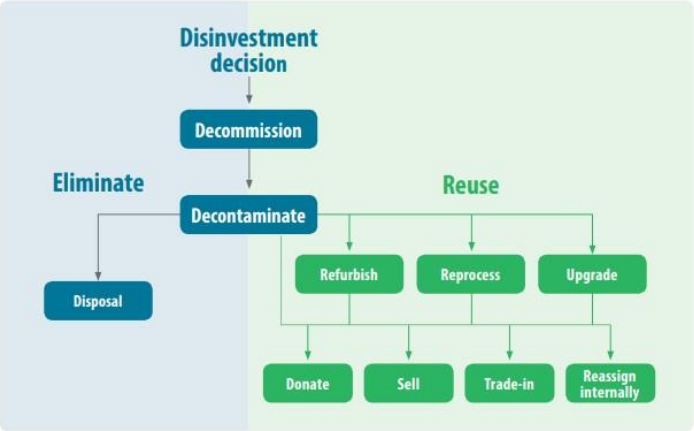

Figure 36: Medical device decommissioning

Disposal of medical devices includes intentional burial, deposit, discharge, dumping, placing or release of any waste material into or on air, land or water.

Consider the following procedures while decommissioning and disposal of oxygen cylinder, concentrator and LOX tank.

8.1. Oxygen cylinder

- Contact the oxygen cylinder supplier or the healthcare provider as they provide specific instructions and assistance in the proper disposal process.
- Use the bleed valve or regulator to release any residual oxygen in the cylinder. Do this in a well-ventilated outdoor area, away from open flames or ignition sources.
- Use an adjustable wrench or cylinder wrench to carefully unscrew and remove the valve from the cylinder. This step ensures that the cylinder cannot be used again and reduces the risk of accidental use or storage.

- Place the valve in a plastic bag and securely seal it. Label the bag as "Disused Oxygen Cylinder Valve" to indicate its contents clearly.
- Ensure that the oxygen cylinder is completely empty by pressing the purge valve or using a purpose-built cylinder depressurizing device. Once depressurized, mark the cylinder as "Empty" or "Not In Use" using a permanent marker.

8.2. Oxygen concentrator

- Refer to the manufacturer's instructions or contact suppliers directly to determine their recommended disposal and decommissioning procedures.
- Remove any accessories, tubing, masks, or other attachments from the oxygen concentrator
- Thoroughly clean and disinfect the oxygen concentrator according to the manufacturer's instructions. This ensures that any potential pathogens or contaminants are eliminated.
- If the oxygen concentrator is equipped with data storage capabilities, ensure that all sensitive and personal information is securely removed or wiped clean.
- Disable the oxygen concentrator by disconnecting or removing any internal components that may pose a risk if improperly handled or reused.
- If the oxygen concentrator is beyond repair or recycling, it should be disposed.

8.3. Liquid oxygen

- If there is a small amount of liquid oxygen left in the container, it should be vented in a controlled and safe manner. Release the pressure gradually and allow the liquid to evaporate naturally.
- If the tank has come into contact with other materials, it is important to decontaminate it before disposal. Use appropriate decontamination procedures recommended for liquid oxygen.
- If the thank is no longer usable or if it has reached its expiration date, it should be decommissioned. This may involve purging the container, rendering it safe for transportation and storage, and marking it as decommissioned.

Note

➢ Contact appropriate regulatory authorities to inquire about the proper method of disposal of medical oxygen therapy devices.

- Other medical oxygen device shall be decommissioned and disposed according to the national medical device decommissioning and disposal directive.

CHAPTER NINE

LOGISTICS MANAGEMENT INFORMATION SYSTEM

Logistics Management Information System (LMIS) is the system of records and reports that use to collect, organize, analyse and present logistics data gathered across all levels of the system for sound decision making. The Medical Oxygen Logistics Management Information System (MO-LMIS) is crucial for effective inventory management; used to monitor and track the transaction of oxygen to ensure an uninterrupted supply of oxygen and its devices in the health facilities. It helps to track the availability, distribution, and consumption of medical oxygen, as well as to identify and address gaps in the supply chain. Both manual and computer-based MO-LMIS can be implemented.

9.1. Medical oxygen recording and reporting consumption tools

A. Bin card

- Should contain the item name, unit of issue (m^3/L), received, Issued, loss/adjustment, balance.
- Should be maintained for filled and empty cylinders and other medical oxygen devices
- Medical oxygen should be recorded on the stock-keeping record (bin card) whenever it is issued and received.
- When the stock keeping record is full, a new record is should be started, using the ending balance from the previous record.
- Entries should also be recorded when stock is counted during a physical inventory.
- Should be used at central and mini stores

B. Oxygen use from oxygen source tracking tool

- Health facilities that are using oxygen source can use the weekly report for oxygen use and enter information about the plant production capacity (Annex-III).
- The weekly report includes the record of the amount of oxygen produced and cylinders filled, by day, during the reporting period.
- The reporting tool requires to log the number of cylinders filled (if oxygen plant is used to fill cylinders) and/or the average daily flow rate and hours of operation (if produced oxygen is piped into facility).
- Log data on any day oxygen is produced or cylinders are filled.

- The total amount of oxygen produced is the sum of oxygen produced to fill cylinders (multiply number of cylinders filled with size of cylinders) and oxygen piped into the facility (multiply number of hours of plant operation with average daily flow rate).
- Throughout the reporting period, use the weekly report form to enter the amount of liquid oxygen consumed or purchased during the reporting time period (Annex-iv).
- The weekly report for oxygen use from liquid oxygen records data whenever oxygen is purchased or consumed.

C. Internal Facility Report and Resupply Form for Medical Oxygen

- When Medical Oxygen is issued from the main store room to mini-store, the mini-store staff will provide essential logistics data on the Internal Facility Report and Resupply Form (IFRR).
- After completing the report section of the form, the mini-store staff will take the IFRR to the main store to obtain the needed medical oxygen.
- The main-store manager will use the information in the report section to determine re-supply quantities and issue the medical oxygen.
- In order to maintain the quality and safety of the medical oxygen, and to better manage the medical oxygen in a Health Centre or Hospital, most of the medical oxygen should be stored in the main store.
- Medical oxygen should be issued to the mini-stores in small quantities.
- The IFRR is used to record data on the products that are reported and resupplied while issuing medical oxygen to mini-stores within a Health Centre or Hospital.
- The IFRR should be kept in the respective mini-stores and completed when they schedule to come for re-supply.
- Products need to be reported in agreed upon defaults units (m^3 or L), which are pre-printed in the IFRRs.
- When issuing the medical oxygen both the person receiving the medical oxygen and the store manager sign the IFRR.
- After issuing the medical oxygen, the store manager updates the Bin Card.

9.2. Medical oxygen Consumption Tracking Tools

The requirement for oxygen and its availability at the health facility level can significantly differ from one day to another. Maintaining consistent records can assist in better forecasting the need for oxygen and identifying the most effective approach to meet it sustainably. Oxygen

consumed within a healthy facility is often supplied using a variety of sources, such as gas cylinders of various sizes, concentrators, or pressure swing adsorption plants. This can make consistent and centralized record keeping difficult. Different units of measurements and frequency of use across sources further complicates tracking of oxygen use. Users of the tool would initially evaluate the different sources of oxygen within the health facility, as well as the units of measurement employed to describe the volume or mass of oxygen acquired or consumed (see annex).

- Whenever the hospital uses a medical oxygen plant or oxygen concentrator to deliver oxygen directly to the patient, the oxygen used by each patient should be recorded.
- The medical oxygen use tracking record includes information such as the device used to deliver the medical oxygen, flow rate (lit/min), no. of patients, total consumption Lit/min, total consumption KL/day and total consumption in ton.
- Understanding patterns of oxygen consumption in a health facility is a critical step in planning effective short- and long-term strategies for oxygen infrastructure and procurement. It enables implementers to tailor the mix of oxygen-generation and oxygen-delivery sources to match the needs of the facility, while understanding and weighing unique cost and operational considerations for each option. Ultimately, better planning can lead to increased access to oxygen and improved quality of care.

