MEETING TARGETS AND MAINTAINING EPIDEMIC CONTROL (EPIC) PROJECT

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Planning guide:

Setting up liquid oxygen (LOX) systems in hospitals in low- and middle-income countries

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EpiC Meeting Targets and Maintaining Epidemic Control

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Objectives and how to use this guide

This planning guide offers high-level guidance to ministries of health (MOHs), hospital administrators and managers in low- and middle-income countries, and relevant NGOs to plan steps for setting up a system of liquid oxygen (LOX) in hospitals, noting that there are many nuances that could be facility and context specific.

This resource was developed by the Meeting Targets and Maintaining Epidemic Control (EpiC) project in consultation with PATH and Clinton Health Access Initiative (CHAI) as a high-level tool and not meant to be exhaustive or cover all the considerations/situations that may come up and should be used in addition to other more technical and LOX-specific tools. In fact, it is expected to be the first step in planning a facility-based LOX implementation journey, particularly for countries without previous experience with LOX systems.

Medical oxygen is critical for the treatment of severe cases of COVID-19 and other life-threatening conditions such as severe pneumonia, severe malaria, sepsis (from bacteria and viruses), trauma, and complications of birth or pregnancy. While there are multiple modalities for oxygen delivery, this planning guide focuses on LOX because, depending on the context and setting, LOX can offer an affordable cost-per-liter option to deliver oxygen to facilities with sufficient demand (or pooled demand across facilities if distribution patterns allow), high purity (>99.5% v/v of oxygen) of medical oxygen, and good elasticity in the face of fluctuating demand.

Cryogenically produced LOX is generated off-site by a third party, and health facilities can be equipped with a vacuum-insulated evaporator (VIE) system that can also be configured to fill high pressure gas cylinders via filling station that consists of cryogenic pump, high pressure vaporizer, and filling ramp.

The LOX tank can supply a centrally piped system throughout the health facility by passive vaporization, which does not require a power supply aside from system controls and alarms. With access to three-phase power, a LOX tank can also be connected to a cylinder filling station in order to fill medical gas cylinders for transport to nearby facilities. Benefits like lower operation costs, lower maintenance costs, and less dependency on electricity can make it more advantageous than pressure swing absorption (PSA) and concentrators for some health facilities.

This resource will focus on planning steps to set up **liquid VIE systems in high-volume medical oxygen-consuming hospitals** (see Box 1). While the focus of this guide will be on VIE systems, in some cases, health officials may consider establishing a liquid-to-gas cylinder filling station, also called hub-and-spoke, that can fill cylinders with gas from a cryogenic liquid source and then distribute to facilities throughout the catchment area.

This guide identifies the infrastructure needed to expand access to VIE systems to more facilities and relevant technical assistance associated with implementation.

Before setting up a VIE system in the facility, there should be an enabling environment for the implementation of LOX in the health care setting. This may include but is not limited to national level bodies that are interested in and committed to expanding access to LOX, and developing/adopting national standards, regulatory requirements, and sustainable financing. This guide will not cover this aspect, assuming that countries that are moving forward with LOX have an enabling environment.

Box 1. VACUUM-INSULATED EVAPORATOR SYSTEM

A hospital-based LOX system is known as a vacuum-insulated evaporator (VIE) system, which typically comprises a bulk cryogenic liquid storage tank and a vaporizer that passively converts the liquid into a gas. The VIE system is often complemented by a piped distribution network (valves, piping, alarms, and terminal units) through which oxygen is supplied to patients' bedsides in health facilities.
A bulk tank can also be set up to vaporize LOX and to use a cryogenic pump to fill cylinders, or a combination of piping and booster compressor to enable a hub-and-spoke option with a LOX supply chain.

Note: A bulk cryogenic liquid tank is insulated with medium and a vacuum, minimizing heat exchange to maintain the product at a steady pressure and temperature to facilitate operations and minimize off-gassing.

