USAID MEDICINES, TECHNOLOGIES, AND PHARMACEUTICAL SERVICES (MTaPS) PROGRAM

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Rwanda Biomedical Centre

Healthy People, Wealthy Nation

REPORT OF AN IN-COUNTRY IMPLEMENTATION WORKSHOP IN RWANDA:

Quality Assurance Practices for Medical Oxygen Systems

November 26, 2023

Photo Credit: Kate Kikule

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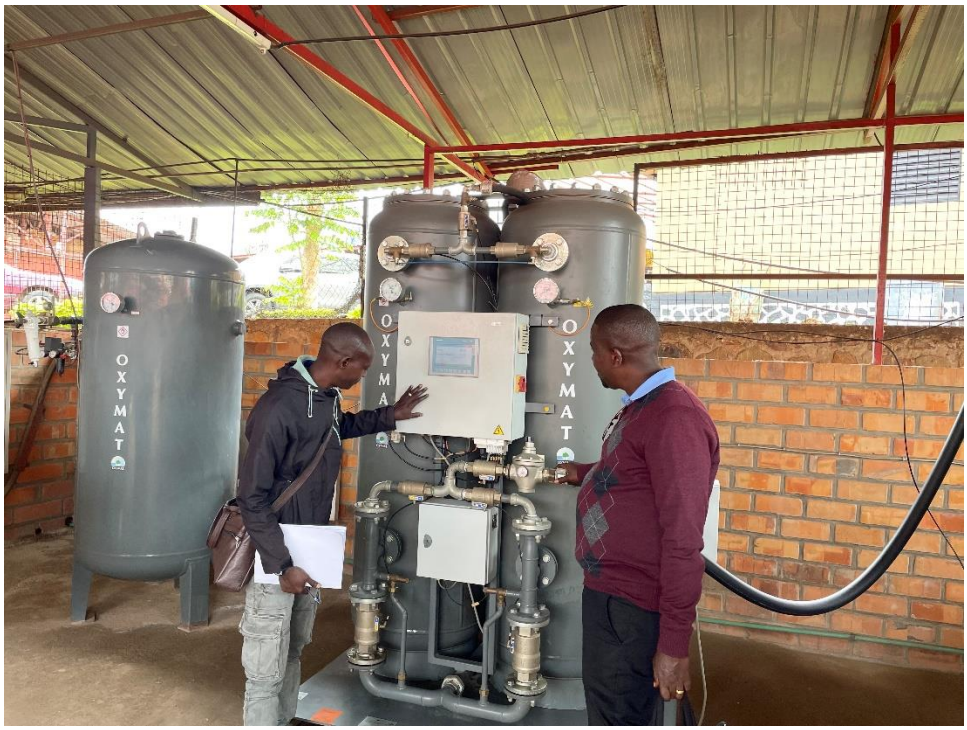
Date	November 21-23, 2023	
Time	9am-5pm daily	
Location	Main venue: Sainte Famille Hotel, Kigali, Rwanda Facility visits: University Teaching Hospital Kigali (CHUK), Kibagabaga District Hospital	
Facilitators	Rwanda Biomedical Centre (RBC): • Eng. Francine Umutesi • Eng. Jean-Baptiste Dusenge • Eng. Annick Ishimwe	MTaPS: • Antoine Gatera • Jean Mirimo • Kate Kikule • Martha Gartley
Coordination	• Noel Habimana (MTaPS) • Lauren Herzog (MTaPS) • Alisha Parikh (MTaPS)	
Participants	This workshop targeted: - Government bodies: Ministry of Health (MOH), RBC, Rwanda Food and Drugs Authority (RFDA) - Private sector supplying medical oxygen - Partners (e.g., Build Health International [BHI], CHAI, Jhpiego, MTaPS) - Hospital staff (biomedical technicians, anesthetists, pharmacists, clinical staff) - District Health Unit representation - Representatives from relevant national associations The workshop had over 40 participants from different sectors and roles (see Annex 1 for a detailed list)	
Funding	USAID/MTaPS	
Background	Medical Oxygen is an essential medicine, its importance underscored by the Covid-19 pandemic. In Rwanda, medical oxygen had been available at national and provincial Hospitals, but in 2020, RBC, responsible for the nation's oxygen systems, was quick to recognize that the gap in supply was substantial. As a result, RBC acquired 20 additional pressure swing adsorption (PSA) oxygen generator plants to cover almost all district hospitals and is now operating a total of 36 plants across 27 facilities, approximately a fourfold increase. Additionally, almost all facilities (90%) with a PSA plant(s) have been fully piped to ensure delivery of oxygen directly to the patient's bedside. The RBC team of biomedical engineers and technicians monitor and support this equipment at health facilities daily. RBC is seeking to enhance these practices with the aim of safe and sustainable operations and assurance of continued purity and overall quality outputs. To this effect, RBC, supported by the USAID/MTaPS Program, ran a three-day workshop to review its medical oxygen supply chain from a quality assurance (QA) perspective to ensure that these practices are inculcated into daily operations to meet its long-term goals.	
Main objectives	1. Objective: Orient stakeholders at different levels of Rwanda's medical oxygen supply chain on the importance of QA of medical oxygen and identify areas for improvement, leveraging international best practices.	

	2. Specific objectives: • Review the status of QA practices of medical oxygen in the country • Introduce stakeholders to MTaPS' QA of medical oxygen technical resource • Conduct site visits to two facilities to observe medical oxygen practices • Reflect on current practices and consider how they can be modified, considering key practices from the MTaPS resource and other international guidance, to improve medical oxygen QA practices in Rwanda
Meeting agenda	A detailed agenda of the three-day workshop can be found in Annex II.



Participants examining the oxygen generation plant at CHUK National Teaching Hospital in Kigali; Photo Credit: Kate Kikule

MEETING PROCESS AND OUTCOMES

This workshop was held to orient stakeholders at different levels of Rwanda's medical oxygen supply chain on the importance of QA of medical oxygen and identify areas for improvement, leveraging international best practices to develop a draft QA framework for medical oxygen in Rwanda.

To achieve this, the workshop was conducted in four phases—theory, data collection, analysis, and output development—as shown in figure 1 below. The slide deck that guided the meeting can be found in Annex III.

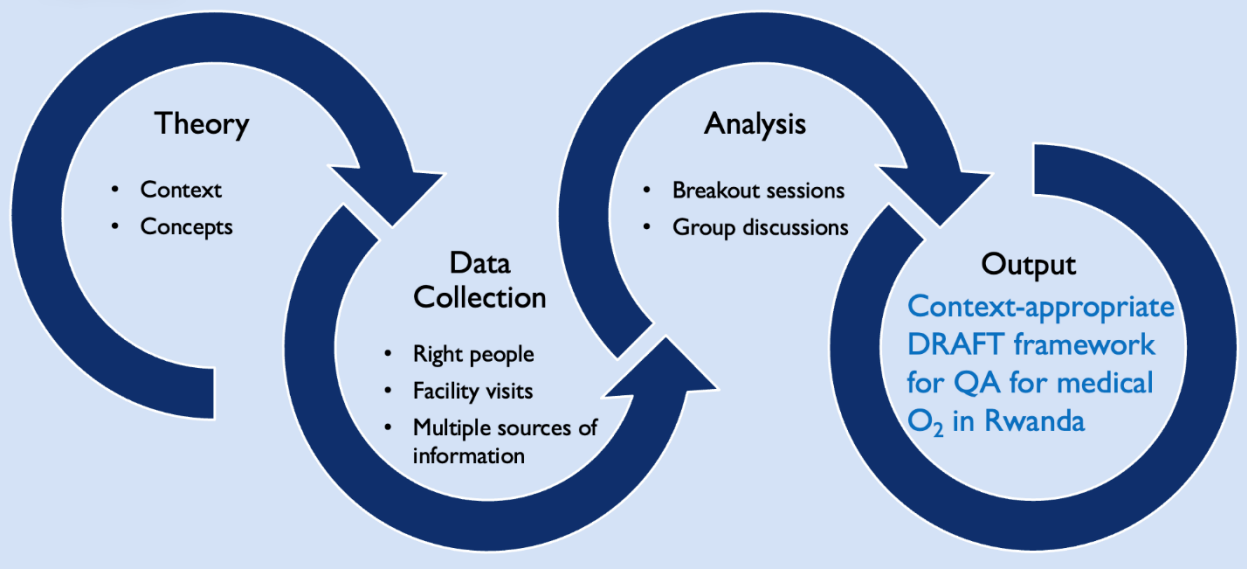


Figure 1. Workshop phases

PHASE 1: THEORY

OVERVIEW OF OXYGEN IN RWANDA
PRESENTED BY ENG. FRANCINE UMUTESI

RBC's Medical Technology Division is responsible for the nation's oxygen systems. Prior to Covid-19, there were 8 plants in Rwanda, not all of which were functional. In the early days of the pandemic, Rwanda was quick to act on its current gap with regard to supply, as well as to plan for surge demand, and acquired 26 additional PSA oxygen generator plants and received five more from partners, for a near fourfold increase in total available supply.

Currently, medical oxygen supply systems have been installed in national, provincial, and almost all district hospitals, with a total of 39 plants operating across 35 facilities. Almost all facilities with a plant have direct piping (90%, up from 47%), as well as a back-up manifold(s) to ensure a secondary supply. Some facilities (e.g., CHUK) have ward-level emergency reserve manifolds. Additionally, there are many facilities with cylinder-filling capabilities via a booster compressor and filling station.

MEDICAL OXYGEN SYSTEMS OPERATIONS
PRESENTED BY ENG. JEAN-BAPTISTE DUSENGE

Strategic management of medical oxygen systems is handled by RBC. With some exceptions, they are largely supported by an on-site biomedical technician, operated by a trained operator, and service and repairs are conducted under a service-level agreement with the plant suppliers.

Cylinder filling and transportation: Cylinders are typically moved throughout facilities with trolleys, but there are facilities whose trolleys are no longer functioning safely and so cylinders are rolled and moved however they can be managed. Moving cylinders to and from facilities takes place predominantly in an ad hoc manner. There are plans to structure an appropriate transport system, where lower-level facilities that fall within a catchment can benefit from a plant's excess capacity using a hub and spoke model, and where delivery vehicles are optimized (full out/full in).

There is a partner, Build Health International (BHI), that is actively engaged in Rwanda's oxygen systems. Non-functional plants have been assessed by BHI, most of which have been fixed (under BHI's global "Find and Fix" program). BHI has also started a training program and plans to build a regional training center in Rwanda for practical, hands-on training for in-facility medical oxygen systems operations, maintenance, and repair.

PRINCIPLES OF OXYGEN QA
PRESENTED BY KATE KIKULE

QA practices along the medical oxygen supply chain play a vital role in ensuring that the medicine remains effective for its purpose and is safe for both the patient and user, and that suppliers and end-users alike have confidence that quality requirements are being continuously met. Thus, QA practices within the oxygen supply ecosystem must be maintained to ensure that oxygen administered to the patient is of acceptable purity and consistent quality. Additionally, QA practices are essential for systems sustainability. The USAID MTaPS Program has developed a comprehensive technical resource to this effect: Quality Assurance Practices for Medical Oxygen Systems (see Figure 2).

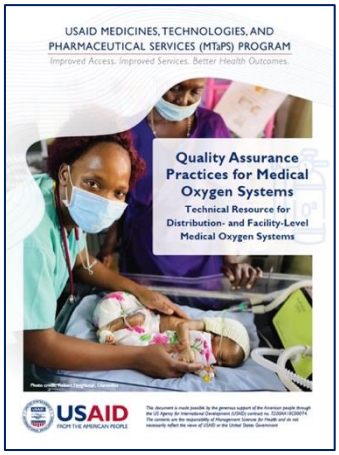


Figure 2: MTaPS Quality Assurance Practices for Medical Oxygen Systems - Technical Resource

QA practices at the health facility are shared by many cadres of the workforce; however, verification and acceptance of medicines, including oxygen, should be a responsibility assigned to a specific role which typically falls within the facility quality unit. In the case of medical oxygen, the facility biomedical personnel play an integral role establishing and managing QA practices.