MO-LMIS Data quality

Data quality is the process of maintaining the accuracy, completeness, and timeliness of logistics data. The availability of accurate and complete data is fundamental for establishments of effective medical oxygen SCM system. For that proper data management system should be implemented to ensure data quality which helps to support evidence based decision making.

- To monitor the quality of the MO-LMIS all staff responsible for maintaining logistics records should be appropriately trained and have adequate time to carry out this responsibility.
- Data should be reported regularly and supply chain managers should review the reports to verify the quality of the data. It should also be validated by comparing different reports to ensure that data are accurately and consistently entered, aggregated, and reported.
- If an electronic system is installed there should be a regular backup of data.

CHAPTER TEN

RATIONAL USE OF MEDICAL OXYGEN

Medical oxygen is considered to be used rationally when patients receive it according to their clinical needs, in doses appropriate to their individual needs, for an appropriate period, and at a low cost to them and their community. Medical oxygen therapy is not without risks and challenges, and it requires careful management and monitoring to ensure its optimal and safe use.

10.1. Prescription of Medical Oxygen

Medical oxygen is prescription medicine and it should be prescribed, administered and monitored according to the followings key considerations to ensure the rational uses.

- Prescribe medical oxygen by licensed clinicians who can assess the patient's condition and determine the appropriate oxygen delivery device, flow rate, and target saturation level.
- The prescription should include full details of types of device to deliver, flow rate(s) to administer, and patient specific oxygen saturation target.
- Use it only when indicated and discontinued based on targeted oxygen saturation.
- Clinician who initiates oxygen therapy should communicate clearly to the person who actually administers oxygen to the patient
- Record the prescribed medical oxygen and what exactly has been given to the patient.
    - In emergencies, however, treat the patient first and subsequently make written records of oxygen therapy. In all other situations, oxygen should be prescribed in accordance with the standards before administration is started.
- The prescription should have a section for 'oxygen' in the or in the electronic prescribing record in all health facilities as indicated below.

Table 5: Medical oxygen section for hospital prescription charts

Patient Name: _____			Indication*: _____				
Circle target oxygen saturation range			Date Administered				
88 – 92%	94 – 98%	Others					
Thick here if saturation not indicated □							
Starting delivery device: _____							
Flow rate _____							
PRN □ **Continuous** □							
Date and signature: _____							
Name of prescriber: _____							
***Saturation is indicated in almost all cases except for terminal palliative care.**							

10.2. Medical Oxygen Saturation Target Range

The medical oxygen saturation target range is the range of oxygen levels in the blood that is considered optimal. The normal range of SPO2 for health individuals is between 94% and 100%. However, the normal oxygen saturation range may vary depending on age, health status, and altitude.

Oxygen saturation target must be set for all patients on admission. Health facilities should also establish their own standards on the handling and use of compressed medical oxygen. This allows to know if the oxygen saturation is appropriate for each patient receiving oxygen.

Patient's oxygen requirement may vary over time so the prescribed oxygen concentration may be too high or too low even a short time after the prescription was written. A target oxygen saturation range of 94–98% will achieve normal or near-normal oxygen saturation for most patients who are not at risk of hypercapnic respiratory failure. Oxygen should be prescribed to a target saturation range rather than prescribing a fixed concentration of oxygen. This will allow the healthcare professional to adjust each patient's concentration of oxygen to achieve the safest oxygen saturation range for each patient.

The prescriber may indicate a starting concentration, device or flow rate, but there needs to be an agreed system for adjusting the oxygen concentration upwards or downwards according to a patient's needs. As a patient improves, he or she is likely to require a lower over a time period that will vary between patients. On the other hand, a deteriorating patient may need an increased concentration of oxygen. In most instances, failure to achieve the desired oxygen saturation is due to the severity of the patient's illness, but it is important to check that the oximeter is correctly placed and functioning normally as well as checking that the oxygen delivery device and the oxygen flow rate are correct. If the oxygen is being delivered from a cylinder, ensure that it is an oxygen cylinder and the cylinder is not empty or near empty.

10.3. Administration of Oxygen Therapy

Oxygen therapy can be administered through different routes, devices, and methods, depending on the patient's condition, oxygen requirement, and types of oxygen source availability. During the administration of oxygen therapy:

- Healthcare professional administering the oxygen therapy should be aware of the hazards of hypoxemia and hyperoxemia and the signs and symptoms of inadequate or excessive oxygen delivery.
- The delivery device and flow rate used for individual therapy should be documented alongside the SpO2 on the bedside observations chart or electronic observations system
- The nurse should sign the prescription chart or the electronic equivalent on every drug round with clinical pharmacist to confirm that the patient is either receiving appropriate oxygen therapy or else has SpO2 within the target range on air at the most recent observation round.

Some of the key activities of clinical pharmacists in the administration of oxygen therapy are:

- Providing recommendation on the selection of the appropriate oxygen delivery device, flow rate, and target saturation range
- Reviewing and verifying the oxygen prescriptions and orders, and ensuring that they are consistent with the current guidelines and evidence-based practices,
- Assessing and monitoring the patient's clinical condition, oxygen response, and oxygen consumption, using pulse oximetry and/or arterial blood gas analysis, and providing feedback and recommendations to the prescriber and the nursing staff on the titration and adjustment of oxygen therapy to achieve the target saturation range.

- Identifying and reporting any adverse events, complications, or errors related to oxygen therapy, such as oxygen toxicity, hypercapnia, hypoxia, oxygen misconnection, or oxygen wastage, and implementing corrective and preventive actions to avoid recurrence.
- Evaluating and documenting the effectiveness and outcomes of oxygen therapy, such as the improvement of symptoms, oxygen saturation, and quality of life, and conducting quality improvement and research activities to enhance the knowledge and practice of oxygen therapy.

10.4. Medical Oxygen therapy toxicity

Oxygen therapy can be beneficial for many people, but it also has some risks and complications. One of the possible complications of oxygen therapy is oxygen toxicity, which is a condition that occurs when a person breathes in too much oxygen for a prolonged period of time. Oxygen toxicity can damage the lungs, eyes, brain, and other organs.

The clinical settings in which medical oxygen toxicity occurs are predominantly divided into two groups; one in which the patient is exposed to very high concentrations of oxygen for a short duration, and the second where the patient is exposed to lower concentrations of oxygen but for a longer duration. Acute toxicity typically manifests with central nervous system (CNS) effects, while chronic toxicity has mainly pulmonary effects.

Patients at risk for pulmonary oxygen toxicity should be monitored for oxygen saturation and elevated work of breathing; need for evaluations of pulmonary function testing and chest x-ray. Similarly, eye exams assessing acuity and looking for lens opacification can be done to detect early ocular oxygen toxicity.

CNS toxicity manifests as tachycardia and diaphoresis. Severe cases of oxygen toxicity can lead to cell damage and death. Healthcare workers who either prescribe, administer or monitor for medical oxygen therapy should pay attention for patients at risk for oxygen toxicity include hyperbaric oxygen therapy patients, patients exposed to prolonged high levels of oxygen, premature infants, and underwater divers.

To prevent oxygen toxicity, it is important to follow the prescribed oxygen dose and duration, and to monitor the oxygen levels in the blood regularly. The following patient chart should be used to follow up medical oxygen therapy toxicity.

Table 6: Patient follow up chart for medical oxygen therapy toxicity

Patient name: ----------							Indication:----------				
Target saturation range: ----------; Delivery device: ----------; Flow rate: ----------											
Date & time	Headache	Hyperventilation	Cold shivering	Seizure	Burning on inhalation	Uncontrollable coughing	Hemoptysis	Hyperemia of the nasal mucosa	retinal edema (in premature babies)	diaphoresis	tachycardia

10.5. Monitoring oxygen therapy

Monitoring oxygen therapy is an important process to ensure the safety and effectiveness of oxygen treatment for patients who have breathing problems due to various conditions. Monitoring oxygen therapy involves measuring the oxygen levels in the blood and adjusting the oxygen dose and duration according to the patient's needs and goals. Some of the methods and devices used for monitoring oxygen therapy are:

10.5.1. Pulse oximeters

Pulse oximeters can provide a continuous and non-invasive monitoring of oxygen saturation (SpO2), which is the percentage of oxygen-bound haemoglobin in the blood. Pulse oximetry should be available to all healthcare staff managing patients receiving oxygen therapy. All measurements of oxygen saturation should be recorded in the observation chart along with the code for the oxygen delivery system that is being used.

