Bridging the gap between oxygen needs and technical solutions

May 4, 2021.

Breathing is the first action we do in life.
<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Presenter:</th>
</tr>
</thead>
<tbody>
<tr>
<td>13:40 - 14:10</td>
<td>The Oxygen Ecosystem: Sources, distribution, delivery. Multi-disciplinary engagement.</td>
<td>Alejandra Velez, Technical focal point, Oxygen scale-up WHO Health Emergency Programme</td>
</tr>
<tr>
<td>14:10 - 15:10</td>
<td>Round Table with Experts and Partners</td>
<td>Expert Panel and Facilitators</td>
</tr>
<tr>
<td>15:20 - 15:25</td>
<td>Recommendations for medical devices specifications and procurement.</td>
<td>Adriana Velazquez, Lead Medical Devices and In Vitro Diagnostics WHO Access to Medicines and Health Products Division</td>
</tr>
<tr>
<td>15:25 - 15:30</td>
<td>Wrap up &amp; next steps.</td>
<td>Janet Diaz</td>
</tr>
<tr>
<td>Topics:</td>
<td>Organization</td>
<td>Expert</td>
</tr>
<tr>
<td>---</td>
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</tr>
<tr>
<td><strong>1</strong> Base line data</td>
<td></td>
<td></td>
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<tr>
<td><strong>Q1</strong> A recurring challenge appears to be a lack of available data to inform policy makers, planners, and/or procurers to strategically scale-up resources (equipment, HR, and finances to ensure continuity) needed for increasing and continued oxygen access. How have your teams addressed this challenge to realize end-to-end oxygen therapy solutions?</td>
<td>CHAI</td>
<td>Martha Gartley Tayo Olaleye</td>
</tr>
<tr>
<td><strong>2</strong> Forecasting demand</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Q2</strong> Knowing there are different tools and approaches to quantify the oxygen demand at facility/national level, what would be your recommendations for getting this input to determine the oxygen mix solution?</td>
<td>UNICEF</td>
<td>Beverly Bradley</td>
</tr>
<tr>
<td><strong>3</strong> Power supply and Infrastructure</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Q3</strong> Considering the challenges to bring electricity, mainly to the remote areas, would you consider the solar panels as an option for the PSA plants? What are the pros and drawbacks of the solar panels?</td>
<td>ALIMA</td>
<td>Hassan Bouziane Antoine Maillard</td>
</tr>
<tr>
<td><strong>Q4</strong> It has been said that piping health facilities, could increase the access to oxygen therapy. Knowing that many facilities in LMIC are old buildings and modular structures, what would be a proposed way forward to plan for piping?</td>
<td>BUILD HEALTH INTERNATIONAL</td>
<td>Jim Ansara</td>
</tr>
<tr>
<td><strong>4</strong> Logistics</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Q5</strong> What would be the considerations for shipping/transport of PSA plants + cylinders into the country and inside the country?</td>
<td>CHAI</td>
<td>Martha Gartley Tayo Olaleye</td>
</tr>
<tr>
<td>Topics:</td>
<td>Organization</td>
<td>Expert</td>
</tr>
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<td>---------------------------------------------</td>
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</tr>
<tr>
<td>Human resources availability and training: Clinical and Technical</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q6   Considering many of the technicians in charge of the biomedical equipment haven’t received a formal education, what would be your suggestions / strategies for technical training?</td>
<td>ASSIST INTERNATIONAL</td>
<td>Jim Stunkel Benjin Joshua</td>
</tr>
<tr>
<td>Q7   We know that is has been a challenge to bring oxygen therapy and ventilation to LMIC, what would be your suggestions on the way forward?</td>
<td>PAHO</td>
<td>Alexandre Lemgruber</td>
</tr>
<tr>
<td>Long term sustainability</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q8   We have been talking about “long-term and sustainable solutions”, would you think that the application of Life Cycle Cost Analysis for contextualized solutions is feasible in the context of Emergency Procurement / LMIC?</td>
<td>PATH</td>
<td>Alexander Rothkopf</td>
</tr>
<tr>
<td>Q9   What can MoH can do with biomedical equipment that is underused? How to build &quot;brand related&quot; equipment bundles (accessories, consumables, spare parts)?</td>
<td>ASSIST INT</td>
<td>Jim Stunkel Benjin Joshua</td>
</tr>
<tr>
<td>Quality Assurance and Supplier’s management</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q10  Once the needs have been defined, what would be the main the considerations you would suggest for Quality Assurance process at country level?</td>
<td>WHO</td>
<td>Ingrid Lara</td>
</tr>
<tr>
<td>Q11  How could countries negotiate with liquid oxygen suppliers? (Considering their strength in distribution strategies and management of cylinders, but general perception of unaffordable costs).</td>
<td>UNICEF</td>
<td>Beverly Bradley</td>
</tr>
</tbody>
</table>
1770s  Discovery of oxygen as an element and first publications.

