



WHO technical consultation on oxygen access scale-up for COVID-19



**World Health
Organization**



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Abbreviations

ACT-A	Access to COVID-19 Tools Accelerator
ARDS	acute respiratory distress syndrome
ASU	air separation unit
AVSU	area valve servicing unit
CSCS	COVID-19 Supply Chain System
EBC	Every Breath Counts
ESFT	Essential Supplies Forecasting Tool
GC	gas chromatography
HeRAMS	Health Resources and Services Availability Monitoring System
HIC	high-income countries
HMIS	health management information system
HPLC	high-pressure liquid chromatography
IP	International Pharmacopeia
LIC	low-income countries
LMIC	low- and middle-income countries
LMIS	logistics management information system
LVA	local valve assembly
MoH	Ministry of Health
NFPA	National Fire Protection Association (United States)
NGO	nongovernmental organization
OEM	original equipment manufacturer
Ph Eur	European Pharmacopoeia
PNFP	private-not-for-profit
PPE	personal protective equipment
PPM	planned preventive maintenance
PSA	pressure swing adsorption
QA	quality assurance
SARA	Service Availability and Readiness Assessment (tool)
SEIR	Susceptible-Exposed-Infected-Recovered
SLA	service level agreement
SPA	Service Provision Assessment (survey)
TA	technical assistance
UMIC	upper middle-income countries
UNICEF SD	United Nations Children's Fund Supply Division
USP	US Pharmacopeia
VIE	vacuum-insulated evaporator
VPSA	vacuum-pressure swing adsorption
VSA	vacuum swing adsorption
WHO	World Health Organization

Introduction

The World Health Organization (WHO) and other agencies and organizations are increasing their capacity to provide technical support to accelerate oxygen scale-up activities at country level, specifically in low- and middle-income countries (LMIC). To support this, WHO convened a consultation, held over four meetings, with groups that have proven experience implementing oxygen scale-up activities.

Oxygen is an essential medicine (1) used to care for patients at all levels of the health care system, including in surgery, trauma and maternal and child care. The COVID-19 pandemic has highlighted the need for and gaps in oxygen globally. At the launch of the consultation (16 October 2020), there were over 39 million confirmed cases and over 1 million deaths from COVID-19.¹ Severe pneumonia from COVID-19 has resulted in a surge in oxygen demand globally.

WHO recognizes the urgent need for a global effort to scale up the availability, accessibility and affordability of quality medical oxygen. Since the onset of the COVID-19 pandemic, the global COVID-19 Supply Chain System (CSCS) Biomedical Consortium has focused on responding to these needs through a comprehensive, multidisciplinary approach to forecasting, technical specifications, quality assurance (QA), procurement and distribution of oxygen supplies.

However, even before the COVID-19 pandemic, there were reports that in the majority of LMIC, there was a struggle to access reliable medical oxygen. For example, across sub-Saharan Africa 31% of facilities have interrupted oxygen availability, and 25% have no availability at all (2, 3). It was also reported that the availability of oxygen for medical use is the primary rate-limiting factor for treatment once a diagnosis has been made (4). Specific barriers to availability may include: high cost, lack of funding for long-term operations, lack of trained human resources, weak supply chains and non-continuous and unreliable power supply access (5). Medical oxygen has often been omitted in holistic planning efforts while strengthening health systems, and technical guidance related to installation and maintenance of oxygen systems is limited.

This consultation identified gaps and further actions to scale up access to medical oxygen. The consultation facilitated the understanding of the critical challenges of oxygen sources and distribution systems and highlighted the need for operational guidance to scale up, in an efficient, transparent and sustainable manner in the short term, for the COVID-19 surge, but with a long-term vision beyond the current emergency response.

This consultation was by invitation only and subject to the eligibility criteria of implementation entities with a known track record of technical expertise working at country level in oxygen scale-up projects, involving intergovernmental organizations, including the United Nations (UN) and its specialized agencies, nongovernmental organizations (NGOs), academic institutions and philanthropic foundations.

¹ WHO Weekly operational update on COVID-19, 16 October 2020 (<https://www.who.int/publications/m/item/weekly-update-on-covid-19---16-october-2020>).

Methods

The global CSCS convened in April 2020 to confirm the Biomedical Consortium as part of global actions to respond to the declared COVID-19 pandemic. The Biomedical Consortium gathers UN agencies and other partners involved in the funding, procurement and distribution of priority biomedical equipment. At weekly meetings, partners raised increasing awareness about the lack of sustainable oxygen systems needed for the clinical treatment for COVID-19 globally, especially in LMIC. Moreover, the size of the emergency response demanded at-scale solutions.

WHO organized this technical consultation to outline the challenges, the gap and propose a way forward to increase access. Meetings were held on 16 and 30 October, and 13 and 27 November 2020. The following themes were discussed:

1. Estimation of need-gap for oxygen in different geographies.
2. Pressure swing adsorption (PSA) oxygen generator plants – technical queries and challenges for implementation.
3. Oxygen distribution systems – technical queries and challenges for implementation.
4. Mapping and data platforms to facilitate the monitoring of information and the construction of baseline data related to oxygen scale-up activities.

The selection of participant entities was based on their technical expertise of the subject matter. Invitations to the participants, including terms of reference, were sent prior the series of consultations. Each entity appointed representatives to participate in the discussions (see Annex 2). The necessary measures to avoid conflicts of interest and to follow the Framework of Engagement with Non-State Actors rules were assessed by the WHO technical unit in consultation with the legal unit, and no conflicts were identified. Appropriate WHO confidentiality undertakings were signed and submitted to WHO by all participating entities. Two independent experts served as co-chairs to moderate the discussions. Their declarations of interests were also assessed by the technical unit and no conflicts were encountered.

At each meeting, the technical unit of WHO presented the background content and key queries for discussion. Co-chairs moderated the discussion. This report captures the deliberations, conclusions and recommendations that resulted from the four meetings.

MEETING 1: ESTIMATING NEED-GAP FOR OXYGEN (16 October 2020)

Objectives of first meeting

Given the urgent need by stakeholders to understand, at a high level, the gaps in medical oxygen availability and accessibility in LMIC, the objectives of this meeting were to:

- Provide background on medical oxygen as it relates to clinical care for COVID-19.
- Discuss technical aspects that inform need-gap analysis for oxygen scale-up.
- Achieve common understanding on forecasting oxygen scale-up at the global level.

Entities were invited to provide feedback by rating, in order of importance and proposed methodology of the two baseline assumptions suggested to provide the high-level estimate for global COVID-19 oxygen need-gap. The rapid survey was answered by 5 of the 10 participating entities.

Background to first meeting

Scale up access to medical oxygen

- Scale-up intends to promote equitable access to quality oxygen by reaching more patients, at the right time and in a more sustainable way.
- Scale-up requires a multidisciplinary effort that requires stakeholders to develop strategic planning, tools, advocacy and technical support to achieve the intended outcome.
- Scale-up needs to be integrated into longer term sustainability, requiring implementation programmes, resource allocation, local technical/engineering and medical capacity building, task shifting and, in some situations, cultural change. It could also have potential links to other programmes, such as sustainable energy solutions in health facilities, adapted to different contexts, and oxygen and non-invasive respiratory support.

To scale up oxygen, the overall need must be quantified and coupled with an understanding of existing capacity to determine the need-gap.

Discussion on approach and assumptions in estimating total oxygen need-gap

Medical oxygen need-gap analysis

- There continues to be an urgent need for high-level quantification of the medical oxygen need-gap for advocacy, financing and strategic purposes. This is also the case regarding planning for diagnostics and personal protective equipment (PPE).
- The medical oxygen need-gap is understood as the forecasted demand minus the baseline supply capacity.

Need-gap = Estimated demand – Existing capacity

- WHO's COVID-19 Essential Supplies Forecasting Tool (ESFT) v.4² can quantify and project oxygen demand as it relates to the COVID-19 surge at the national level in m³/day; as well as demand for diagnostics and PPE.

² WHO COVID-19 ESFT version 4 (<https://www.who.int/publications/i/item/WHO-2019-nCoV-Tools-Essential-forecasting-2021-1>).

- WHO's COVID-19 ESFT v.4 calculation pathway is as follows (see Fig. 1).

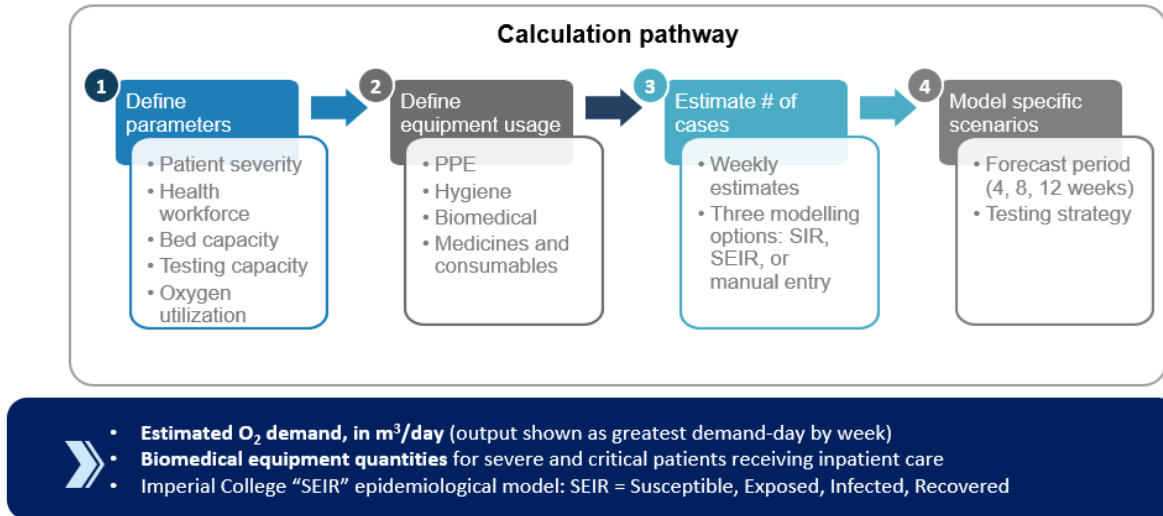


Fig. 1. WHO ESFT v.4 calculation pathway

- Input flow rates for oxygen demand are in line with averages for severe and critical patients receiving inpatient care according to WHO clinical guidelines (6, 7).
 - 75% will be severe, hospitalized for 7 days, and receiving 10 L/min on average.
 - 25% will be critical, hospitalized for 14 days, and receiving 30 L/min on average.
- The estimate of cases is made using data outputs from the Susceptible-Exposed-Infected-Recovered (SEIR) epidemiological model from Imperial College London, projected over a set period of time. The model takes the effective reproductive number on the date it is run and forecasts that over a set number of weeks. In order to allow a country to modify their “status quo” outcome there is an option to indicate if they will be strengthening or relaxing measures, showing a 50% reduction or a 50% increase in cases respectively over the set period of time.
- Presented output (see Table 1) is the aggregated oxygen demand over 138 LMIC³ according to three scenarios: strengthened, status quo and relaxed, and in 4-, 8- and 12-week intervals (current as of 13 October 2020).

³ It is assumed that all high-income countries (HIC) will have mechanisms and/or resources to manage the quantification of and address the need for medical oxygen.

Table 1. Estimating daily oxygen requirements for 138 LMIC using WHO ESFT v.4

	O ₂ demand estimate, m ³ (max. day)		
	Strengthened	Status quo	Relaxed
4-weeks	4 068 772	4 884 188	10 130 207
8-weeks	5 985 774	7 656 029	34 880 669
12-weeks	5 985 774	8 133 104	44 111 535

- These estimates were presented as an approach for high-level forecasting bearing in mind the following:
 - All other non-COVID-19 hypoxaemia oxygen demand (including seasonal) is not calculated in ESFT.
 - The COVID-19 pandemic is still evolving, and country-level response strategies are therefore adapting and responding.
- Demand estimates will be affected by transmission rates, public health interventions, availability and efficacy of therapeutics, and, when available, vaccines.
 - Real-time epidemiologic data are included with the aim of taking into account some of these variables. In addition, countries have the opportunity to choose a demand scenario in line with public health interventions.
 - The impact of vaccines on the proportion of patients with severe disease remains to be elucidated.
 - Validation of ESFT estimates is a priority.
- WHO acknowledges that there are other tools⁴ for the quantification of oxygen demand with greater granularity for application at national, subnational and facility level. These models may have different applications apart from forecasting supply needs, such as sizing oxygen sources or calculating oxygen demand at the time.

Limitations of approach

- COVID-19 oxygen demand estimates seem high, potentially because of epidemiological assumptions.
- Anecdotal experience indicates that late care-seeking behaviour results in a higher percentage of patients arriving in a more critical state (more severe hypoxaemia), which might not be captured. If this is indeed the case, more patients may progress to critical condition, and daily needs may be higher. However, they may also have higher mortality so the duration of treatment may be shorter.
- Total quantified demand is unlikely to be met for the following reasons:
 - high and long-term investments needed

⁴ Examples include:

PATH: <https://www.path.org/resources/quantification-and-costing-tools/>

UNICEF: <https://www.unicef.org/innovation/documents/oxygen-system-planning-tool>

Open Critical Care: <https://opencriticalcare.org/oxygen-supply-demand-calculator/>

- high volume of supplies forecasted
- existing capacity of secondary and tertiary facilities (where bulk of treatment most likely will take place) will be unable to absorb projected surge
- health care provision status quo could affect use uptake as oxygen has often been treated as a scarce commodity, and rationing could be seen even after availability increases.
- Aggregated quantification for oxygen demand cannot help decision-makers at country level forecast the supply mix solutions at different levels of care.
- Quantified need with this approach is over and above a pre-existing need-gap (compared with the non-COVID-19 hypoxaemia gap).