This document includes the following components:

- Section 1: Process for selecting facilities and developing costed plans to expand use of LOX
- Section 2: Checklist for costed plan items
- Section 3: Technical considerations for facilities to set up VIE system

Installation and utilization of LOX systems is contingent upon compliance with national and international guidelines, such as WHO technical consultation on oxygen access scale-up for COVID-19; UNICEF's Oxygen System Planning Tool; Health Technical Memorandum 02-01: Medical gas pipeline systems Part A: Design, installation, validation and verification; Health Technical Memorandum 02-01: Medical gas pipeline systems Part B: Operational management as well as the availability of technical guidance on the use of medical oxygen. This planning guide complements other resources developed by CHAI, PATH, and Open Critical Care. The process, checklist, and technical considerations should be adapted to the individual country context and verified with relevant stakeholders.

Section 1. Process for selecting facilities and developing costed plans to expand use of VIE system

Step 1: Identify priority facilities where VIE systems could be set up jointly with relevant stakeholders, including donors, international and local implementing partners (IPs), Ministry of Health/Ministry of Industry, or other relevant government bodies.

Communication and coordination with relevant stakeholders are critical to ensure selection of the appropriate facilities and that the relationships between hospital administration, supplier of a VIE system, and supplier responsible for the maintenance of the system (if different) is set up in the right way. Potential supplier/s of LOX need to ensure compliance of the system with their operational and safety directives, and the civil contractor needs to ensure construction of a reinforced concrete slab to bear loading of system. At higher level, medical oxygen technical working groups, if they exist, may include all relevant health system stakeholders, like donors and regulatory bodies such as Ministry of Industry and MOH. If there is no technical working group, relevant stakeholders may have to be involved individually.

Selection of facilities for setup or expansion of LOX should be based on several parameters, including need for medical oxygen and realized demand or consumption; consistent and, preferably, high demand for medical oxygen at one facility or at pooled facilities; proximity to a supplier; road access and safety; availability of space in the facility; existence of local regulations for hazardous materials; and availability of personnel who are or can be trained in the management and operations of LOX systems. An additional factor to consider is market dynamics of a new market entrant versus an incumbent, including how that affects the volumes they would consider, and whether the rest of the network of facilities can potentially benefit and may already be using medical oxygen. For example, one small tank in an entire country does not make a strong business case for a supplier. However, a cluster of even smaller tanks that are located close to each other may be a sustainable supply plan both from a health system and supplier's perspective.

VIE systems are suitable for large hospitals with significant and consistent demand for medical oxygen. Several characteristics may be indicative of this type of demand, such as facility type (e.g., referral hospitals may be more likely to have clinical and equipment capacity to utilize medical oxygen), hospital with large number of beds, bed occupancy rates, oxygen flow rates, high patient volumes, the representation of wards that utilize high volumes of oxygen (e.g., critical care units such as intensive care units, high dependency units). At the same time, the utilization of oxygen in the wards depends a lot on the size of the ward and how it is defined in each country. Thus, these characteristics must be applied with consideration of the context. A cost benefit is realized when facilities are located close to an existing LOX production plant or bulk storage hub, depending on the distribution model, due to reduced transportation costs.

Selected facilities should be discussed with the national and subnational medical oxygen technical working groups, relevant local stakeholders, and subject matter experts, including a technical team lead, technical analyst, financial analyst, and engineer experienced in oxygen systems. You may decide to include a representative from all potential suppliers, if possible.

In some cases, when there is small demand in a catchment area or when facilities are in remote areas and/or far from a manufacturer, the hub-and-spoke distribution model (also known as a liquid-to-gas cylinder filling station) should be considered. This distribution model consists of a cryogenic liquid tank coupled with a cryopump, high-pressure vaporizer, and filling ramp that serves as a high-pressure gas cylinder filling and distribution hub. Cylinders are filled with medical oxygen transformed into gaseous state at the hub and then delivered by trucks to nearby facilities.

Step 2: Understand operational & safety requirements, ensure sourced equipment and infrastructure plans are sound, and engage these sources in the facility assessment process.

Procurement options and costs. Any procurement process should follow the requirements of the entity completing and/or funding the procurement. Steps should be taken to explore potential payment options (e.g., procurement of tanks vs. leasing of tanks, long-term contract). To optimize their own operations, it would be advantageous for LOX gas suppliers to enter into long-term contracts with health facilities or, depending on health system context, with a central procurement body, such as a state or national supply chain agency. Leasing of tanks may prove advantageous because the supplier will scope and provide answers to technical questions, which should be included as an expectation in the purchase order. Maintenance contracts with LOX suppliers can help users ensure the proper functioning of VIE systems, prevent costly repairs, and ensure a sustainable supply of LOX. These contracts typically include routine preventative maintenance and LOX refilling services.