In addition to medical oxygen meeting purity and quality standards (e.g., purity must be between 90-96% for patient application), based on existing international standards (e.g., International Pharmacopoeia, US Pharmacopeia) and determined by Rwanda Regulatory Authorities (RFDA, Rwanda Standards Board [RSB], Rwanda Utilities Regulatory Authority [RURA]), the principles of Good Manufacturing Practice (GMP) should be applied along any facility's oxygen production. These include personnel; premises and equipment; source-specific requirements; transportation and storage; documentation and

recordkeeping; quality control; complaints and recall; and self-auditing. These are all described briefly below.[1]

i) Personnel

Personnel are required along the medical oxygen supply chain. Though QA practices are largely focused on personnel within health facilities, outside personnel, either individuals or agencies in the broader enabling environment, can also help strengthen the QA of medical oxygen systems. It is important to identify all personnel who play a role.

ii) Premises and equipment

Facilities with oxygen services should be outfitted with purpose-built equipment and infrastructure that will enable specified operations and support QA activities, complete with features to facilitate safe operations. The premise must be well ventilated, be accessible only by authorized personnel, and remain clean at all times. Additionally, any equipment that comes in contact with the medical oxygen stream must be rated for oxygen use[2].

iii) Source-specific requirements (PSA)

Medical oxygen in Rwanda is generated using PSA technology. PSA oxygen generator plants can produce oxygen that is up to 96% pure. When used for medical applications, the minimum acceptable purity is 90%—this product is referred to as Oxygen 93 in many pharmacopoeia monographs.[3] Clear standard operating procedures (SOPs) and work instructions for operations should exist (tailored for each facility if applicable) to minimize risks to the quality of the product and to any personnel working along the oxygen supply chain. QA practices should be clearly indicated on the SOPs where appropriate and applicable.

iv) Transportation and storage

Good distribution practices (GDP) are a necessity when transport is part of the medical product supply chain; this includes medical oxygen. GDP follow the same principles of GMP: personnel; premises and equipment; operations (instead of production and transport in GMP); documentation; complaints and recall; and self-inspection/auditing. Clear SOPs and work instructions, tailored to facility and context, should be developed to minimize risk to the quality of the product and to any personnel working along the oxygen supply chain. These should cover:

- Transport and transfer of oxygen
- Storage of oxygen, including:
  - Fit-for-purpose and labelled containers/vessels
  - Designated storage area with enough area for segregation and safe movement

[1] Note that while intrinsically linked, comprehensive safety assurance practices were not covered in this workshop. It should be noted, however, that many quality assurance practices serve as mitigating measures for potential safety risks.
[2] European Industrial Gases Association, EIGA 2015 (currently withdrawn) DOC 99/15/Part 1: Good manufacturing practice guide Part I for medical gases
[3] European Industrial Gases Association, EIGA 2018 DOC 152/18: Comparison of European, US & Japanese pharmacopoeia monographs for medicinal gases https://www.eiga.eu/uploads/documents/DOC152.pdf

v) Documentation and recordkeeping

Documentation and record-keeping practices are critical aspects of quality management systems and should be established and maintained as they will support QA across the medical oxygen supply chain. The following documents should be developed, and recordkeeping should be undertaken to support medical oxygen QA systems (adapted from EIGA DOC 99/15[2] & EU[4,5]

- The **quality management plan** and **risk management plan:** Foundational documents for each facility, covering production, storage, distribution, and delivery of medical oxygen.
- Documented **SOPs** and work-instructions: These are established, documented procedures for responsibilities along the supply chain, covering necessary activities to be carried out to ensure that quality product reaches the patient. SOPs must reflect each facility's unique oxygen ecosystem and should cover:
    - Daily operations of PSA plants and cylinder filling stations (where applicable)
    - Medical gas pipeline system (MGPS) checks
    - Planned preventive maintenance procedures (as per manufacturer instruction)
- Activities requiring **recordkeeping**
    - **Operations:** PSA plant production and cylinder filling (where applicable) – recording results from a set testing frequency, the analysis results, and process-control parameters, as well as relevant operational details
    - **Checks:** Results from any system checks (e.g., MGPS)
    - **Stock management** (e.g., cylinders, spares, tools)
    - **Non-conformance:** Deviations in process or product (or any otherwise abnormal event), as well as details regarding the ensuing investigation and outcome, are also to be recorded. This will facilitate traceability if a recall is necessitated by an adverse event.
    - **Training:** Training of all cadres on oxygen quality-related matters, including refresher courses and any comprehensive assessments

All **documents should be permanent in nature**. Any changes to process or procedure should go through a formal (and documented) process justifying those changes. All records should be kept electronically; where doing so is not possible, they should be kept in ink in a pre-defined format. All documents and records are to be kept for a minimum of five years. [5]

vi) Quality control

Quality control is complementary to QA, comprising the testing of production processes as well as batch testing of product to indicate whether a medical product meets pharmacopeial specification or in-house standards at a specific point in time. [1] This point-in-time data informs quality systems functionality; a positive outcome supports QA.

vii) Complaints and recall

A channel for complaints shall be in place through which any person (e.g., personnel on the oxygen supply chain, caregivers, or patients) experiencing an issue with medical oxygen can request that it be

[4] European Commission 2011 & later EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en

[5] European Commission 2010 EudraLex - Volume 4 - Good Manufacturing Practice, Medicinal Products for Human and Veterinary Use, Annex 6 - Manufacture of Medicinal Gases https://health.ec.europa.eu/system/files/2016-11/2009_07_annex6_0.pdf

examined for any abnormalities in quality, which in turn could potentially trigger a recall. A process for recall should be established for the management of complaints, covering their reception, steps for investigation to determine cause, resolution via necessary corrective measures (inclusive of recall), and all necessary reporting (both internally and to the original complainant). [3, 1]

viii) Self-auditing

Self-audits serve as an opportunity for growth and improvement and help to ensure QA. These serve to ensure that the whole manufacturing process is being carried out under the applied quality framework (such as GMP) and that appropriate quality control is taking place. Audits are to be conducted with a frequency established in the facility quality management plan. Self-audits are to be planned and should be carried out by appropriately trained personnel.

DATA COLLECTIONFACILITATED BY ENG. JEAN-BAPTISTE DUSENGE, MARTHA GARTLEY, AND KATE KIKULE

Participants from the workshop, Kate Kikule, and Jean Baptiste during the field visit to CHUK medical oxygen generation facility; Photo credit: Jean Mirimo

Workshop participants were encouraged to assess and gather QA- related information on Rwanda's medical oxygen systems. It was planned that this could be achieved from a few angles:

- Discussions between workshop participants, representing all cadres and sectors involved in medical oxygen systems
- Via health facility visits

Two facilities were visited—CHUK and Kibagabaga District Hospital—to enable a compare/contrast regarding their medical oxygen systems. For these visits, the workshop participants were divided into four groups. As not all participants had a technical or health facility-based background, the groups were given a focus topic and a worksheet to support information gathering. The groups were given the following topics (worksheets can be found in Annex IV):

- Group 1: Hospital layout and flow
- Group 2: Resources for operations (personnel, infrastructure, and equipment)
- Group 3: Complementary supply chain structures
- Group 4: QA responsibilities for applicable roles (from the MTaPS QA resource "checklists" in the annex)

After the visits, the groups convened to discuss and collate their findings, and one member of each group presented observations to the workshop.

HOSPITAL LAYOUT AND FLOW

For Kibagabaga, the visit was centered around the plant room. At CHUK, the visit was centered around the biomedical department, where the plants are housed, as well as in two patient wards (private and ICU). The following were observed:

	Kibagabaga District Hospital	CHUK
Plants	One plant – new – 16 Nm3/hr	Two plants, old
Housing	• Dedicated, well ventilated • Small as compared to other similar facilities	• Dedicated housing within biomedical department • Plants are separated
Piping	Facility-wide, direct from plant	Facility-wide
Cylinder filling	No. Facility wants, but plant meets facility demand (has no surplus capacity)	Yes (one plant used for filling)
Secondary system	Yes, backup manifold by ER	• Yes, centralized manifold (secondary) • Ward-level emergency reserve manifolds (tertiary)
Cylinders	Acquired from an external supplier	• Used within the facility • Not stored in an orderly manner, not segregated • Three different paint/color codes

RESOURCES FOR OPERATIONS (PERSONNEL, INFRASTRUCTURE, AND EQUIPMENT)

To note - many of the observations on infrastructure and equipment were captured by group 1

Role	**Responsibilities related to medical oxygen**
Facility manager/ administrator	Overall management for plant, not a formal management structure for operations.
Pharmacist	No involvement in Kibagabaga District Hospital.
Logistics/store manager	Availability/involvement if cylinders are bought from an outside supplier/source.
Biomedical Engineer	Maintenance and work with administrator. Note that biomedical engineers in Rwanda are few. They are typically not based at a health facility; they hold centralized positions and support facilities on as-needed basis.
Biomedical technician	Operator
Quality controller	Separate from operator
Head of oxygen production	There is only one facility in Rwanda with this type of plant management structure: Ruhengeri (one of the first plants in country, now multiple operational plants)
Plant operator	Trained operator, different from biomedical technician.
Transporter (intra-facility)	From the delivery truck to the manifold (Kibagabaga) From plant to manifold (CHUK)
Transporter (trucking)	N/A

Additional relevant observations:

- Training: Good, but need more for safety and need to add refresher training for healthcare providers on basic technical aspects of oxygen systems.
- Quality Improvement teams: Informed by biomedical technicians
- Biomedical engineers and technicians: Responsible for medical oxygen (systems and quality)
- If there is a problem in wards, healthcare providers call biomedical technicians directly.

COMPLEMENTARY SUPPLY CHAIN STRUCTURES

Supply chain system/reach	Describe mechanics and logistics
Central pharmacy	No involvement in medical oxygen supply or systems
Ward-level	Any oxygen and associated ancillary equipment is ordered from the biomedical center
Biomedical engineering department	• At Kibagabaga, they are responsible for keeping a supply • Warranty for plants covers repair and maintenance • No spare parts store, just service provider as needed
Cylinder delivery (WITHIN facility)	• Sourced from outside • CHUK produced to keep a supply
Cylinder delivery (TO/FROM FACILITY)	Pull: cylinders are always delivered/supplied based from an order.
Other (specify):	It should be noted that it is ill advised in Rwanda for cylinders to be used directly by bedside for safety issues.

QA RESPONSIBILITIES FOR APPLICABLE ROLES

Worksheets for group 4 comprised all applicable 'checklists' from the annex of the MTaPS Quality Assurance Practices for Medical Oxygen Systems technical resource. To summarize the observations of the group, almost every one of the practices was considered as a 'gap'; however, many of them are happening informally. Further, a broad comment from most technical participants was the lack of formal in-facility management structure relating to medical oxygen systems (even in terms of responsibility). A structure as such could also help to further accelerate closing the gaps.

ANALYSIS
FACILITATED BY ENG. JEAN-BAPTISTE DUSENGE AND MARTHA GARTLEY

The workshop participants were encouraged to reflect on current practices, including observations from the facility visits, and consider how they could be modified or enhanced to improve medical oxygen QA practices in Rwanda. More specifically, groups were merged and tasked with the following focuses for analysis:

- Groups 1 and 2: QA practices along the medical oxygen supply chain ("what?" and "how?")
- Groups 3 and 4: Human resources – (Re)defining roles and responsibilities ("who?" and "how?")

The following were presented by respective groups to facilitate their analysis of all information gathered throughout the workshop.

ix) QA along medical oxygen supply chain

What	How	Quality Achievements	Quality Gaps
PRODUCTION PSA technology	• Atmospheric air: filtered, dried, compressed • Concentration in oxygen generator to desired purity • Piped or boosted	• Most have a PSA plant and cylinder manifold back-up (secondary supply) • CHUK and some others have tertiary (emergency) • Housing	• Documentation • No written SOP • Sorting of cylinders (empty/full – use signage and physical segregation) • Tagging full cylinders • Ambient oxygen sensor in plant room (safety) • Batch establishment and recordkeeping (help facilitate recall if ever adverse event) • Purity will fluctuate: Health Care Providers have requested to be notified immediately what they are working with.
DISTRIBUTION	• MGPS to bedside (direct from PSA or cylinders on manifold) (Cylinders not recommended for bedside use – safety hazard)	90% of facilities with MGPS	• Insufficient/inappropriate trolleys (repair/invest) • SOPs for safe cylinder movement • Terminal Units: more than one type of connection system (currently working toward harmonization).

What	How	Quality Achievements	Quality Gaps
STORAGE	Safely stored in dedicated room, vertical, chained	• *Some* facilities have a dedicated room • *Some* have adequate aeration/ventilation	• Need for adequately ventilated, dedicated storage facilities for oxygen plants and cylinders in **all** facilities where used. • Need for reinforcing segregated inventory (empty/full/noncompliant) • Color coding (e.g., CHUK uses three color codes!), avoid contamination by harmonizing e.g., ISO 32. • Tagging (batch tracking, testing tracking) • Sealing of full cylinders • Environmental monitoring tools (temperature and O_2) • Cylinder sorting and storage SOPs • Cylinder chain for stability during storage • Small cylinders with integral valves for patient transport, ambulance, and critical care units • Cleaning and hydrostatic testing for all cylinders (high-pressure gas cylinders)
TRANSPORT High-pressure vessels, dangerous transport	• Cylinder trucks • Cylinder trolleys	Most have trolleys There is a truck. For both, not enough.	• Regular trucks being used alongside normal cargo. 4-4x4 trucks in pipeline. • Some hospitals still use hand transportation. • Driver certification program for handling dangerous goods.
WORKSHOP AND SPARE PARTS	Maintenance and repair activities	• Some have their own space • Need for continuous capacity building	• Some specific dedicated tools unavailable (dynamometric wrench to ensure consistent/"right" tightness/torque applied). • Insufficient supply of spare parts, new contracts spec'ing minimum spares in-country to minimize down-time. • Working on systems to log maintenance and repairs.

x) (Re)defining roles and responsibilities

Levels	Staff positions	Standard roles	Our context		
			Observation	Gaps/challenges	Opportunities
External to health facility (MOH, national, etc.)	Regulations and capacity development, M&E		• Resource mobilization • Coverage • Certification (RFDA, RURA, RSB) • M&E • Capacity	• Coverage • Certification: 1. Premise license prior to commissioning, register for manufacturing authorization, including inspection (public and private) 2. GMP for premise 3. Adherence to pharmacopoeia standard • Guidelines (transport, structure)	• Political will • Intersectoral collaboration, MOH to convene standards bodies (not just government, but sector so including private, NGO, etc.)
Councils and associations	• Consultants • Implementation • Regulations		Solicit for input/ information	N/A	We count on their willingness
NGOs	• Technical & financial support • System strengthening		• Technical and financial support • Capacity development • System strengthening	None	• Well-coordinated • Still available (we never know what the future holds)
Private suppliers and distributors		• Production • Transport • QA • Maintenance	• Production capacity still low • Transport standards unknown • QA of product unknown • Quality: color codes inconsistent	Still gap in production capacity and evidence of quality (less an issue of supply as government has invested in their own systems)	As/if demand increases, they should increase supply accordingly to meet demand