Suggestions

No consensus was reached on the approach, but the following suggestions were made:

As COVID-19 has not proliferated in LMIC in the same way as in HIC, the approach should:

- Focus estimates on the longer term, considering continuous oxygen demand across all needs, across all levels of the health system.
- Consider the pre-existing need-gap of all other hypoxaemia-causing illness in addition to addressing potential surge requirements for COVID-19 advanced care needs.
- Consider potential for use of demand estimates from COVID-19 ESFT as a high-level proxy for existing demand in LMIC from other hypoxaemia-causing morbidities, acknowledging that this need-gap will have to be assessed at national or subnational level when planning for implementation.

Existing capacity in LMIC

Proposed approaches for estimating existing capacity in LMIC

- There are not enough baseline data about existing capacity at country level. Therefore, it is challenging to quantify the availability and accessibility for oxygen production and supply.
- Three approaches were presented to estimate the existing capacity for oxygen production and possible supply mix solutions in LMIC countries (see Table 2).
- The overall assumption in the three approaches is that patients in LMIC do not have guaranteed, continuous access to medical oxygen, even when existing oxygen production capacity is fully utilized.

Table 2. Baseline assumptions on availability and accessibility of oxygen in LMIC

Existing capacity	CSCS ⁵	WHO ACT-A ⁶	PATH/EBC ⁷
LIC ^a	5–10%	0%	20%
LMIC	25%	20%	40%
UMIC ^b	50–75%	40%	60%

Notes: ^a For CSCS, low-income countries (LIC) represent a range, including those classified as “fragile and conflict states”, the latter estimated as having lower availability/accessibility; ^b For CSCS, upper middle-income countries (UMIC) are a range, with small island UMIC as a subcategory estimated as having lower availability/accessibility.

Limitations of presented approaches

- All approaches lack baseline data.
- Pre-existing gaps that could impede oxygen scale-up have not been considered, such as lack of availability of related equipment, ancillary devices and reliable power supply – all needed for continuous oxygen delivery.

Suggestions

No consensus was reached on the approach. However, the following suggestions were made:

- Collect data, country by country, and collate to propose a range of existing capacity. Assessment should be done in a holistic and comprehensive manner, considering different factors along the cycle starting from the accessibility of oxygen sources up to the capacity to deliver oxygen to the patient.⁸
- In reality, the existing capacity at country level is also related to the adsorptive capacity of their health systems. This needs to be considered for strategic planning.

Oxygen supply mix solutions in LMIC

Proposed approach for oxygen supply mix solutions in LMIC

Two approaches (see Table 3) were presented to evaluate the consequences of supply mix assumptions at a high level. The CSCS approach was not considered here. The two main differences between the considered approaches are that the ACT-A approach proposed varying supply mix by level of care; whereas the PATH/EBC approach opted not to explore this level of granularity.⁹

⁵ COVID-19 Supply Chain System (CSCS) formed to respond to the current pandemic.

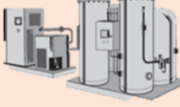


⁶ WHO/Access to COVID-19 Tools Accelerator (ACT-A): Effort done for costing global oxygen needs.

⁷ PATH/Every Breath Counts (EBC): *Estimating the cost of oxygen need in LMICs: oxygen cost calculations to meet the daily increase in COVID-19 cases*, 22 September 2020, shared with WHO, included rough assumptions on existing capacity. In the absence of quality data on access, assumptions were developed specifically for a cost modelling exercise led by PATH and EBC. The assumptions are not meant as standalone indicators of existing capacity in LMIC.

⁸ Biomedical equipment for COVID-19 case management: inventory tool: interim guidance (<https://www.who.int/publications/i/item/WHO-2019-nCov-biomedical-equipment-inventory-2020.1>).

⁹ Note: PATH/EBC baseline assumptions were developed as part of a broader cost estimation exercise; they do not reflect the reality of decision-making in many countries and were not meant as standalone equipment recommendations for filling oxygen needs. This type of estimation should be done in direct consultation with key decision-makers on a country-by-country basis.

Table 3. Baseline assumptions of oxygen supply mix solutions in LMIC¹⁰

		Oxygen Source →	 PSA Oxygen Plant	 Oxygen conc., 10 LPM (0.6 m ³ /hr)	 Oxygen Cylinder, 7 m ³
WHO / ACT-A	Tertiary hospitals		70% (3 sizes)	10%	20%
	District hospitals		60%	20%	20%
	Health center		0	60%	40%
PATH/EBC	Global supply mix		40% (1 size)	20%	40%

Limitations of presented approaches

- Oxygen supply mixes are context specific (even geographical distributions within a country may vary independent of the level of care).
- These models do not appear to consider referral and safe transport of patients who require oxygen therapy, which is a priority in COVID-19 contexts and beyond COVID-19.
- Availability of funds at country level comes in phases. Thus, decision-makers often secure supply based on what is fiscally feasible.
- If the supply mix is to address the need-gap indicated by the demand estimate, then the focus needs to be on where treatment is provided – most likely at secondary and tertiary facilities. Health centres and smaller district hospitals would not need product mix assumptions.
- There are many different contextual nuances that make it impossible to compare the operational requirements and models for each source at scale (PSA or liquid) versus bedside oxygen concentrators.

Noted clarifications

- Cylinders are not a “source”. Cylinders come from an at-scale source, either PSA or liquid.
- PSA onsite could be interchangeable with a bulk tank, if this is a feasible option.
- In order for a PSA to be the direct source, there must be a direct pipe to the bedside of the patient, which is not common in LMIC.
- Assumptions are being made to arrive at global estimates for the sake of advocacy or for estimating *potential costs*, but not as prescribing targets that countries should be aiming to meet.

Suggestions

No consensus was reached on the approach. However, the following suggestions were made:

- Even if the approach of different solutions for different types of facilities is based on adsorptive capacity of facilities (that the means to use each equipment are considered, including proper

¹⁰ Assumptions are being made to arrive at global estimates for the sake of advocacy or for estimating *potential costs*, but not as prescribing targets that countries should be aiming to meet.

site, energy supply, maintenance staff, clinical staff, etc.), it is not possible to systematically deliver this type of oxygen mix due to logistic constraints.

- Broader product mix considerations may address how many patients are going to be treated in each level of care and at which flow rate.
- There are well known bottlenecks for the manufacturing and supply of PSA plants in terms of timelines that need to be considered for emergency readiness and response plans.
- Place an emphasis on securing resources for long-term operations for whichever model of supply mix is proposed. All biomedical equipment sourced requires long-term maintenance, as well as training for clinical and technical staff, which has cost implications.

Other impacts on oxygen scale-up

Available equipment and clinical care

- Limitations in care because of product availability:
 - In the context of the current pandemic, bedside oxygen concentrators have proved a more practical solution – not only for remote areas but in all levels of care – from an economic and timeliness perspective. However, they may not be suitable for all health facilities, as they require a consistent/reliable source of electricity, and they are not appropriate when high-pressure or high flows of oxygen are needed to treat patients. Additionally, astronomical numbers of bedside concentrators would be required to produce the volume of oxygen needed, especially for secondary and tertiary facilities.
 - Upscaling the decentralized oxygen sources may include bedside concentrators of 20–30 L/min. Still, the questions remain as to whether decentralized oxygen sources have higher costs over time and if they are pervasive in the market.
 - There is limited availability of (and research on) alternative air entrainment devices at different levels of care.
- Anecdotal findings shared included:
 - Piped systems may be a significant factor in improving oxygen therapy.
 - Patient treatment is commonly governed by availability of oxygen delivery devices at the level of care where the patient is treated rather than clinical indication. Thus, flows delivered might not reflect flows needed.

Cylinder-specific challenges

- Cylinders also bring other types of challenges related to safety management, maintenance, and distribution.
- High cost of the pressurized oxygen cylinders when supplied by third parties is a critical barrier for oxygen access.

Facility-level needs (including energy)

- The lack of sustainable energy solutions for health facilities implies the efficiency of the systems installed is not 100%. And in many cases, this is due to a lack of power supply.

Lack of knowledge and information

- Accessories that are of good quality and affordable and required for oxygen delivery (e.g. pressure regulators and flowmeters, humidifiers) can be difficult to procure in local markets. Also, customs clearance can present a barrier for some standalone goods. This emphasizes the importance of comprehensive solution planning and packaging.
- An overlooked barrier to scaling up can be lack of provider knowledge on oxygen therapy.
- Clinical training is required to ensure use of oxygen commensurate with clinical indications.

Conclusions

Large-scale needs require large-scale solutions. Medical oxygen scale-up requires a multidisciplinary approach from various stakeholders, based on context-specific assessments and situational analyses.

In this meeting, an approach to estimating high-level oxygen demand for LMIC, based on the COVID-19 ESFT, alongside a set of baseline assumptions, was proposed. Consensus was not reached, largely due to the approach not reflecting the specific and collective realities of the participating entities.

However, the COVID-19 ESFT provides a structured calculation pathway, and its outputs could be used as a starting point for need estimation. If the assumption is taken that COVID-19 projected oxygen demand is greater than the pre-existing need-gap, it is possible that even if only a percentage of this estimated demand is addressed, it will implicitly tackle part of the existing gap. Limitations in the granularity of this approach were acknowledged. Additionally, if another forecasting tool is to be used, there should be a focus on long-term holistic understanding of the oxygen need-gap across all levels of the health system, including peripheral and rural facilities. Estimated need-gap and costing exercises should include all aspects of a comprehensive operational model to ensure the oxygen supply will continuously reach patients, and include infrastructure, power supply, human resources, related medical devices for distribution and delivery of oxygen, etc.

On the other hand, while there was broad agreement that baseline assumptions presented to date are not substantiated by the data, this technical group recognized the urgent need to collect these data collectively and systematically to better inform decision-makers at different levels to directly strengthen understanding of the need-gap, but also to further advocacy efforts to increase access to appropriate oxygen systems, especially for LMIC. The group agreed to continue to report on the use of assessment tools and the technical constraints relating to oxygen systems being unable to provide continuous oxygen supplies.

The momentum on oxygen scale-up, both globally and at country level, as a response to the current pandemic, needs to be harnessed and transferred to ensure that response strategies strengthen the health system to work towards closing existing need-gaps in a sustainable manner.

Areas for further action

1. To collect systematic data on the following:



- a) oxygen flow rates and use of oxygen delivery devices to further validate assumptions for the COVID-19 ESFT v.4;
 - b) existing capacity, associated supply mix solutions, and on the constraints affecting the oxygen systems (production, distribution and delivery), country by country.
2. To explore the use of other oxygen planning tools to estimate oxygen demand for the purpose of supporting informed and strategic decision-making around oxygen scale-up.
 3. To complete any high-level exercises, we must advocate for a multidisciplinary approach (full wrap-around solution requires more than just oxygen sources).

MEETING 2: PSA TECHNICAL QUERIES (30 October 2020)

Objectives of second meeting

PSA oxygen generation plants have been found to be a suitable at-scale solution for oxygen production. The main objective of this meeting was to leverage the empirical knowledge from all participating entities to identify and understand technical and operational elements that need to be considered in implementing PSA plants for planning, procurement, installation, training and maintenance to ensure that PSA plants operate efficiently and effectively, optimizing production of medical oxygen over the course of their life cycle.

The consultation was documented, showcasing all inputs and points of view regarding key technical and operational challenges of PSA oxygen plants. The outcome of this meeting helped to shape the contents of an interim operational guidance document designed to broadly build up technical capacity for a sustainable implementation of PSA oxygen plants (see Annex 3).

Background to second meeting

Oxygen sources

Medical oxygen is generated through air separation units (ASU): cryogenic fractional distillation (“liquid”) and PSA. Derivatives of PSA, known as vacuum swing adsorption (VSA) and a hybrid vacuum-pressure swing adsorption (VPSA), have been commercialized in the last decade. Production capacity, operational requirements and running costs are different for the different sources.

Liquid oxygen is always produced offsite for reasons of volume and safety and is typically third-party owned and operated. Liquid oxygen production and distribution, along with the VSA and VPSA technologies, are out of the scope for this meeting.

PSA technologies are either bedside oxygen concentrators or larger oxygen generating plants. PSA plants can be located onsite/offsite; connected to filling manifolds/direct piping/both; leased/owned; and operated under various models (e.g. “full fee for service”, “payment for supply availability”, among others). Most of the group dialogue focused on publicly owned/operated PSA plants, assuming they are located at health facilities and may, or may not, distribute oxygen to surrounding health facilities. While there are advantages to this degree of autonomy when managing the oxygen production, unless resource commitment and allocation are made for continuous and long-term operations, owners will face the risk of underused or poorly maintained systems or delivering oxygen of inadequate quality.

Solutions for oxygen supply should be strategically chosen according to the specific context: typically, a mix of various types of sources. Taking a holistic approach to implement an oxygen supply solution will ensure sustainability of operations. Apart from the oxygen source itself, factors to be considered are, for example: related medical devices (e.g. delivery interface, non-invasive ventilation/invasive ventilation); equipment for distribution (e.g. cylinders, piping); supportive infrastructure; continuous and reliable power supply; and clinical and maintenance personnel.

