Bridging the gap between oxygen needs and technical solutions

May 4, 2021.

Breathing
is the first action we do in life.

World Health Organization

HEALTH EMERGENCIES programme

Draft Agenda

Tuesday 4 May 2021		13:30 to 15:30 hrs. CET time
13:30 - 13:40	**Welcome remarks.** Background: Oxygen timeline.	**Janet Diaz** Lead, Clinical Management for COVID-19 WHO Health Emergency Programme
13:40 - 14:10	The **Oxygen Ecosystem:** Sources, distribution, delivery. Multi-disciplinary engagement. **Holistic Oxygen/Biomedical Equipment assessment:** Humanitarian procurement. Phased technical approach to build a proposal. Decision-tree process. Adapt, adopt and implement technical solutions. Orientation to tools and resources.	**Alejandra Velez** Technical focal point, Oxygen scale-up WHO Health Emergency Programme
14:10 - 15:10 15:10 – 15:20	**ROUND TABLE WITH EXPERTS AND PARTNERS** **OPEN QUESTIONS AND ANSWERS**	**EXPERT PANEL AND FACILITATORS**
15:20 - 15:25	**Recommendations for medical devices specifications and procurement.**	**Adriana Velazquez** Lead Medical Devices and In Vitro Diagnostics WHO Access to Medicines and Health Products Division
15:25 - 15:30	**Wrap up & next steps.**	**Janet Diaz**

Round table with experts and partners … (1)

	Topics:	Organization	Expert
1	**Base line data**		
Q1	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?	**CHAI**	**Martha Gartley** **Tayo Olaleye**
2	**Forecasting demand**		
Q2	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?	**UNICEF**	**Beverly Bradley**
3	**Power supply and Infrastructure**		
Q3	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?	**ALIMA**	**Hassan Bouziane** **Antoine Maillard**
Q4	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?	**BUILD HEALTH INTERNATIONAL**	**Jim Ansara**
4	**Logistics**		
Q5	What would be the considerations for shipping/transport of PSA plants + cylinders into the country and inside the country?	**CHAI**	**Martha Gartley** **Tayo Olaleye**

Round table with experts and partners … (2)

	Topics:	Organization	Expert
5	**Human resources availability and training: Clinical and Technical**		
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?	**ASSIST INTERNATIONAL**	**Jim Stunkel** **Benjin Joshua**
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?	**PAHO**	**Alexandre Lemgruber**
6	**Long term sustainability**		
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?	**PATH**	**Alexander Rothkopf**
Q9	What can MoH can do with biomedical equipment that is underused? How to build "brand related" equipment bundles (accessories, consumables, spare parts)?	**ASSIST INT**	**Jim Stunkel** **Benjin Joshua**
7	**Quality Assurance and Supplier's management**		
Q10	Once the needs have been defined, what would be the main the considerations you would suggest for Quality Assurance process at country level?	**WHO**	**Ingrid Lara**
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).	**UNICEF**	**Beverly Bradley**

Background: Oxygen timeline: identifying technical guidance for LMICs

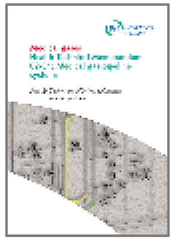
1770s
Discovery of oxygen as an element and first publications.

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

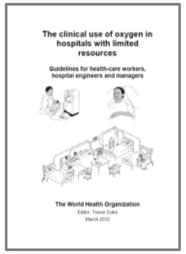
1970s
PSA started being used commercially for medicinal use.

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

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



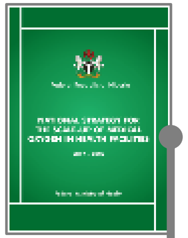
2012
WHO: "The **Clinical Use of O_2** in Hospitals with Limited Resources".



2015
WHO:
- **Intn'l Pharmacopoeia** (O_2 included).
- "Tech. Guidance & Specs. for **O_2 Concentrators**".

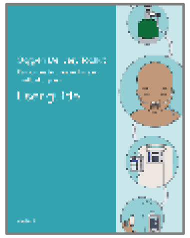
2016
- WHO: "**O_2 Therapy for Children**".
- Ethiopia: first LMIC to publish "**National O_2 Scale-up Roadmap**".

2017
- WHO Model List of **Essential Medicines**: adds O_2.
- Nigeria: **National O_2 Policy and Scale-up Strategy** (published A_2O_2 event).
- Formal EBC launch.



2019
- **WHO-UNICEF: "Tech. Specs & Guidance for O_2 Therapy Devices**".
- First documented case of SARS-CoV-2.

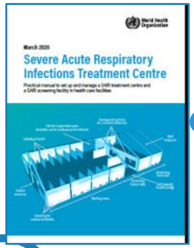
2020
- **Declaration of pandemic.**
- Publication of various interim tech. guidance documents.

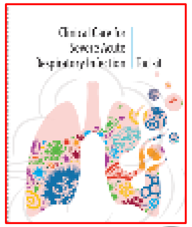


Background: Oxygen timeline: technical and operational guidance

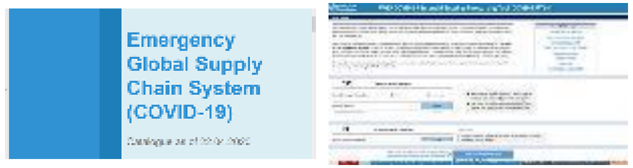
2020:
Declaration of pandemic
11 March 2020

April
SARI treatment centre, SARI TOOLKIT

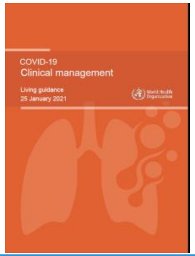




April
Consortium, Global Supply Chain Catalogue v1, ESFT



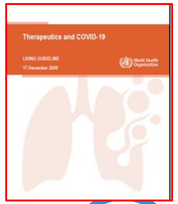
May
Clinical Guidance v2



June
Biomed inventory tool

June
WHO PSA technical specifications

Sept
1st Living guideline on Therapeutics: corticosteroids .