If the user purchases the hardware outright, the supplier filling the tanks could be different from the supplier that sold the hardware.

Capital investments are required by suppliers to establish equipment and infrastructure for LOX production and distribution, including air separation units (ASUs), cylinder filling hubs, tanker trucks, qualified technical personnel, and offices. For onsite LOX systems to achieve cost-effective production, capacity utilization must be optimized To achieve cost-effective and efficient utilization of LOX systems in healthcare facilities, it is essential to carefully assess the following key factors:

Proximity to the supplier: A critical factor to consider is the distance of the hospital from the supplier/manufacturer base, as distribution patterns and transportation costs will affect the cost of the product and who will pay for service on a monthly, quarterly, or less-frequent basis as determined by the contract.

Sizing: Sizing the cryogenic tank units requires expertise to determine peak demand (for the vaporizer) and continuous demand coupled with rate of refill (for the tank), the latter of which must be tied to the replenishment cycle (see Table 2. Cryogenic tank sizing). Note that a balance between tank size, the potential for wastage (from both boil-off and unused headspace gases), and supplier routing for efficient distribution will need to be considered, and a buffer should be added to account for increase in demand associated with facility growth. For example, a tank that is too large will be a financial burden for a hospital and lead to sustainability challenges. Also, buffer is needed because (1) about 10% of the volume in the tank is unusable as it must remain in the vessel to maintain operating pressure, and (2) space is needed for holdover in the event of a delayed drop schedule. Finally, a supplier will need flexibility to plan effective distribution; otherwise, the costs of inefficient distribution routing will fall to the facility/MOH. Where an ambient vaporizer is used, it must have adequate airflow to absorb sufficient heat and prevent icing (an electrically heated vaporizer is available for colder climates and the capacity of the vaporizer is directly proportional to the number of fins on the vape; more fins means larger surface area for heat transfer). The vaporizer must be sized correctly to meet the maximum flow rate anticipated by the medical facility.

Setting up tanks: Consider competent civil works and how a tank can be safely installed at the site. LOX tanks are very heavy and require specially designed, reinforced concrete slabs to bear loading. Consider any existing human resources that can be leveraged to manage the facility-based LOX implementation. If there is not an established space for a tank, this might require concrete slabs or other infrastructure-related investments. It is also important to conduct an environmental risk assessment and identify environmental factors such as seismic effects and extreme winds that may affect functioning of VIE systems.

Piping: Costs for piping depending on each facility's existing piping infrastructure (sometimes only a couple wards in a facility are properly piped for oxygen) are necessary. With the increase in supply of LOX from a new tank, piping may need to be made available in additional inpatient wards to ensure access and enhance provider workflows.

Ensuring safety: Proper utilization of VIE systems requires mandatory inspections and continuous maintenance by a licensed expert. If the inspections are missing or something is not working properly, a LOX supplier will not fill the tank. LOX companies will only fill tanks owned externally (by a facility or a different supplier company) if they meet their safety and operational requirements in terms of specifications. Furthermore, they will refuse to fill tanks if maintenance is not up to date. As a result, the ownership model pursued is likely to affect prices and terms/conditions. Ensuring safety reduces the likelihood of hazards and dangers associated with LOX.