Two critical gaps have been underscored and exacerbated by the COVID-19 pandemic and surge in medical oxygen demand: insufficient availability and accessibility to adequate supply of medical oxygen in many LMIC; and lack of publicly available operational guidance for at-scale oxygen solutions, including PSA generation plants.

PSA plant value chain (life cycle)

The value chain is a step-by-step concept depicting the life cycle of a product from inception up to when it delivers the intended outcome (see Fig. 2).

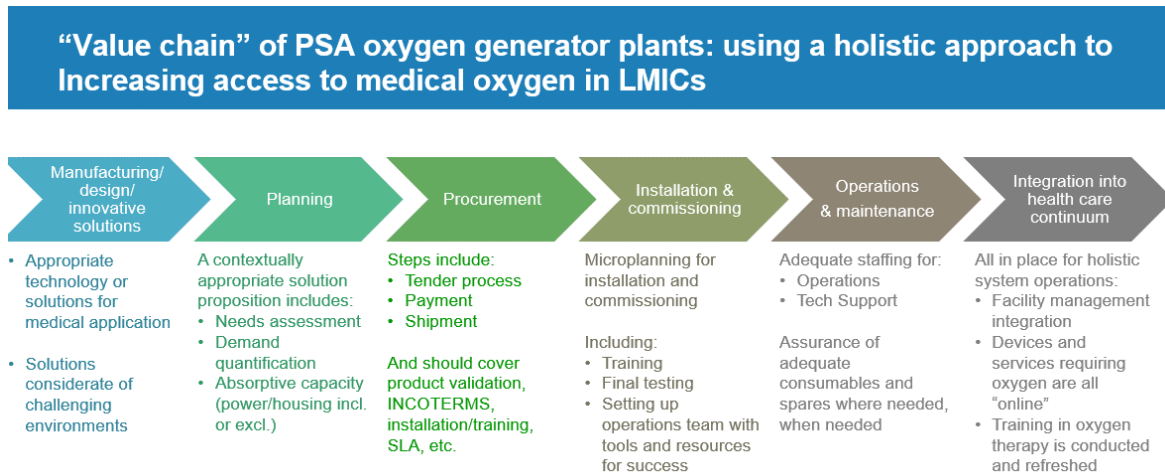


Fig. 2. Value chain of a PSA oxygen generator plants

Careful assessment and planning at each step along the value chain will help to ensure longer term sustainability of a PSA plant, and ultimately, the quality of the oxygen delivered to the patient. There are known challenges in this process, related to technical, operational, logistical and financial aspects that decision-makers consider when choosing PSAs as an at-scale solution. Structured discussion from this meeting targeted some of the technical and operational issues with the intent to explore best practices to support successful management of this oxygen source.

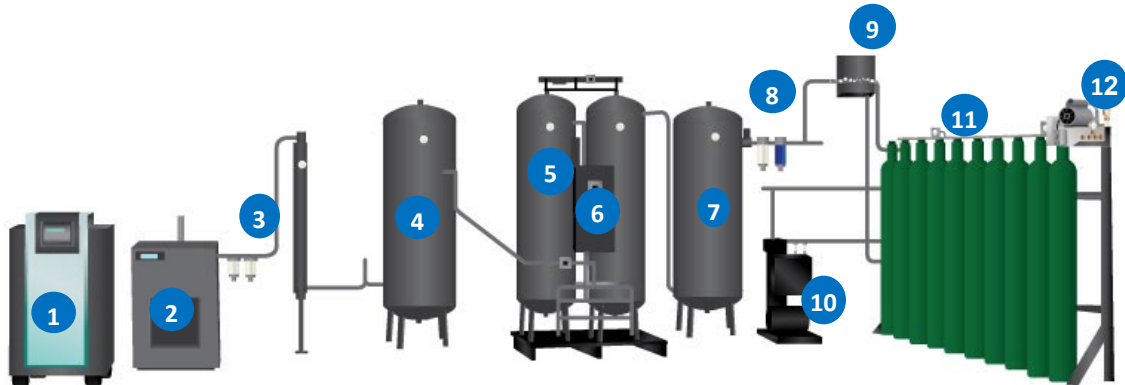
PSA plant configuration overview

An oxygen generation system can be split into three discrete phases:

- supply and reserve
- distribution (either by piped network or cylinders intra- or interfacility)
- delivery to patient (after regulation and conditioning).

PSA plants are an assembly of different original equipment manufacturer (OEM) components, consisting of up to 11 main parts, depending on the manufacturer and configuration (see Fig. 3). PSA plants themselves have the potential for production capacity of 2–200 Nm³/hr.

WHO has published *Technical specifications for pressure swing adsorption (PSA) oxygen plants* with the minimum requirements of certifications for safety and quality, and considerations for warranty and service level agreements (SLA) (8).



1 Air compressor	4 Compressed air tank	7 Product/buffer tank	10 Booster compressor
2 Refrigeration/air dryer	5 PSA – O ₂ generator	8 Bacteria filter	11 Cylinder filling ramp
3 Filtration assembly	6 Control panel	9 Oxygen sensor	12 Vacuum pump

Fig. 3. PSA oxygen generation plant components

The plants can be configured in different ways (e.g. single, duplex, multiplex) to satisfy the oxygen demand required, and they may or may not have an add-on option of a booster compressor with a high-pressure gas cylinder filling ramp. As with many other types of biomedical equipment, operation of these plants requires continuous and reliable power supply, planned preventive maintenance (PPM) programmes and responsive systems for corrective maintenance.

Identified common operational challenges

1. Efficiency of the system is directly affected by poorly sized and configured plants (including inadequate size compressor and refrigerant dryer, lack of in-built redundancy and inappropriately designed plant housing). This results in unnecessary operational overheads or complete abandonment of plants.
2. Certain operating environments can cause premature damage to the system. Hot and/or humid climates and dust can have an impact on production capacity by either damaging or rapidly ageing the filtration system and sieve beds.
3. There is a lack of publicly available technical guidance for system operations. For example, a drop in either output capacity or product purity during daily operations requires immediate troubleshooting by trained operations and maintenance personnel.
4. There is lack of generic technical guidance for preventive and curative maintenance. Clear routines for PPM can be perceived as complicated as there are product-specific nuances. Consideration of this aspect needs to be made during the planning and procurement phases to ensure adequate budget for requisite spares, and adequate contact time and a support structure for knowledge transfer. This training of staff is key to improving access and availability, and, ultimately, integration into the health care continuum step of the value chain (9).
5. Requirements for a functional SLA are not clearly defined, and if/when an end-user can financially sustain an SLA, the lack of clarity and precision in agreements often results in end-

- user dissatisfaction. Remote, unstable, or high-security contexts add a challenge to SLA commitment on the vendor's part.
6. There is lack of comprehensive quality standards for the system post-installation: no post-commissioning third-party testing guidelines, no indication of frequency of testing, and no homologized standards on oxygen purity and remaining impurities. Further, some national pharmacopoeias have omitted the inclusion of medical oxygen generated by PSA/VSA systems, leading to confusion about the use of these oxygen sources for medical applications.
 7. Although there are different guidelines about safe operations of filling ramps (filling manifolds), the potential for harm to technical and medical personnel is often overlooked, and improvements for mitigation measures are necessary.

Summary on deliberations about PSA equipment technical queries

Air compressors

Site altitude is an important factor when sizing the air compressor (Fig. 3, no. 1) to ensure a plant's rated output capacity is realized.

In general, air compressors function by drawing in atmospheric air at fixed volumes which is then compressed. As the elevation above sea level increases, atmospheric air pressure decreases, which means ambient air becomes less dense – *the molecules are less tightly packed*. Thus, with the same volume of intake, there are fewer molecules of air to compress, and so less air will be pushed through the next phase of the system. Table 4 illustrates the rate of reduction of compressor output as it relates to the decrease in air density.

Table 4. Air compressor performance at altitude (10)

Altitude above sea level		Atmospheric pressure		Approximate reduction of air density and compressor output
meters	feet	kPa	psi	
0	0	101.3	14.7	0%
305	1000	97.9	14.2	4%
610	2000	93.7	13.6	8%
914	3000	90.3	13.1	12%
1219	4000	86.9	12.6	17%
1524	5000	83.4	12.1	21%
1829	6000	80.6	11.7	26%
2134	7000	77.2	11.2	31%
2438	8000	74.4	10.8	36%

Note: Change of temperature often realized with change in altitude is not factored into this representation.

This is an example of a critical component in system design and configuration and would typically be one aspect of a more complex set of criteria that will affect the efficiency of operations. It is imperative that environmental details – elevation, temperature, humidity – are captured, and that the buyer actively informs to this effect in the tender process so that the manufacturer is adequately informed to make an appropriate offer. Pre-emptive stocking/advance procurement could present an added set of challenges if the final site is unknown; every 300 m or so gradation above sea level will have an impact on output capacity of the air compressor, and therefore on the overall system. The possibility of site reallocation of a PSA will be dependent on the design of this component, among other factors, like the structural requirements of the target unit.

Filtration assembly

The filtration assembly (Fig. 3, no. 3) is a composite component and varies depending on the manufacturer. The WHO technical specifications for PSA plants generating oxygen with 93%±3% of purity, indicate the following:

- pre-filter (> 5 micron)
- coalescing filter (0.01 micron)
- coal filter (coal tower, alternatively activated carbon filter), as applicable.

While the ultimate objective is quality related – product purity and continuity thereof – there is lack of clarity with respect to components mandated for approval or marking of stringent regulatory authorities. There are various types and configurations of a filtration assembly, and this information will have to be further explored with manufacturers.

PSA sizing (total Nm³/hr) and configuration, including backup supply

Understanding the oxygen need-gap and the absorptive capacity from each targeted health facility is essential information for sizing and configuring PSA plants.

While there is no straightforward approach to PSA plant sizing and configuration for the primary source, the following are some critical technical criteria to consider for decision-making within a broader framework:

- quantification of demand:
 - average flow rates per ward for different level hospitals
 - hypoxaemia prevalence by ward
 - bed occupancy
 - extreme treatment needs (e.g. COVID-19 surge);
- additional sources of oxygen to be considered in the supply mix;
- the hospital layout, for example, if the wards or departments have individual buildings, whether there is the possibility of direct piping to all, or whether piping some wards with a manifold of cylinders, or if cylinders will be used bedside;
- out-of-facility need (if plant operates as a centralized source for many other facilities), then demand quantification for the catchment is the aggregation of individual facility demand as described above and should take into consideration additional requirements for equipment to accommodate for transportation and buffer capacity.

Consideration must also be given to operational requirements. Ideally, plants are sized assuming full-time operations (24 hours/day, 7 days/week). However, scheduled and unscheduled breaks in production may happen. It is important to ensure that resources are planned out accordingly, such as continuous power supply, adequate spare parts and shift-work human resources for operations.

Planning for security of supply is akin to a safety net in oxygen therapy that should not be seen as a luxury, but rather essential. From one perspective, redundant systems have a higher up-front cost implication, may add constraints to the already existing challenges about continuous and reliable power supply for operations or require robust supply chain for assurance of timely arrival of spares parts and even add challenges about the filling and storage of cylinders. However, the investment will provide assurance of continuity of supply. When planning backup systems, options need to be context- and need-driven. In addition to redundant systems, other options include cylinders sourced from a third-party vendor and bedside concentrators.

Finally, criteria to be considered with respect to single versus multiplex plant configurations include expected fluctuations in demand (seasonal); flexibility required for performing maintenance tasks; foreseen future reallocation; and opportunity to reduce the risk of relying on a single configuration.

Control panel

Very often, suppliers include software from a third-party developer in the control panel. Currently, some of this software can allow for remote monitoring from a central unit or even from the manufacturing site. It may be that the software requires licence updates and, consequently, instead of being an advantage in LMIC, it could represent a drawback of extra cost and complexity engaging with overseas OEMs of the software.

From a few shared experiences, simplifying systems and minimizing automation may enable more autonomous operations. Therefore, even if considering remote monitoring as a tool for continuous support of the end-user, both feasibility and cost-effectiveness need to be determined prior to investment. Further investigation of pros and drawbacks of remote monitoring and its applicability in LMIC merit attention.

Oxygen purity monitoring

PSA plants produce oxygen $93\pm 3\%$ from ambient air; the manufacturers must provide clear terms and certificates on how this is quantified and qualified. There are two distinct aspects related to purity monitoring: the purity of oxygen itself and the remaining impurities in the product stream. The European Pharmacopoeia (Ph Eur) and the US Pharmacopeia (USP) are the existing monographs for Oxygen 93; both indicate product purity requirements. With respect to the impurities, the two pharmacopoeias have different lists of impurities – Ph Eur lists seven (7), and USP lists three (3) – but neither give any indication with regard to frequency of testing (11). The International Pharmacopoeia (IP) is currently working to include oxygen generated using PSA/VSA technologies for medical applications (12).

On the other hand, without clear guidance on frequency and methods for routine testing, as well as appropriate tools (e.g. certified oxygen analysers), there is concern that contaminants in the output of the system can go undetected and can be widespread within the distribution system (either piping or cylinders filled) reaching the patients, and potentially affecting them.