Levels	Staff positions	Standard roles	Our context		
			Observation	Gaps/challenges	Opportunities
Transporters	• Transportation • QA records		*Same as suppliers	• No dedicated transporters • No dedicated vehicles • GDP in addition to GMP for producers who carry supply • Safety for ALL transporters	Dedicated role/person who is responsible during transport and segregation.
Internal administrators	Awareness • Infrastructure • Capacity • Resources/ continuity of services • Maintenance • Insurance • Consulted		• Administrators are oriented and consulted • Small infrastructures • Oxygen-related resources are not managed in a way to support sustainability, inclusive of QA • Maintenance supported by RBC	• Infrastructure, equipment (cylinders, manifolds, toolbox) • Focus on sustainability of systems including QA • Machine insurance (Hospital insurance to cover plants and associated equipment)	Existing framework contracts for maintenance, new opportunity for private companies (tenders)
Technical	PSA leadership • Production • Transport • Maintenance	• Biomedical. Engineers • Mechanical Engineers • Electrician • Drivers • Transporters • Medical and nurses	• Staff not meeting standard management structure with associated roles & responsibilities • Shortage of staff • Cylinder transport still an issue • Biomed still need more training, especially on maintenance and repairs (including refreshers)	• No separate leadership in plant management (should operate as formalized team structure) • Technicians are overloaded. • Hospital to maintain quality control in line with RFDA standard	• Continuous capacity building by MOH/RBC and partners • Framework contracts, e.g., existing framework contracts for maintenance • Evaluate each facility/plant to ensure adequate staffing structure.

GAP ANALYSIS

The following gaps were identified across all themes:

- Training (including refreshers):
  - Technical/use
  - Safety
- Documentation and recordkeeping
  - Documentation in the form of guidelines, SOPs, work instructions (though some are in progress, and many informally in practice)
  - Recordkeeping (where present, it is inconsistent—a need for harmonization and digitization)
- Lack of signage and labelling
  - Operations, e.g., cylinder segregation
  - Safety, e.g., no smoking, oxygen as an oxidizer, authorized persons only

Some more specific gaps identified and discussed were:

- Transport/distribution - Storage and segregation - Harmonization for some equipment/compatibility	- Training/mentorship - Human resources in quantity - Capacity building of technical team needed

OUTPUT

PLANNING FOR SUCCESS

It has been identified and acknowledged that QA responsibilities are cross-cutting, and QA practices are intrinsically linked with both safety and sustainability of medical oxygen systems. The following shall be considered to ensure success of any QA:

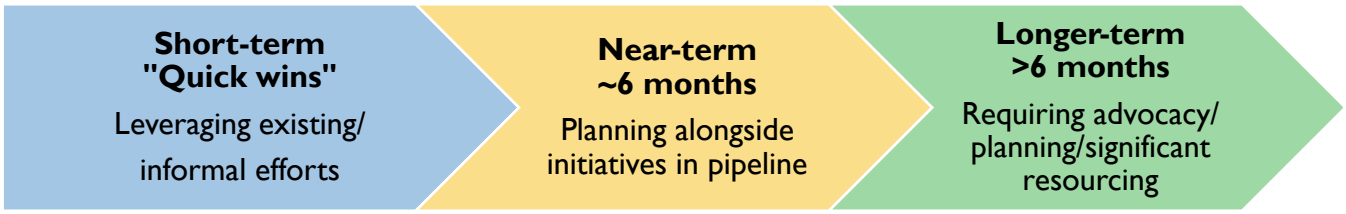
- **Leadership engagement and support** will be necessary for successful medical oxygen systems operations.
- **Partners support:** Willing and able partners to contribute expertise and to help ensure that technical and surge support (if/where needed) can be possible.
- **Resourcing** will enable QA practices along the medical oxygen supply chain. Oxygen must be planned out as a business model. Continued financial sustainability (inclusive of resourcing for human resources, infrastructure, equipment, spares, and consumables) must be guaranteed.
- **Teamwork** is necessary as QA cuts across all cadres of the medical workforce. Collaboration will be essential to ensure that QA practices are comprehensive and effective.

SETTING REALISTIC GOALS

QA practices are ongoing. Embarking on tackling these practices can easily be staged to start with some of the more accessible tasks that will require only nominal additional resourcing from present ("quick wins"). Beyond the immediacy, more advocacy, planning, and resourcing may be required to enable practice implementation.

While not exhaustive, the following oxygen QA framework was developed within which activities were identified from this workshop.

This approach can be used to inform existing efforts. It can also be integrated into broader systems planning and policy documents, such as the forthcoming medical oxygen "roadmap" for sustained operations.



Documentation (all 'permanent' unchanging information)

- SOPs: formalize existing practice into documented SOPs
  - cylinder management
  - labelling
  - operations
  - validation

Recordkeeping
Templates exist, practices are taking place, but there lacks consistency.

- Checklist via WhatsApp (consider a digital database, e.g., Google Sheets)
- Alert/notification: hours of operation, time to next service.

Advocacy
Keep leadership on board—this will ensure longer-term success!

Regulations and standards
Collaborate with RFDA, RSB, RURA finalize national oxygen-related regulations and standards

Audits
Planning for and conducting internally as best practice. Will fall in line with RFDA plans to conduct audits/inspections.

Trainings
Continue to work with technical partners on training curriculum, plan for expanding to maintenance and repair for biomed techs.

Resourcing

- Four vehicles for cylinder distribution. Safety and quality practices to be applied at outset to ensure GDP
- Small cylinders with integral valve to ensure safe, quality-assured delivery of medical oxygen during patient transport

Monitoring and evaluation
Contribute QA to framework

- Understand system baseline
- Establish key performance indicators

Operational
Painting cylinders to one standard

Increasing workforce

- Transition of biomedical diploma program to degree will increase biomedical engineering workforce in Rwanda.
- Recalibration leadership and management of in-facility medical oxygen systems.

Infrastructure related

- Improving storage and segregation (dedicated rooms, barriers/cages, safety chains, etc.)
- Harmonization of connections (terminal units)

Trainings/mentorship
Develop more robust programs. Consider leveraging training and teaching institutions.

Meeting observations	Participants in the workshop, spanning sectors and cadres, actively participated in discussions throughout the workshop. Notable discussions that took place were in the Q&A period after group presentations from the following workshop sessions: - Data collection - Analysis Additionally, the apex activity concluding the workshop was a group effort to draft the technical framework for QA practices along the medical oxygen supply chain. This final session, facilitated by Eng. Jean Baptiste, took the format of a live (projected) document development—all participants could "see" their contributions coming together in a structured framework format.
Gathering momentum	RBC showcased the workshop as a success, including highlighting progress on the draft QA framework at the MOH-hosted oxygen technical working group meeting during the same week on 24 November 2023. Eng. Francine Umutesi (RBC, Division Manager Medical Technology) presented a summary of the workshop deliberations and highlighted the draft QA framework for medical oxygen systems in Rwanda. The meeting took note of the support provided by USAID MTaPS to RBC to conduct the workshop and generate the draft resource which could be incorporated in the Rwanda roadmap and strategy for medical oxygen systems.
Next steps	MTaPS Global: • Advocate for RBC at the global level where applicable/appropriate for QA initiatives regarding medical oxygen systems and investments for sustainability. MTaPS in-country: • Follow up with RBC on framework/plans for implementation/incorporation into the Rwanda Medical Oxygen Roadmap/Strategy • Continue to engage with RBC regarding work with RFDA/RSB (Rwanda Standards Board)/RURA (Rwanda Utilities Regulatory Authority) for the finalization of regulations and standards regarding medical oxygen and associated systems requirements. • Continue to participate in the technical working group for medical oxygen.

Annex 1. Participants

Hosting team, RBC:
Eng. Francine Umutesi
Eng. Jean-Baptiste Dusenge
Eng. Anicet Cyusa
Eng. Annick Ishimwe

Hosting team, MTaPS:
Antoine Gatera (MTaPS Rwanda Country Project Director)
Jean Mirimo (MTaPS)
Kate Kikule (MTaPS)
Martha Gartley (MTaPS Consultant)

Attendees:

No.	Name of Participant	Sex	Location	Organization	Designation
1	Alexis Murwawza	M	Kibungo	Kibungo	Biomed
2	Amizeru Willy	M	Kigali	Merc Centre Ltd	
3	Andrew Johnston	M	Kigali	BHI	Director of training
4	Crispin Kamawa	M	Kigali	Rame	BMET
5	Denis Akishuri	M	Kigali	USAID IRGMG	
6	Dr. Christian Mukwesi	M	Kigali	RMH	Anesthesiologist
7	Dr. Christine Mutaganwa	F	Kigali	BHI/Jhpiego	GHPM
8	Dr. Fabien Nwrunziza	M	Byumba	Byumba TH	Clinical Director
9	Dr. Hitayezu Donatien	M	CHUB	MOH	Anesthetist
10	Dr. Kibako Peter	M	Kigali	Kibagabaga	Anesthetist
11	Dr. Kwbamo Pierre	M	Kabagabaga	MOH	Clinical Director
12	Dr. Muhire Philbert	M	Musanze	Ruhengeri	DG
13	Dr. Niyonzina Charles	M	Kibungo	Kibungo Hospital	Director of Medical Services
14	Dusenge Jean Baptiste	M	Kigali	RBC	Director of O_2 unit
15	Emmanuel Nizyimana	M	Byumba	Byumba TH	Biomed tech
16	Eugene Rugwizangoga	M	Kigali	Jphiego	MD/Tech director
17	Francine Umutesi	F	Kigali	RBC	DM-MTD
18	Gatera Antoine	M	Kigali	MSH	
19	Hakizimana Steven	M	Karongi	Kibuye RH	Director of Nursing
20	Hakorimana Juliens	M	Kigali	Fitescom	
21	Hyacinthe Mushumbamniza	M	Kigali	CHAI	Manager
22	Ingabire Lea	F	Kigali	RAME	Biomed consultant
23	Ishimwe Annick	F	Kigali	RBC	Analyst MTD
24	Ivan Mwikarago	M	Kigali	RFDA	Anesthetist
25	JMU Nkurunziza	M	Kigali	RBC	Electromechanical Eng.
26	Jonas Twizeyimana	M	Kigali	CHAI	Sr. Technical Associate
27	Khgabo Jean Bosgo	M	Kigali	RBC	Electrician/Chem Eng.
28	Maniriho Gilbert	M	Kigali	KPHR	Maintenance tech
29	Martha Gartley	F	Toronto	MTaPS	P.Eng.
30	Mbarushimana Normand	M	Karongi	Kibuye RH	BMET
31	Mirimo Boaz	M	Musanze	Ruhengeri	BMET

No.	Name of Participant	Sex	Location	Organization	Designation
32	Mirimo Jean	M	Kigali	MSH	STH
33	Mugabo Moise	M	Kigali	CHUK	Maintenance officer
34	Muhiyimana Grace	F	Gasabo	Kibungo Hospital	Pharmacy
35	Muvunandinda Jean Robert	M	Musanze	Ruhengeri	Anesthetist
36	Noel Habimana	M	Kigali	MSH	Ops Specialist
37	Pacifique Kweera Rugero	M	Kigali	Connex	Engineer
38	Paul Bernard Kwiezere	M	Kigali	AWB	Director of AWB
39	Ronald Rudakubana	M	Kigali	RBC	BME
40	Ugirashbuja Adolphe	M	Kigali	Kalimbi	Operation Manager
41	Umutesi Sandrine	F	Kibungo	KLTH	Anesthetist
42	Valens Kubwimana	M	Kigali	RURA	Engineer

Annex II. Agenda

DAY 1: **Tuesday, November 21, 2023** Location: Sainte Famille Hotel and Kibagabaga District Hospital		
Time	**Agenda item**	**Facilitator**
9:00-9:45	Official opening Participant Introductions and icebreaker	Eng. Francine Umutesi (RBC) Jean Mirimo (MTaPS)
9:45-10:15	Overview of oxygen in Rwanda	Eng. Francine Umutesi
10:15-10:30	Overview of MTaPS technical resource on oxygen QA	Kate Kikule (MTaPS)
10:30-11:00	Coffee	
11:00-11:30	Deep dive into Rwanda medical oxygen systems and supply chain	Eng. Jean-Baptiste Dusenge (RBC)
11:30-11:45	**Activity:** Post-it query exercise	Martha Gartley
11:45-12:15	Setting intentions and workshop objectives	
12:15-13:15	Lunch	
13:15-13:30	Planning for strengthening QA practices in Rwanda	Annick Ishimwe (RBC)
13:30-14:00	Planning for facility visit	
Facility 1 visit – Kibagabaga District Hospital		
14:00-15:00	**Showcase: Facility oxygen system and supply chain**	Eng. Jean Baptiste Dusenge & Kibagabaga DH staff
15:00-16:30	**Facility walk-through**, O_2 systems space and flow, resources, supply chain, QA activities	
16:30-17:00	Day 1 closing remarks	Jean Mirimo