Quality assurance[1]: The supplier selection process should also include a quality assurance review. It is critical to ensure that the LOX comes from a trusted/verified LOX supplier that can consistently deliver LOX that meets a stringent regulatory authority's (SRA's) pharmacopeia standards (e.g., United States Pharmacopeia [USP], British Pharmacopeia [BP], European Pharmacopeia [Ph Eur], International Pharmacopeia [Ph. Int], or equivalent local regulations) and is safe and effective for use with patients. Test results and the specification for the LOX are provided on a certificate of analysis (COA) and should be provided to the purchaser of the LOX with every batch; a sample COA should be reviewed as part of the supplier selection process. An air separation unit (ASU) should be approved by an SRA for medical oxygen production, meaning that the manufacturer has had its product dossier and facility reviewed and approved by an SRA.[2] If not SRA approved, facilities manufacturing LOX for medical use should comply with Pharmaceutical Inspection Co-operation Scheme (PIC/s) or WHO current good manufacturing practices (WHO cGMP).[3] If the supplier is not SRA approved for medical oxygen and not manufacturing under GMP, a risk assessment, which includes discussion with the supplier's quality team, should be completed. In addition, all LOX storage tanks must be certified for medical oxygen use both at the site of the ASU and at the hospital. It is advisable to confirm with a supplier that VIEs under consideration:

- Adhere to and bear standards for LOX tanks: API620, API650, EN14620, EN14015, EN ISO14122-1/3 and OSHA 1910.23/24, EIGA/CGA/127/13/E and NFPA 59A.
- Adhere to and bear a "U Stamp" from ASME Boiler and Pressure Vessel Certification standards or bear a CE marking under the EU's Pressure Equipment Directive (PED 2014/68/EU)[4]
- Ensure pressure vessel certification, as well as BS EN 13458 parts 1-3 covering
    1. Fundamental requirements
    2. Design, fabrication, inspection, and testing
    3. Operational requirements
- Are cleaned to [ISO 23208: 2017 for oxygen application]

[1] At a minimum, the manufacturer quality management systems should adhere to ISO 9001:2015 (or latest available version) to ensure consistency and meeting of applicable local regulatory requirements. Preference should be given to manufacturers who adhere to cGMP.

[2] Oxygen is produced by an air separation unit (ASU) through liquefaction of atmospheric air and separation of the oxygen by continuous cryogenic distillation. The oxygen is then removed and stored as a cryogenic liquid.

[3] In addition to PIC/s framework, a helpful set of guidelines could be EIGA's DOC 99/15/Part 1 and DOC/99/15/Part 2: Good Manufacturing Practice Guide Parts 1 & 2 for Medical Gases.

[4] A "U" stamped tank indicates that the tank is built to the latest edition of the American Society of Mechanical Engineers (ASME) code. A CE marking indicates that the tank is built to the EU specifications for pressure equipment.

- **Operations and maintenance**: The tank and vaporizer can operate continuously and passively, and therefore do not need continuous operators. In the absence of operators, a staff member trained on the management of the medical gas pipeline system (MGPS) should be reachable if there is an issue. For the sustainable functioning of the LOX system, regular inspections and preventative maintenance should be conducted as recommended by the manufacturer/supplier. If the tank or vaporizer malfunctions, an expert with specific LOX technical background is needed to troubleshoot and conduct repairs while following proper safety procedures. Having such an expert available will not be a feasible or efficient use of resources for each individual site. Outsourcing maintenance and repair may be a better option for sites that do not have a LOX technician. An adequate stock of spare parts should be kept for maintenance of the VIE system.

Refills: The LOX tank supplier should have a clear procedure for refilling that meets international standards to manage risks. Refills should be included as a budget line item and/or funds allocated to support maintenance and monthly refills.

Note: A power source is required for the following:

- Passive VIE systems: For controls and to power the pump when a truck delivers the product. Some trucks have a diesel-powered generator that they bring to operate the pump.
- Administrative and other support: If you are running a cylinder filling station, consider having an office to process all matters related to operations, as well as reception/processing of orders, management of documentation, and housing for the manifold system.

Step 3: Visit and assess hospitals jointly with a team that includes LOX technical team lead, financial/cost analyst, and technician or engineer experienced in oxygen systems.