10.5.2. Arterial or capillary blood gases

Arterial or capillary blood gases should be measured and the oxygen device and flow rate should be noted on arrival at hospital for most patients requiring emergency oxygen therapy. Blood gas measurements should be repeated in all critically ill patients and in many other cases according to the response to treatment.

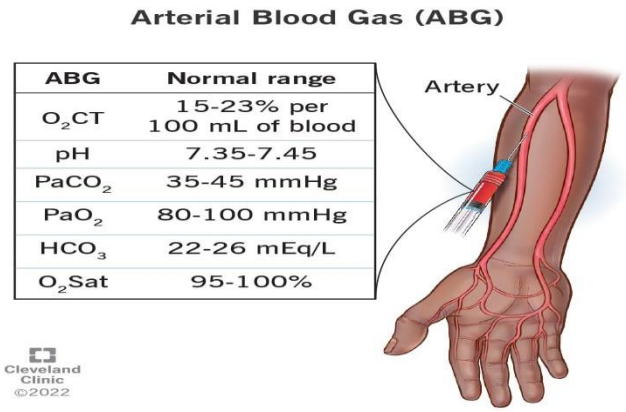

Figure 2. Arterial or capillary blood gases

10.5.3. Physiological monitoring/'track and trigger' systems

These are methods of assessing and responding to the clinical condition of patients by measuring and recording their vital signs, such as blood oxygen saturation, pulse rate, blood pressure, and respiratory rate. All acutely ill patients should have physiological monitoring assessment system in addition to pulse oximetry. Tachypnea is a sensitive indicator of deteriorating respiratory function.

10.6. Weaning and Discontinuation of Oxygen Therapy

Weaning and discontinuation of oxygen therapy is the process of reducing and stopping the use of supplemental oxygen in patients who have improved oxygen saturation levels. Oxygen therapy will be reduced gradually as the patient recovers and oxygen therapy can be discontinued once the patient can maintain satisfactory oxygen saturation, while breathing air.

Most stable convalescent patients will eventually be stepped down to 2 L/min via nasal cannula prior to cessation of oxygen therapy. Patients at risk of hypercapnic respiratory failure may be stepped down to 1 L/min via nasal canulla as the lowest oxygen concentration prior to cessation of oxygen therapy.

Oxygen therapy should be stopped once a patient is clinically stable on low-concentration oxygen and the oxygen saturation is within the desired range on two consecutive observations. Oxygen saturation on air should be monitored for 5 min after stopping oxygen therapy. If it remains in the desired range it should be rechecked at 1 hour. If the saturation falls below the patient's target range on stopping oxygen therapy, restart the lowest concentration that maintained the patient in the target range and monitor for 5 min. If this restores the saturation into the target range, continue oxygen therapy at this level and attempt discontinuation of oxygen therapy again at a later date provided the patient remains clinically stable. If a patient requires oxygen therapy to be restarted at a higher concentration than before to maintain the same target saturation range, the patient should have a clinical review to establish the cause for this deterioration.

10.7. Medical Oxygen and Related Device Handling

The handling of oxygen therapy equipment and related devices requires careful attention and adherence to the following guidelines and precautions.

- Place "Oxygen in Use" signs in visible areas to alert others of the potential fire hazard.
- Never place the oxygen source or delivery device near an open flame, and keep the oxygen source at least six feet away from any heat or ignition sources.
- Always turn off the oxygen source when not in use, and store it in a cool, dry, and well-ventilated place. Avoid exposing the oxygen source to direct sunlight, extreme temperatures, or moisture.
- Always check the oxygen level on the oxygen source before using it, and replace it when it is low or empty. Do not use oxygen sources that are damaged, leaking, or expired.
- Always follow the oxygen prescription and instructions from the health care provider, and use the appropriate oxygen delivery device and flow rate for the patient's condition. Do not adjust the oxygen flow rate or switch the oxygen delivery device without consulting the health care provider.
- Always keep the oxygen delivery device clean and dry, and change it regularly to prevent infection or blockage. Do not use oil, grease, or petroleum-based products on the oxygen delivery device, as they may cause fire or explosion.

- Always use caution and wear protective equipment when handling oxygen cylinders, as they are heavy and pressurized. Do not drop, drag, or roll the oxygen cylinders, and secure them with a cart, rack, or stand to prevent them from falling or tipping over. Do not use oxygen cylinders that are dented, rusted, or have missing or broken valves.
- Regular preventive and curative maintenance must be strengthened.

a. Use and Operation Safety

- Only properly trained personal should handle compressed cylinders, pipeline and manifold.
- Open the valve slowly and only with the proper regulator in place. Stand with the cylinder between yourself and the regulator (cylinder valve outlet facing away) when opening the cylinder valve, pipe line and manifold valves.
- Keep the cylinder clear of all-electrical circuits, flame, and sparks.

Never leave the valve open when equipment is not in use, even when empty; air and moisture may diffuse through an open valve, causing contamination and corrosion within the cylinder.

10.8. Patient safety

Like all other medications medical oxygen is not without risks. Some of the potential adverse drug events (ADEs) and pharmacovigilance issues related to medical oxygen that need to be monitored and addressed are the following.

- Oxygen toxicity: This is a condition where the exposure to high concentrations of oxygen for a prolonged period of time causes damage to the lungs, brain, eyes, and other organs. Symptoms of oxygen toxicity include cough, chest pain, and shortness of breath, headache, nausea, vomiting, seizures, and coma. Oxygen toxicity can be prevented by monitoring the oxygen saturation and adjusting the oxygen flow rate accordingly.
- Fire and explosion hazards: Oxygen is a highly flammable gas that can ignite easily in the presence of heat, sparks, or flames. Therefore, medical oxygen should be stored and handled with care, away from sources of ignition, combustible materials, and oil or grease. Patients and caregivers should also avoid smoking or using electrical devices near medical oxygen.
- Adverse drug interactions: can occur when oxygen is administered together with other drugs that have an effect on the respiratory system. For example, some drugs can increase the sensitivity of the respiratory center to carbon dioxide, which can lead to hypoventilation

and hypercapnia when oxygen is given. Other drugs can decrease the affinity of hemoglobin for oxygen, which can reduce the oxygen delivery to the tissues when oxygen is given. Therefore, the pharmacological profile and the potential interactions of any co-administered drugs should be considered when prescribing oxygen therapy.

- Medication errors: These are errors that occur in the prescribing, dispensing, administration, or monitoring of medical oxygen. Examples of medication errors include wrong dose, wrong route, wrong patient, wrong time, or wrong oxygen source. Medication errors can lead to under-oxygenation or over-oxygenation, which can have serious consequences for the patient's health and safety. Medication errors can be reduced by following the best practices of medicine management, such as using standardized protocols, labels, and devices, and checking the identity and prescription of the patient before administering medical oxygen.

By implementing appropriate pharmacovigilance systems and practices, the safety and effectiveness of medical oxygen can be ensured and optimized for the benefit of patients. Reporting ADEs and other complaints related to medical oxygen is important for identifying and mitigating the risks associated with this drug. ADEs and other complaints can be reported to the relevant national authorities.

CHAPTER ELEVEN

MONITORING AND EVALUATION

11.1. Introduction to Medical Oxygen SCM Monitoring and evaluation

The monitoring and evaluation (M&E) refers to all indicators, tools, and processes used to measure whether a program or project has been implemented according to the plan (monitoring) and meets the desired result (evaluation). It involves periodic and on-going data collection, compilation, analysis, and reporting. It is used to evaluate programs and results regularly to determine whether progress is being made towards the targets and defined objectives.