DAY 2: **Wednesday, November 22, 2023** Location: CHUK and Sainte Famille Hotel		
Time	**Agenda item**	**Facilitator**
Facility 2 visit – CHUK		
9:00-9:15	Recap of Day 1/Overview of Day 2	
9:15-10:00	**Showcase: Facility oxygen system and supply chain**	Eng. Jean Baptiste Dusenge & CHUK staff
10:00-11:00	**Facility walk-through**, O_2 systems space and flow, resources, supply chain, QA activities	
11:00-11:30	Travel back to main facility meeting room and coffee break	
11:30-13:00	Compilation of observations from both facility visits: ▫ Showcase findings ▫ Walk-through observations	Eng. Jean Baptiste Dusenge & Martha Gartley
13:00-14:00	Lunch	
14:00-16:30	**Breakout work session: Opportunities for QA activity implementation** **Groups 1 & 2**: Medical O_2 supply chain **Groups 3 & 4**: Roles and responsibilities	Eng. Jean Baptiste Dusenge & Martha Gartley

16:30-17:00	Day 2 closing remarks	Eng. Jean Baptiste Dusenge

Day 3:	**Thursday, November 23, 2023**	
Location:	Sainte Famille Hotel	
Time	**Agenda item**	**Facilitator**
9:00-9:15	Recap of Day 2/Overview of Day 3	
9:15-10:00	**Breakout presentations:** Rwanda's medical oxygen supply chain (**Groups 1 & 2**)	Eng. Jean Baptiste Dusenge & Martha Gartley
10:00-10:45	**Breakout presentations:** Roles and QA-related responsibilities for O_2 in Rwanda (**Groups 3 & 4**)	Eng. Jean Baptiste Dusenge & Martha Gartley
10:45-11:15	Coffee	
11:15-12:15	**Putting the pieces together:** Recap of QA principles, overview of QA findings	Annick Ishimwe
12:15-13:15	Lunch	
13:15-16:00	Building a contextually appropriate implementation plan for QA strengthening in Rwanda	Eng. Jean Baptiste Dusenge
16:00-16:45	Summary of a QA framework for O_2 in Rwanda (for national level and adaptable for facility level)	
16:45-17:00	Workshop close-out remarks	(all Facilitators participated)

Annex III. Presentation

The following slides were used during the meeting to give a project overview and help to steer the discussion.

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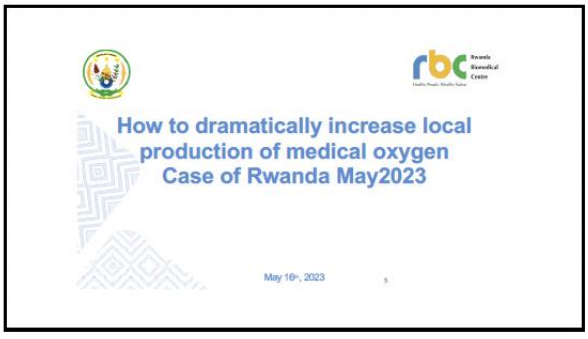

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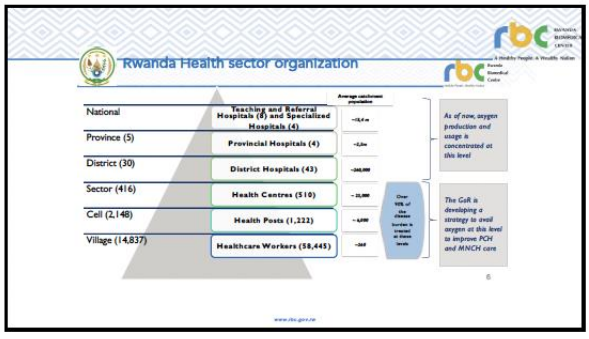

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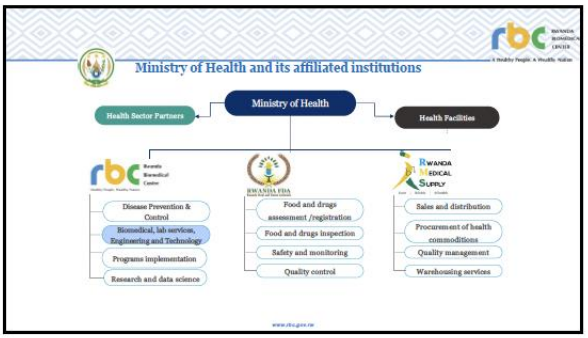
Ministry of Health and its affiliated institutions
Ministry of Health
Health Sector Partners
Health Facilities
Disease Prevention & Control
Biomedical, lab services, Engineering and Technology
Programs implementation
Research and data science
Food and drugs assessment /registration
Food and drugs inspection
Safety and monitoring
Quality control
Sales and distribution
Procurement of health commodities
Quality management
Warehousing services

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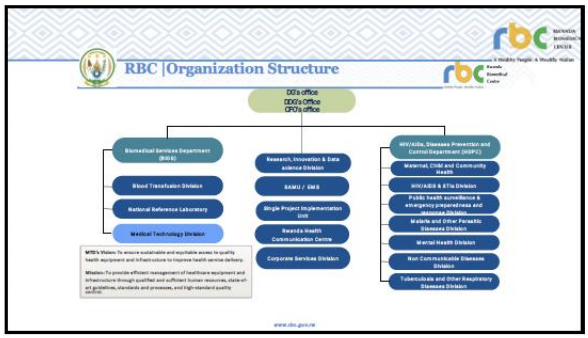
RBC |Organization Structure
DG's office
DDG's Office
CFO's office
Biomedical Services Department (BMD)
Blood Transfusion Division
National Reference Laboratory
Medical Technology Division
Research, Innovation & Data science Division
RAMU / EMS
Single Project Implementation Unit
Rwanda Health Communication Centre
Corporate Services Division
HIV/AIDs, Diseases Prevention and Control Department (HDPC)
Maternal, Child and Community Health
HIV/AIDS & STIs Division
Public health surveillance & emergency preparedness and response Division
Malaria and Other Parasitic Diseases Division
Mental Health Division
Non Communicable Diseases Division
Tuberculosis and Other Respiratory Diseases Division

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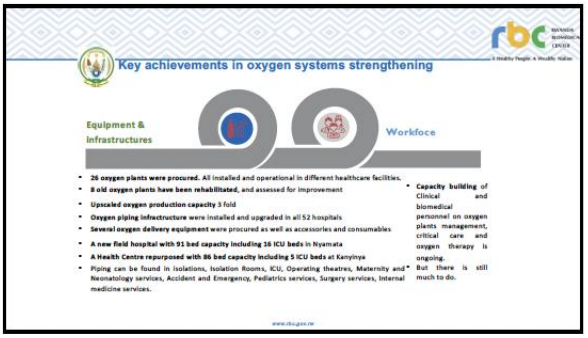
Key achievements in oxygen systems strengthening
Equipment & Infrastructures
Workforce
26 oxygen plants were procured. All installed and operational in different healthcare facilities.
8 old oxygen plants have been rehabilitated, and assessed for improvement
Upscaled oxygen production capacity 3 fold
Oxygen piping infrastructure were installed and upgraded in all 52 hospitals
Several oxygen delivery equipment were procured as well as accessories and consumables
A new field hospital with 91 bed capacity including 16 ICU beds in Nyamata
A Health Centre repurposed with 86 bed capacity including 5 ICU beds at Kanyinya
Piping can be found in Isolations, Isolation Rooms, ICU, Operating theatres, Maternity and Neonatology services, Accident and Emergency, Pediatrics services, Surgery services, Internal medicine services.
Capacity building of Clinical and biomedical personnel on oxygen plants management, critical care and oxygen therapy is ongoing.
But there is still much to do.

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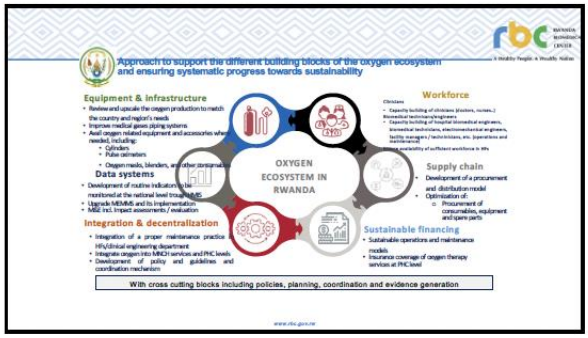
Approach to support the different building blocks of the oxygen ecosystem and ensuring systematic progress towards sustainability
Equipment & infrastructure
Workforce
Data systems
OXYGEN ECOSYSTEM IN RWANDA
Supply chain
Integration & decentralization
Sustainable financing
With cross cutting blocks including policies, planning, coordination and evidence generation

10


"Post-it" Activity
Instructions:
1) each person to post a minimum of 3 notes
2) be sure to include the # on each post-it
We will revisit all post-its at the end of day 2 and see if we have addressed them adequately.
1 Personnel
2 Premises & equipment
3 Source-specific requirements (PSAVSA or LOA)
4 Transportation & storage
5 Documentation & record keeping
6 Quality control
7 Complaints & recall
8 Self-auditing

11


Setting intentions, facility-specific workshop objectives
Objective:
Orient stakeholders at different levels of Rwanda's medical oxygen supply chain on the importance of quality assurance of medical oxygen and identify areas for improvement leveraging international best practices.
Specific Objectives:
Review the status of practices of medical oxygen in the country
Introduce stakeholders to MTaPS quality assurance of oxygen technical resource
Conduct site visits to facilities to observe medical oxygen practices
Reflect on current practices and consider how they can be modified, considering key practices from the MTaPS resource and other international guidance, to improve medical oxygen quality assurance practices in Rwanda.

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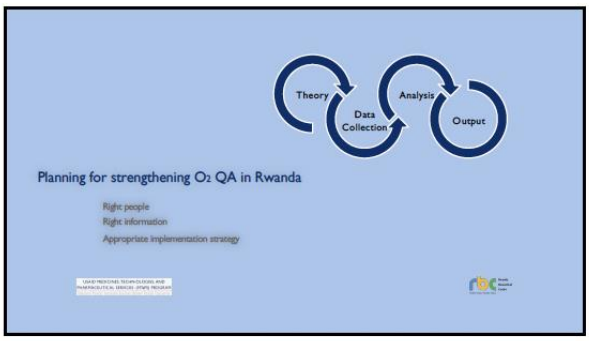

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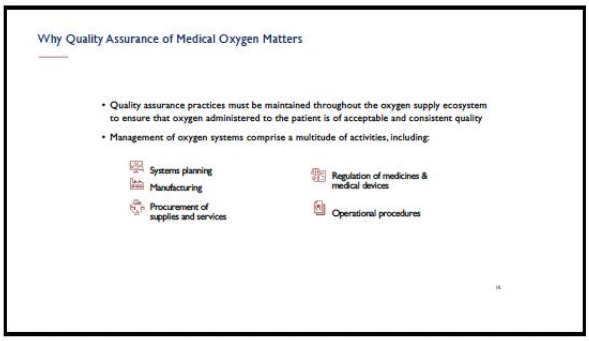

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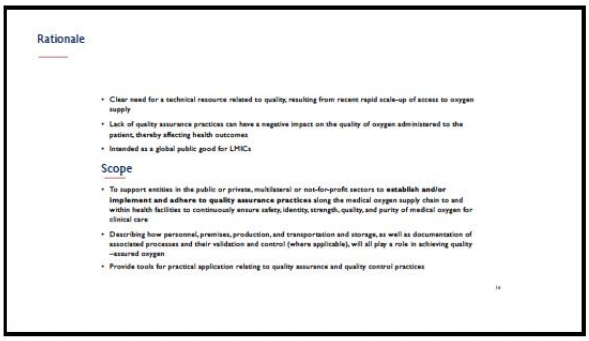

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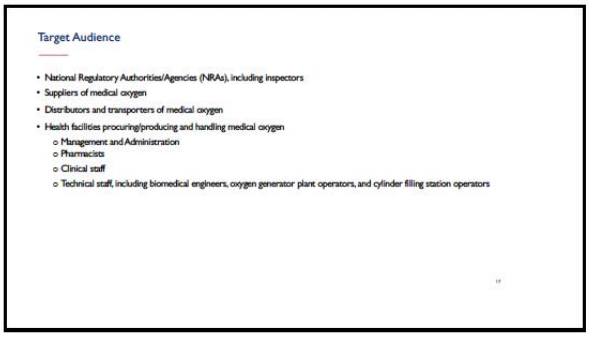

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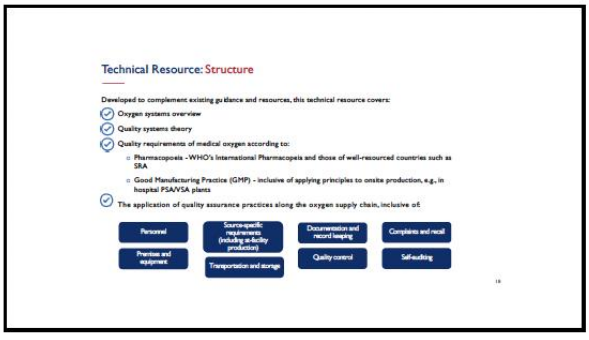

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Technical Resource: Content (1)

Quality assurance will require clearly defined parameters for practices and should be applied, maintained, and monitored across the following domains:

Personnel

Including, but not limited to, staff of health facilities, oxygen manufacturers, government, private sector, NGOs, oxygen suppliers, and distributors

Premises and equipment

Purpose-built infrastructure and equipment for medical oxygen complete with requisite safety features

Source-specific requirements

Medical oxygen shall be of acceptable quality in terms of identity and purity and shall be handled and stored appropriately

Transportation and storage

Good distribution practices should be applied, as oxygen is a medicine

19

Technical Resource: Content (2)

Quality assurance will require clearly defined parameters for practices and should be applied, maintained, and monitored across the following domains:

Documentation and record keeping

SOPs and work instructions to facilitate continuity in practice and process & record keeping to track these activities and their outcomes

Quality control

Testing the oxygen produced at a set frequency, to be done independently of the production team

Complaints and recall

Any issue or complaint that arises regarding medical oxygen shall be able to pass through clear, appropriate channels; can help to facilitate recall if/when necessary

Self-auditing

Internal reviews of a facility's medical oxygen supply chain to ensure continuity of the production and delivery of quality-assured products

20

Technical Resource: Tools for Practical Application (1)

The Annexure of the document contains applicable resources, including:

- **Role-specific QA supplements**
  - Checklists have been developed to accompany specific roles, and detail activity, action items, frequency of application, and required documentation
- Record keeping
  - Templates for recording oxygen quality when produced on site
  - Examples of certificate of analysis (CofA) for when liquid oxygen (LOX) is procured

21

Technical Resource: Tools for Practical Application (1a)

A2: Job-aid for head of production

Description: A necessary member of the team for ensuring quality medical oxygen systems, the head of production has oversight of all activities related to the production of medical oxygen when an on-site oxygen generator plant is used. Will liaise with the AP for quality control if/where needed.