Some prioritization may be required in this data collection in anticipation of challenges. For example, the hospital may not track bed turnover rate, so you may choose to collect three months of patient admissions instead and make an estimate. Another example: Hospitals often do not document oxygen consumption and do not have calculated need. Estimates made "off the cuff" during data collection can vary greatly in precision, so these may be skipped if too difficult to collect. Information to be collected includes:

- Location (GPS coordinates)
- Hospital size & number of beds by ward as different wards can consume oxygen at different rates depending on the typical patient.
- Bed occupancy rates
- Flow rates
- Prevalence of hypoxemia cases
- Annual number of outpatient department patients

- Bed turnover rate
- Number of beds with oxygen piping outlets at the bedside
- Number of beds that will require oxygen piping outlets at the bedside
- Public, private, or faith-based facility
- Number of qualified health care workers and technicians in oxygen systems
- Daily oxygen consumption, both at baseline levels and surge levels (while typical deliveries should only account for baseline levels, a maximum purchase amount in line with surge levels due to COVID-19 needs should be written into the contract)
- Estimated annual oxygen consumption/need
- Current oxygen sources (for example, cylinders, manifolds with piping system, oxygen concentrators, PSA plant)
- Availability of oxygen delivery interfaces/devices
- Availability of pulse oximetry
- Existence of equipment inventory and preventative maintenance practices
- Current or planned supply to other facilities (in case of hub-and-spoke considerations)
- Current or potential location of the oxygen tank
- Details on the supply of oxygen to the hospital (e.g., existing contracts, supplier, supply routines). Details on existing production sources (capacity, operational details) and existing supply, which could be in any form (e.g., cylinders), and not just existing LOX supply.
- Obtain cost information, as available, in order to compare costs across delivery modalities

Before setting up LOX infrastructure, evaluate the hospital for the following requirements for the VIE systems:[5]

- Power supply may be considered for filling pumps (three-phase) when there is no pipeline connection in the hospital, monitoring systems, alarms, and other safety features (single-phase). Except for the filling pumps, monitoring systems, alarms, and other safety features, the VIEs do not require electricity to operate.

[5] WHO. Oxygen sources and distribution for COVID-19 treatment centers. Geneva: World Health Organization; 2020. Available from: https://www.who.int/publications/i/item/oxygen-sources-and-distribution-for-covid-19-treatment-centres

- VIE and supportive infrastructure must be within a secure, fenced, well-ventilated area that is free of overhead powerlines and located at a safe distance from other potential sources of ignition, such as diesel generators.
- Parking and smoking must be prohibited.
- The fenced area can only be accessed by appropriate personnel and must be fitted with safety signage prescribed by local and international safety directives.
- Use of and access to specialized tanker trucks designed to carry oxygen in liquid form from the point of production to the point of use.
- A vaporizer, along with a central pipeline distribution system, is required, as are requisite shut-off valves, a pressure-reducing system, safety valves, and flow regulators.
- A second (or even third) vaporizer is recommended to optimize system security.
- Consider a safe distance of the LOX tank installation site from open flames, pits, ducts, openings to underground systems, roads, railways, fuel vent pipes, and storage vessels.

Note any existing infrastructure (e.g., reach of MGPS and number of outlets, vacuum swing adsorption (VSA) and PSA plants' capacity, and number of concentrators and functionality).[6] [7]

Note: *Generally, co-location of LOX and PSA/VSA sources within a facility is not recommended because it is not efficient and may be duplicative; a few examples when this would be done include complementing a significant and documented gap in supply, or where a PSA would be ready for decommissioning or simply nonfunctional. Doing so would require a multitude of operational considerations that add complexity to such a scenario.*

[6] A vacuum swing adsorption (VSA) plant separates air into its two principal constituents, nitrogen and oxygen, using adsorption technology (zeolite sieve beds). The air is compressed via downstream vacuum prior to the separation process. The oxygen is sent to an O_2 compressor and then delivered to point of use as product.

[7] Pressure swing adsorption (PSA) oxygen generating plants are a source of medical-grade oxygen that also separate air into its two principal constituents, nitrogen and oxygen, using adsorption technology (zeolite sieve beds). The air is compressed upstream via a compressor.

During the hospital visits, staff should determine if there are locations suitable for a tank, as well as for truck access, and these visits should ideally be completed with the LOX supplier, or at minimum confirmed with the LOX supplier prior to final selection to ensure the site meets their requirements such as being accessible to their tanker trucks.[8] Depending on regulations, some hospitals in urban areas may not have space for a tank, and residential areas are often off limits for a tanker truck, so reliance on filling stations may be the only option. When prioritizing facilities for LOX support (e.g., during facility visits and afterward) it is important to discuss factors that may affect sustainability after external funding support ends (as relevant), as each facility will have to maintain the costs and operations related to LOX (see below).