Regular monitoring and evaluation of the oxygen supply chain enhances efficiency and effectiveness by identifying challenges and informing areas for improvement. Effective implementation of oxygen supply chain monitoring and evaluation systems improves the accessibility of oxygen at health facilities. Therefore, it's essential to have an implementable M&E framework that helps to continuously improve medical oxygen supply management performance.

The main objective of the M&E framework is to provide stakeholders with the necessary information to effectively manage the supply of medical oxygen and essential oxygen devices and ensure informed decision-making at all levels. Hence, data recording, reporting, and progress tracking mechanisms have to be created.

11.2. Key performance Indicators (KPIs)

Indicators are variables that measure the change of a phenomenon. They are useful tools for managers to track the performance of medical oxygen and device supply chain management systems. A well-defined performance indicator is clearly linked to an important input, process, or outcome and helps managers identify problems timely. They are keys to communicating important performance gains and losses to stakeholders.

Key performance indicators are developed for the activities in the guideline; measurable indicators to assess progress and success, verification means, and targets for the indicators are defined. Routine systems should include indicators on the availability and functionality of oxygen technologies and supplies, as well as the consumption or actual use of oxygen therapy.

There are a total of five KPIs that will be regularly gathered, utilized and reported by health facilities. The lower administrative bodies will aggregate and report to the next level. Some of the indicators will be used by the lower level, and some will be reported to the next level. All indicators are described in the performance indicator reference sheet.

Health facilities, administrative bodies, and other stakeholders should support the implementation of the M&E system and utilize data for strengthening the medical oxygen SCM and ensuring a sustainable supply of oxygen.

11.2.1. Performance indicators reference sheet for medical oxygen and device SCM

1. Availability of effective medical oxygen supply management system

Definition	Percentage of effectiveness criteria fulfilled by the facility on the implementation of medical oxygen supply management system(SMS)
Formula	$\frac{\text{Sum of weight of met criteria for effective medical oxygen SMS}}{\text{Total weight of criteria of effective medical oxygen SMS}}\ x\ 100$
Interpretation	This indicator measures the effectiveness of medical oxygen supply management systems in health facilities. Since oxygen is a life-saving product, its supply management should be as effective as possible to ensure the availability of medical oxygen 24/7 within a health facility. A multidisciplinary group is responsible for the availability and safe use of oxygen. The HF should include this vital product in its facility-specific medicine list and quantify it regularly along with other commodities. Filled oxygen cylinders should be inspected during receiving, and a proper recording and reporting system should be established to ensure appropriate consumption. The HF is considered to have an effective medical oxygen supply management system if it meets at least 80% of the criteria. Refer to the criteria in Table 7 below.
Disaggregation	By health center, hospital
Aggregation	Percentage of health facilities with effective Medical Oxygen Supply System = $\frac{\text{Number of health facilities that have effective Medical Oxygen SMS}}{\text{Total number of } health\ facilities}$ x 100
Sources	Official assignment letter for focal person, facility-specific medicine list, quantification reports, policy or guideline or SOP, medical oxygen reporting and requesting forms, bin cards, monthly consumption reports, receiving documents at the store, and medical oxygen prescriptions or patient cards.
Method of data Collection	Data is collected by reviewing the different documents mentioned above using the checklist provided in the table below. MOH, RHB, and other administrative bodies can also collect through surveys and during supportive supervision.

Reporting Frequency	It should be reported semi-annually to the next higher level and annually to MOH

Table 7: Checklist for assessing the availability of effective medical oxygen supply management system

S.N	Criteria	Weight	Score
1	Medical oxygen and consumable oxygen devices are included in the FSML	5	
2	Medical oxygen and consumable oxygen devices are included in the facility pharmaceutical quantification	5	
3	Presence of focal person for medical oxygen supply management	10	
4	Presence of guideline/SOP for medical oxygen supply management	10	
5	Oxygen cylinders are checked during receiving to ensure proper filling (see signed receiving documents)	15	
6	Medical oxygen is stored in secured and separate area for empty and filled cylinders	10	
7	Presence of updated Bin card for medical oxygen stock management (for filled and empty cylinders) (check at oxygen storeroom)	15	
8	The facility uses internal facility reporting and requesting forms (IFRR) for oxygen supply (check 3 recent reports from maternal, inpatient, ICU and emergency)	15	
9	Presence of monthly consumption report (check 3 recent reports)	10	
10	Oxygen prescriptions contain flow rate and monitoring frequency	5	
	Total score		
	Availability of effective medical oxygen supply management system; If $\geq$ 80%, Yes; If < 80%, No.		

2. Percentage of patients who get their prescribed oxygen

Definition	The proportion of patients who have received prescribed oxygen in the health facilities
Formula	$\frac{\text{Number of patients who received oxygen prescribed}}{\text{Total number of patients who prescribed with oxygen in the health faci}}$
Interpretation	This indicator measures the ability of the HF to fulfill the oxygen demand as required. Medical oxygen is a lifesaving medicine that should be available 24/7. The health facility should ensure its continuous availability by establishing a proper supply system and monitoring needs and consumption trends. Oxygen should be available for every patient who needs it. If a single patient is denied oxygen therapy due to a supply problem, the health facility should identify the cause of the interruption of the supply immediately. This indicator will measure the proportion of

	patients who receive prescribed oxygen from each service delivery unit in the health facility, which is related to the availability of oxygen and the performance of the supply system.
Disaggregation	By health center, hospital
Aggregation	Percentage of health facilities with 100% of patients who received their prescribed oxygen = $\frac{\text{Number of health facilities with 100\% of patients who received prescribed medicine}}{\text{Total number of health facilities}}$ x 100
Sources	Prescription charts (for medical oxygen section) of medical chart
Method of data collection	Data is collected by reviewing patient charts using the reporting tool described in Table 8 below. MOH, RHB, and other administrative bodies can also collect through surveys and during supportive supervision.
Reporting Frequency	It should be reported monthly to the next higher level and annually to MOH

Table 8: Reporting tool for % of patients who received their prescribed oxygen within admitted HF

Name of HF - …… Month - ……..			Year - ……	
S.N	Name of service delivery units	Number of patients who prescribed with oxygen (a)	Number of patients who received oxygen within the HF (b)	Number of patients who didn't get Oxygen due to stock out/supply problem
	Total			
% of patients who have received prescribed oxygen in the health facilities $^{a}/_{b}\,x100$				

3. Presence of good medical oxygen cylinder storage practice

Definition	The availability of proper storage system that meets acceptable conditions (minimum requirement) for oxygen cylinders and consumable supplies
Formula	$\frac{\text{Sum of requirements or standards met by the health facility}}{\text{Total number of medical oxygen storage requirements (10)}} \; x \; 100$
Interpretation	This indicator measures the condition of oxygen cylinders stored against the minimum storage conditions required to protect the integrity and safety of the product. Evaluators can apply the indicator at oxygen cylinder stores to identify facilities that need improvement. The good storage guideline standards are a set of standards that a well-functioning cylinder store should maintain and have in place. There are a total of 10 criteria (refer to Table 9 below). Storage facilities are expected to meet at least 80% of the requirements.
Disaggregation	By health center, hospital
Aggregation	Percentage of health facilities that have good medical oxygen cylinder storage practice = $\frac{\text{Number of health facilities with 80\% and above score of storage practice}}{\text{Total number of health facilities}}$ x 100
Sources	Checklist for standard storage condition
Method of data collection	Data is collected by observation of the storage premises using the criteria checklist provided in Table 9. MOH, RHB, and other administrative bodies can also collect through surveys and during supportive supervision.
Reporting Frequency	It should be reported monthly to the next higher level and annually to MOH

Table 9: Good medical oxygen cylinder storage condition criteria

SN	Criteria		Weight	Score
1	Oxygen cylinder is stored:-	In a clean, cool, dry, well-ventilated areas away from flames, sparks, or any source of heat or light or ignition or corrosive chemicals.	15	
2		Securely to prevent the cylinder from falling or any physical damage.	10	
3		Away from areas that would block escape routes or fire exits.	5	
4	All cylinders are colour coded as per the national standard		15	
5	Statutory hazard notices are placed in areas where oxygen is stored.		10	
6	Cylinders are stored in upright and secured with a chain, strap, or cable to a stationary building support (i.e. Structural Beam) or to a cylinder cart to prevent cylinders from tipping or falling.		15	
7	Proper precautionary signs, such as “Storage of flammable, oxidizer, or toxic materials” mark are labelled in cylinder storage areas.		5	

8	Empty cylinders are segregated from full cylinders and stored separately.	10	
9	Caps used for valve protection are kept on the cylinders at all times, except when the cylinder is actually being used or charged.	10	
10	Empty cylinders labelled with "Empty" mark.	5	
	Total score		
	Availability of good medical oxygen cylinder storage practice; If ≥ 80%, Yes; If < 80%, No.		