Qualifications/requirements/experience: Engineer (civil, mechanical, biomedical, electrical) with project management skills and work experience in the health-care sector.

Tasks related to medical oxygen QA adapted from EKGA Doc 195/20 (25) and EKGA Doc 143/22 (30):

Activity	Details	Frequency	Documentation
Develop and finalize facility-specific SOPs for production	Working with production team, base operational SOPs on manufacturer's instructions and have SOPs finalized/approved by AP, Reg.aff. QA, Head Technician	Once, but revisit if/when needed	Documented, part of facility quality management plan
Ensure production in accord with SOPs	Review all records to ensure that production team is consistently following SOPs and recording necessary information	Quarterly	Review of records
Ensure continuity of supply	Ensure that secondary supply has been established for facility, that it remains adequate, and that it is activated appropriately	Once, but revisit if/when needed	Documented, part of facility quality management plan
Ensure thorough and timely PPM program	Review all records to ensure that PPM is conducted according to plans and necessary records are created	Quarterly	Review of records
Validate the on-site oxygen generator plant, alongside the AP	Equipment tested for functionality, safety, and performance, and to ensure that it operates in line with specifications	Typically, following installation and after any major repair or other work	To record, with AP, if indicated with PPM
Validate cylinder filling, analysis, and release process, alongside AP	Equipment tested for functionality, safety, and performance, and to ensure that it operates in line with specifications	Typically, following installation and after any major repair or other work	To record, with AP, if indicated with PPM

22

Technical Resource: Tools for Practical Application (1b)

A5: Job-aid for quality controllers

Description: Carries out quality control activities as they relate to medical oxygen within the health facility.

Qualifications/requirements/experience: Technical or clinical background with experience in the health-care sector. Important to distinguish QC role and that controller be experienced and adequately trained.

Tasks related to medical oxygen QA adapted from EKGA DOC 195/20 (25)

Activity	Details	Frequency	Documentation
Calibrate monitoring and measuring equipment	Ensure that all equipment used in monitoring and measuring is calibrated as per manufacturer requirements	At each calibration interval, as indicated by device manufacturer	Record all details in a standardized format
Test quality of product	Test the following: ☐ On-site oxygen generator plant output, as per batch definition in the facility quality management plan (record values from oxygen generator plant AND from secondary hand-held analyser) ☐ Cylinder filling, minimum one per batch, to be released by AP	Daily, for each batch as defined in the quality management plan	Standard QC record template; prepare CoA for QA if any are to be sent elsewhere; non-conformances reported and flagged in QSI
Test secondary systems	Ensure automatic switch-over to secondary supply, before applicable LL • Main power supply outage affects primary source • Pressure or purity drops from primary source	PPM, to be carried out as scheduled with plant operator	Record all details in a standardized format
Test monitoring and alarm systems	All alarms and controls shall be tested for operating limits (e.g., pressure, oxygen concentration, CO, CO_2, automatic shut-off, vent valves) • Test one function at a time • Observe that audio, visual, and—where applicable—operational control is activated	PPM, to be carried out as scheduled with plant operator	Record all details in a standardized format

23

Technical Resource: Tools for Practical Application (2)

The Annexure of the document contains applicable resources, including:

- Role-specific QA supplements
  - Checklists have been developed to accompany specific roles, and detail activity, action items, frequency of application, and required documentation
- **Record keeping**
  - Templates for recording oxygen quality when produced on site
  - Examples of certificate of analysis (CofA) for when liquid oxygen (LOX) is procured

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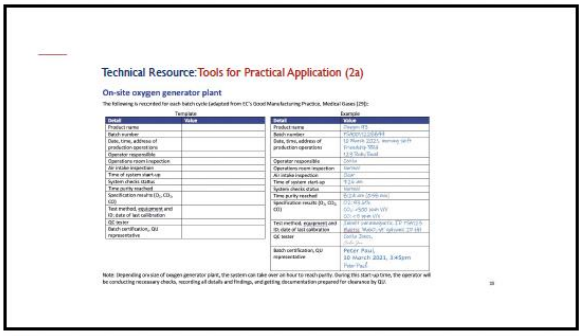

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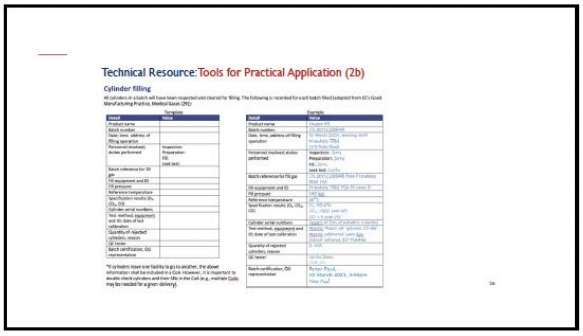

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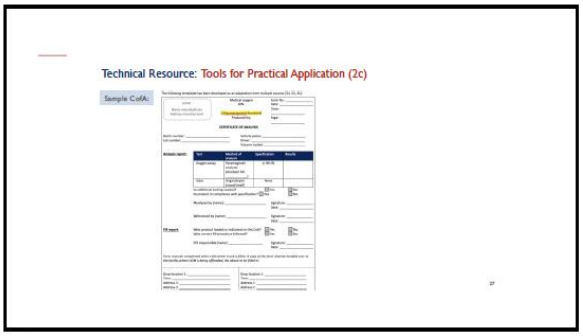

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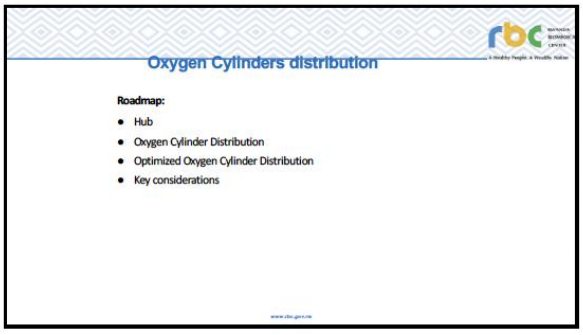

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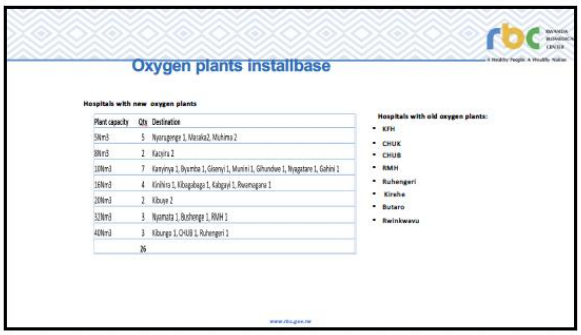

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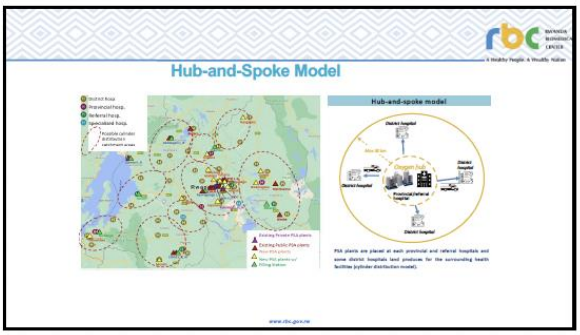

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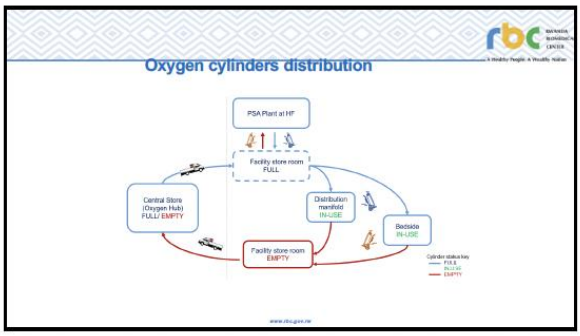

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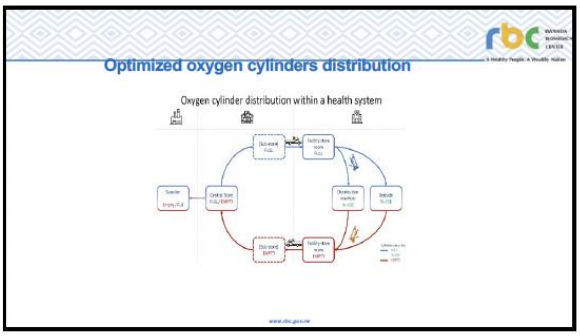

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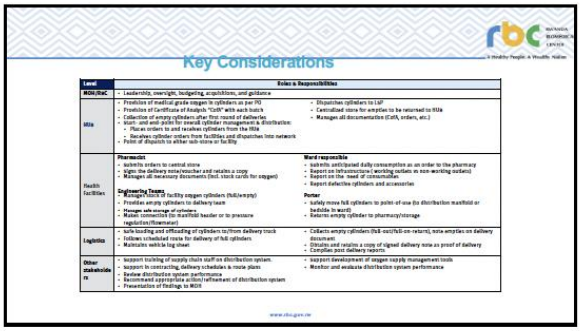

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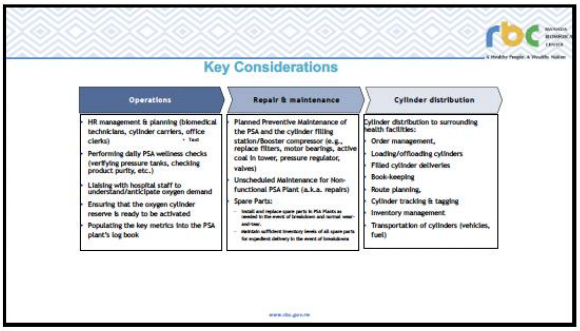

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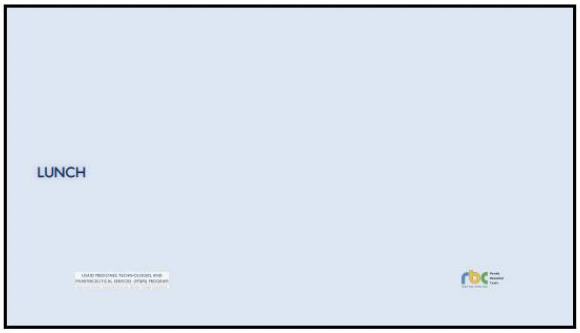

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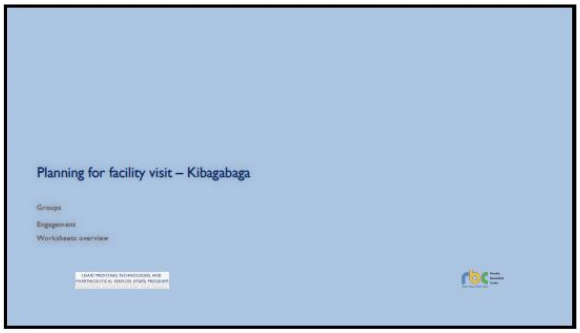

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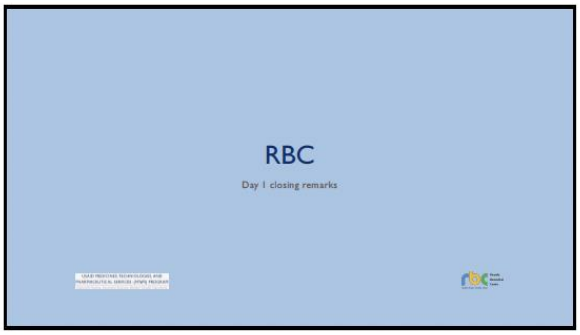