1970s  PSA started being used commercially for medicinal use.

2006  NHS/DoH “HTM 02-01: Medical Gases”.

2015  WHO:
- Internt’l Pharmacopoeia (O₂ included).
- “Tech. Guidance & Specs. for O₂ Concentrators”.

- Nigeria: National O₂ Policy and Scale-up Strategy (published A₂O₂ event).
- Formal EBC launch.

2020  • Declaration of pandemic.
- Publication of various interim tech. guidance documents.

1902  First application of an air separation process by fractional distillation. Carl Linde.

1980  Oxygen included in European Pharmacopoeia (2nd ed.).

2012  WHO: “The Clinical Use of O₂ in Hospitals with Limited Resources”.

2016  WHO: “O₂ Therapy for Children”.
- Ethiopia: first LMIC to publish “National O₂ Scale-up Roadmap”.

- First documented case of SARS-CoV-2.
Background: Oxygen timeline: technical and operational guidance

2020:
Declaration of pandemic 11 March 2020

April
SARI treatment centre; SARI TOOLKIT

June
Biomed inventory tool

Sept
1st Living guideline on Therapeutics: corticosteroids

Nov
WHO PPE and specifications for COVID-19

2021
Clinical guidance v3

Living Guideline updated

Total cost: $184.5M
Total units: 2.45M
Total countries: 149

Biomed Consortium:
Background: Oxygen is an essential medicine across the health interventions.


Therapeutic Oxygen must be an affordable medicine for treatment of different interventions.

… Including in COVID19, surgery, trauma, pneumonia and maternal and childcare…
Background: Scaling-up access to medical oxygen

Multidisciplinary effort

Ultimate goal: quality $O_2$ reach safely the patient

Longer term sustainability will require a holistic approach and an ecosystem of resources.
The Oxygen Ecosystem (in brief…)

- **Equitable scale-up** means quality oxygen reaching more patients, at the right time and in a more sustainable way.
- **Sustainable action** requires implementation programmes, resource allocation, local capacity building and, in some situations, cultural change.
- **Multidisciplinary stakeholder** action is needed to develop strategic planning, tools, advocacy and technical support.
# Overview of oxygen supply sources

<table>
<thead>
<tr>
<th></th>
<th>PSA bedside concentrators</th>
<th>PSA / VSA / PVSA (O_2) generator plants</th>
<th>Cryogenic liquid</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description</strong></td>
<td>Different flow rates, typical: 5, 8 or 10 L/min – medical use</td>
<td>Different sizes and configurations: single and duplex 2–200+ Nm³/hr</td>
<td>Produced mainly for heavy industry; serves medical sector where GMP allows</td>
</tr>
</tbody>
</table>
| **Requirements**   | • Situated onsite, bedside.  
                    • Continuous and reliable electrical source.  
                    • Device-specific spares needed.  
                    • Timely technical maintenance (preventive every 6 months).  
                    • Need for IPC measures as is situated bedside. | • Various own/operate models.  
• Often situated onsite.  
• Continuous and reliable electrical source during plant and booster operations.  
• Detailed technical and financial planning for long-term operations and maintenance (~20 years). | • Third party responsible for production and supply chain.  
• Plants must be offsite. Bulk liquid tanks with passive vaporization for onsite storage (specialized materials).  
• CAPEX and OPEX are very high, borne by third party. |
| **Additional considerations** | • Difficult to optimize for at-scale needs.  
• Not suitable for high-flow or higher-pressure needs (e.g., patient ventilators).  
• Depending on the capacity and oxygen therapy, flow could be split among patients. | • Need > 4 technicians for 24/7 operation.  
• Continuous supply at all atmospheric pressures.  
• Supply can be piped bedside and/or plant can fill cylinders to be used bedside or transported elsewhere. | • Goods and service contract.  
• Product can be used via high-pressure gas cylinders or piped bedside from bulk tank. |

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World Health Organization

HEALTH EMERGENCIES programme
Overview of PSA oxygen generation plants

Sizing and configuring the solution

- Site-specific environmental considerations in planning stage (elevation, humidity, dust...).
- Plant size based on facility and catchment need.
- Planning for back up supply: via redundant system, secondary plant, emergency booster/filling and cylinder stocking.