4. Percentage of patients who have received oxygen therapy according to standard treatment protocol

Definition	The proportion of patients provided with oxygen therapy as per the standard of practice
Formula	$\frac{\text{Number of patients or charts who have received oxygen therapy as per the standard treatment protocol}}{\text{Total number of patients who received oxygen therapy (reviewed medical records)}} x$
Interpretation	This indicator measures the adherence to standard treatment protocols among clinical practitioners. It was used to measure the rational use of medical oxygen within health facilities, and the result helped to take actions to optimize its use. Besides, it is a quality indicator that is used to evaluate the quality of care by optimizing the therapy and preventing the risk of toxicity. The health facility should ensure rational prescribing and administration of medical oxygen. The indicator will be measured by randomly selecting at least 10 medical records of patients who received oxygen therapy.
Disaggregation	By health center, hospital By service delivery points
Aggregation	None
Sources	Patient medical record
Method of data collection	Data is collected by reviewing medical records of patients' who received oxygen therapy. MOH, RHB and other administrative body can also collect through survey and during supportive supervision.
Reporting Frequency	It should be reported annually to the next higher level and annually to MOH

5. Availability of safe medical oxygen delivery practice

Definition	The implementation of safe medical oxygen therapy and appropriate risk mitigation practice
Formula	$\frac{\text{Sum of weight of met criteria for safe medical oxygen delivery practice}}{\text{Total weight of criteria of safe medical oxygen delivery practice}} \times 100$
Interpretation	This indicator measures the presence of safe medical oxygen therapy and appropriate risk mitigation and incident reporting practice. It is an indicator that used to measure the capacity of the health facility in providing oxygen therapy to patients safely with proper risk mitigation mechanism to prevent potential adverse events such as toxicity, medication errors, and fire hazards. The health facility should follow the proper implementation of risk mitigation strategies for avoiding oxygen related hazards and ensure good patient care by providing the necessary capacity building for the healthcare providers, and utilize audit and feedback to optimize the therapy. The HF is considered to have a safe medical oxygen delivery practice if it meets at least 80% of the criteria. Refer to the criteria in Table 10 below.
Disaggregation	By health center, hospital
Aggregation	None
Sources	Patient medical record
Method of data collection	Data is collected by reviewing medical records of patients' who received oxygen therapy. MOH, RHB and other administrative body can also collect through survey and during supportive supervision.
Reporting Frequency	It should be reported annually to the next higher level and annually to MOH

Table 10: Criteria for safe medical oxygen delivery practice

S.N	Criteria	Weight	Score
1	Presence of saturation level monitoring practice for all patients on medical oxygen as per the standard (check randomly records of 2 patients on medical oxygen therapy or patient charts)	20	
2	Presence of inspection practice for oxygen quality at source and delivery devices	20	
3	Presence of leak checking practice at service delivery points or store (ask ward nurses the practice)	20	
4	The health facility provides orientation on proper oxygen handling and prevention and management of hazards related with medical oxygen for staffs. (check orientation report or attendance)	15	

S.N	Criteria	Weight	Score
5	Implementation of scheduled preventive maintenance practice for medical oxygen devices (check documented report of maintenance practice or equipment history file)	15	
6	Presence of reported and documented adverse events (toxicity) and incidents (fire, explosion)	10	
	Total score		
Availability of safe medical oxygen delivery practice; If ≥ 80%, Yes; If < 80%, No.			

11.3. Medical oxygen audit

Auditing is the inspection or examination of a process or quality system to ensure compliance with requirements. It is an on-site verification activity. It evaluates an operation or method against predetermined instructions or standards to measure conformance to these standards and the effectiveness of the systems.

Medical oxygen is a lifesaving product, and its supply chain, along with devices and consumable supplies, is resource-intensive and complex. Continuous evaluation and auditing practices involving relevant stakeholders need to be instituted to ensure the sustainable supply of safe and quality-assured medical oxygen in health facilities.

Thus, periodic and continuous oxygen audits should be conducted, and supportive supervision should be provided for health facilities, oxygen device operators, and healthcare providers.

The audit can be conducted both internally by the health facility and externally by health service administrators and other stakeholders.

If medical oxygen audits are conducted regularly in health facilities along with continuous follow-up, it enables the sustainable availability and rational use of medical oxygen and devices, reducing wastage and leakages in health facilities and production sites.

Purpose of the audit

- To provide guidance and technical assistance to improve medical oxygen and device SCM systems
- To identify, recognize, and learn from good practices, which can then be shared with other health facilities
- To identify areas for improvement and require support from the RHB or other partners

Auditors from outside the health facility (external audit): The regional health bureau or Ministry of Health, including lower-level health administration offices, should have clearly defined objectives and timelines for conducting audits and providing supportive supervision to health facilities.

Auditors from the health facility (internal audit): The health facility management and senior experts should conduct an internal audit and provide ongoing supportive supervision within the health facility.

External auditor's team members: MOH/RHBs or respective lower health service administrators will establish an auditing team with relevant knowledge and experience related to medical oxygen and devices SCM, which includes, minimally, a biomedical engineer, pharmacy (supply chain manager), physician, senior nurse, and clinical pharmacist.

Internal auditor's team members: The auditors/supervisors team should include the pharmacy head, BME head, senior physician/nurse, clinical pharmacist, finance, and human resource personnel.

Process of medical oxygen audits and supportive supervision

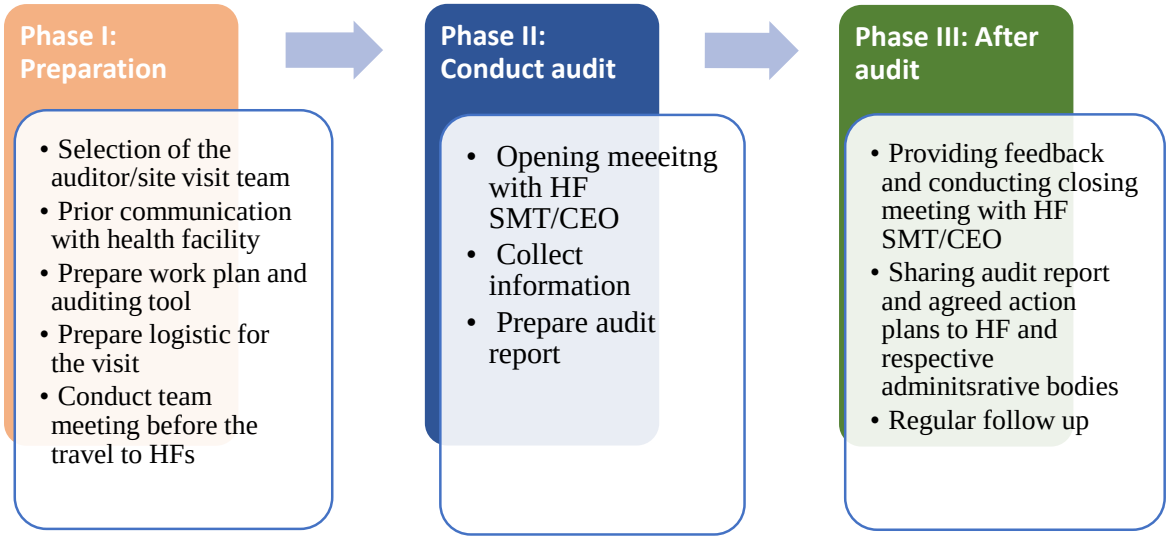

Figure 37: Process of medical oxygen audit and supportive supervision

Phase I: Preparation for audit or supportive supervision

- **Selection of the auditing/site visit team**

- RHB/MOH and respective administrative bodies will recruit the auditing team and assign a leader for the team who will coordinate the process of auditing and site visit. In case of internal audit the health facility will establish the supervisor team members which comprises of the relevant expertise.
- The responsible administrative body will make the necessary logistics for the activity
- The team will begin the task by communicating the HF's head and other relevant representatives about the specific date and objective of the visit prior to the visit.
- The team will then gather information on medical oxygen SCM performance of HF (from M&E reports or previous visit reports)
- Team will prepare detail work plan and audit tool and sends to team members
- Team will meet physically and discuss on how to conduct the audit and get orientation on tools and related issues
- Team will share the auditing tool to the visited HFs before the visit as necessary.