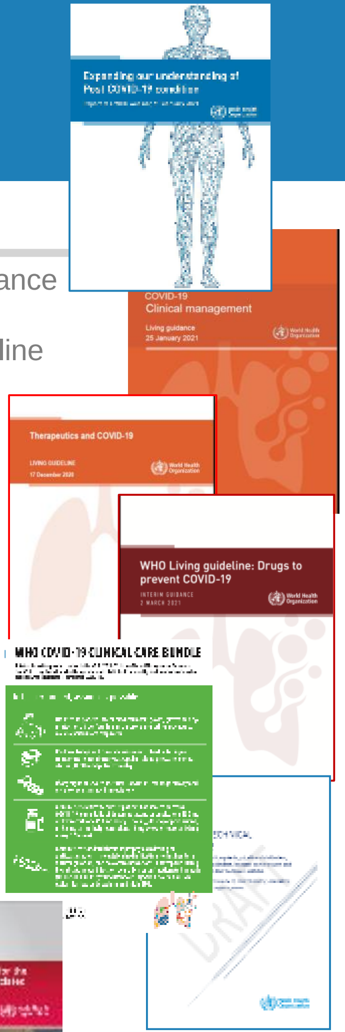


October
O2 Technical Consultation

Nov
WHO PPE and specifications for COVID-19

Nov
WHO Priority medical devices and specifications for COVID-19

2021
Clinical guidance v3
Living Guideline updated



Biomed Consortium:

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

World Health Organization

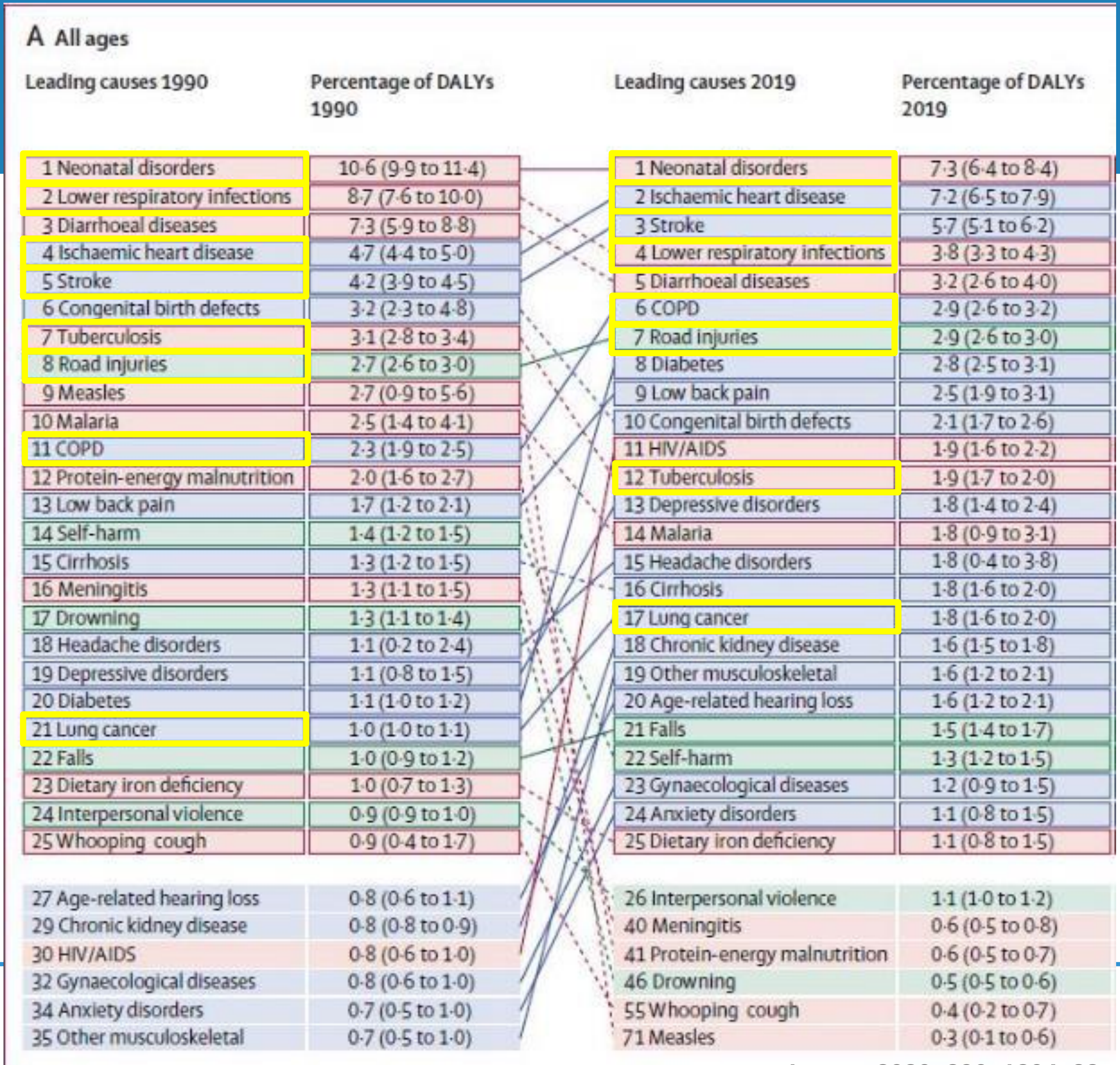
HEALTH EMERGENCIES programme

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

Global Burden of Disease Study 2019: systematic analysis 1990 – 2019.