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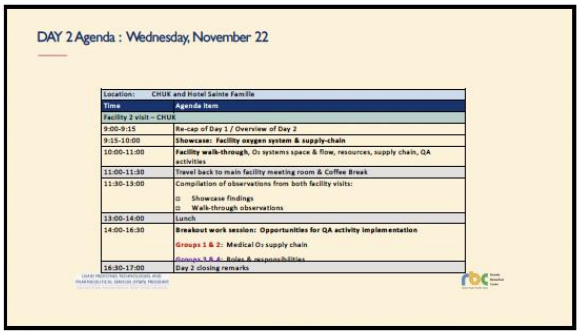

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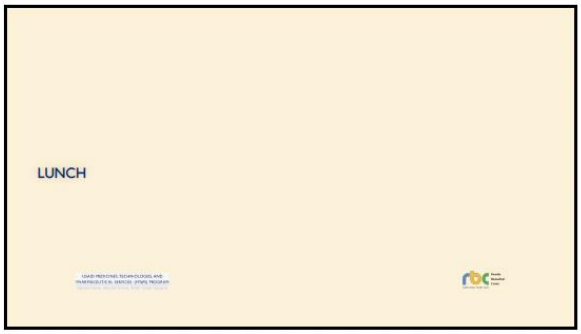

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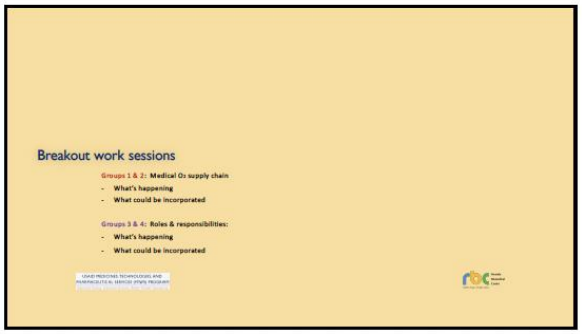

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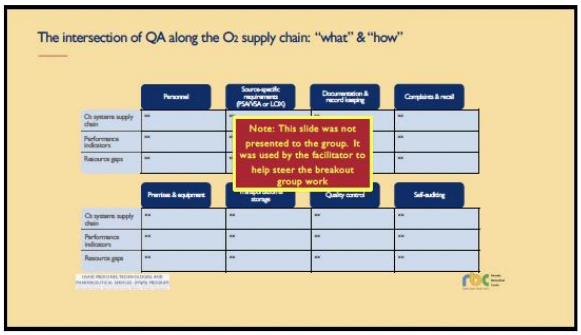

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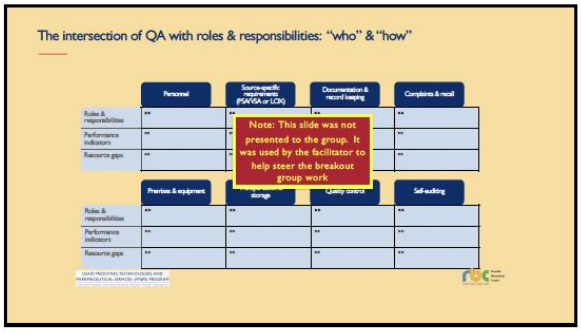

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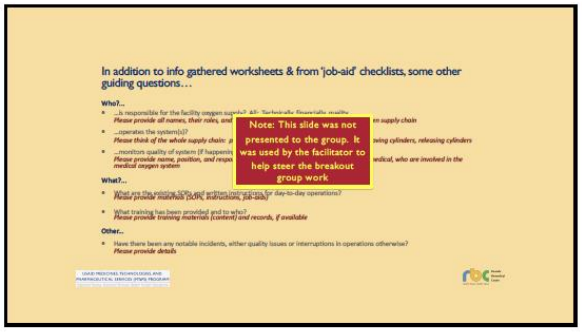

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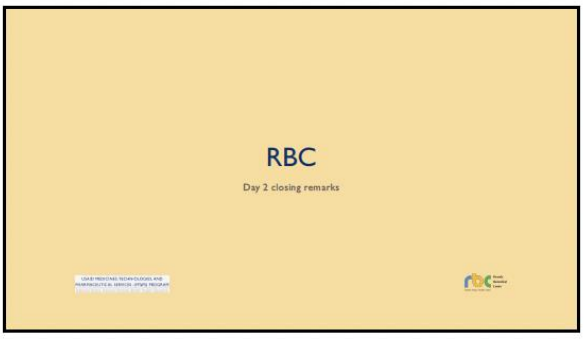

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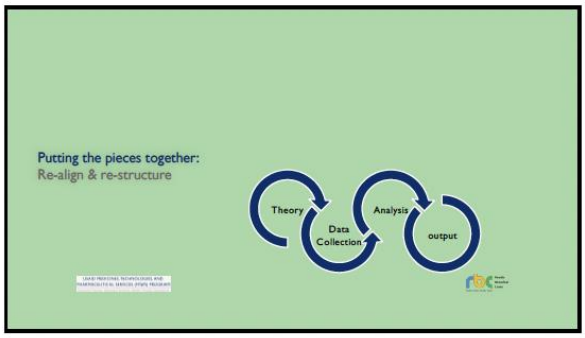

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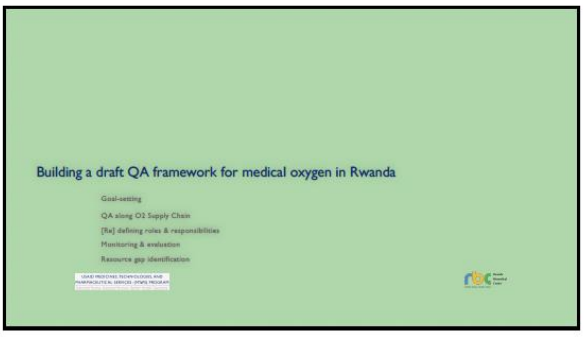

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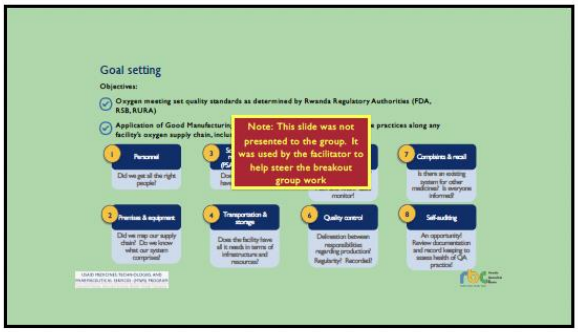

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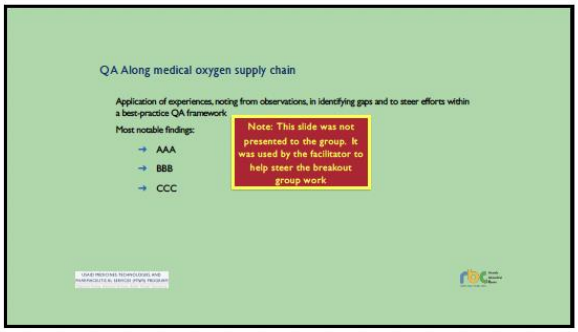

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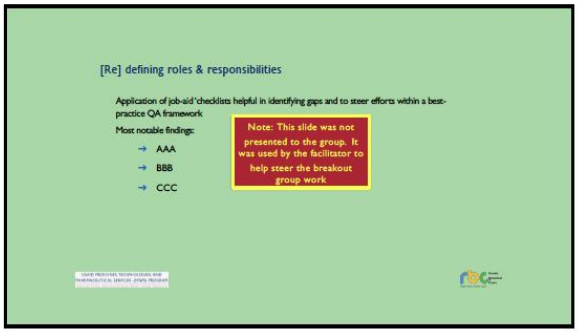

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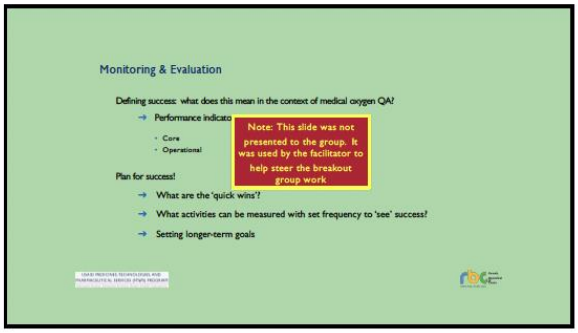

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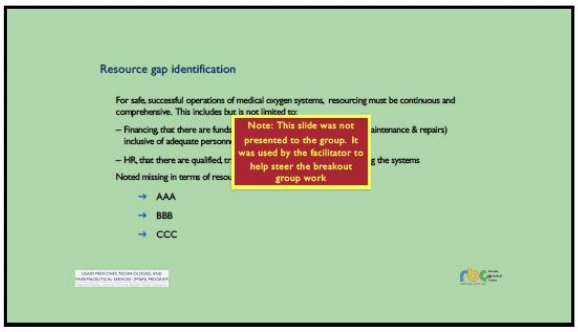

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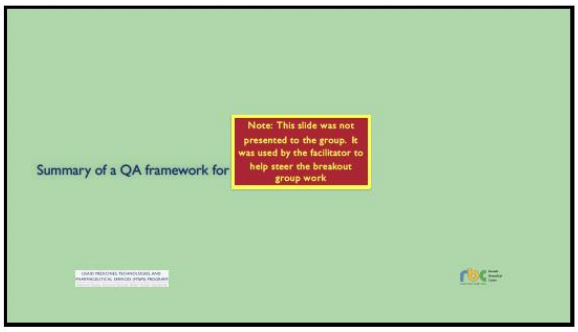

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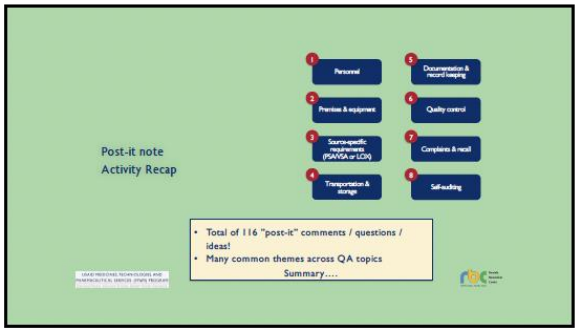
Post-it note
Activity Recap
1 Personnel
2 Premises & equipment
3 Source-specific requirements (PSAVSA or LCM)
4 Transportation & storage
5 Documentation & record keeping
6 Quality control
7 Complaints & recall
8 Self-auditing
• Total of 116 "post-it" comments / questions / ideas!
• Many common themes across QA topics
Summary….

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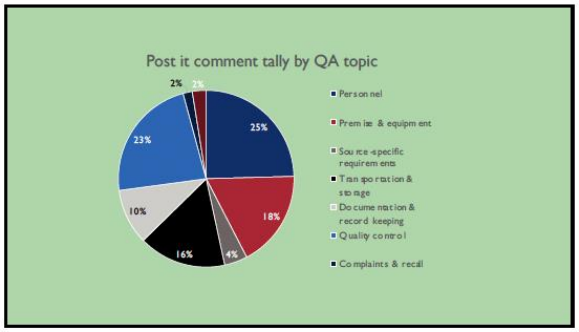
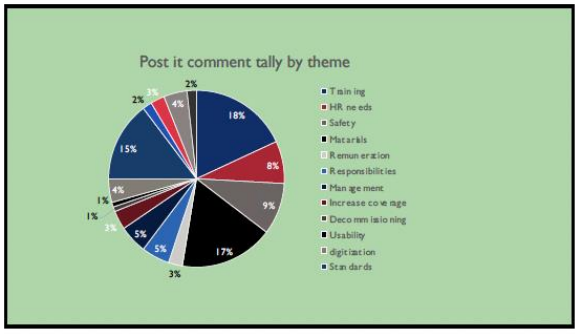
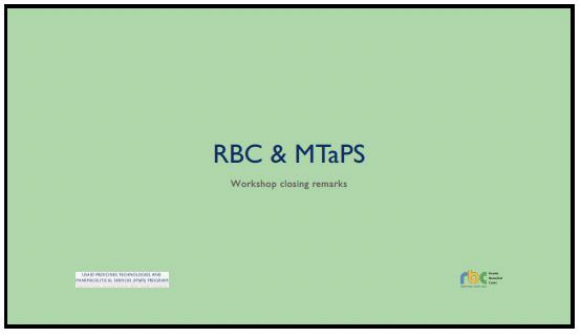

Post it comment tally by QA topic
25%
18%
4%
16%
10%
23%
2%
2%
Personnel
Premises & equipment
Source-specific requirements
Transportation & storage
Documentation & record keeping
Quality control
Complaints & recall

62


Post it comment tally by theme
18%
8%
9%
17%
5%
5%
3%
1%
1%
4%
15%
2%
2%
4%
Training
HR needs
Safety
Materials
Remuneration
Responsibilities
Management
Increase coverage
Decommissioning
Usability
digitization
Standards

63


RBC & MTaPS
Workshop closing remarks

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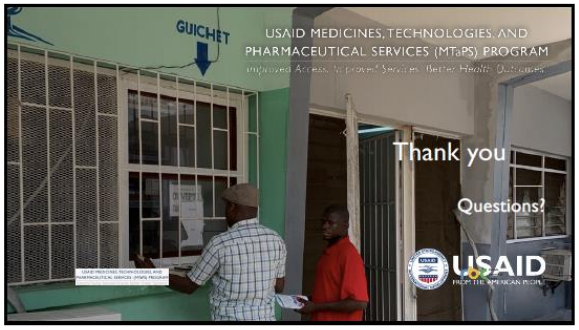
GUICHET
USAID MEDICINES, TECHNOLOGIES, AND PHARMACEUTICAL SERVICES (MTaPS) PROGRAM
Improved Access, Improved Services, Better Health Outcomes
Thank you
Questions?
USAID

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Annex IV. FACILITY VISIT WALK-THROUGH WORKSHEETS

GROUP 1: HOSPITAL LAYOUT & FLOW WORKSHEET

Potential key informant: Hospital administrator

Hospital layout & oxygen infrastructure	CHUK
On the adjacent plan, please annotate: Production: □ All sources of oxygen, indicate type (e.g., PSA plant, oxygen concentrator, cylinder cache [indicate status: full/empty/out-of-circulation]) □ If the facility provides cylinders to other facilities, indicate the dispatch/reception area Storage: □ If cylinders are used: ○ where are they stored ○ how are they stored Distribution: □ Which wards are directly piped □ Which wards have distribution manifolds Other: □ Workshop for repairs of medical equipment □ Pharmacy **Describe any other observations:**	

GROUP 2: RESOURCES FOR OPERATIONS

GROUP 2A – PERSONNEL

Potential key informant: Biomedical engineer and/or hospital administrator

Fill in the following table for personnel who do not administer oxygen to a patient.