Phase II: Conduct audit

- **Conducting opening meeting with the health facility SMT/CEO**
    - After arriving at the HF, the auditing team will have an opening meeting with SMT/HF head and discuss the purpose of the visit.
    - The HF will assign at least one staff dedicated to accompany the team during the visit.
- **Conduct the audit**
    - The team will collect the information through observation, review of documents, and interviewing relevant expertise in different departments, and also patients or care givers.
    - The team collects information as per the audit tool and agrees findings at specific point.
    - The team should collect information on medical oxygen and device SCM, rational use, functionality of LOX tank, PSA plants, manifold, concentrators, and cylinders and other oxygen devices, safety and quality issues.
- **Prepare audit report**

- The team prepared an audit report based on the information collected. The report should be prepared immediately at the end of the visit.
- Preliminary report should be presented and shared to the HF by the team before leaving the facility. Final report along with agree action points will be shared within a few days after the end of the visit.

Phase III: After audit

- **Feedback**
  - At the end of the visit, the team will undertake closing/debriefing meeting with HF SMT/head and present findings with recommendations.
  - The audit report and agreed action plan should be sent to HF, respective administrative bodies and other relevant stakeholders for continuous follow-up.
  - HF and the responsible administrative bodies should perform regular follow-up after the audit to ensure that improvements are made.

Note: Supportive supervision at all levels should be conducted using the tool developed to assess the medical oxygen SCM guideline implementation and optimize the availability and use of medical oxygen in health facilities.

Performance review meeting

A review meeting is a platform used to identify best practices and areas for improvement. In addition to continuous follow-up and auditing, regular evaluation platforms like review meetings should be conducted at all levels.

The medical oxygen SCM performance should be evaluated regularly by the health facility using the M&E indicators and audit tool. A facility-based review meeting should be conducted to discuss findings from KPI/M&E reports and internal audits and take corrective action accordingly.

Performance review meeting sessions should be conducted at all levels as per below schedule.

- Facility level – quarterly
- Regional level – biannually
- National level – annually

The regional and national review meeting involves all stakeholders and helps to disseminate best practice and provide strategic directions.

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ANNEXES

Annex 1: Product list

S. N	Product Name	Product Type	Unit	Accessory Name	Spare Parts/Consumables	Remark
Low Flow Oxygen Delivery Device (Consumables)						
1	**Nasal Cannula/Prong - Oxygen**	A. Nasal Cannula/Prong - Oxygen, Adult	Each	NA		
		B. Nasal Cannula/Prong - Oxygen, Pediatric	Each	NA		
		C. Nasal Cannula/Prong - Oxygen, Neonate	Each	NA		
2	**Face Mask - Oxygen**	A. Face Mask - Oxygen, Adult	Each	NA		
		B. Face Mask - Oxygen, Pediatric	Each	NA		
		C. Face Mask - Oxygen, Infant	Each	NA		
3	**Nasal Catheter - Oxygen**	A. Nasal Catheter - Oxygen, Adult	Each	NA		
		B. Nasal Catheter - Oxygen, Pediatric	Each	NA		
		C. Nasal Catheter - Oxygen, Neonate	Each	NA		
High Flow Oxygen Delivery Device (Consumables)						
4	**Venturi Mask**	A. Venturi Mask - Adult (Large)	Each	NA		
		B. Venturi Mask - Pediatric (Medium)	Each	NA		
		C. Venturi Mask - Neonate (Small)	Each	NA		
5	**Non-rebreathing Mask**	A. Non-rebreathing Mask - Adult (Large)	Each	NA		
		B. Non-rebreathing Mask - Pediatric (Medium)	Each	NA		
		C. Non-rebreathing Mask - Infant (Small)	Each	NA		

S. N	Product Name	Product Type	Unit	Accessory Name	Spare Parts/Consumables	Remark
6	**CPAP Mask**	A. CPAP Mask - Adult (Large)	Each	NA		
		B. CPAP Mask - Pediatric (Medium)	Each	NA		
		C. CPAP Mask - Neonate (Small)	Each	NA		
Medical Oxygen Administration Devices (Consumables)						
7	**Endotracheal Tube Cuffed**	A. Endotracheal Tube Cuffed- 3CH	Each	NA		
		B. Endotracheal Tube Cuffed- 3.5CH	Each	NA		
		C. Endotracheal Tube Cuffed- 4.5CH	Each	NA		
		D. Endotracheal Tube Cuffed- 5.5CH	Each	NA		
		E. Endotracheal Tube Cuffed- 6CH	Each	NA		
		F. Endotracheal Tube Cuffed- 6.5CH	Each	NA		
		G. Endotracheal Tube Cuffed- 7CH	Each	NA		
		H. Endotracheal Tube Cuffed- 7.5CH	Each	NA		
8	**Tracheostomy Tube**	A. Tracheostomy Tube - with 90 degree curvature size 3.0	Each	NA		
		B. Tracheostomy Tube - with 90 degree curvature size 4.5	Each	NA		
		C. Tracheostomy Tube - with 90 degree curvature size 6.0	Each	NA		
		D. Tracheostomy Tube 6.5 mm with 90 curvature	Each	NA		

S. N	Product Name	Product Type	Unit	Accessory Name	Spare Parts/Consumables	Remark
		armoured with low Pressure Cuff Universal inflation funnel and pilot balloon plastic				
		E. Tracheostomy Tube 7.0 mm with 90 curvature armoured with low Pressure Cuff Universal inflation funnel and pilot balloon	Each	NA		
		F. Tracheostomy Tube 7.5 mm with 90 curvature armoured with low Pressure Cuff Universal inflation funnel and pilot balloon	Each	NA		
		G. Tracheostomy Tube 8 mm with 90 curvature armoured with low Pressure Cuff Universal inflation funnel and pilot balloon metallic	Each	NA		
Oxygen Source Devices						
9	**Oxygen Concentrator**	A. Oxygen Concentrator - 10 LPM	Each	1x Flow splitters		Flow splitter with four out put is recommended to use
			Each	2x Nasal cannula (in cm)	X	
			Each	1x External intake filter	X	

S. N	Product Name	Product Type	Unit	Accessory Name	Spare Parts/Consumables	Remark
			Each	1x Surge suppressors		
			Each	1x Voltage stabilizers		
			Each	1x Flow meter	X	
			Each	1x Humidifier bottle	X	Qty of humidifier bottle depends on the number of oxygen out put from concentrator
		B. Oxygen Concentrator - 5 LPM	Each	1x Flow splitter		Flow splitter with two out puts is recommended to use
			Each	2x Nasal cannula (in cm)	X	
				1x Externak intake filter	X	
			Each	1x Surge suppressors		
			Each	1x Voltage stabilizers		
			Each	1x Humidifier bottle	X	Qty of humidifier bottle dependes on the number of oxygen out