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

… Including in COVID19, surgery, trauma, pneumonia and maternal and childcare…



A All ages

Leading causes 1990	Percentage of DALYs 1990
1 Neonatal disorders	10·6 (9·9 to 11·4)
2 Lower respiratory infections	8·7 (7·6 to 10·0)
3 Diarrhoeal diseases	7·3 (5·9 to 8·8)
4 Ischaemic heart disease	4·7 (4·4 to 5·0)
5 Stroke	4·2 (3·9 to 4·5)
6 Congenital birth defects	3·2 (2·3 to 4·8)
7 Tuberculosis	3·1 (2·8 to 3·4)
8 Road injuries	2·7 (2·6 to 3·0)
9 Measles	2·7 (0·9 to 5·6)
10 Malaria	2·5 (1·4 to 4·1)
11 COPD	2·3 (1·9 to 2·5)
12 Protein-energy malnutrition	2·0 (1·6 to 2·7)
13 Low back pain	1·7 (1·2 to 2·1)
14 Self-harm	1·4 (1·2 to 1·5)
15 Cirrhosis	1·3 (1·2 to 1·5)
16 Meningitis	1·3 (1·1 to 1·5)
17 Drowning	1·3 (1·1 to 1·4)
18 Headache disorders	1·1 (0·2 to 2·4)
19 Depressive disorders	1·1 (0·8 to 1·5)
20 Diabetes	1·1 (1·0 to 1·2)
21 Lung cancer	1·0 (1·0 to 1·1)
22 Falls	1·0 (0·9 to 1·2)
23 Dietary iron deficiency	1·0 (0·7 to 1·3)
24 Interpersonal violence	0·9 (0·9 to 1·0)
25 Whooping cough	0·9 (0·4 to 1·7)
27 Age-related hearing loss	0·8 (0·6 to 1·1)
29 Chronic kidney disease	0·8 (0·8 to 0·9)
30 HIV/AIDS	0·8 (0·6 to 1·0)
32 Gynaecological diseases	0·8 (0·6 to 1·0)
34 Anxiety disorders	0·7 (0·5 to 1·0)
35 Other musculoskeletal	0·7 (0·5 to 1·0)

Leading causes 2019	Percentage of DALYs 2019
1 Neonatal disorders	7·3 (6·4 to 8·4)
2 Ischaemic heart disease	7·2 (6·5 to 7·9)
3 Stroke	5·7 (5·1 to 6·2)
4 Lower respiratory infections	3·8 (3·3 to 4·3)
5 Diarrhoeal diseases	3·2 (2·6 to 4·0)
6 COPD	2·9 (2·6 to 3·2)
7 Road injuries	2·9 (2·6 to 3·0)
8 Diabetes	2·8 (2·5 to 3·1)
9 Low back pain	2·5 (1·9 to 3·1)
10 Congenital birth defects	2·1 (1·7 to 2·6)
11 HIV/AIDS	1·9 (1·6 to 2·2)
12 Tuberculosis	1·9 (1·7 to 2·0)
13 Depressive disorders	1·8 (1·4 to 2·4)
14 Malaria	1·8 (0·9 to 3·1)
15 Headache disorders	1·8 (0·4 to 3·8)
16 Cirrhosis	1·8 (1·6 to 2·0)
17 Lung cancer	1·8 (1·6 to 2·0)
18 Chronic kidney disease	1·6 (1·5 to 1·8)
19 Other musculoskeletal	1·6 (1·2 to 2·1)
20 Age-related hearing loss	1·6 (1·2 to 2·1)
21 Falls	1·5 (1·4 to 1·7)
22 Self-harm	1·3 (1·2 to 1·5)
23 Gynaecological diseases	1·2 (0·9 to 1·5)
24 Anxiety disorders	1·1 (0·8 to 1·5)
25 Dietary iron deficiency	1·1 (0·8 to 1·5)
26 Interpersonal violence	1·1 (1·0 to 1·2)
40 Meningitis	0·6 (0·5 to 0·8)
41 Protein-energy malnutrition	0·6 (0·5 to 0·7)
46 Drowning	0·5 (0·5 to 0·6)
55 Whooping cough	0·4 (0·2 to 0·7)
71 Measles	0·3 (0·1 to 0·6)