Role	Responsibilities* related to medical oxygen	Received oxygen training?
Facility manager/ administrator		☐ Safety ☐ Technical (role-specific)
Pharmacist		☐ Safety ☐ Technical (role-specific)
Logistics/store manager		☐ Safety ☐ Technical (role-specific)
Biomedical Engineer		☐ Safety ☐ Technical (role-specific)
Biomedical technician		☐ Safety ☐ Technical (role-specific)
Quality controller		☐ Safety ☐ Technical (role-specific)
Head of oxygen production		☐ Safety ☐ Technical (role-specific)
Plant operator		☐ Safety ☐ Technical (role-specific)
Transporter (intra-facility)		☐ Safety ☐ Technical (role-specific)
Transporter (trucking)		☐ Safety ☐ Technical (role-specific)
Other (specify):_____		☐ Safety ☐ Technical (role-specific)
Other (specify):_____		☐ Safety ☐ Technical (role-specific)

* *Depending on facility size/needs, some responsibilities can be absorbed by personnel with complementary roles.*

Who **is overall responsible** for quality of medical oxygen? _____

Have clinical staff (doctor, physician assistant, anesthetist, nurse, midwife, etc.) been trained in:

- **Where and how** to report issues with oxygen systems? ☐ Yes ☐ No
  If yes, describe:_____
  _____
  _____
- Safety related to medical oxygen? ☐ Yes ☐ No

Are there quality improvement teams? ☐ Yes ☐ No

If yes, do non-clinical personnel participate? ☐ Yes ☐ No

GROUP 2B – INFRASTRUCTURE & EQUIPMENT

Potential key informant: Biomedical engineer and/or technician

xi) Technical Workshop

- ☐ clean, well-lit, spacious
- ☐ clean drop sheets
- ☐ ability to work with clean (oil-free, lint-free) hands and clothing
- ☐ spares and consumables available, or quickly attainable, to facilitate the PPM schedule
- ☐ computers to manage information/data
- ☐ adequate tools to carry out all PPM activities
- ☐ hand-held oxygen analyzer

xii) Oxygen generator plant (accessible only by authorized personnel)

- ☐ appropriate housing and regulated climate (if applicable)
- ☐ in-built analyzers/sensors (O_2, CO, CO_2, moisture), alarms, automatic shut-off features, pressure relief valves, purge valves
- ☐ room monitor to ensure safe ambient conditions

xiii) Medical gas pipeline system (MGPS)

- ☐ pipelines themselves color coded and clearly labelled for oxygen use
- ☐ ample accessory sets (for each terminal unit) comprising flowmeters and humidifiers

xiv) Cylinder filling station (if applicable, and accessible only by authorized personnel)

- ☐ vacuum pump (a small compressor)
- ☐ ample space for the management of cylinders: filling, movement, inspection, sorting, and storage of cylinders (rejected).
- ☐ No steps, grade-change facilitated by ramp(s) where applicable to facilitate safe movement of cylinders.

xv) Cylinders

- ☐ Ample (in terms of quantity)
- ☐ Appropriately painted and paint available for touch-ups
- ☐ Enough cylinder accessory sets (comprising pressure regulators, flowmeters, and humidifiers

xvi) Cylinder delivery

- ☐ fit-for-purpose vehicles (if applicable – cylinder transport and delivery to/from facility)
- ☐ Trolleys

GROUP 3: COMPLEMENTARY SUPPLY CHAIN STRUCTURES

Potential key informant: Biomedical engineer and/or hospital administrator

Supply chain system/reach	Describe mechanics & logistics (e.g., push, pull, consumption based/period, orders, tickets, etc.)	How does medical oxygen fit in, if at all
To facility		
Central pharmacy		
Ward-level		
Biomedical engineering department		
Cylinder delivery (WITHIN facility)		
Cylinder delivery (TO/FROM FACILITY)		
Other (specify): _____		

Example descriptions:

- monthly deliveries pushed based on average consumption figures,
- ordered on an as-needed basis,
- ordered based on systematic collection of facility / ward consumption
- service ticket generation
- emergency service request
- systematic replenishment with [insert] frequency

GROUP 4: EXISTING QUALITY IMPROVEMENT INITIATIVES
The following checklists are to be split out across your group.

xvii) Job-aid for authorized person

Potential key informant: Biomedical engineer and/or pharmacist

Description: The role of the AP is to take overall responsibility for the quality of oxygen in a health care facility—the production of Oxygen 93 and/or the acquisition of oxygen from an external source. The AP must have a comprehensive understanding of the clinical application of oxygen and the monograph requirements under the nationally recognized pharmacopoeia. This role shall be nominated. (Tasks adapted from EIGA Doc 195/20.)

Activity	Details	Frequency	Documentation
Establish and fill QA and QC roles that correspond with facility oxygen services	As responsible for overall quality, ensure that all roles and responsibilities of QA and QC respectively are covered, and that personnel have appropriate training and experience. Nominees may require a deputy to ensure comprehensive and continuous coverage.	Once, at outset of system implementation/in absence of QA practice	Nominees to be provided with detailed descriptions of duties and responsibilities for O_2 QA; facility-level QA organigram to be developed
Lead development of facility-specific medical gas operational policy	Details of facility-specific system, comprising needs assessment, capacity, operational protocols, quality requirements, personnel roles and responsibilities. Includes: • quality management plan • risk management plan	Once, at outset of system implementation/in absence of QA practice *Revisit at specified interval (e.g., every 5 years and with any adverse event or source change)	
Ensure that the oxygen meets quality requirements of the nationally recognized pharmacopoeia	☐ Sign off on oxygen: • on-site production (PSA/VSA), as per testing protocol in operational policy • cylinders delivered, as per CoA ☐ Notify health care providers in the event of an Oxygen 93 and Oxygen 99 blend	As needed	Signatory on QC documents

Activity	Details	Frequency	Documentation
QA during procurement of oxygen generator plants	☐ Involve technical team in procurement ☐ Ensure that product meets nationally accepted regulatory requirements for medical devices.	As needed	Follow internal procurement processes, ensure vendors provide appropriate quality-related documentation
Lead training program	☐ Develop and/or adapt training content with department or activity leads ☐ Ensure all staff who work with oxygen have been trained on oxygen safety and risks, safe equipment operations and handling, and equipment maintenance (where applicable) ☐ Manage trainers administering specific modules ☐ Ensure O_2 content incorporated into CPD	Set into CPD cadence after onboarding	Maintain a training log, to be revisited every year (or at a frequency set out in facility operational plan)
Manage CAPA processes	With quality unit, investigate any off-specification oxygen and/or any (reported) adverse events, taking: ☐ corrective action ☐ preventive action	As needed	Thorough documentation of event and CAPA
Authorize "permit to work"	Provide sign-off on "permit-to-work" applications	Prior to any PPM and repairs as needed	Strict documentation in line with facility risk management plan
Lead internal audits	Review, at a minimum: ☐ Previous audit and associated resulting activities (if applicable) ☐ Production data, metrics, trends ☐ Specifications, application, appropriateness ☐ Equipment status ☐ Efficacy of in-process controls ☐ Non-conformance events, associated investigations, efficacy of CAPA ☐ Existing contracts (if applicable), e.g., PPM, quality agreements with external entities	Annually, unless otherwise triggered by significant adverse event.	Audit reports, inclusive of trends, adverse events; plans for required system or process change
Report adverse events to NRA	Part of vigilance practice as per national requirements, ensure facility management is informed	As needed	Stringent recordkeeping of any adverse event

xviii) Job-aid for head of production

Potential key informant: Biomedical engineer and/or technician

Description: A necessary member of the team for ensuring quality medical oxygen systems, the head of production has oversight of all activities related to the production of medical oxygen when an on-site oxygen generator plant is used. Will liaise with the AP for quality control if/where needed. (Tasks adapted from EIGA Doc 195/20 and EIGA Doc 149/22.)

Qualifications/requirements/experience: Engineer (civil, mechanical, biomedical, electrical) with project management skills and work experience in the health care sector.

Activity	Details	Frequency	Documentation
Develop and finalize facility-specific SOPs for production	Working with production team, base operational SOPs on manufacturer's instructions and have final SOPs approved by AP; flag all QA requirements	Once, but revisit if/when needed	Documented, part of facility quality management plan
Ensure production in accord with SOPs	Review all records to ensure that production team is consistently following SOPs and recording necessary information	Quarterly	Review of records
Ensure continuity of supply	Ensure that secondary supply has been established for facility, that it remains adequate, and that it is activated appropriately	Once, but revisit if/when needed	Documented, part of facility quality management plan
Ensure thorough and timely PPM program	Review all records to ensure that PPM is conducted according to plan and necessary records are created	Quarterly	Review of records
Validate the on-site oxygen generator plant, alongside the AP	Equipment tested for functionality, safety, and performance, and to ensure that it operates in line with specifications	Typically, following installation and after any major repair or other work	To record, with AP, if indicated with PPM
Validate cylinder filling, analysis, and release process, alongside AP	Equipment tested for functionality, safety, and performance, and to ensure that it operates in line with specifications	Typically, following installation and after any major repair or other work	To record, with AP, if indicated with PPM

Activity	Details	Frequency	Documentation
Validate any monitoring and measuring equipment, ensure calibration process is established and clear	Validation will take place upon commissioning; however, after any major work, equipment shall be tested for functionality, safety, and performance and to ensure that it operates in line with specifications; additionally, calibration protocols—if/when indicated—shall be clearly established based off manufacturer's guidance	Validation as needed, typically after major repair; calibration as indicated by manufacturer of measuring device	To record, with AP, if indicated with PPM
Facilitate technical trainings, alongside AP	Deliver any technical modules covered in a training cycle, at the request of AP; can deputize for capacity building, if appropriate	At intervals set in quality management plan	To record, with AP
Conduct periodic review of operational log for preventive control parameters	Monitor purity, flow, temperature, pressures, vibrations, power, capacity, and any other variable established in the risk management plan as preventive control parameters	Quarterly	Review of records
Manage "permit-to-work" system applications	Responsible for the execution of technical work, and thus shall manage all activities under "permit to work," including any third-party contractors (AP has the ultimate responsibility)	Prior to all PPM events, and as needed in case of repairs	Record via "permit to work" application process
Participate in internal audit	At the request, and under the guidance, of the AP	Annually, unless otherwise triggered by a significant adverse event	Audit report, inclusive of trends, adverse events; plans for required system or process change
Support CAPA processes	With quality unit, investigate (reported) adverse events, taking ☐ corrective action and ☐ preventive action	As needed	To record, with AP

xix) Job-aids for technial staff

Potential key informant: Biomedical/mechanical/civil engineer, respective mechanic/technician, mechanic/technician, pharmacist.

Plant operations

Description: Day-to-day operations of medical oxygen systems must be carried out with great care to ensure continued quality outputs. Operators shall be dutiful with regard to task, meticulous with regard to recordkeeping, and fastidious with regard to cleanliness.

Qualifications/requirements/experience: To operate on-site oxygen generator plants, fill cylinders, and manage pipeline distribution networks, operators can be technicians of the following disciplines: biomedical technician, mechanic, electrician, builder/contractor. They shall also have experience in the health care sector, and shall have received training from the oxygen generator plant manufacturer.

The following QA requirements have been developed for specific components of the system. An operator of a specific unit is assumed to be capable of and responsible for the cleaning and maintenance of said component. (Tasks adapted from EIGA Doc 195/20 unless otherwise indicated.)