Booster compressors

In most health facilities in LMIC, even if there is a piping system, is still indispensable to have booster compressors and filling manifolds to fill cylinders that serve as backup supply. Booster compressors are a common point of failure in PSA operations when not well maintained. As they work with high pressure (raising the pressure of oxygen from ~6 bar to < 150 bar), they require a stringent maintenance regime that normally should be taught by the vendor.

Additional critical challenges

- There are few well-known manufacturers that meet requirements for medical use (strictly Teflon fittings and oil-free technologies). Historically, the primary market for booster compressor manufactures has been industry. The perceived lack of competition has resulted in reliance on two prominent vendors.
- The above circumstance prolongs manufacturing lead times, estimated at 6 to 8 weeks minimum, and can be a constraint for emergency response.

- The boosters are a significant cost driver in comparison with the rest of the PSA components.

Cylinder filling

There are no standardized quality assurance and quality control processes for emptying cylinders (e.g. purge/vacuum, hydrostatic testing). When cylinders arrive at the filling station empty, they must be purged/vacuumed of any remaining content to minimize potential cross-contamination.

Failure of cylinders themselves (i.e. a crack or a rupture) is very rare. The primary concerns remain about contamination and standard operating procedures for filling, handling and management.

Conclusions

There are different technical requirements for the design and configuration of PSA generation plants and filling ramps for medical use of which the buyer and/or end-user should have an enhanced understanding to facilitate smooth procurement and set-up to result in successful outcomes.

Clear operational gaps addressed in this consultation are as follows:

- There is a lack of guidance to estimate demand and determine the size of the gap in oxygen. Appropriate and reliable estimation procedures are difficult to develop because oxygen is used for many different clinical indications, patients are not appropriately screened, and there is no tracking of oxygen requirements.
- There is a lack of publicly available operational guidance for PSA plants. Without knowing the “what”, “how” or “why” of operations – even if only high level – inappropriate procurements and set-up can result, and systems can reach their end-life sooner than expected. There is an urgent need for building capacity in LMIC. This includes guidance on appropriate installation and training on running and maintaining plants. There is also no guidance on appropriate configurations (sizes) of plants.
- The booster compressor is a critical component. It enables cylinder filling for intra-hospital distribution or for backup supply, as well as for external facilities that rely on a centralized plant as their oxygen source. These are specialized components that are costly, belong to a limited market and require specific maintenance tasks. They end up being one of the main reasons for PSA plant downtime in LMIC.
- There is a lack of publicly available guidance for frequency, procedures and tools for testing the output oxygen purity and impurities and/or contaminants.

PSA plants are part of a more complex oxygen system needing a holistic approach for strategic planning and careful consideration to be utilized optimally, safely and effectively for their intended lifespan (~10 years minimum). The ultimate indicator of success is that quality oxygen is being provided to the patients in need in a sustainable manner.

To ensure that all requirements for the operation of PSA plants are met, a multidisciplinary approach should be taken:

- Conduct needs assessment and evaluate absorption capacity.
- Budget for human resources, training, power supply, ancillary equipment and requisite maintenance.
- Plan for security of supply, such as redundancy, secondary source, backup manifold or high-pressure gas cylinders should be considered.
- Establish/strengthen relationships with (local) suppliers to ensure product suitability and long-

term service agreements.

- Innovate operational models and designs that address topics like sustainable sources of energy.

Increasing medical oxygen access in LMIC also implies working with regulatory agencies, suppliers and other stakeholders to reduce costs, promote innovations (both at product and system level and business models), surge absorptive capacity, reduce problems related to logistics and distribution with the aim of allowing health systems more autonomy in managing their oxygen sources.

Areas for further action

1. To build out a “global good”: publicly available operational guidance that can support decision-makers with a frame of best practices, to mitigate associated risks, and increase potential with respect to successfully reaching the end of the value chain, or rather, that the oxygen reaches the patient in a safe and sustainable manner.
2. To carry out, with appropriate stakeholders, a more comprehensive market landscaping exercise for booster compressors, and to also explore the potential opportunity of financing options for this costly piece of equipment. Note that partners have some of this work already underway.
3. Call for the IP to include the Oxygen 93 and, with that, serve as a reference for other national pharmacopoeias.
4. Call, with other stakeholders, to develop guidance on purity testing of the medical oxygen produced by PSA.

MEETING 3: OXYGEN DISTRIBUTION CHALLENGES (13 November 2020)

Objectives of third meeting

Scaling up access of appropriate medical oxygen sources is only effective if scaling up access to distribution systems and to delivery interfaces are done in parallel. There is a gap with respect to publicly available operational guidance and training relating to medical oxygen distributions systems.

The main objective of this meeting was to leverage the empirical knowledge from all participating entities to identify and understand technical and operational elements that need to be considered when implementing medical oxygen distribution systems.

The expected outcome of this meeting was to shape and inform what will be an interim operational guidance document, which is needed to build up technical capacity more broadly for a sustainable implementation of oxygen systems (see Annex 3).

Background to third meeting

Oxygen sources overview

As mentioned in the previous meeting report, solutions for oxygen supply should be strategically chosen according to the specific context and could be a mix of various types of systems.

The two predominant technologies for producing medical oxygen at scale are: cryogenic fractional distillation (“liquid”) and PSA. Less common options are VSA and hybrid VPSA; which have been commercialized in the last decade and merit acknowledgement.

The VSA technology produces oxygen in a similar manner to PSA, using the same zeolite for nitrogen adsorption; however, the mechanism for pushing ambient air through the system differs. VSA uses an oil-free blower (not a compressor), which decreases filtration requirements, is less affected by elevation and is less sensitive to environmental wear and tear. VSA uses one adsorption tower, reducing the unit footprint. The output pressure achieved is 3.8 bars, which might not be enough to feed into a distribution network, thus warranting the need for an additional pressure booster – which implies extra cost and operational challenges.

VSA and VPSA technologies were not illustrated in this meeting but distribution systems may be applied in the same manner as those for PSA plants and liquid tanks.

Oxygen distribution configurations

When planning for oxygen systems, the following components need to be considered:

- source of oxygen, including reserve (i.e. backup supply)
- distribution method within a facility, such as direct piping, cylinder manifold to piping, bedside cylinders
- distribution accessories, including alarms and regulation devices, which are compatible with the distribution method.

When PSA is the primary production source

PSA plants can be located onsite, in health facility grounds, or offsite. There are three configurations that can be considered, which are shown in Fig. 4. In general, the PSA can be either connected directly to a piped network onsite or via a filling manifold (commonly known as a “filling ramp”) to re-pressurize

oxygen to fill cylinders.

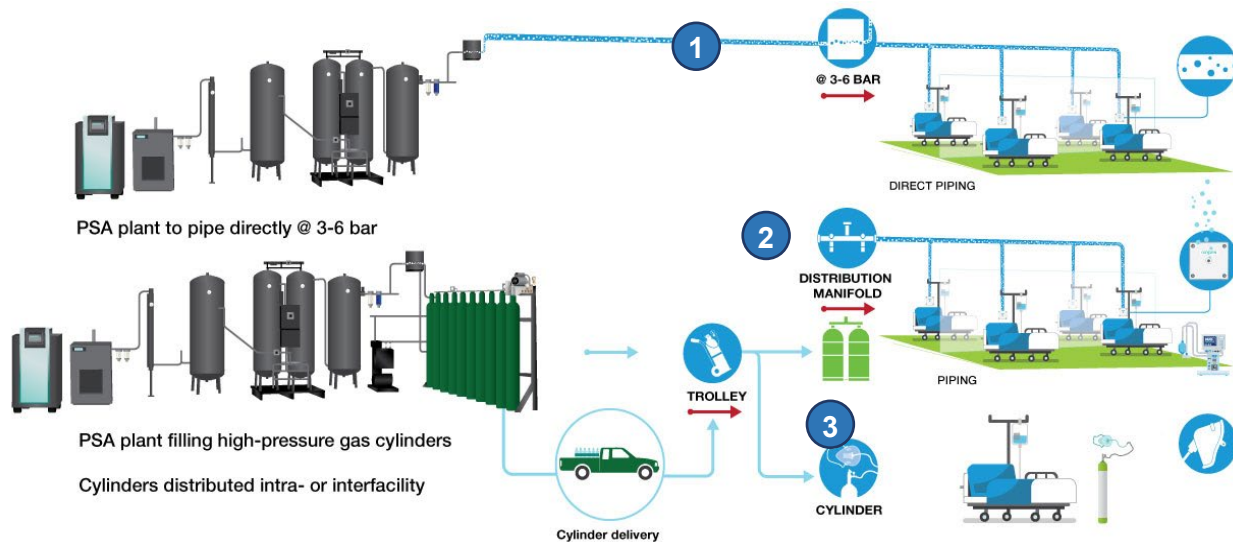
Fig. 4, configuration 1, illustrates how the oxygen produced from a PSA plant can be distributed through a piping system directly to the patient wards and then, to the bedside terminal units.

Another modality for distribution relies on filling high-pressure gas cylinders, which requires the PSA plant configuration to include a booster compressor and a filling manifold. The booster compressors increase the output pressure from 3–6 bar to upwards of 150 bar in the connected cylinders. Once full, these cylinders can then be transported either within the facility or to another facility altogether.

These high-pressure gas cylinders can be connected to facility- or ward-level manifolds, also known as “distribution manifolds”, where the oxygen will feed into a piped distribution network to the bedside terminal units (Fig. 4, configuration 2).

High-pressure gas cylinders can also be located directly at the bedside (Fig. 4, configuration 3), provided they are securely strapped or chained in place. Movement of these cylinders – whether full or empty – must be done safely and by using a trolley.

Finally, regulation and conditioning of oxygen flows serve to ensure that pressure remains at a safe level along the pathway.



Note: Only the primary distribution network is illustrated and not the reserve supply.

Fig. 4. Distribution configurations when PSA is the primary production source

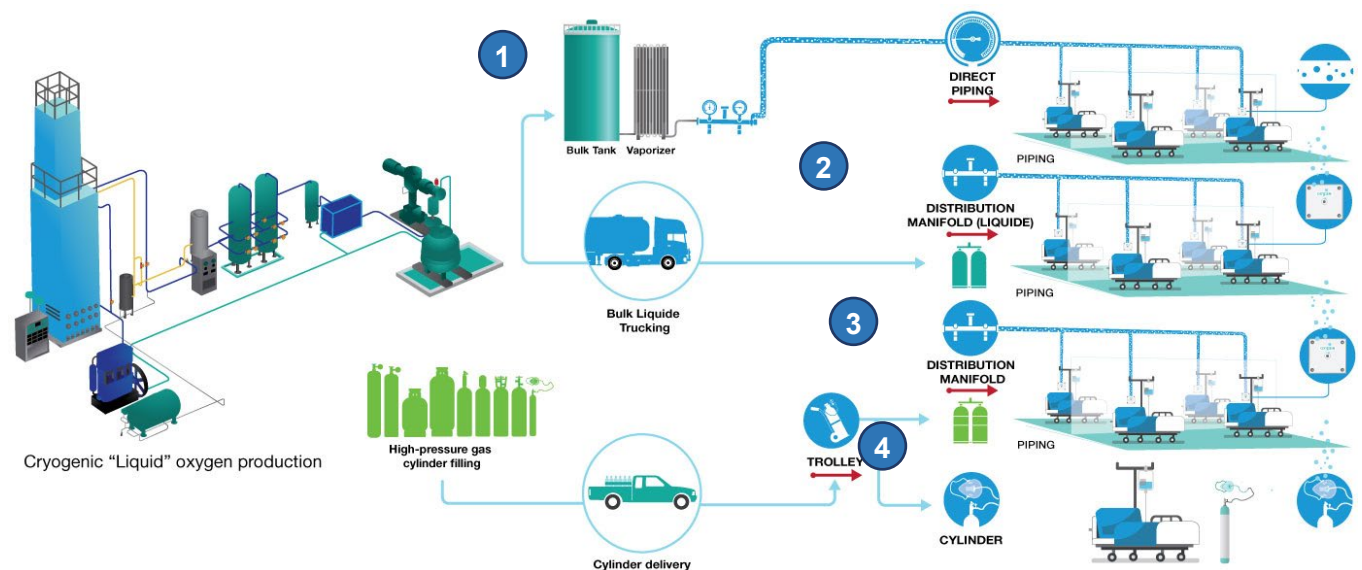
When liquid oxygen is the primary production source

Cryogenic liquid oxygen will be always produced offsite by a third party (e.g. private company). The oxygen produced can leave the production site as either liquid or gas.

If liquid is transported, it is done so in specialized bulk liquid trucks designed to carry oxygen in liquid form from the point of production to the point of use. The truck itself is vacuum insulated, and through specialized connections, the truck will typically fill a pre-installed onsite vacuum-insulated evaporator (VIE) or bulk tank (Fig. 5, configuration 1). These onsite bulk tanks have an external vaporizer, which passively converts the oxygen from liquid to its gaseous form and maintains the product at a set pressure to then feed the piped network that reaches bedside terminal units. Also possible, but less common,¹¹ is to fill liquid cylinders (Fig. 5, configuration 2). They have in-built vaporizers and are connected to a manifold that regulates the line pressure, and subsequently distributes the gas through a piped network. Because liquid cylinders will always have unusable product, it is not common to transport them back and forth in a system as there will be unnecessary risk in doing so.