Lancet 2020; 396: 1204–22

World Health Organization

Background: Scaling-up access to medical oxygen

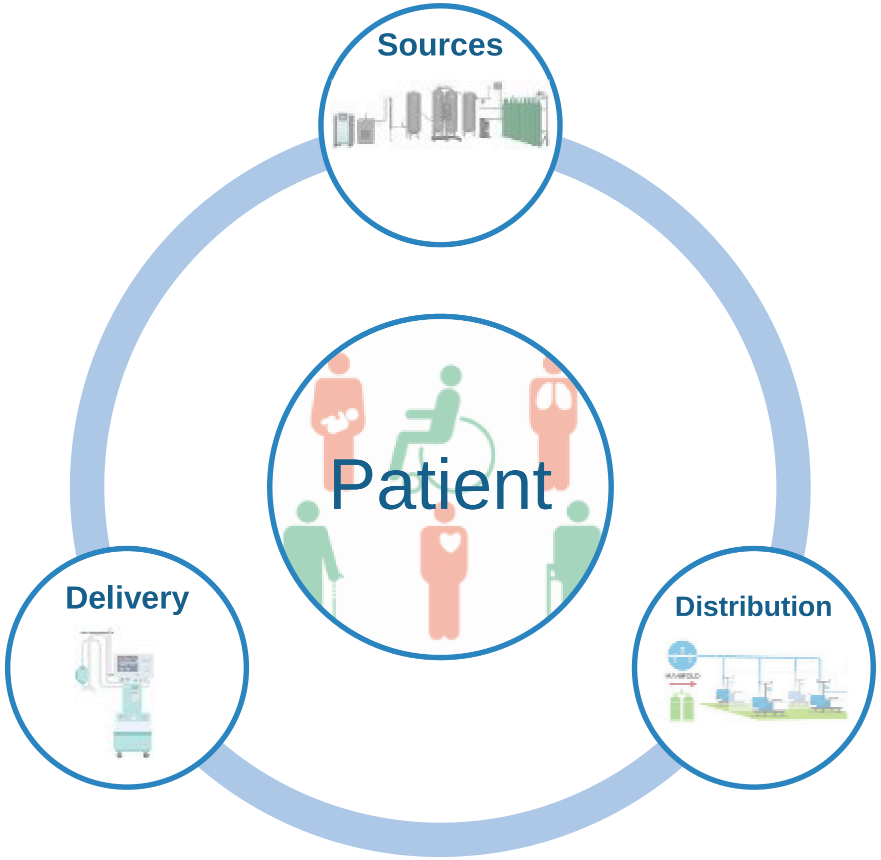
Multidisciplinary effort

Ultimate goal: quality O_2 reach safely the patient

Continuous and evolving cycle

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

	PSA bedside concentrators	PSA / VSA / PVSA O_2 generator plants	Cryogenic liquid
Description	 Different flow rates, typical: 5, 8 or 10 L/min – medical use	 Different sizes and configurations: single and duplex 2–200+ Nm^3/hr	 Produced mainly for heavy industry; serves medical sector where GMP allows
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.

Overview of PSA oxygen generation plants

Sizing and configuring the solution

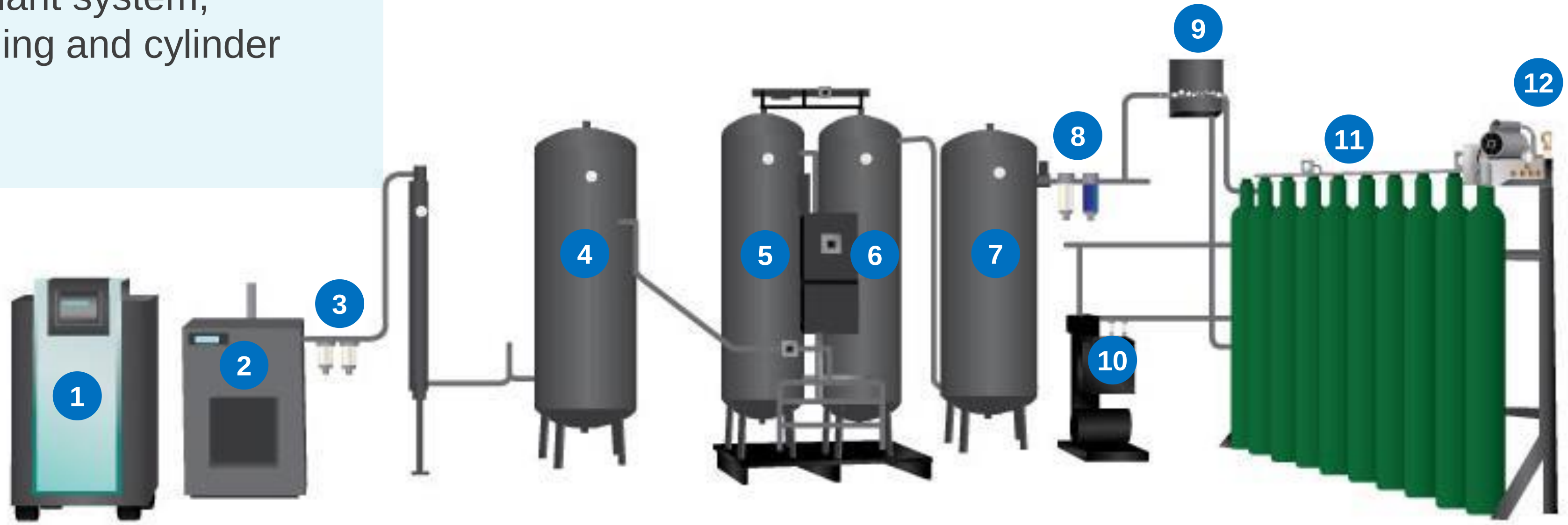
- Site-specific environmental considerations in planning stage (elevation, humidity, dust…).