Step 4: Start planning for sustainability of VIE systems with every facility and with higher government authorities.

Help government partners (national, subnational, or hospital administrators) estimate the cost to set up and maintain a filling tank for the lifespan of the tank or until it will be decommissioned. Ensure that there is a clear understanding of total costs with some accounting for what might be covered in the near term by donors or other external funds and which costs will roll over to the government's responsibility in the longer term. Facility administration may be able to reallocate existing budget used to purchase oxygen through filled cylinders to LOX or identify other sources for the maintenance budget.

High demand for liquid oxygen and subsequent increased frequency for VIE refills require logistical considerations to ensure uninterrupted supply of medical oxygen and health service. In addition, when meeting or exceeding peak demand — as may occur during a pandemic — vaporizers that convert oxygen from a liquid to gaseous state may require additional monitoring. Higher flow volumes, particularly in hot, humid environments, will cause ice build-up on the vaporizer, which can be mitigated by increasing the vaporizer size, twinning the vaporizer, or de-icing with water or heating. It is important to keep updated inventory of VIE systems, performing scheduled preventative maintenance checks and developing maintenance programs in collaboration with the suppliers. Hospitals should consider signing mid- or long-term service agreements and provide training to in-house technical staff in handling VIE systems. See more in *Table 3. Risk mitigation measures to be considered in the sustainability plans.*

[8] This shall be, at minimum, a 5 meter by 5 meter area, and 8 meters away from any buildings.

Section 2. Checklist for costed plan items

This checklist includes suggested items and considerations for setting up a VIE system.

Table 1. Checklist for costed plan items

<table>
<tr><th>#</th><th>Inputs to be costed</th><th>Considerations</th></tr>
<tr><td colspan="3">1. Storage and vaporization</td></tr>
<tr><td>1.1</td><td>Vacuum-insulated storage tank, vertical and secured on a reinforced concrete plinth, with its safety devices, redundant valves, pressure gauges</td><td>Can be procured by the hospital or leased. Choice of three sizes:
▪ Small (Up to 1-ton tank, ~875 L of liquid oxygen)
▪ Medium (3-, 5-, 10-, and 20-ton tanks)
▪ Large (±25-ton tanks).

Hubs will depend on larger tanks, upwards of 50 tons, which have greater associated costs but are justified if hubs are strategically placed where they can serve a broader distribution network.</td></tr>
<tr><td>1.2</td><td>Vaporization</td><td>Passive vaporizer connected to existing distribution network via pressure regulators

Check if gas can be piped directly to patients through an existing piping system, and the function and quality of piping if a system does exist. If there is no piping, compressed gas cylinders could be considered.

Consider adding the cost for additional piping within a health facility (usually focused on priority wards). The increased supply from a new LOX tank could justify installing more piping and oxygen outlets in additional inpatient wards.</td></tr>
</table>

<table>
<tr><th colspan="3">2. Hub and spoke distribution network</th></tr>
<tr><td>2.1</td><td>Liquid-to-gas cylinder filling station components, including:
Bulk storage tank
Liquid/cryogenic pump
High-pressure vaporizer
Cylinder filling ramp
Cylinders for refilling</td><td>The filling station aspect of this system will require housing.
The pump shall be shielded as a safety precaution.
Cryopumps should be placed in open areas away from public spaces and filling ramps where personnel are actively working. This helps to reduce noise levels and prevent occupational injuries. Filling stations require separate housing for storing cylinders.
Cylinders shall be stored in a covered, secure manner, with full cylinders separate from empty.
Access for delivery/pickup shall be considered in planning the hub site.</td></tr>
<tr><td>2.2</td><td>Supply chain logistics support for hub and spoke model, including:
Computers
Software for order management
Software for planning and managing routing for the cylinders for facilities
Alarm systems</td><td>Vehicles
Fuel
Human resource needs, including recruitment, remuneration, and capacity building of the hospital staff
Assess existing or adopt new software for logistics management support
Filling stations will require alarm systems similar to VIE systems</td></tr>
<tr><th colspan="3">3. Ancillary</th></tr>
<tr><td>3.1</td><td>Ancillary devices, spares, patient delivery interfaces, including:
Distribution manifold, fully automatic change over
Cylinders and ancillary devices for cylinder use (regulators, flowmeters, humidifiers)
Non-heated bubble humidifiers</td><td>Check availability of sufficient ancillary accessories, including pressure regulators and flowmeters to be used with cylinders for bedside use.