Another option is to fill standard high-pressure gas cylinders at the point of production. This can be done in large quantities, and then cylinders can be distributed by truck to health facilities to facilitate continuity of supply. In the same manner as the high-pressure gas cylinders filled by a PSA, these cylinders can be connected either to facility- or ward-level distribution manifolds, where the oxygen will flow into a piped distribution network to bedside terminal units (Fig. 5, configuration 3). Last, the cylinders can be used directly at the bedside (Fig. 5, configuration 4). No matter what the configuration, cylinders must be safely handled, including securing any in-use cylinders in place, and moving them around safely – whether full or empty – with a trolley.

In all cases, regulation and conditioning of oxygen flows serve to ensure that pressure remains at a safe level along the pathway.



Note: Only the primary distribution network is illustrated and not the reserve supply.

Fig. 5. Distribution configurations when cryogenic "liquid" oxygen is the primary production source

Considerations for piped network design

Considerations at the preliminary design phase of the piped network design include:

¹¹ Not common because total usable capacity is on the high end for a high-pressure gas cylinder manifold, and on the low end for the bulk VIE tank or the PSA plant.

- departments, wards and services to be piped
- the total number of terminal units
- the total terminal units in use at a given time (the concept of diversified flow)
- test pressures and flows to be used
- system-level flows (aligning with the source sizing/availability).

For optimal and safe operations, ward or line isolation capabilities are essential, as are sufficient area valve servicing units (AVSUs) and local valve assemblies (LVAs), all in appropriate locations. Alarm panels must be strategically located so action is triggered when appropriate. As distribution is a key aspect of supply, planning should include a backup. Consideration can be given to piping configurations, namely twinning or annular rings, to achieve this.

Summary on deliberations about oxygen distribution challenges

Oxygen purity and remaining impurities

Monitoring the purity of the gas delivered is critical to ensure quality of care. Two variables should be monitored in the output of the source and along the distribution system: purity of oxygen and remaining impurities.

In the pharmacopoeias, there is clear guidance about testing purity and impurities of oxygen produced by cryogenically liquid sources. Testing contaminants is normally done by high-pressure liquid chromatography (HPLC) or gas chromatography (GC) by national drug testing laboratory sites or certified third-party laboratory sites. Access to these laboratories can be an issue in LMIC.

There is no clear guidance relating to the frequency of and existing methods (if any) to test purity and impurities onsite (i.e. when the source is a PSA plant). Moreover, there is no guidance about appropriate measuring/testing devices.

If the oxygen production source is a PSA plant, oxygen purity may be affected when:

- maintenance fails (usually when the dryer fails), the oxygen purity drops automatically;
- there is improper installation, with inadequate spacing where the PSA is installed or if the air is not drawn from above the roof and the nitrogen discharged may affect the inlet air.

The potential impact that impurities can have on the patient is unknown. Also, there is potential for contamination of the system that may be more related to mismanagement than the source of production itself, for example when reusing cylinders. Thus, it is important that management of the system follows best practice, for example, that the compressor and refrigerator/dryer are maintained in a timely manner; that rigid standard operating procedures for the refilling of cylinders are followed to mitigate potential routes of contamination; and that pipelines are always flushed (purged) and the flow purity tested following installation or after any maintenance activity.

Bulk tank troubleshooting

As mentioned previously, onsite bulk tanks have an external vaporizer, which passively converts the oxygen from liquid to gaseous form and maintains the product at a set pressure that can then feed the piped network, reaching the bedside terminal unit.

In countries with low ambient temperatures, when the need for oxygen surges unexpectedly and exceeds the planned drawing capacity, the bulk tank vaporizers may freeze up more quickly, impacting

the continuity of supply. To prevent this from happening, planning for a redundant system of bulk tanks may minimize this risk. For example, if there are two bulk tanks working in parallel, it would allow for sufficient time for passive vaporization and may be worth the extra cost. When redundancy is not in place, finding buffer bulk tanks in an emergency may be more complicated.

Cylinder distribution interfacility

While some publicly available guidance exists, e.g. WHO-UNICEF, 2019 (13); HTM-02-01 Part B, 2006 (14), mismanagement of cylinders continues to be a challenge in health facilities. If oxygen is outsourced under contract, often management and maintenance of the cylinder fleet is left to the vendor. There are many best practices to put into place, from end-to-end implementation. Ensure:

- cylinders are sized according to application or use-case;
- cylinders are purged (residual pressure removed) after use;
- cylinders are safely filled in cascade;
- adequate management of inventory, i.e. optimizing fleets (full-out, full-on-return).

If the oxygen source is used as “a hub” to feed other facilities in the surrounding area, the number of cylinders may be underestimated and should be calculated carefully to ensure that the cylinders themselves are not the bottleneck in optimizing supply availability.

Another common problem is timely, safe transport and safety in placement of cylinders. Devices to ensure safety should be selected according to the size (and weight) of the cylinder and include, but are not limited to, cylinder dollies (carts) and chains. Biomedical engineers, technicians, logisticians and related health workers need to be trained in cylinder management and maintenance.

Manifold type and changeover

There are three types of manifold changeover system: automated, semi-automated and manual; each with application strengths and challenges, and all requiring a power supply. There is no guidance on the advantages and drawbacks of each system. However, the following points can be considered.

- If using the manifold as backup of a PSA plant functioning as a primary source connected to a piped network, the manifold should be automated, where changeover to cylinder manifold will take place in case of a pressure drop.
- If using the manifold as a primary source, the preference, from a cost and ease-of-use perspective, is to limit user complexity, and to facilitate user maintenance and upkeep with a manual changeover and an alarm (audio: horn; visual: strobe) at the nurses’ and clinicians’ station so that they know when they are at the end of the primary supply.

Piping standards

Medical gas piping standards (e.g. HTM-02-01/NFPA 99/ISO 7396-1) have not been updated recently and have practical limitations to be applied in all settings, specifically in LMIC; however, most LMIC adopt and adapt either United States’ National Fire Protection Association (NFPA) or European standards. There are a few national or international agencies dedicated to medical gases, including EIGA (Europe); AIGA (Singapore); ANZIGA (Australia/New Zealand); CGA (United States of America); JIMGA (Japan); and SACGA (South Africa).

In general, standards push for redundancy in the piped network. For example, NFPA 99 requires three oxygen outlets per bed in critical wards to secure supply. However, this may not be possible in all settings. When this is not possible, in practice, if an outlet were to fail (an uncommon event), the

oxygen outlet from an adjacent bed could be split. Further, implementing sophisticated electronic controls and alarms along the systems could also be a limitation for continuous operations in LMIC.

Often, the inability to meet the above standards due to high costs or the inability to meet technical requirements have prohibited the installation of piped oxygen networks in LMIC. Therefore, a question is to what level can existing standards be adapted for broader application, specifically for LMIC, without compromising access, safety and quality of the oxygen delivery?

Piping materials

Historically, copper has been the material of choice for medical oxygen piping as per standards. However, perceived high costs and access to quality materials have been reported as challenges. Other materials have been proposed by vendors, for example polyurethane medical gas hose, polyamide or metal alloys. However, major concerns exist about the risk of fire. These may be mitigated through selection of the material housing the pipeline (e.g. cement, concrete or masonry) or certification of the material for medical application.

Experience was shared about the successful use of fittings made of other non-certified components (even if made of copper). This type of fitting (“pro press”) is certified for industrial oxygen systems but not for medical applications.

Actions should be taken to ensure that risks are mitigated so that quality oxygen is safely and effectively delivered to the patient.

Piping design (circuitry)

Design of circuitry will always be a tactical exercise customized to the site. Twinned and annular lines are two different strategies to increase security of supply when designing piping networks, especially in critical care or isolation wards. However, the cost-effectiveness of this solution should be compared with other possible scenarios that yield security – for example, the allocation of backup cylinders.

In general, regardless of the design, pipelines themselves will not break down unless a catastrophic disaster arises. While problems that can be seen in pipelines relate to leakages and consequent loss of system pressure, system downtime is usually caused by PSA plant failures and system errors arising as a result.

Environmental considerations

Environmental aspects, specifically harsh conditions like extreme temperatures, high humidity and the presence of dust, and altitude may impact the functionality of PSA plants and the electronic components along the distribution systems (e.g. in the control panels and alarms). This could lead to an increase in maintenance tasks to overcome these additional challenges. Good solutions do not necessarily have to be sophisticated or expensive. Positive results will be realized if the approach is practical and takes into consideration contextual needs or challenges.

Conclusions

Technical and operational challenges of distributions systems (i.e. filling and distribution manifolds, bulk tanks, cylinders and piping) and for production technologies could be reduced or even mitigated with careful planning for an optimal oxygen system and sustainable allocation of resources for

continuous operations.

Key aspects discussed:

- Proper housing and maintenance can significantly reduce failures and contamination of the system.
- There is a need for guidance on the frequency and methods for testing of both purity and impurities of the produced oxygen gas at the point of production and along distribution systems. This also applies to batch production of liquid oxygen offsite, regardless of the transfer and transport method used.
- Specific issues were discussed related to the mismanagement of cylinders, especially when refilling them and regarding maintenance standards (vessel sizes, valve connections, appropriate regulators and flowmeters, etc.) in certain geographies.
- Redundant systems for storage (i.e. bulk tanks, distribution manifold) and distribution (i.e. pipelines) increase the security of supply yet also increase the complexity of planning and implementation and costs. Aligning with the existing capacity and context is crucial to planning and implementation.
- International and national standards for medical gases have practical and cost limitations when fully applied in LMIC. Some of the requirements could be perceived as a *luxury*, rather than a *need* to ensure safety and continuity of quality medical oxygen.

Areas for further action

1. To build out a “global good” for design, installation, validation and verification of oxygen distribution systems: a publicly available operational guidance that can support planners and/or decision-makers with a frame of best practices, to mitigate associated risks, and increase potential for successfully delivering oxygen to the patient in a safe and sustainable manner.
2. To explore the feasibility for increasing the implementation of pipeline networks in second level and referral facilities in LMIC, as this may improve the overall access to oxygen therapy and thus quality of care.
3. To explore the experience of implementors using piping materials other than copper as a potential pathway for the international community, exploring critical aspects that could be updated in the international standards.
4. To discuss with different entities (e.g. Plumbers Without Borders) and the private sector (e.g. Viega) about different types of fittings in the piping network that could be used in medical applications safely, which may inform updates relating to policy and standards.
5. To discuss with the private sector actors who have inherent and relevant experience in cylinder fleet management (i.e. inventory, optimizing fleets, full-out/full-on-return, and understanding appropriate cylinder size according to the medical application) to build on strategies and best practices for cylinder management.
6. Plan further consultations with stakeholders on international standards, regulations and business models related to medical gases and medical oxygen systems.

MEETING 4: MAPPING AND DATA PLATFORMS TO FACILITATE SUSTAINABLE OXYGEN SCALE-UP (27 November 2020)

Objectives of fourth meeting

Participants in this meeting sought a potential pathway to update mapping of existing oxygen systems, together with partners' implementation activities, identification of needs-gap, supplier positioning, maintenance networks, logistics and supply corridors, as well as visualization of different indicators. The aim was to provide information for advocacy purposes, enable better understanding of breakthroughs, and create the possibility to measure the impact of collective actions towards scaling up access to medical oxygen (Fig. 6).

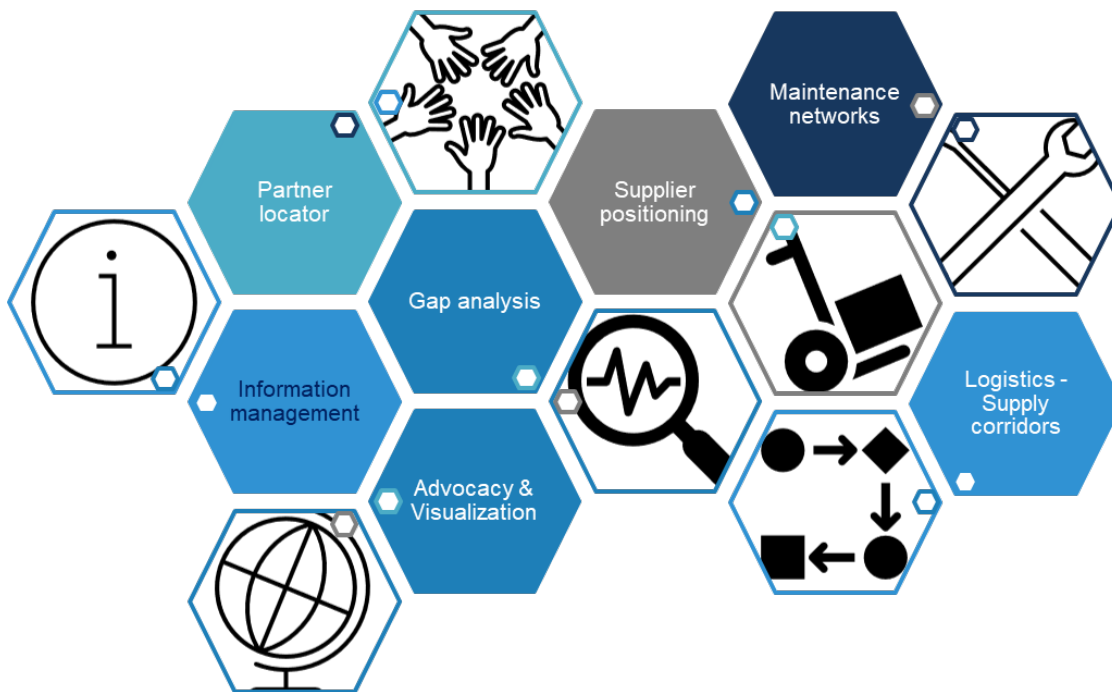


Fig. 6. Themes to map to optimize collective efforts

Background to the fourth meeting

Efforts in scaling up medical oxygen have increased in recent years. Previous meetings have indicated the lack of publicly available and reliable baseline data regarding the existing oxygen systems, especially in LMIC settings. Although progress has been made, and many approaches have been taken for data collection, data utility has not been optimized to illustrate existing capacities and need-gaps.