- 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+ Nm^3/hr
Option of skid-mounted or containerized systems

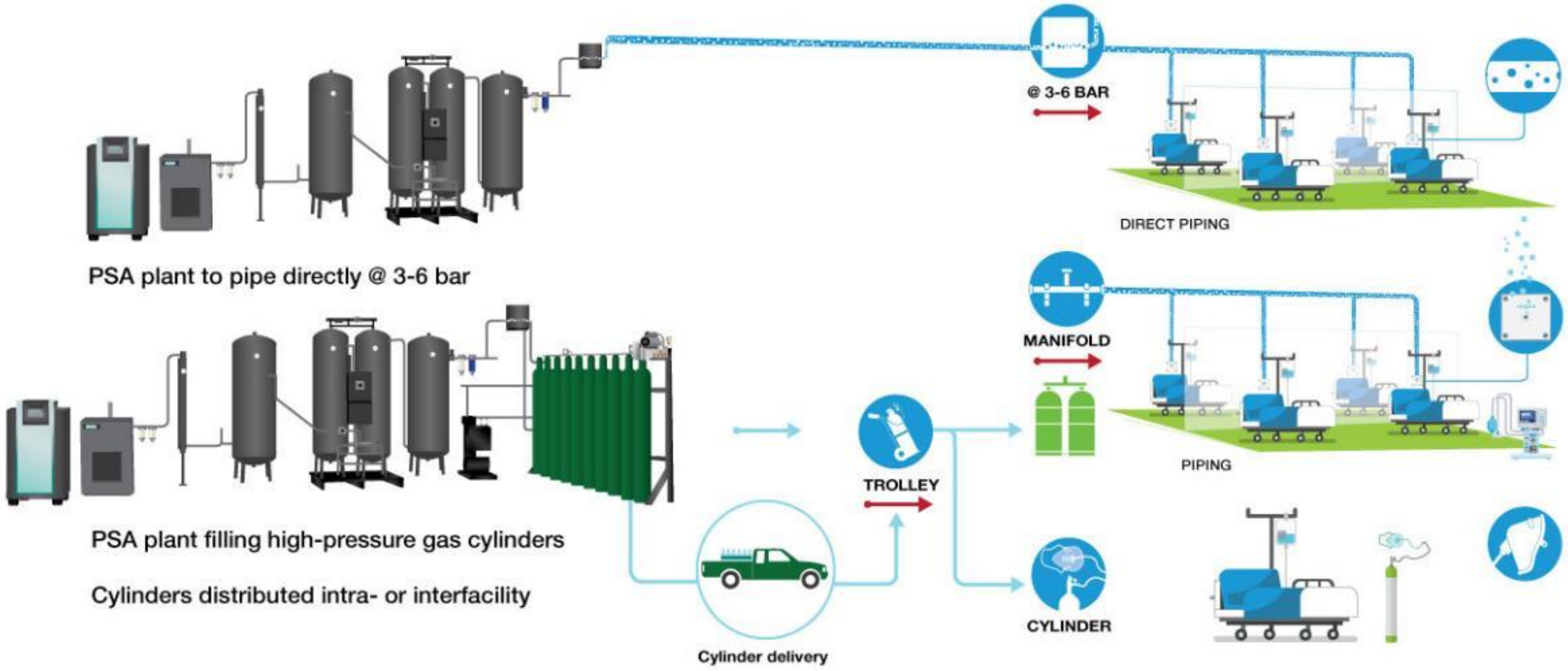
1 Air compressor
2 Refrigeration/air dryer
3 Filtration assembly
4 Compressed air tank
5 PSA – O_2 generator
6 Control panel
7 Product/buffer tank
8 Bacteria filter
9 Oxygen sensor
10 Booster compressor
11 Cylinder filling ramp
12 Cylinder vacuum pump



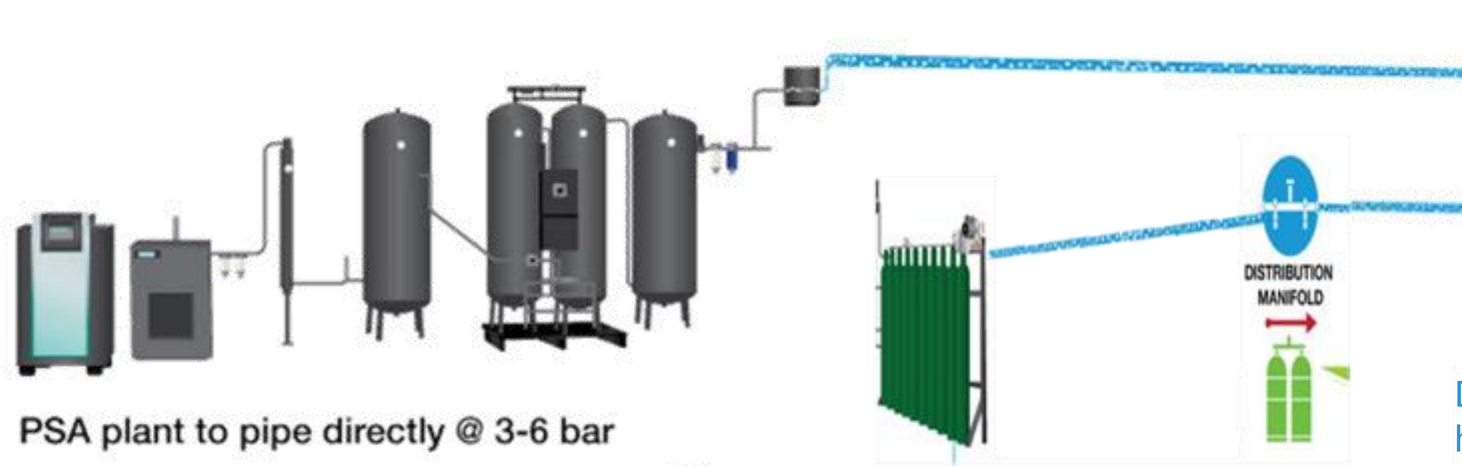
WHO Technical Specifications: https://www.who.int/publications/i/item/technical-specifications-for-pressure-swing-adsorption(psa)-oxygen-plants