S. N	Product Name	Product Type	Unit	Accessory Name	Spare Parts/Consumables	Remark
						put from concentrator
			Each	1x Flow meter	X	
10	**PSA Plant**	A. Oxygen Plant - Extra Large (100 Nm3/hr)	Each			
		B. Oxygen Plant - Large (60 Nm3/hr)	Each			
		C. Oxygen Plant - Medium (30 Nm3/hr)	Each			
11	**Medical Liquid Oxygen**	A. Cryogenic LOX Plant	Each			
		B. Cryogenic LOX Tank	Each			
12	**Cylinder - Oxygen**	A. Cylinder - Oxygen, Size "E" (Gaseos pressure volume 680 L), Liquid volume (10 L)	Each	1x Humidifier bottle		
			Each	2x Nasal cannula (in cm)		
			Each	1x Regulator		
			Each	1x Flow meter		
		B. Cylinder - Oxygen, Size "G" (Gaseous pressure volume 3400 L), Liquid volume 30 L	Each	1x Humidifier bottle		
			Each	2x Nasal cannula (in cm)		
			Each	1x Regulator		
			Each	1x Flow meter		
		C. Cylinder - Oxygen, Size "J" (Gaseous pressure volume 6800 L), Liquid volume 50 L	Each	1x Humidifier bottle		The listed accessories are not applicable when oxygen
			Each	2x Nasal cannula (in cm)		

S. N	Product Name	Product Type	Unit	Accessory Name	Spare Parts/Consumables	Remark
			Each	1x Regulator		cylinder to be used with other medical devices like Anesthesia machine
			Each	1x Flow meter		
13	**HFNC Machine**	NA	Each			
14	**CPAP Machine**	NA	Each	1x PEEP Chamber	Breathing tube (in cm)	
15	**BiPAP Machine**	NA	Each			
16	**Ventilator - Mechanical, ICU**	NA	Each	Disposable adult breathing circuit	X	
			Each	Disposable pediatric breathing circuit	X	
			Each	Bacterial filter	X	
			Each	Battery	X	
			Each		Oxygen sensor	
17	**Resuscitator - Manual**	A. Resuscitator - Manual, Adult	Each	NA		
		B. Resuscitator - Manual, Pediatric	Each	NA		
		C. Resuscitator - Manual, Infant	Each	NA		
		D. Resuscitator - Manual, Neonate	Each	NA		
Oxygen Monitoring Devices						
18	**Pulse Oximeter**	A. Pulse Oximeter - Hand Held	Each	3x Adult SPO2 probes	X	
			Each	2x Paediatric SPO2 probes	X	
			Each	2x Neonatal	X	

S. N	Product Name	Product Type	Unit	Accessory Name	Spare Parts/Consumables	Remark
				SPO2 probes		
			Each	1x Battery	X	
		B. Pulse Oximeter - Finger Tip	Each	1x Battery	X	
19	**Monitor - Patient**	NA	Each	2x ECG cable	X	
			Each	1x ECG Electrodes	X	
			Each	SPO2 probe	X	
			Each	NIBP Cuff with cable	X	
			Each	IBP disposable kits	X	
			Each	Temperature probe dual	X	
			Each	Power backup (Battery)	X	
			Each	ETCO2		
Medical Oxygen Quality Regulation Devices						
20	**Oxygen Analyzer**		Each			If it is already available in the health facility, may not be needed to procure
Supplement of Medical Oxygen Delivery Devices						
21	**Oxygen cylinder filling station**	A. Refilling station for extra large plant	Each			
		B. Refilling station for large plant	Each			
		C. Refilling station for medium plant	Each			

Annex 2: Oxygen use from PSA oxygen-generation plants tracking tool

Facility name: _____

Reporting Time Period: Start date (YYYY/MM/DD)_____End date (YYYY/MM/DD)_____

Use to record the information about the plant production capacity (a) and tool to record the amount of oxygen produced and cylinder filled(b) during the reporting period.

Number of cylinders filled, and oxygen piped into the facility

S.no.	(YYYY/MM/DD)	Number of hours of a single plant* operation after meeting purity level *(A)*	Average daily flow rate *(in liter)* *(B)*	Total oxygen produced in liter by the plant A*B=C	Total volume of oxygen filled in cylinders(D) from the plant	Total volume of oxygen piped to the wards from the single plant (C-D)=E
1						
2						
3						
4						

*** Note: this template is for a plant and if the plant is duplex, fill for each of it**

Responsible person: ……

Annex 3: Bin card

BIN CARD

Name of Health Facility: _____

Product Name, Strength and Dosage Form: _____

Unit of Issue: _____ **Maximum Stock Level: _____**

Emergency Order Point: _____ **Average Monthly Consumption (AMC): _____**

Date	Doc. No. (Receiving or Issuing)	Received from or Issued to	Quantity					Remarks
			Received	Issued	Loss/Adj	Balance		

Annex 4: Internal Facility Report and Resupply Form for medical oxygen

Internal Facility Report and Resupply Form for Medical Oxygen

Name of user ward: _____ **Consumption Period From: _____To: _____**

Ser. No.	Item	Unit of issue (m3/L)	COMPLETED BY UNIT				COMPLETED BY STORE			
			Beginning Balance	Quantity Received	Loss/ Adjustment	Ending Balance	Calculated Consumption E = A+B+/- C-D	Maximum Quantity F =E * 2	Quantity Needed to Reach Max. G = F – C	Quantity to be Supplied
			A	B	C	D	E	F	G	H
1										
2										
3										
4										
5										
6										
Remarks :										
Completed by User wards (Name, Date, and Signature) :							Completed by (Name, Date and Signature) :			
Approved by (Name, Date, and Signature) :										

Annex 5: Medical Oxygen Consumption Recording tool

Name of Ward: _____

s.no.	(YYYY/MM/DD)	Patient name	Card no.	Indication	Starting delivery device	Flow rate(L/Min)	Total Minute patient on oxygen	Total Oxygen used by a patient (in Litre)	Recorded by(Name of care provider)
1.									
2.									
3.									
4.									
5.									
6.									
7.									
8.									
9.									
10.									
11.									
12.									
13.									
14.									
15.									
16.									

Name of ward coordinator: _____ **Signature: _____**

Annex 6: Medical Oxygen SCM Audit Tool

Section I: General information

Date of visit: ……..

Name of HF: ……..

Type of HF: Health center/ Primary hospital/ General hospital/ Specialized Hospital

Name of HF head: …… Mobile: ……..

Audit team members

	Name	Profession	Mobile	Email
1.				
2.				
3.				
4.				
5.				

Section II: Health facility basic infrastructure

S.N	Medical oxygen infrastructure	Response	Remark
1.	Total number of beds available		
2.	Total number of inpatient beds available		
3.	Number of oxygen beds available		
4.	Number of ICU beds available		
5.	Number of emergency beds available		
6.	Total number of ventilators available		
7.	Total number of functional ventilators available		

Section III: Oxygen concentrator

S.N	Questions	Response (Y/N/NA)	Remark
8.	Number of oxygen concentrators available • **5 LPM – …….** • **10 LPM – …….**		
9.	Number of functional oxygen concentrators available • **5 LPM – …….** • **10 LPM – …….**		
10.	Number of non-functional oxygen concentrators available • **5 LPM – …….** • **10 LPM – …….**		

11.	Are the concentrators placed 1-2 feet (0.3-0.6 meter) away from the wall?		
12.	Are the concentrators being plugged directly in the wall power socket?		
13.	Spare filter available for oxygen concentrators?		
14.	Power back up is available for oxygen concentrator?		
15.	Are they providing oxygen purity of greater than 82%? (if no, mention in remarks)		
16.	Does the facility staff clean the filter of oxygen concentrator?		
17.	Humidifier bottle available with oxygen concentrator?		
18.	Water in humidifier is changed or not?		
19.	Water is changed daily or not?		
20.	What is the frequency of cleaning the filter (in days)?		
21.	Does the HF have information, education, and communication (IEC) materials displayed related to oxygen concentrator?		
	Section IV: Oxygen Cylinder		
S.N	**Questions**	**Response (Y/N/NA)**	**Remark**
22.	Number of cylinders available in the HF • **30 L – ……** • **50 L – ……**		
23.	Number of filled cylinders • **30 L – ……** • **50 L – ……**		
24.	Number of empty cylinders • **30 L – ……** • **50 L – ……**		
25.	Does the HF check the pressure of cylinders when it is received from the supplier? (check filed receiving checklist at store)		
26.	Are oxygen cylinders stored in secured and separate area for empty and filled ones?		
27.	Is there routine cylinder maintenance practice? (check previous quarter filed mainetnace report)		