Different components: PSA, power generation, booster/filling, etc.
Different configurations: single, duplex, multiplex
Different sizes: 2–200+ Nm³/hr
Option of skid-mounted or containerized systems

WHO Technical Specifications: https://www.who.int/publications/i/item/technical-specifications-for-pressure-swing-adsorption(PSA)-oxygen-plants
PRIMARY SYSTEM
SOURCE (production and reserve) + DISTRIBUTION (piped network or trolleys) + DELIVERY (regulation and conditioning)
Direct piping + cylinder filing ramp as backup for hospital (manifold) or to distribute interfacility.

Two PSA oxygen plants, supplying one hospital, and with a booster compressor and filing ramp as a back-up or for other hospital consumption.

In this scenario systems operate in a waterfall with a primary, secondary, and reserve supply.
**COMMON PSA SIZES AND CONSIDERATIONS (Examples)**

<table>
<thead>
<tr>
<th>PSA Capacity</th>
<th>Cost without booster</th>
<th>Cost with booster</th>
<th># Cylinder</th>
<th>Housing size</th>
</tr>
</thead>
<tbody>
<tr>
<td>9 - 10 m³/hr 150 - 167 L/min</td>
<td>$50,000.00 USD</td>
<td>$82,420.00 USD</td>
<td>8 - 10</td>
<td>240 X 595 x 270 cm (Container)</td>
</tr>
<tr>
<td>13 - 30 m³/hr 216 - 333 L/min</td>
<td>$61,000.00 USD</td>
<td>min $88,777 USD</td>
<td>16</td>
<td>240 X 595 x 240 cm (Container)</td>
</tr>
<tr>
<td>32-42 m³/hr 533 - 713 L/min</td>
<td>$103,000.00 USD</td>
<td>$131,000.00 USD</td>
<td>52</td>
<td>223.5 x 823 x 269.3 cm</td>
</tr>
</tbody>
</table>

The number of cylinders are estimated in an operation of 24hrs, if working time is reduce also the number of cylinders.

Human resources- It will be necessary to have at least one person working for 6 hours to move 200 cylinders inside the gas house, in addition to the personnel necessary to move cylinders to other hospitals.

Technical-economic proposal of each manufacturer is different in accessories and configurations. 

Cylinder's capacity in this calculations is ~50 L. Cylinders calculated with a filling pressure of 150-180 bar.
DISTRIBUTION SYSTEM

Cylinders

Oxygen Cylinder Safety

Intended for health workers and all personnel managing medical oxygen.

Do

- Do learn proper medical cylinder safety handling.
- Do transport cylinders correctly.
- Do set up cylinders for clinical use at a safe distance from the patient.
- Do store cylinders correctly.

Do not

- Do not alter, transport or handle cylinders incorrectly.
- Do not use un-certified medical oxygen cylinders.
- Do not use oil, lubricants or alcohol-based hand sanitizer on cylinder's fittings.
- Do not attempt to repair a cylinder or a valve if leakage is detected.

Images are for illustrative purposes only.

WHO-UNICEF technical specifications and guidance for oxygen therapy devices:

Dimensions (Height x diameter) (mm)

- 535 x 102
- 865 x 102
- 930 x 140
- 1320 x 178
- 1520 x 229

1.8 m

1.5 m

1.25 m

1 m

0.75 m

0.5 m

0.25 m
DISTRIBUTION SYSTEM
Piped network, regulation and conditioning
PRIMARY SYSTEM
SOURCE (production and reserve) + DISTRIBUTION (piped network or trolleys) + DELIVERY (regulation and conditioning)
Bedside delivery & monitoring medical devices

- **Pulse Oximeter**

**Primary medical device list for the COVID-19 response and associated technical specifications**

- **Protection equipment**
- **Diagnostic**
- **Treatment**
- **Rehabilitation or palliation**