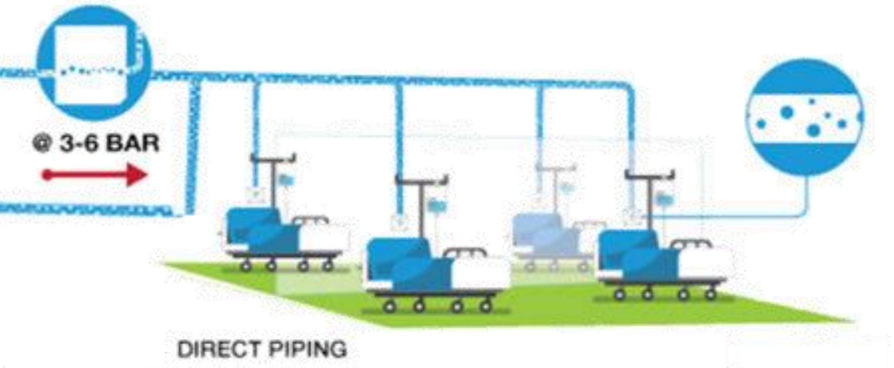
PRIMARY SYSTEM

SOURCE (production and reserve) + DISTRIBUTION (piped network or trolleys) + DELIVERY (regulation and conditioning)

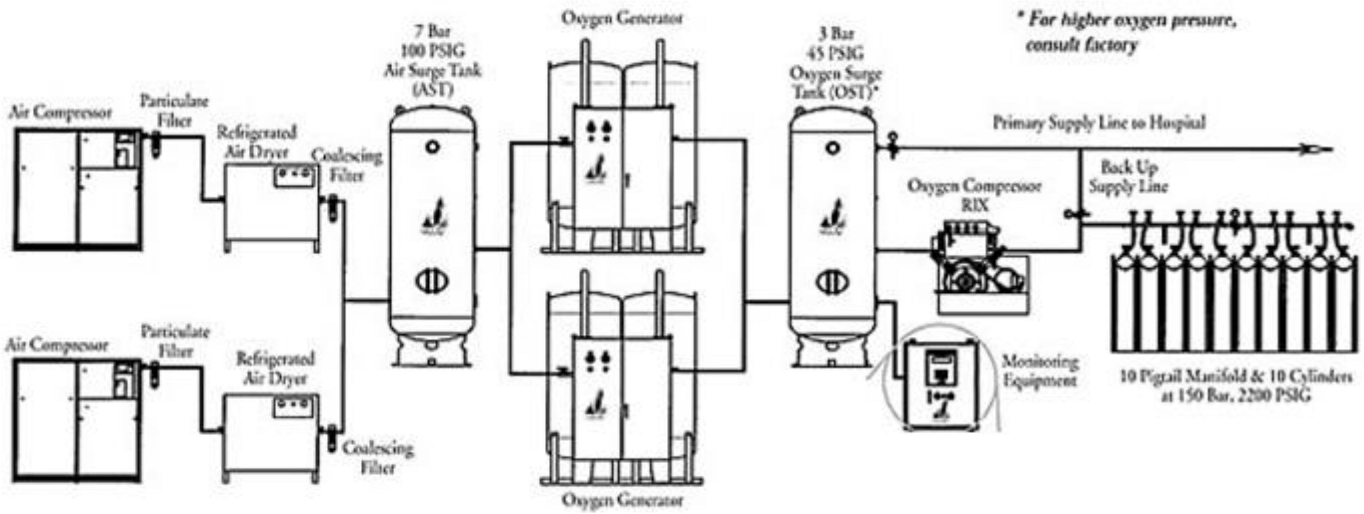


MANY POSSIBLE CONFIGURATIONS WITH BACK UP SUPPLY





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)

PSA Capacity	Cost without booster	Cost with booster	# Cylinder	Housing size
9 - 10 m^3/hr 150 -167 L/min	$50,000.00 USD	$82,420.00 USD		
	$113,400.00 USD	$180,386.00 USD	20, ~50 L Water capacity at 150 bar	240 X 595 x 270 cm (Container)
13 - 30 m^3/hr 216 - 333 L/min	$61,000.00 USD	min $88,777 USD		
	$128,200.00 USD	max $228,000 USD	60, ~50 L Water capacity at 150 bar	240 x 595 x 240 cm (Container)
32-42 m^3/hr 533 - 713 L/min	$103,000.00 USD	$131,000.00 USD		
	$216,800.00 USD	$413,200.00 USD	100, ~50 L Water capacity at 150 bar	223.5 x 823 x 269.3 cm

Cylinders per day according to booster capacity

Booster compressor capacity	# Cylinders /day
3 m^3/hr – 50 L/min	8-10
6 m^3/hr – 101 L/min	16
12 m^3/hr – 200 L/min	32
16 m^3/hr – 266 L/min	52
32 m^3/hr – 533 L/min	103

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

- 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.