Longer term sustainability will require a holistic approach and a resource ecosystem focused not only on oxygen production but also on distribution and delivery, ongoing maintenance and upkeep. Mapping out all activities relating to oxygen scale-up can serve to identify any remaining gaps, bottlenecks and operational challenges related to medical oxygen access and thus aid in achieving appropriate solutions that reach more patients.

Oxygen scale-up partner activities

In 2017, oxygen was listed as an essential medicine by WHO (1). In the same year, the Every Breath Count (EBC) Coalition was established (15) as the first formal platform to integrate the work of global partners (e.g. international and local NGOs, social enterprises, private sector, UN agencies, and funders) for whom medical oxygen is a priority. Since the pandemic was declared, an increasing number of entities have engaged to work on oxygen access scale-up activities. Nevertheless, the partners' landscape remains relatively sparse, with few fruitful formal collaborations. Unsurprisingly, the funding available has also been lean, with few donors interested in the topic because of the complexity of oxygen systems. Often, investments have been driven by clinical needs and portable and single-use medical devices associated only with paediatric pneumonia – just one of many clinical conditions requiring oxygen therapy. Moreover, these investments have targeted specific settings, lacking consideration of the different levels of referral pathways.

Existing data capture and management systems that relate to medical oxygen

Historically, oxygen had been overlooked, and few systematic data were captured to inform public health systems about access and affordability of oxygen. The Lancet article, *Oxygen availability in sub-Saharan African countries: a call for data to inform service delivery* (5), is one of various calls highlighting the need to build baseline information.

On the other hand, some platforms built for different purposes have managed to partially capture related information, including:

- WHO's Service Availability and Readiness Assessment (SARA) tool which captures oxygen availability, but only in a binary way (i.e. available/unavailable). It does not indicate the extent or status of oxygen delivery systems. Furthermore, the data collected are not publicly available.
- Health Resources and Services Availability Monitoring System (HeRAMS) is a collaborative approach that aims to ensure core information on essential health resources and services is systematically shared and readily available to decision-makers at country, regional and global levels. It contains some information about oxygen components, but as it is contributor driven, there is no indication of reliability, completeness and timeliness.
- In 2015, Ouma et al. assembled a geocoded inventory of public hospitals (government, private-not-for-profit [PNFP], faith-based and NGO) offering emergency services across 48 countries in sub-Saharan Africa. Additional information included catchment population and road networks (16). This resource could be reviewed and leveraged for the purpose of

understanding oxygen availability in the emergency and referral pathways on those geographies.

- The EBC Coalition facilitates a platform for all actors involved to share information and:
 - keeps a running database of entities working in each country on COVID-19 response efforts;
 - maintains a database of oxygen-related procurement, particularly if related to PSA oxygen generation plants.
- The United Nations Children’s Fund Supply Division (UNICEF SD) has run country-office surveys on use of supply platforms, achievements and lessons learned.

Thus, while progress has been made to collect baseline information, it is believed that the remaining gaps are substantial, and yet remain unquantified. Furthermore, data utility has not been optimized to illustrate gaps to interested partners. Since Meeting 1 of this technical consultation series, entities agreed that to be able to quantify the needs, a concerted global effort is required to understand:

- existing capacity, at both national and subnational levels (e.g. oxygen sources at scale, distribution systems, power availability, human resources – clinical and technical);
- identification of need-gaps along oxygen systems.

Examples of datasets to be collected: Supplier positioning

At the outset of the pandemic, an effort was made by the WHO-convened CSCS in collaboration with CHAI/PATH, to illustrate the utility of one such dataset in relation to supplier positioning of sources at scale: PSA/VSA plants and liquid vendors.

Supplier positioning: PSA and VSA plant manufacturers

A rapid market assessment of relevant suppliers was conducted in China, Europe and North American markets (see Table 5). The following findings were recorded from the rapid assessment – adapted from the PATH/CHAI *Respiratory care equipment market report (17)*:

- 25+ active manufacturers of PSA plants are present in the focus markets.
- Two VSA plants’ manufacturers are present in the focus markets.
- Broad differences exist among the suppliers regarding:
 - quality assurance certifications
 - lead times
 - models available (e.g. some suppliers do not make units larger than 30 Nm³/hr)
 - configurations and assembly of the systems.
- Additional suppliers in Africa and India have been identified beyond the initial report.

Table 5. PSA and VSA plant manufacturers

No.	Supplier	Country	No.	Supplier	Country
1	AirSep	USA	14	OGSI	USA
2	Atlas Copco/BeaconMedaes	Sweden	15	Ox-Air	USA
3	Can Gas Systems Company Ltd	China	16	Oxymat	Slovakia
4	Chengdu Tcwyr New Energy Tech.	China	17	Oxywise	Slovakia
5	G Samaras	Greece	18	Özcan Kardeşler	Turkey
6	Hunan Eter Electronic Medical	China	19	PCI gases	USA
7	Hydrogaz	Poland	20	Pneumatech Medical Gas Solution	Germany
8	Inmatec	Germany	21	Sanghi	India
9	Intakatech	South Africa	22	ShanDong MedTech	China
10	Jiangyin Dongpeng Purifying Equip.	China	23	Hengda Purification Equip.	China
11	Mil's	France	24	Suzhou HITE Gas	China
12	MVS Engineering	India	25	Sysadvance	Portugal
13	Novair	France	26	Tesa Medikal	Turkey

Note: there is an increased number of authorized vendors and/or distributors of these products who require additional QA processes – not only for the products themselves, but for all after sales aspects, including warranties and long-term service agreements. The solutions proposed by vendors of oxygen sources need to be adapted to the context needs related to oxygen distribution systems.

WHO does not prequalify, endorse or validate any vendors. Best practice dictates that a quality assurance (QA) process is conducted by the purchaser before procurement.

Supplier positioning: global liquid oxygen production

Another similar exercise was carried out regarding industrial liquid oxygen production. It was found that this product is produced at industrial scale in various locations, but not always for medical applications and not always available in harder to reach or more remote areas. Fig. 7 depicts the geographic availability of liquid oxygen, and while this map is not exhaustive and does not represent in-country reach (i.e. remote locales), it can serve as a starting point for strategic planning of oxygen access scale-up.

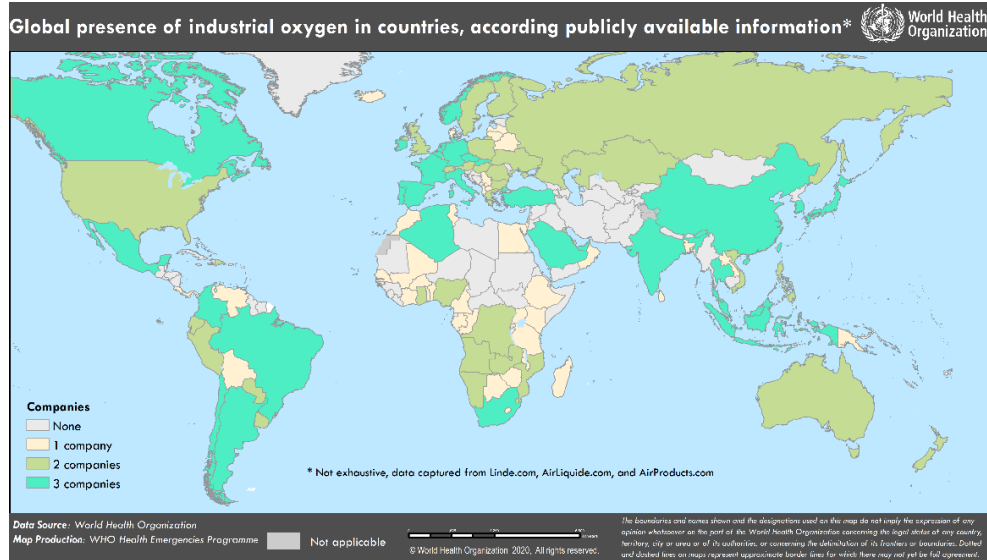


Fig. 7. Liquid oxygen production

High-level findings from this exercise included:

- Three companies (Air Liquide, Air Products, the Linde Group) represent most of the market.
 - These companies have subsidiaries. Most notably, the Linde Group is a major conglomerate with many smaller operations – many of which are well known in more localized geographies (e.g. Afrox, Praxair).
- In addition to these three, Gulf Cryo and AirWater produce oxygen for medical use.
- Two other larger companies, Messer Group and Nippon Gases, do not currently produce oxygen for medical use. The former, Messer, has sold off its medical gases division to Air Liquide.
- Other companies that produce high-purity oxygen, but do not currently sell to the medical market as they do not have the requisite quality management systems to do so.

Fig. 8, adapted from the CHAI/PATH report on liquid oxygen shared with the CSCS (18), portrays most vendors in the liquid oxygen space, highlighting medical oxygen vendors.



Fig. 8. Liquid oxygen producers – parent companies and subsidiaries

The liquid oxygen market is ripe for engagement, though bottlenecks associated with QA in shifting industrial to medical oxygen are being observed. Identified barriers for uptake include perceived high cost and no sense of ownership by the end-users, plus the need for continuous investment in a goods and service contract. The same logistics and transport challenges remain, regardless of the type of oxygen source, to distribute liquid oxygen to decentralized and remote areas.

Proposed Global Oxygen Data Platform

In order to identify the gaps and measure progress made along the supply chain, datasets need to capture oxygen systems holistically. WHO proposes to develop a global data system to serve as a centralized repository of oxygen scale-up efforts, intended to become a global good. The system will be multifaceted, capable of being used for real-time aggregation, analysis and interpretation of medical oxygen access scale-up activities in different contexts, with information captured in both prospective and retrospective manners.

This platform would aspire to:

- showcase recent, ongoing or upcoming activities;
- leverage previous accomplishments to multiply success;
- facilitate rapid, standardized and systematic collection of targeted datasets;
- illustrate system status: full visibility of information and activities (considering data sharing only if/where permissible);
- support to shape global, national and subnational strategies, including policy work and roadmaps;
- potentially increase visibility of a fragmented, opaque market.

With respect to the types of data collected, the following are some examples of thematically relevant datasets:

- facility characteristics and readiness;
- oxygen therapy availability;
- local and regional market landscaping;
- partner presence and activity mapping.

The level of granularity of data can be defined on a rolling basis and with the input of both, contributors and users alike. Participation in such a platform would be wholly voluntary. However, improving transparency with respect to activities and accomplishments will help to strengthen efforts of the broader community. It is anticipated that contributors to such a platform would be ministries of health, health facilities, clinical/research networks, NGOs and UN agencies. Users of such a platform could include but would not be limited to policy-makers, ministries of health, facilities, NGOs, clinical associations, oxygen champions/advocates, donors, researchers and vendors.

Although the concept presented is only preliminary, and necessitates a more detailed plan, the identified next steps to start the process include:

1. Define content to be housed on the platform.
2. Develop (or leverage) existing tools, surveys, apps etc.
3. Ensure accessibility:
 - a) translate all resources to (at least) UN official languages;
 - b) establish legal parameters, timeframe, methods of contribution and use;
 - c) resource a support network for contributors.
4. Manage and maintain content so that it remains current and relevant.
5. Build out a team for data curation, aggregation, analysis and interpretation.
6. Facilitate information capture both prospectively and retrospectively (to avoid duplication).

Fig. 9 illustrates how data can be collected to help determine the need-gap for oxygen availability and accessibility.

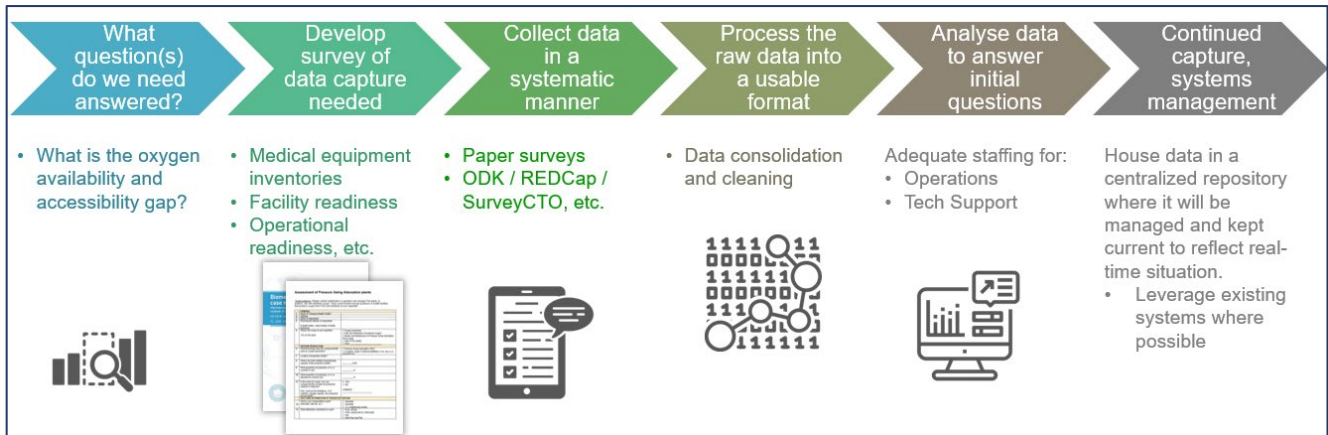


Fig. 9. Data capture – the process flow for utilizing data to drive action and results

Data collection should be transparent and targeted with clear intention and benefit for action. Doing so with purpose will help to mitigate loss of commitment or interest, which could ultimately erode trust or, even worse, leave contributors vulnerable or exposed. There are known sensitivities with respect to sharing data.