Compatibility:
Piping: ensure that flowmeters are compatible with the terminal units installed as part of the distribution system
Cylinders: ensure that regulators are compatible with the cylinders as well as regulators with flowmeters</td></tr>
</table>

4. Operational requirements		
4.1	Tracking and administrative equipment (see under 2.2)	Computer(s), software per facility
4.2	Delivery and installation of equipment	To be discussed with a supplier. Tank volume, tank location, and tanker distribution routing will determine a supplier's cost. One tank at one facility should not be considered in isolation. Installation must include civil work (geotechnical work, preparation to cast slab, site safety, and security [see in 5.1]).
4.3	LOX refill	Refills will be based on the volume, size of the VIE system, and delivery scheduling.
5. Support Infrastructure		
5.1	Security: fencing to secure the site	VIE system to be fenced and only accessible by authorized staff Ensure unobstructed access at all times (no parking) Please note that wherever you are establishing a filling station, the cryopump and other equipment will need to be sheltered (to minimize contact with elements) as well as to minimize noise pollution, especially close to patients.
5.2	Upgrade to infrastructure ▪ Civil works ▪ Piping	Constructing of concrete slabs is required for the installation of the VIE systems. Manifold or cylinder storage rooms may need to be erected for liquid-to-gas filling setups. The existing piping connection needs to be upgraded or newly installed for the delivery of LOX in hospital wards.
5.3	▪ Installation of water and electrical utilities ▪ Installation of 63 Ampco plug required for filling ▪ Consumption of electricity during operation of filling station	Only include these costs if hospital need this. Water is needed for both installation and de-icing. Electrical power is needed for controls as well as for pump operations (filling if no pump with truck and for cryopump at filling station).

6. Technical assistance to expand LOX in facilities		
6.1	TA to negotiate supplier agreement for the specified hospitals	TA to agree on time-bound purchases of medical LOX from major industrial gas manufacturers and/or supporting national or subnational health authorities to set up framework agreements to purchase LOX with own funding. In some cases, an agreement already exists. In other cases, activities should be costed for negotiation of an agreement with the supplier.
6.2	Training on daily operations and safety for at-facility staff	This training is relevant for staff at the facility where the VIE system is established. If you are pursuing a filling station model, include training on safe handling and administration for health staff from all facilities that are recipients of the filling station.
6.3	Cost for maintenance, including: ▪ Training qualified staff in maintenance ▪ Outsourcing maintenance aspects of VIE system through a service level agreement support ▪ Activities to support monitoring and documentation system	Maintenance costs can be part of the sustainability plan.
6.4	Clinical and nonclinical capacity building, if needed	▪ Clinical TA (if needed) to ensure health care workers are trained on safe delivery of oxygen to patients ▪ Nonclinical TA (if needed) to build technical capacity of engineers
6.5	Logistics support around LOX distribution and other optimization of supply chain	ISO trucks that transport LOX are part of a supplier's offering and should stay within their purview.

7. Facility or district-based sustainability plan (Consider both upfront and long-term maintenance costs in each facility)		
7.1	Dedicated and qualified technical staff for maintenance, required every three to six months	Maintenance provider is outsourced to a separate company and is named in a service level agreement (SLA)
7.2	Training costs for reporting and tracking field complaints/errors, communicating recalls, etc.	Equipment in need of significant repair is documented in data book and checked with authorized inspection agency (AIA)[9]
7.3	Quarterly maintenance visits during which third-party AIA uses checks/certifications (adherence to safety and operational directives of LOX vendor)	Records of maintenance activities are kept, especially replaceable and functional test results
7.4	Time-limited engineering support for facility modifications, repairs, and/or adaptations	Consider including in the SLA for long-term maintenance in each facility currently using or planning to receive LOX

[9] Basic maintenance or average repairs do not get documented in the data book. If there are changes, repairs, adjustments, or modifications that in any way affect the original integrity of the tank, these must be incorporated into the data book and all works checked by an AIA. This can be discussed with the tank manufacturer on acquisition. In a lease model, this will be out of facility purview, as the asset will belong to the LOX vendor.