DISTRIBUTION SYSTEM
Cylinders

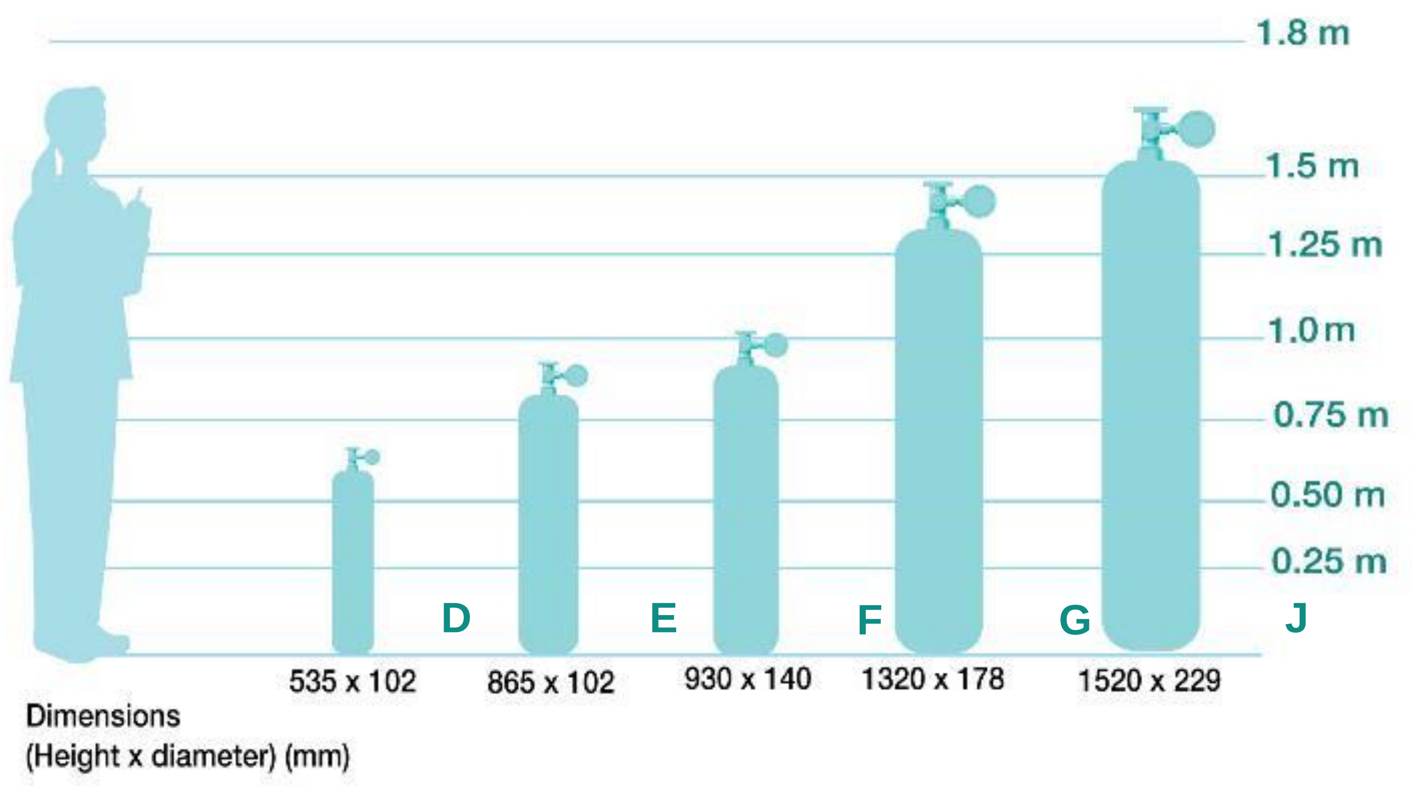
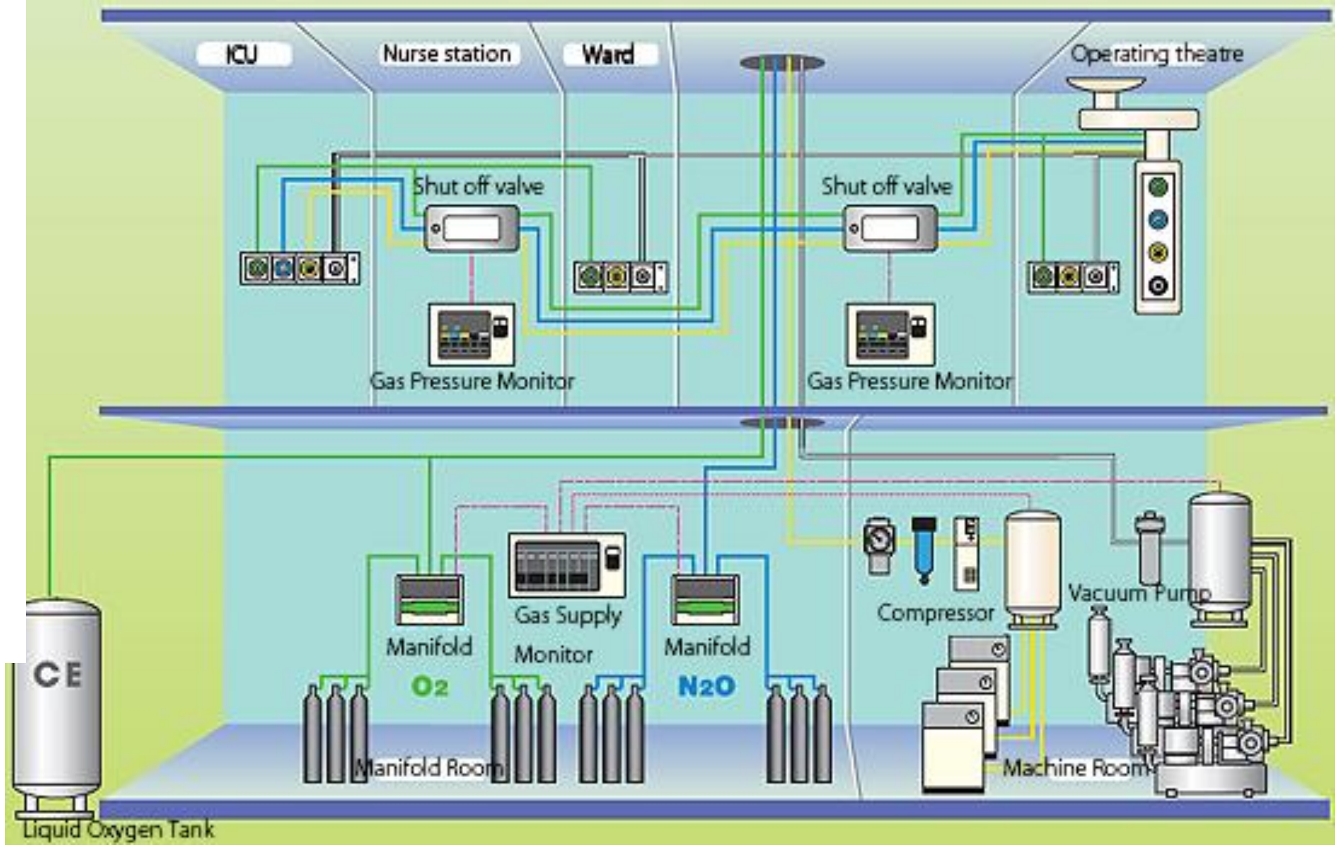