On the other hand, the opportunity to pull datasets from existing systems should be explored. One example would be to draw on health management information systems (HMIS), and to create a bidirectional pathway for cross-cutting information to be used. Additionally, other established data capture and management platforms focusing on logistics aspects (e.g. logistics management information systems) could be similarly integrated.

WHO is offering to facilitate this initiative to build the Global Oxygen Data Platform, including a team staffed to clean and analyse datasets as they are populated and/or become complete. WHO has migrated all data collection and management to the REDCap web-based platform, where access is secure, limited and password protected. The WHO COVID-19 Response Clinical Pillar has had recent success with the WHO Global COVID-19 Clinical Data Platform to inform appropriate clinical interventions, public health response and generation of evidence-based guidelines (<https://www.who.int/teams/health-care-readiness-clinical-unit/covid-19/data-platform>).

Partner and implementation mapping

While the proposed Global Oxygen Data Platform could have significant breadth of content, an aspect of this mapping – the “where, what, why, how, who” of oxygen scale-up activities at country level – could be easily captured with some rapid organization among the different stakeholders. Fig. 10 exemplifies how this high-level information could be captured and shared to help the coordination of partners’ presence and progress regarding activities.

Country	Partner presence	Country O ₂ policy	Activities				Systems integration (e.g. LMIS)
			Baseline / gap-analysis	Scale-up strategy/ road-map	Local and regional market landscaping	Clinical, biomedical, technical training (etc.)	
A	---	In-progress	⊖	☒	☒	☒	HeRAMS
B	---	Yes	☑	☑	☒	☒	No
C	---	Yes	☑	☒	☑	⊖	OpenLMIS
D	---	No	<div style="background-color: #4a7ebb; color: white; padding: 5px; text-align: center;"> Activities can be substantial stand-alone undertakings; however, they are part of the bigger picture. </div>				
...	---						
Y	---	Yes	<div style="background-color: #fce4d6; padding: 5px;"> ✓ Sharing information more broadly can result in collectively closing the gap. ✓ Leveraging existing systems and resources will support effort of sustainability (e.g. training platforms). ✓ Activities must be measurable, key indicators targeted at the ultimate objective. ✓ Partners are often limited for reasons of funding or expertise; however, once the benefit is understood, the multidisciplinary effort can be done. </div>				
Z	---	No					

Note: information herein is for illustrative purposes and does not reflect current country situation.

Fig. 10. Illustrative format of partner and oxygen scale-up activity mapping

Discussion on mapping and/or a data platform to better facilitate safe, reliable, lasting solutions

Utility

What information could be managed in such a platform to help with scale-up efforts?

The metadata that can answer the “where, what, why, how, who” have the potential for remarkable utility, not only for near- and longer-term purposes, but immediately with respect to the current pandemic response and synergized efforts. This can help to prioritize next steps as granularity increases. The information collected should be in relation to key indicators and leverage existing data already available. The following goals are to be considered when developing such a platform:

1. Gain broader understanding of the need-gap (what exists, what will be needed), which can be visualized locally or in broader geographies, such as a region.
2. Identify variables that affect oxygen availability along the patient pathway at different referral levels and geographical distributions.
3. Represent all hardware components in oxygen systems as assets and the interconnection with pharmaceuticals and data management systems.
4. Measure outcomes and potentially align with quality-of-care standards:
 - a) How much oxygen is accessible at primary, secondary or tertiary facility?
 - b) How much oxygen is reaching the patient?
5. Identify partners and their respective expertise, geographic footprint, current funded efforts, past efforts (geographically and topically) to build out a “global team”, allowing integration with other relevant stakeholders in different parts of health services, e.g. maternal, neonatal and child health, safe surgeries initiatives.
6. List trained, qualified technical staff available at national and subnational levels, ideally in a live roster that can help to develop a support network.
7. Develop national-level dashboards indicating key information such as where oxygen and associated commodities sit on essential equipment and medicines lists, and to what level these extend; how oxygen is financed and procured; and where it is covered under health insurance schemes.
8. Aggregate data across existing platforms that countries may have used, e.g. the biomedical

inventory tool (19) or Service Provision Assessment survey (SPA) (20) or SARA (21); compiling information to avoid duplicating efforts; and reviewing experience users had during these exercises.

It is important to have clear understanding of the utility of the data collected. There is a propensity for data to be captured for the sake of amassing information, and so it is important to be targeted and not let activities become cumbersome or unwieldy. This will require constantly challenging the level of granularity, discussing counterfactual aspects and matching the “live” aspect with the real status of functional information.

Finally, with the imminent release of the Universal Health Coverage Compendium,¹² the suggestion was made to explore the use of this tool to support countries integrate oxygen system’s needs, including financial aspects.

Sensitivity

What could be the potential risks for governments to share their data?

This is not a small issue; permission from governments to share information is crucial. The intended and unintended consequences of sharing data must be explicit. Countries do not want to be overlooked or deprioritized. This is always a complicated subject to navigate, but any time data are collected, the objective should be made explicit. WHO does understand this and this is one reason for the participation in the proposed platform to be user-driven.

Advocacy

Could this type of platform support advocacy efforts for oxygen scale-up?

To have baseline information of the existing oxygen systems and needs-gap could help to better advise decision-makers, to set a benchmark and allow for funds allocation. Donors often require granular information; therefore, having the ability to present a broader case can help to extend donor priorities for more comprehensive and lasting solutions.

On the other hand, consideration should be given to advocate for the costing component that the operationalization of any platform or tool would demand.

Market transparency

From the consumer’s perspective, would public information help aggregate demand, give visibility and therefore be an advantage – to the consumer?

Could some supply perceptions be debunked with greater transparency (e.g. original equipment manufacturers considered “premium” brands)?

From the supplier’s perspective, could this consolidated information be of benefit – to the supplier?

From the consumer’s perspective, having greater visibility for supply options, indicative pricing and service capabilities can help in making informed and strategic decisions and guide future negotiations during the purchase process.

From the supplier’s perspective, the oxygen sources at scale are commonly designed and manufactured in ad hoc basis, so vendors need to secure their upstream supply and negotiate lead

¹² <https://www.who.int/universal-health-coverage/compendium/interventions-and-SDG-goals>

times based on estimated demand. A platform similar to the Global Fund or GAVI, where demand has been aggregated and is shared in a transparent manner, would be promising. However, to better understand supplier's perspective, it would be useful to engage with vendors to ascertain what would most benefit them and whether they could envision engaging with this type of platform.

Implementation – partner networks and technical assistance (TA)

Could expanded efforts in mapping partnerships strengthen networks and improve coordination?

What additional TA would you expect to be required to support countries that are under-represented?

UNICEF's Scaling Pneumonia Response Innovations (SPRINT) is a successful initiative that includes scaling up access to oxygen, with a particular focus on primary health care. SPRINT has been launched in Central and West Africa, starting with Senegal and Ghana, and there is the opportunity to expand the initiative and support additional countries (see <https://www.unicef.org/innovation/productinnovation/SPRINT>). Also, the EBC partner mapping is highly useful, especially if it can track partners' activities at country level.

Different types of expertise will be needed for TA on oxygen scale-up. TA relating to supply could help strengthen commodity procurement, acquisition and supply management. TA relating to health care provision and technical and engineering services provision, including capacity building and continuing education platforms, will be needed. Another relevant TA need is on advocacy, in particular, in making the case for initial investment and continuity of funding.

Conclusions

- The need to get baseline information about medical oxygen access in most LMIC countries and to be able to measure the impact of actions taken by all stakeholders is quite clear. However, it is understood that an initiative of this nature will require time and so clear steps must take place now.
- Past and ongoing strategies should be shared (and documented) to learn from successful models implemented by different stakeholders. This information can also inform policy makers, and further illustrate and potentially unblock common bottlenecks impeding equitable access.
- For this type of global mapping, the suggestion is to start at the level of "metadata" with clear and targeted (key) objectives. In parallel, an in-depth exploration of existing data platforms should be carried out to see if there is already a suitable modality for broader and more in-depth data capture.
- Data should be collected, cleaned and analysed in a systematic manner. This process should not be carried out repetitively with different tools.
- Oxygen systems are dynamic in nature, and thus the data will change. This undertaking should aim to tackle the challenge of being able to reflect changes in a timely manner.
- There is always a risk associated with data quality. This can be mitigated by clearly representing the benefit of the Global Oxygen Data Platform to end-users and entities providing inputs.



Way forward following this technical consultation series

- There is a need for collaboration to build interim operational guidance on oxygen generation plants, pipeline distribution systems, high-pressure gas cylinders, booster compressors, and filling stations and distribution manifolds (strategic planning, procurement, commissioning, operations and maintenance for oxygen systems). A draft outline can be found in Annex 3. Individuals are invited to express formal engagement to become a reviewer in whole or in part.
- Global Oxygen Data Platform (mapping): additional working sessions will be needed to define the pathway and feasibility of building this global good, to finalize the concept phase, to identify the resources to launch this initiative and to involve all needed stakeholders.
- All entities are invited to suggest additional topics for further consultation to WHO, as well as additional experts that could participate. The following topics have already been suggested:
 - medical oxygen systems implementation according to different levels of care (including transport/referral);
 - sustainable energy solutions for health facilities on different levels of referral pathways;
 - capacity building on different levels of referral pathways;
 - acute actions taken because of the pandemic vs longer term actions and commitments necessary for successful, sustainable systems.

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Annex 1. Meeting agendas

Meeting 1 agenda

Friday 16 October 2020 (Meeting 1)		
16:00–16:05	Welcome remarks	Mike Ryan Executive Director, WHO Health Emergencies Programme
16:05–16:20	Introduction Meeting objectives, review of agenda, ToR, introduction of participants	Janet Diaz Lead, Clinical Management for COVID-19, WHO Health Emergencies Programme
16:20–16:40	Background <ul style="list-style-type: none"> Oxygen timeline and map Oxygen scale-up 	Janet Diaz
16:40–17:00	Assumptions <ul style="list-style-type: none"> Estimate of oxygen demand Assumptions on baseline oxygen availability and access Assumptions on oxygen supply mix solutions 	Alejandra Velez Focal point, oxygen scale-up, WHO Health Emergencies Programme
17:00–17:05	Leg stretch	
17:05–17:50	Discussion <ol style="list-style-type: none"> Is the oxygen demand calculated from the COVID-19 Essential Supplies Forecasting Tool (EFST) acceptable to estimate the oxygen needs for countries to take action? Which baseline assumptions that have been presented about oxygen availability and accessibility at country level should be used to inform gap analysis? Which baseline assumptions on oxygen supply mix should be used to inform cost forecasting? Are there any other assumptions that we should be considering? 	Fetnah Ramirez (co-chair) Edgardo Diaz (co-chair)
17:50–18:00	Wrap-up and next steps	Janet Diaz

Meeting 2 agenda

Friday 30 October 2020 (Meeting 2)		
16:00–16:05	Introduction <ul style="list-style-type: none"> Review of agenda and meeting objectives Participant attendance Summary of Meeting 1 	Janet Diaz Lead, Clinical Management for COVID-19, WHO Health Emergencies Programme
16:05–16:25	PSA technical and operational overview <ul style="list-style-type: none"> Oxygen sources overview PSA plant value chain PSA configuration overview Discussion framework 	Alejandra Velez Focal point, oxygen scale-up, WHO Health Emergencies Programme
16:25–17:25	Discussion “Round-robin” technical considerations, six common queries	Fetnah Ramirez (co-chair) Edgardo Diaz (co-chair)
17:25–17:30	Wrap-up and next steps	Janet Diaz

Meeting 3 agenda

Friday 13 November 2020 (Meeting 3)		
16:00–16:05	Introduction <ul style="list-style-type: none"> Review of agenda and meeting objectives Participant attendance Summary of Meeting 2 	Janet Diaz Lead, Clinical Management for COVID-19, WHO Health Emergencies Programme
16:05–16:25	Overview of oxygen sources at scale <ul style="list-style-type: none"> Review of PSA and cryogenic liquid Outline of VSA Medical oxygen distribution networks, including piping and high-pressure gas cylinders <ul style="list-style-type: none"> Configurations with PSA plants Configurations with liquid High-level considerations for piped network design <ul style="list-style-type: none"> Technical Operational 	Alejandra Velez Focal point, oxygen scale-up, WHO Health Emergencies Programme