Activity	Details	Frequency	Documentation
Provide input to head of production on SOPs and work instructions, noting QA activities	All activities for start-up and operation of the complete unit shall be made; activity to be carried out with the head of production and manufacturer/distributor of plant	Once, prior to commissioning of the unit *Refine as needed	SOPs to be documented in facility quality management plan, a form developed enabling recordkeeping of procedures followed and any notable parameters
Conduct facility check (Adapted from: EIGA Doc 149/22))	Ensure the following: ☐ Fire safety system and fire suppression equipment are present and functional ☐ Room O_2 levels are between 19.5% and 23.5% at all times ☐ Ambient air conditioned to manufacturer-specified operating conditions ☐ Monitor and maintain air intake, notify HP of any risks (acute: fire; protracted: new construction nearby) ☐ No unauthorized or unrelated work in oxygen generator plant and cylinder filling room ☐ Production room remains clean at all times	Daily * It must be ensured that staff are working in a safe environment and that external contamination risks are minimized and/or mitigated	Record all details in a standardized format
Operate the unit per SOPs	☐ Adherence to established SOPs ☐ Follow work instructions (where applicable) ☐ Carry out QA activities and make records	Every time the unit is operational (e.g., start-up, operations, shut-down)	Record operations in template, indicate procedures followed and any notable parameters

Activity	Details	Frequency	Documentation
Trigger secondary and/or emergency source in the event of unresolvable issue	Notify head of production in the event of any deviation in established operational values	During PPM or under abnormal conditions/adverse event	Record the start-up of the secondary and/or emergency source, including justification
Carry out PPM and repairs (or accompany third party and support recordkeeping in the case of a service level agreement) (Adapted from EIGA Doc 149/22 and EIGA Doc 33/18)	☐ Complete request for "permit-to-work" authorization with head of production ☐ Carry out all work as per manufacturer recommendation ☐ Use only parts or spares labelled "Clean for oxygen service" and include inspection documentation and cleaning certificates[6] ☐ Ensure materials used/connected to system are clean of mill scale, rust, dirt, weld slag, flux, oils, greases, and any other organic or inorganic particulates and solvents before recommissioning *Ensure adequate spares availability	As per PPM schedule, recommended by manufacturer and outlined in the quality management plan	Record all details in a standardized format
Oxygen purity analyzer maintenance (both in-built and secondary hand-held)	☐ Calibrate periodically as per manufacturer's instructions[7] ☐ Conduct PPM as per manufacturer's instructions ☐ Replace sensor at frequency set by manufacturer	As per PPM schedule, recommended by manufacturer and outlined in the quality management plan	Record all details in a standardized format

[6] Non-metallic materials—gaskets, valve packing, insulation, and lubricants—shall be certified for oxygen service. Consult the supplier before using these materials.
[7] Calibration gases may be difficult to acquire. Consider when selecting analyzer sensor type during procurement.

Cylinder filling

(Tasks adapted from EIGA Doc 209/17.)

Activity	Details	Frequency	Documentation
Determine "batch" definition, with AP (see ICH Q13 here)	Based on filling station size (filling ramp/manifold connection points): ☐ Determine how many cylinders filled comprise a batch ☐ Determine number of cylinders from a batch need testing ☐ Establish nomenclature to indicate batch number and cylinder within batch to facilitate batch tracing ☐ Develop template for recordkeeping of each batch filled	Once, prior to commissioning of the station, refined if any physical changes are made to hardware	Definition to be documented in quality management plan, record template to be used during operations
Establish SOPs and work instructions for filling, alongside the head of production and based on specs from manufacturer of cylinders	These SOPs shall cover: Checks: ☐ Cylinder color-coding paint intact ☐ Cylinder valves for oxygen service ☐ Visual checks: valve for cleanliness and damage, shell for damage ☐ Cylinder up to date on testing (last hydrostatic test, test ring intact) Preparation: ☐ Cylinder purge (cylinders may/may not have residual pressure valve; SOP specific to type of cylinder valve and requisite purge shall be developed) Fill and post fill: ☐ Fill schedule ☐ Fill pressure requirements ☐ Valves leak-tested and closed ☐ Batch labelling ☐ Coordinate with QC for batch testing	Every batch filled	Record all details in a standardized format

Activity	Details	Frequency	Documentation
Manage cylinders	☐ Keep cylinders sorted by categories, for example: empty, full, prepared deliveries, faulty/rejected cylinders, etc. (if needed, can use chalk or crayon to make a temporary marking) ☐ Safely maneuver cylinders using a trolley or forklift (for pallets) ☐ Maintain product rotation (e.g., first-in, first-out)	Continuous	Follow pharmacists' stock-management recordkeeping
Booster compressor PPM	☐ Liaise with plant operator ☐ Carry out all work as per manufacturer recommendation ☐ Use only parts or spares labelled "Clean for oxygen service" and include inspection documentation and cleaning certificates[8] *Ensure adequate spares availability	Every 1,000 hours of operations and earlier, if context indicates	Record all details in a standardized format
Facilitate for testing	Batch labeling to be completed to facilitate testing by quality controllers (different personnel)	Every batch filled	Record all details in a standardized format

Pipeline management

(Tasks adapted from EIGA Doc 13/20.)

Activity	Details	Frequency	Documentation
SOPs and work instructions development	Develop written procedures, alongside head of production, for: ☐ system shutdown/start-up ☐ PPM ☐ Planning for repairs ("permit to work")	Once, when system is installed, and updated when/if needed	Documented templates for use when/as needed
Operations check	☐ Manifold alarms and change-over functioning ☐ Monitoring of alarms (master/ward)	Continuous	Record when normal, flag if/when deviation occurs

[8] Non-metallic materials—gaskets, valve packing, insulation, and lubricants—shall be certified for oxygen service. Consult the supplier before using these materials.

Activity	Details	Frequency	Documentation
PPM: Broad system check	Conduct a full walk of pipeline system (See PPM checklist in EIGA 013/20 Appendix F): ☐ Any abnormal/accidental interference with damage to system ☐ System signage and markings remain intact	Daily, no need for "permit to work"	Record all checks on a standardized template
PPM: Targeted checks	☐ Leak test all exposed fittings and flanges ☐ Test cathodic protection system (if applicable) ☐ Full pipeline pressure check	Every 3 months Every 3 months Every 6 months	Record all checks on a standardized template
Repair work preparation (accompany third party and support recordkeeping)	☐ All personnel must be trained in oxygen safety and work safety for oxygen pipelines ☐ Solicit for authorization under "permit to work" with head of production; only decommission necessary areas ☐ All parts or spares used in oxygen systems must come labeled "Clean for oxygen service" and include inspection documentation and cleaning certificates (EIGA DOC 33/18) ☐ If piping is to be opened, ensure depressurization and purging with air (EIGA DOC 149/22) ☐ Establish provisionary grounding if any welding will be conducted	As needed	All work intended to be carried out shall be recorded by "permit to work" process
System start-up	☐ Ensure materials used/connected to system are clean of mill scale, rust, dirt, weld slag, flux, oils, greases, and any other organic or inorganic particulates and solvents before recommissioning (EIGA DOC 149/22 and EIGA DOC 33/18) ☐ Purge with oxygen to remove working shield gas (air or nitrogen) and test all outlets to ensure working purity achieved ☐ Conduct leak test upon re-start after prolonged shut-down ☐ Coordinate with QC to test purity at recommissioned bedside terminal units	As needed, typically after major repair	All work completed, inclusive of confirmation of final purge and leak test, shall be recorded by "permit to work" process
System drawings	Maintaining a current "redline" of the system drawings will ensure that any future works are carried out most efficaciously Also, those undertaking any adjacent work must know where pipelines run to avoid any breach	Whenever changes are made to original pipeline network	Drawing directly onto a "live" copy of the original system drawings in a notable color

xx) Job-aid for head of quality control

Potential key informant: Pharmacist / other staff with technical background removed from operations.

Description: Responsible for all quality control activities as they relate to production of medical oxygen within the health facility. Liases with AP.

Qualifications/requirements/experience: Technical or clinical background, experience in healthcare sector (Adapted from EIGA Doc 195/20)

Activity	Details	Frequency	Documentation
Develop quality control processes	With AP, develop quality control processes: ☐ In-line with facility quality management plan ☐ Complementary to risk management plan ☐ Monitoring all preventive controls ☐ Monitoring to ensure compliance with pharmacopoeia ☐ Escalation of quality issues (develop communication ladder)	After initial development, revisit with frequency indicated in operational plan	Documents to be included in the facility medical gas operational policy, templates to be used for daily activities
Manage QC team	☐ Support team in activities if/when needed ☐ Work to troubleshoot when any issues arise	As needed	Record if troubleshooting uncovers quality issue
Verify quality control processes	Ensure that QC processes support QA of facility oxygen; review: ☐ QC records for completion ☐ QC records for conformance to specifications	Annually, unless otherwise triggered by a significant adverse event	Record in facility audit
Equipment maintenance and calibration	With QU, ensure that operational and QC teams maintain and calibrate equipment as per manufacturer recommendations	PPM as per manufacturer instruction	Record all details in a standardized format
Equipment validation	Ensure that equipment for manufacture of medical oxygen has been validated according to NRA requirements	As needed, typically after major repair	Record all details in a standardized format
Facilitate trainings alongside AP	Support AP in administration of training	At intervals set in quality management plan	Record, with AP

Activity	Details	Frequency	Documentation
Participates in internal audit	At the request and under the guidance of the AP	Annually, unless otherwise triggered by a significant adverse event	Generate audit report, inclusive of trends, adverse events; plans for required system or process change
Support CAPA processes	With quality unit, investigate (reported) adverse events, taking: ☐ corrective action and ☐ preventive action	As needed	Record, with AP

xxi) v) Job-aid for quality controllers

Potential key informant: Pharmacist / other staff with technical background removed from operations

Description: Carries out quality control activities as they relate to medical oxygen within the health facility.

Qualifications/requirements/experience: Technical or clinical background with experience in the health care sector. Important to distinguish QC role and that controller be experienced and adequately trained. (Tasks adapted from EIGA Doc 195/20.)

Activity	Details	Frequency	Documentation
Calibrate monitoring and measuring equipment	Ensure that all equipment used in monitoring and measuring is calibrated as per manufacturer requirements	At each calibration interval, as indicated by device manufacturer	Record all details in a standardized format
Test quality of product	Test the following: ☐ On-site oxygen generator plant output, as per batch definition in the facility quality management plan (record values from oxygen generator plant AND from secondary hand-held analyzer) ☐ Cylinder filling, minimum one per batch, to be released by AP	Daily, for each batch as defined in the quality management plan	Standard QC record template; prepare CoA for QU if any are to be sent elsewhere; non-conformance reported and flagged to QU
Test secondary systems	Ensure automatic switch-over to secondary supply (where applicable) if: • Main power supply outage affects primary source • Pressure or purity drops from primary source	PPM, to be carried out as scheduled with plant operator	Record all details in a standardized format

Test monitoring and alarm systems	All alarms and controls shall be tested for operating limits (e.g., pressure, oxygen concentration, CO, CO_2, automatic shut-off, vent valves) • Test one function at a time • Observe that audio, visual, and—where applicable—operational control is activated	PPM, to be carried out as scheduled with plant operator	Record all details in a standardized format

xxii) Job-aid for transporter (and distributor, if applicable)

Potential key informant: Staff with any technical background.

Description: Any vehicle operator or transporter of medical oxygen, either LOX or high-pressure gas cylinders.

Qualifications/requirements/experience: Personnel shall be trained in all the technical characteristics of oxygen and its risks and hazards, as well as in the quality requirements of medical oxygen and the sensitivities associated with working for and in proximity to patients. They shall have a valid driver's license (commercial, if deemed necessary). Any inspection, examination, and/or maintenance of any vehicle (including tanker truck) shall be performed by personnel trained and qualified in auto mechanic work. (Tasks adapted from EIGA Doc 128/21.)

Activity	Details	Frequency	Documentation
Develop, verify, and validate SOPs	All protocols/SOPs shall be developed and tailored to each vehicle to ensure that nuances are captured	At time of acquisition of vehicle, to be re-visited if vehicle is modified/changed	Documented as part of GDP; templates for records developed
Conduct vehicular check	☐ Tire condition and pressure ☐ Safety kit available/complete and not expired ☐ Vehicle and driver documents present ☐ Vehicle fueled up ☐ Brakes functioning ☐ No obvious issues/damage	Every trip	Record all details in a standardized format

Activity	Details	Frequency	Documentation
Observe loading protocol	☐ Engine off and parking brake engaged ☐ Maximum number of cylinders never exceeded[9] ☐ Verify load distribution ☐ Ensure load is secured ☐ Valve guards or caps fitted ☐ Full and empty cylinders segregated ☐ Accessories stored separately: regulators, flowmeters, trollies, etc. (if applicable) ☐ Safely maneuver cylinders using a trolley or forklift (for pallets)	Every **leg** of every trip	Record all details in a standardized format
Maintain vehicle	Follow appropriate maintenance schedule based on mileage. Additionally, ensure: ☐ Cargo compartment structure is sound (floor smooth) ☐ Vents are adequate, unobstructed ☐ Load securing system is intact ☐ Doors/gates open smoothly ☐ Lift is functional (if applicable) *Smoking prohibited in garage ** Oils, greases, solvents to be kept away from vehicle	As per Ministry of Transportation and/or Ministry of Industry requirements (e.g., at a pre-set number of kilometers on odometer)	Record all details in a standardized format

[9] Cylinders come in many sizes, each with its own specifications. The transporter (distributor, if applicable) shall establish equivalents in their SOPs and heed a uniform and conservative estimate for each size—e.g., large cylinders have tare weights of upwards of 70 kg.