28.	Are all oxygen cylinders regularly inspected for corrosion, pitting, cuts, gouges, digs, bulges, neck defects, and general distortions? (check documented last quarter inspection report)		
29.	Are all oxygen cylinders regularly subjected to leak detection using a leak detecting liquid? (check documented last quarter inspection report)		
30.	Is the bottom of the cylinder protected from the ground to prevent rusting?		
31.	Are oxygen cylinders always moved within HF by suitable hand trolley? (check by observation and availability of trollies)		
32.	Are cylinder valve always closed except when the cylinder is in use?		
33.	Are cylinders stored in upright positions and immobilized by chains or other means to prevent them from falling?		
34.	Are full cylinders labeled and stored away from empty cylinders?		
35.	Are the markings for expiry visible on cylinders?		
36.	Are all oxygen cylinder valve covers/caps in place when cylinders are not in use?		
37.	Does the HF have IEC materials displayed related to oxygen cylinders?		
38.	Are cylinder handlers including porters and nurses trained on proper handling of cylinders? (check training report or ask staffs)		
	Section V: Medical Oxygen Pipeline System		
S.N	**Questions**	**Response (Y/N/NA)**	**Remark**
39.	Does the HF have a centralized medical oxygen pipeline system (MOPS) available?		
40.	Is an auto change over installed in the manifold room?		
41.	Manual changeover system available?		
42.	Colour coding of MOPS done as per ISO standards?		
43.	Does the HF have a MOPS operator available?		
44.	Leakage found at pipeline, valve and joints?		

45.	Any oil/grease found on pipeline?		
46.	Number of joints where oxygen is supplied through MOPS?		
47.	General oxygen beds		
48.	ICU beds (without ventilators)		
49.	Ventilator supported beds		
50.	Does the HF have IEC materials displayed related to MOPS?		
	Section VI: PSA Plant		
S.N	**Questions**	**Response (Y/N/NA)**	**Remark**
51.	Capacity of PSA plant (in m^3 per hr): ……..		
52.	Is the plant functional? (If not, mention the reasons on remarks)		
53.	Flow of the PSA plant (in m^3/h)		
54.	Pressure at PSA plant outlet (in bar)		
55.	Are they providing oxygen purity of 93%±3%? (if no, mention in remarks)		
56.	Average running hours per day (in hours)?		
57.	Is the plant operator trained in operations and maintenance of the PSA plant?		
58.	Is there recording system installed to capture routine PSA plant performance? (check performance registers, production recording…)		
59.	Is the PSA plant installed close to diesel generators or any other system which releases smoke or fire?		
60.	Is the preventive maintenance done for PSA plant? (check the company recommendation and performance report)		
61.	Is there any leakage from PSA plant?		
62.	Is the premise clean around the PSA plant?		
63.	Escalation matrix available at the site of PSA plant? (check documented procedure or matrix)		
64.	Mock drill conducted for the plant? (check last practice report or photo)		
65.	Does the HF have IEC materials displayed related to PSA plant?		
	Section VI: Liquid medical oxygen		

S.N	Questions		Response (Y/N/NA)	Remark
66.	LOX tank available in the HF?			
67.	Total capacity of LOX tank (in kiloliter)			
68.	Current stock available in tanks (in kiloliter)			
69.	Are there separate entrance for operators and LOX tankers			
70.	Are the keys of LOX premise easily available with fire/security/administration/operation staff?			
71.	Is there a mechanism to de-ice the vaporizer by using water showers?			
72.	Is the pipeline from LOX tank to vaporizer also getting de-iced?			
73.	Is there any leakage found from LOX tank at the time of visit?			
74.	Is the flooring in the LOX decanting perfectly horizontal so that the LOX is decanted in the tank?			
75.	What is the frequency of LOX tank refilling (in days)?			
76.	SOP available for LOX tank?			
77.	Dedicated staff available for operations and mainetnace of LOX tanks			
78.	Is escalation matrix available at the site of LOX tank?			
79.	Does the HF have any IEC displayed for LOX tank?			
	Section VII: Fire safety			
S.N	**Questions**		**Response (Y/N/NA)**	**Remark**
80.	Is fire safety equipment available at	Wards		
		ICU		
		Manifold room		
		PSA site		
		Cylinder store		
		Other places		
81.	Is the staff trained on fire safety measures (ask at least the following staffs)	Nurse		
		Pharmacy personnel		
		Biomedical professional		
		Porter		

82.	Is fire safety audit done regularly? If not done, ask for reasons (check the last date done)		
83.	Does the HF have any IEC displayed for fire safety?		
	Section VIII: Medical oxygen SCM system		
S.N	**Items**	**Response (Y/N/NA)**	**Remark**
84.	Does the HF included oxygen and its devices into FSML? (check the list)		
85.	Does the HF quantify medical oxygen and devices annually? (check the recent quantification document)		
86.	Does the HF implement IFRR for issuing and monitoring consumption?		
87.	Does the HF generate and follow the consumption of oxygen? (check the presence of monthly consumption report)		
88.	Does the HF maintains bin card for medical oxygen? (check at store)		
	Section IX: Availability of essential oxygen devices		
S.N	**Items**	**Response (Y/N/NA)**	**Remark**
89.	Tubing (ventilator, CPAP)		
90.	Flowmeter		
91.	Flow splitters		
92.	Humidifier		
93.	Nasal canula		
94.	Nasal prong		
95.	Nasal catheter		
96.	Oxygen masks		
97.	Nebulizer		
98.	Oxygen hoods		
99.	Ambu bags		
100.	Venture-mask		
101.	NIV mask		
102.	Breathing circuits (adult, pediatric, neonates)		
103.	Suction tubes		

104.	CPAP machine (adult, pediatric, and neonatal)		
105.	Pulse oximeter - fingertip		
106.	Pulse oximeter - tabletop		
107.	Pulse oximeter - pediatric		

Section X: Recording and reporting system

S.N	Questions	Response (Y/N/NA)	Remark
108.	Is updated information maintained on MEMIS? if not, mention in remarks. (randomly compare functional and non-functional medical oxygen devices from MEMIS against actual status)		
109.	Is the HF implement a proper oxygen and medical device consumption recording tracking system? (check for daily/weekly production and cylinder filled report (for PSA and LOX tank), daily consumption registration, weekly consumption reporting, IFRR, and bin cards at respective units)		
110.	Is the HF conducted internal medical oxygen audit quarterly? (check for last audit report and improvement plan)		

Section XI: Patient survey

Check random three patients admitted and are on oxygen therapy at time of the visit

S.N	Questions	Patient 1	Patient 2	Patient 3
111.	Source of oxygen (cylinder/MGPS/Oxygen concentrator)?			
112.	Is the oxygen ordered to patients using prescription with flow rate?			
113.	Purity (if applicable)			
114.	Flow recommended for patient (check from prescription or patient chart)			
115.	Flow at the time of visit			
116.	Is the oxygen saturation level measured?			
117.	Oxygen delivery device used for the patient? (Face mask/ Nasal prongs/ Nasal canula/ CPAP/ Ventilator)			
118.	Is there any leakage from oxygen delivery device?			

119.	Is the oxygen delivery device correctly fitted to patient			
120.	Is the patient aware about proning techniques?			
121.	Is clinical pharmacist provide oxygen therapy monitoring service for patients? (check records and ask for clinical pharmacists)			

S.N	**Name of audit team members**	**Signature**	**Date**

Annex 7: Medical Oxygen Feedback Format

Copy of the assessment data should be given to the health facility along with this feedback

Key findings

Areas that need improvement