16:25-17:25	Discussion “Round-robin” technical queries for safe, reliable, lasting solutions	Fetnah Ramirez (co-chair) Edgardo Diaz (co-chair)
17:25–17:30	Wrap-up and next steps	Janet Diaz

Meeting 4 agenda

Friday 27 November 2020 (Meeting 4)		
16:00–16:10	Welcome remarks <ul style="list-style-type: none"> • Review of agenda • Participant attendance • Summary of Meeting 3 	Janet Diaz Lead, Clinical Management for COVID-19, WHO Health Emergencies Programme
16:10–16:30	Mapping to optimize the collective efforts <ul style="list-style-type: none"> • Example of supplier positioning mapping Global medical oxygen scale-up mapping <ul style="list-style-type: none"> • Where, What, Why, How, Who • Illustrative data collection methodology 	Alejandra Velez Focal point, oxygen scale-up, WHO Health Emergencies Programme
16:30–17:15	Discussion on the potential value and controversies of a global platform	Fetnah Ramirez (co-chair) Edgardo Diaz (co-chair)
17:15–17:25	Wrap-up of key topics highlighted	Janet Diaz
17:25–17:30	Next steps <ul style="list-style-type: none"> • Publication of technical consultation reports • Collaboration to build interim operational guidance on PSA plants and distribution systems • Data platform and mapping • Identification of other work areas for further working sessions 	Janet Diaz

Annex 2. Meeting attendees

Meeting 1 attendees

Co-chairs

Fetnah Ramirez and Edgardo Diaz

Participating entities

Name	Position	Institutional affiliation
Hans-Joerg Lang	Paediatric Intensivist	ALIMA
Victoria Smith	Senior Monitoring and Evaluation Program Manager	Assist International
Jim Stunkel	Vice President and Director of Operations	Assist International
Jim Ansara	Co-founder and Managing Director	Build Health International
Martha Gartley	Senior Technical Advisor	CHAI
Tayo Olaleye	Country Support Manager	CHAI
Gene Saxon	Lead of the Global Health Program	EPFL
Cliff Roberson	Anaesthesia Advisor	MSF OCP
Hugues Gaertner	Biomedical Advisor (Spain)	MSF
Lisa Smith	Senior Market Dynamics Officer	PATH
Alex Rothkopf	Engineer and Supply Chain Models	PATH
Jonas Karlstrom	Medical Physician – Product Innovation	UNICEF SD
Beverly Bradley	Technical Focal Point for Procurement of Oxygen Therapy Products	UNICEF SD
Smita Kumar	Paediatrician and Senior New-born Advisor	USAID
Helen Petach	Chemist and Supply Chain	USAID

Observing entities

Every Breath Counts: Leith Greenslade.

UNITAID: Ali Cameron, Luis Pizarro.

WHO Secretariat

Dr Tedros Adhanom Ghebreyesus, Dr Mike Ryan, Dr Janet Diaz, Gabriela Jimenez-Moyao, Mohammed Saidu Kouyate, Ingrid Lara, Connie McDonough-Thayer, Kiu Siang Tay, Adriana Velazquez, Laura Alejandra Velez; Pan American Health Organization: Luis De La Fuente. Alexandre Lemgruber, Dina Pfeifer; WHO Regional Office for Europe: Tifenn Humbert, Claudio Meirovich.

Meeting 2 attendees

Co-chairs

Fetnah Ramirez and Edgardo Diaz

Participating entities

Name	Position	Institutional affiliation
Hans-Joerg Lang	Paediatric Intensivist	ALIMA
Victoria Smith	Senior Monitoring and Evaluation Program Manager	Assist International
Jim Stunkel	Vice President and Director of Operations	Assist International
Jim Ansara	Co-founder and Managing Director	Build Health International
Martha Gartley	Senior Technical Advisor	CHAI
Tayo Olaleye	Country Support Manager	CHAI
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Alex Rothkopf	Engineer and Supply Chain Models	PATH
Jonas Karlstrom	Medical Physician – Product Innovation	UNICEF SD
Beverly Bradley	Technical Focal Point for Procurement of Oxygen Therapy Products	UNICEF SD
Helen Petach	Chemist and Supply Chain	USAID
Samy Ahmar	Head of Health	Save the Children

Not in attendance: EPFL: Gene Saxon; USAID: Smita Kumar.

Observing entities

Bill & Melinda Gates Foundation: Douglas Call.

UNITAID: Luis Pizarro.

Not in attendance: Every Breath Counts: Leith Greenslade; UNITAID: Ali Cameron.

WHO Secretariat

Dr Janet Diaz, Tim Das, Ingrid Lara, Gabriela Jimenez-Moyao, Mohammed Saidu Kouyate, Jacobus Preller, Kiu Siang Tay, Adriana Velazquez, Laura Alejandra Velez; WHO Regional Office for Africa: Ama Edwin, Stanislav Kniazkov; Pan American Health Organization: Luis De La Fuente, Alexandre Lemgruber, Ludovic Reveiz; WHO Regional Office for South-East Asia: Manisha Shridhar, Bhagteshwar Singh; WHO Regional Office for Europe: Claudio Meirovich; WHO Regional Office for the Eastern Mediterranean: Houda Langan; WHO Regional Office for the Western Pacific: Socorro Escalante, Gary Greg Kuniyoshi.

Not in attendance: WHO Regional Office for Europe: Tifenn Humbert, Dina Pfeifer; WHO Regional Office for the Eastern Mediterranean: Chiori Kodama.

Meeting 3 attendees

Chair

Edgardo Diaz

Participating entities

Name	Position	Institutional affiliation
Victoria Smith	Senior Monitoring and Evaluation Program Manager	Assist International
Jim Stunkel	Vice President and Director of Operations	Assist International
Jim Ansara	Co-founder and Managing Director	Build Health International
Martha Gartley	Senior Technical Advisor	CHAI
Cliff Roberson	Anaesthesia Advisor	MSF OCP
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Jonas Karlstrom	Medical Physician – Product Innovation	UNICEF SD
Beverly Bradley	Technical Focal Point for Procurement of Oxygen Therapy Products	UNICEF SD
Helen Petach	Chemist and Supply Chain	USAID
Smita Kumar	Paediatrician and Senior New-born Advisor	USAID
Gene Saxon	Lead of the Global Health Program	EPFL

Absent: Fetnah Ramirez (co-chair). Not in attendance: ALIMA: Hans-Joerg Lang; CHAI: Tayo Olaleye; Save the Children: Isah Adamu, Samy Ahmar.

Observing entities

Bill & Melinda Gates Foundation: Douglas Call.

UNITAID: Ali Cameron, Luis Pizarro.

Not in attendance: Every Breath Counts: Leith Greenslade.

WHO Secretariat

Dr Janet Diaz, Tim Das, Ingrid Lara, Gabriela Jimenez-Moyao, Jacobus Preller, Herbert Schmidt, Adriana Velazquez, Laura Alejandra Velez; WHO Regional Office for Africa: Ama Edwin, Stanislav Kniazkov; Pan American Health Organization: Luis De La Fuente, Alexandre Lemgruber, Ludovic Reveiz; WHO Regional Office for South-East Asia: Manisha Shridhar, Bhagteshwar Singh; WHO Regional Office for Europe: Claudio Meirovich; WHO Regional Office for the Eastern Mediterranean: Houda Langar; WHO Regional Office for the Western Pacific: Socorro Escalante, Gary Greg Kuniyoshi.

Not in attendance: WHO Regional Office for Europe: Tifenn Humbert, Dina Pfeifer; WHO Regional Office for the Eastern Mediterranean: Chiori Kodama.

Meeting 4 attendees

Co-chairs

Edgardo Diaz and Fetnah Ramirez

Participating entities

Name	Position	Institutional affiliation
Hans-Joerg Lang	Paediatric Intensivist	ALIMA
Victoria Smith	Senior Monitoring and Evaluation Program Manager	Assist International
Jim Stunkel	Vice President and Director of Operations	Assist International
Jim Ansara	Co-founder and Managing Director	Build Health International
Martha Gartley	Senior Technical Advisor	CHAI
Tayo Olaleye	Country Support Manager	CHAI
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Jonas Karlstrom	Medical Physician – Product Innovation	UNICEF SD
Beverly Bradley	Technical Focal Point for Procurement of Oxygen Therapy Products	UNICEF SD
Smita Kumar	Paediatrician and Senior Newborn Advisor	USAID
Joolan Saroor	Maternal and Newborn Health Program Analyst	USAID
Samy Ahmar	Head of Health	Save the Children
Gene Saxon	Lead of the Global Health Program	EPFL

Observing entities

Bill & Melinda Gates Foundation: Douglas Call.

Not in attendance: Every Breath Counts: Leith Greenslade.

WHO Secretariat

Dr Janet Diaz, Marta Lado, Ingrid Lara, Herbert Schmidt, Adriana Velazquez, Laura Alejandra Velez; WHO Regional Office for Africa: Stanislav Kniazkov; Pan American Health Organization: Alexandre Lemgruber; WHO Regional Office for Europe: Claudio Meirovich; WHO Regional Office for the Eastern Mediterranean: Houda Langar.

Annex 3. Proposed contents for technical guidance

The following is a preliminary proposal of the contents for a forthcoming interim technical guidance for PSA oxygen generation plants, covering strategic planning, procurement, commissioning, operations, and maintenance of these units.

Interim Operational Guidance

Oxygen sources, pipeline distribution, high-pressure gas cylinders, booster-compressors and filling stations and distribution manifolds

Strategic planning, procurement, commissioning, operations and maintenance for oxygen systems

Introduction

Purpose, scope, intended audience, how to read this document

Part A: Oxygen supply

Section 1 – PSA oxygen generation plants

PSA process overview

Compression, Adsorption, Purge and regeneration, Equalization, Swing

Plant components

Description of components and operations: Feed-air compressor, Refrigeration air dryer unit, Filtration assembly/unit, Air tank, PSA generator, Control unit, Product tank, Oxygen sensor – purity analyser

Host facility and infrastructure requirements

Location considerations (environmental), Infrastructure (housing, power), Operational parameters and considerations

Plant sizing and configuration

Determination of need, Sizing and configuring unit(s), Supply security considerations, Plant-to-distribution layout

Installation and commissioning

Training, Initial start-up procedure, Testing, Certification, Handover

Operations and maintenance

Daily and weekly inspections, PPM schedule (biannual, annual), Maintenance briefs (filter element replacement, tank/column maintenance, valve maintenance, safety devices, compressed air tank)

Troubleshooting

Troubleshooting flowchart, Technical procedure briefs (leak test, air regulator adjustment, capacity test, pressure set point, oxygen analyser probe check and calibration, purging)

Section 2 – VSA and VPSA oxygen generation plants

(content to deviate from Section 1 where relevant)

Section 3 – Bulk liquid storage and vaporization

(content under development)

Part B: Oxygen distribution systems

Section 4 – Distribution: pipe networks

Overview

Network considerations, Medical gas application, Operational considerations

Network configuration

Network design process, Pipe sizing, Flow rates, Pressure drop allowance, Pipeline components (terminal units, area valve service units [AVSUs], line valve assemblies [LVAs], isolation valves)

Joining, installation and testing

Brazing, Mechanical joinery, Equipment, Staging of works, Testing, Final inspection of installation

General operational guidelines

Initial start-up, Routine operations, Daily and monthly checks, PPM, Troubleshooting

Section 5 – High-pressure gas cylinders

Overview

Distinguishing one gas from the next, Cylinder accessories

Using high-pressure gas cylinders

Changing a cylinder, storage, Quality assurance, Cleaning cylinders

Maintenance, repairs and troubleshooting

Daily and weekly controls, User – clinician, key weak points, troubleshooting, cylinder testing

Cylinder safety

Leaks and fires caused by cylinders

Section 6 – Filling stations: booster compressors and filling manifolds

Overview

Functionality, Components

Booster compressor sizing and configuration

Sizing of units, Configuration of units

Filling manifold

Configuration, Connections, Purge/vacuum compressor

Installation and commissioning

Placement in plant room, Flow by-pass, Initial start-up procedure, Testing, Certification, Handover

Operations and maintenance

Inspections (daily and weekly requirements, PPM schedule, technical briefs)

Troubleshooting

Section 7 – Distribution manifolds

Introduction

Use-case: primary supply, secondary supply, emergency backup

Manifold types and configuration options

Fully automated manifold, Semi-automated manifold, Manual manifold

Manifold components

Component descriptions and functions

Manifold room



- Construction and layout of manifold rooms, Manifold header configurations, Installation
- Manifold operations
 - General operational guidelines, Initial start-up and checks, Routine operations and bank changing
- Maintenance and repairs
 - Daily and monthly checks, PPM
- Troubleshooting

Part C: Critical complementary guidance to sustain oxygen systems

Section 8 – Human resources requirements

Section 9 – Medical gas operational plan (*or something to this effect*)

Section 10 – Procurement guidance

Considerations, Key requirements, Evaluation criteria, Process overview for technical evaluation (training and commissioning, warranty terms and conditions, service level agreements), tender strategies

Section 11 – Equipment disposal

Dismounting and sorting, Plant disposal

Works cited

Glossary of terms

Annexes

Annex X: Oxygen plant maintenance – checklist and schedule
General system checks to conduct at every service interval, generic PPM schedules

Annex X: Supplementary PSA plant procurement documents
Technical specifications and requirement PSA plant template
Previous experience performance form
Information about bidder
Template to plan for life cycle costs

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