Section 3. Technical considerations for hospitals to set up VIE systems

General requirements of bulk liquid oxygen storage tanks

- Capable of storing liquid oxygen, which is cryogenic in nature at approximately -183°C
- Standard operating pressures of bulk tanks are 16 bar (1.6 MPa, 232 psi); however, some can be as high as 35 bar.
- They are used as storage at point of production, at distribution hubs, or on-site at medical facilities as part of VIE systems.

Fenced cryogenic tank setup on hospital grounds

- Suitable for medical oxygen use
- Material construction complies with the international/national standards
- Installation and commissioning follow proper procedures and protocols that conform to national/international standards

Table 2. cryogenic tank sizing

Size	Volume	Common Use Case	Considerations
Small (“microbulk”)	Up to 1 ton (~875 L of liquid oxygen)	Specially designed concrete slab is not required; they can be placed on smooth, level, paved surface.	Framed and have an affixed vaporization system
Medium	3-, 5-, 10-, and 20-ton tanks*	At-facility medical application	Require a standalone vaporizer and supportive infrastructure (i.e., a slab to ensure stable footing, a fenced enclosure)
Large	25+ ton tanks	Production centers and distribution hubs	

Table 3. Risk Mitigation measures to be considered in the sustainability plan

Risk	Scenario	Mitigative measure(s)
Lack of sustained financing	Default on payments for product delivery	▪ Address need for continued payments prior to investments ▪ Closely monitor consumption, project demands, and plan for expenditures
	Unable to pay for maintenance (if VIE installed by MOH); vendor will cease filling	▪ Address need for continued payments prior to investments
	Unable to pay for staff for safe, continued operations	▪ Acknowledge that dedicated and appropriately trained personnel are required ▪ Address need for continued payments prior to investments
	Underutilization of LOX source (e.g., no distribution)	▪ Plan for additional physical resources such as vehicles, cylinders, tracking and administrative equipment (computer[s], software) ▪ Acknowledge that dedicated and appropriately trained personnel are required ▪ Address need for continued payments prior to investments (power/fuel, staff)
	Safety issues could arise	(Please refer to safety section below)
Only one vendor of LOX	Vendor may have a geographical monopoly, not much room for price negotiation	▪ Work on consolidation of demand and negotiate a volume guarantee while ensuring they continue to provide medical LOX that meets pharmacopeia standards ▪ Look into opening market to other vendors already active in the region

Risk	Scenario	Mitigative measure(s)
Improper equipment sizing	Wastage (O_2 off-gassing or headspace losses)	Size tank based on demand and distance to source/hub
	System freeze-up	Plan distribution system (including vaporizer) to accommodate surge demand. Water supply can support temporary de-icing if needed.
Safety	Missed maintenance	Solicit inspection by LOX provider, document findings and status, and continue on schedule.
	Equipment mishandling	▪ Promote safe practice through frequent trainings and mentorship — conducted, at minimum, once per year ▪ Use restraints (brackets/chains) when cylinders are being filled, transported, or used ▪ Do not allow unauthorized and untrained personnel near equipment
	Oxidized environments/ risk of explosion	▪ Ensure that all staff who have contact with oxygen systems are trained frequently (minimum once per year) ▪ Consider ventilation in all use scenarios
	Transfer of ownership at later date without appropriate transfer of responsibility	▪ Ensure formal transfer of ownership complete with handover of “data book” ▪ Include trainings with equipment experts and specialists in any transfer of ownership agreement ▪ Ensure LOX vendor is aware of ownership
Other risks to consider	▪ 1. Fires, theft, or pilferage ▪ 2. Force majeure or extreme climatic events that could block access to road network and affect LOX resupply schedules ▪ 3. Health workers or labor union strike actions can affect VIE system operations.	▪ Develop a risk management plan specific to the facility. ▪ Identify or develop insurance policies and waivers on these infrastructure investments.

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