**Oxygen therapy**

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
<th>Initial O₂ dose</th>
<th>O₂ dose increase</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Nasal cannula</td>
<td>1–5 L/min</td>
<td>6–10 L/min</td>
</tr>
<tr>
<td>2</td>
<td>Nasal cannula</td>
<td>6–10 L/min</td>
<td>10–15 L/min</td>
</tr>
<tr>
<td>3</td>
<td>Venturi face mask</td>
<td>6–10 L/min</td>
<td>10–15 L/min</td>
</tr>
<tr>
<td>4</td>
<td>Face mask with reservoir bag</td>
<td>6–10 L/min</td>
<td>10–15 L/min</td>
</tr>
</tbody>
</table>

**O₂ concentration**

- FIO₂ 0.25–0.40
- FIO₂ 0.44–0.60
- FIO₂ 0.60–0.95
Humanitarian Procurement of Medical Equipment

Transnational funders contribute as much as 80% of the money spent on equipping health care systems in resource-limited settings.

Governments have challenges managing the funding processes.

HO have short lead times for procurement and few resources for conducting risk assessments and quality assurance.

Before the Pandemic, estimations suggest that between 40 and 70 % of medical equipment (procured and donated, new or refurbished) in LMIC are inoperable, because:

- Lack of needs assessment
- Inappropriate selection of products
- Broken or Incomplete equipment
- Lack of service agreements
- Lack of technicians (biomeds)
- Lack of training on use and maintenance
- Equipment is obsolete or redundant
- Incompatible with infrastructure
- Operations are financially unviable
Holistic and “tiered” approach

Phase 1: Assessment of oxygen need-gap
- Oxygen needs baseline assessment to understand needs at facility, subnational or national level.
- Select and bundle solutions to estimate costs.
- Unbundle and select priorities.

Phase 2: Procurement and implementation
- Preparation of site (including infrastructure, human resources, power supply and other ancillary services).

Phase 3: Sustainability of the project
Phase 1: Assessment of oxygen need-gap

How to do so if there is limited time and resources to do so?

1) Oxygen needs baseline assessment to understand needs at facility, subnational or national level.

- Clinical Need
  - Are there enough and trained medical staff?
    - Yes
    - No
      - Electricity?
        - Yes
        - Infrastructure?
          - Yes
          - Technical staff?
            - Yes
            - Funding covers operating costs?
              - Yes
              - Select the mix solution
            - No
            - ACT
          - No
          - ACT
        - No
        - ACT
    - No
    - ACT
Phase 1: Assessment of oxygen need-gap

Holistic and “tiered” approach

2) Select and bundle solutions to estimate costs.

Contextualise plan for compatibility with…

- Nurse
- Power supply
- Spare parts
- Biomed toolkit
- Ancillary devices
- Accessories and Consumables
- Technician

(Storage)
Phase 1: Assessment of oxygen need-gap (3)

Holistic and “tiered” approach

2) Select and bundle solutions to estimate costs.
Phase 1: Assessment of oxygen need-gap

Holistic and “tiered” approach

2) Select and bundle solutions to estimate costs.
## E.g. of equipment bundles:

<table>
<thead>
<tr>
<th>Item</th>
<th>Quantity per equipment total</th>
<th>Category</th>
<th>Brand specific</th>
<th>Timeframe (approximate consumption)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient monitor multiparametric with ECG, non-invasive blood pressure (NIBP), oxygen saturation (SpO₂), respiratory rate (RR), and temperature (TEMP) sensors</td>
<td>1</td>
<td>Equipment</td>
<td>Brand: XXX; Model: XXX</td>
<td>N/A</td>
</tr>
<tr>
<td>ECG electrodes adult</td>
<td>5</td>
<td>Consumable</td>
<td>No</td>
<td>6 months</td>
</tr>
<tr>
<td>ECG electrodes paediatric</td>
<td>5</td>
<td>Consumable</td>
<td>No</td>
<td>6 months</td>
</tr>
<tr>
<td>3 leads ECG cable</td>
<td>2</td>
<td>Accessory</td>
<td>Yes</td>
<td>1 year</td>
</tr>
<tr>
<td>5 leads ECG cable</td>
<td>2</td>
<td>Accessory</td>
<td>Yes</td>
<td>1 year</td>
</tr>
<tr>
<td>Reusable SpO₂ probes adult</td>
<td>3</td>
<td>Accessory</td>
<td>Yes</td>
<td>1 year</td>
</tr>
<tr>
<td>Reusable SpO₂ probes paediatric use</td>
<td>3</td>
<td>Accessory</td>
<td>Yes</td>
<td>1 year</td>
</tr>
<tr>
<td>Paediatric blood oxygen probe extension wire</td>
<td>2</td>
<td>Accessory</td>
<td>Yes</td>
<td>1 year</td>
</tr>
<tr>
<td>Blood pressure – non-invasive: adult reusable cuffs</td>
<td>3</td>
<td>Accessory</td>
<td>Yes</td>
<td>1 year</td>
</tr>
<tr>
<td>Blood pressure – non-invasive: paediatric reusable cuffs</td>
<td>3</td>
<td>Accessory</td>
<td>Yes</td>
<td>1 year</td>
</tr>
<tr>
<td>Blood pressure extension tube</td>
<td>2</td>
<td>Accessory</td>
<td>Yes</td>
<td>1 year</td>
</tr>
<tr>
<td>External skin temperature probes</td>
<td>2</td>
<td>Accessory</td>
<td>Yes</td>
<td>1 year</td>
</tr>
<tr>
<td>Ground wire</td>
<td>1</td>
<td>Accessory</td>
<td>No</td>
<td>1 year</td>
</tr>
<tr>
<td>European standard power cord</td>
<td>1</td>
<td>Accessory</td>
<td>No</td>
<td>1 year</td>
</tr>
<tr>
<td>American standard power cord</td>
<td>1</td>
<td>Accessory</td>
<td>No</td>
<td>1 year</td>
</tr>
<tr>
<td>United Kingdom standard power cord</td>
<td>1</td>
<td>Accessory</td>
<td>No</td>
<td>1 year</td>
</tr>
<tr>
<td>Battery</td>
<td>1</td>
<td>Spare parts</td>
<td>Yes</td>
<td>1 year</td>
</tr>
</tbody>
</table>

The technical specifications are the minimum standards to ensure quality and safety but they don’t define the appropriateness of the technology in specific settings.
3) Unbundle and select priorities.

- Focus on products or services that make oxygen available in first instance.
- Making strategic choices to support vertical scaling up (institutionalization).
- Making strategic choices to support horizontal scaling up (expansion/replication).
- Diversification of resources: operations, service, training, consumables.
Sharing decisions and accountability in procurement processes

And:

✓ Train on rational and safe use of oxygen.
✓ Start registration of donated equipment.
✓ Integrate technical teams in the health workforce.
✓ Document local prices.
✓ Adapt, adopt and implement gradually the technical solutions.
Resource and partner mapping in-line with GF framework

CCMs and national COVID-19 response managers will want to ensure their response plans accurately assess current and forecasted future oxygen and respiratory care equipment needs, identify best-fit solutions, whilst leverage available in-country expertise. Countries should consider the following activities (if not already completed), and consider using noted resources, to meet these objectives:

**Conduct a rapid respiratory care stakeholder mapping exercise**
- Every Breath Counts partner mapping matrix
- National COVID-19 response task force
- Other relevant in-country coalitions or TWGs.

**Conduct rapid capacity assessments of designated, planned, and/or potential C19 treatment centers**
- WHO Biomedical Equipment assessment tool & phone survey guidance

**Rapid oxygen & respiratory care equipment gap assessment for designated, planned and/or potential C19 treatment centers**
- WHO Essential Supplies Forecasting Tool
- WFSA Oxygen Supply & Demand Calculator
- UNICEF Oxygen System Planning Tool
- WHO Medical devices technical specifications
- WHO PSA plant technical specifications

**Develop high-level supply landscape (public + private) overview**
- PATH/CHAI supplier questionnaires
- PATH/CHAI SSA distributor listing
- Every Breath Counts partner mapping matrix

**Develop robust procurement requests**
- WHO Essential Supplies Forecasting Tool
- WFSA Oxygen Supply & Demand Calculator
- UNICEF Oxygen System Planning Tool
- UNICEF Supply Division Procurement Services

**Develop targeted training plans**
- WHO Health Workforce Estimator
- OpenWHO clinical management and COVID-19 channels
- Project ECHO webinar series from Assist International
  - Clinical
  - Biomedical

**Assess post-C19 financing needs (e.g. equipment maintenance and operation) and identify potential financing mechanisms**
- Ethiopia Redeployment

**General Resources**
- EBC - Coalition meetings: Mondays @17h00 CET/11 EST / Hub for most O₂-related partners and activities (website here)
- C19RM - Operational recommendations resource package from BHI/PIH
- PATH Oxygen Delivery Toolkit

World Health Organization
Ripple effect: Each act has better impact when coordinated in a collective. Is an essential and common good.