Image is for illustrative purposes only.
WHO-UNICEF technical specifications and guidance for oxygen therapy devices:
https://www.who.int/medical_devices/publications/tech_specs_oxygen_therapy_devices/en/

World Health Organization

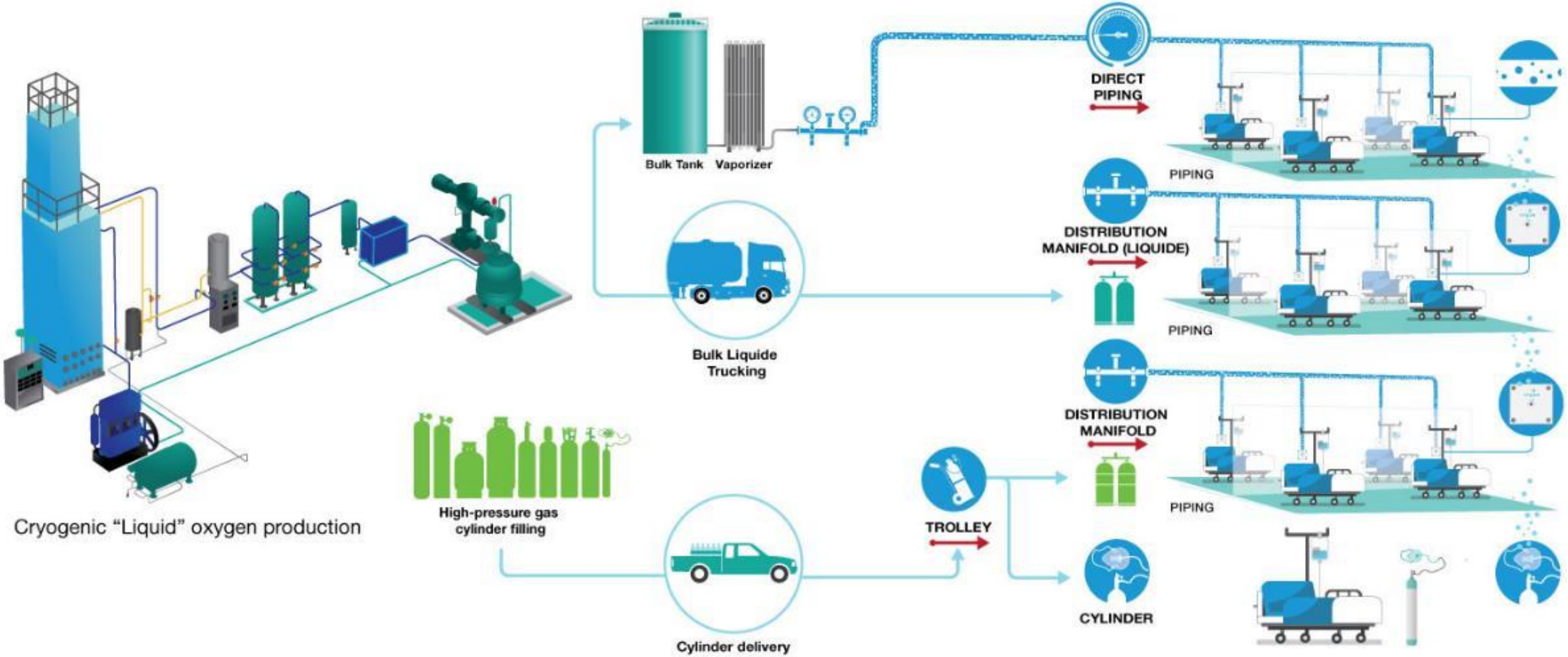
DISTRIBUTION SYSTEM
Piped network, regulation and conditioning

	USA	ISO
Carbon Dioxide	Grey	Grey
He-O_2	Brown and Green	Brown and White
Medical Air	Yellow	Black and White
Nitrogen	Black	Black
Nitrous Oxide	Blue	Blue
O_2-He	Green and Brown	White and Brown
Oxygen	Green	White
Vacuum (Suction)	White	Yellow
WAGD (EVAC)	Purple	Purple

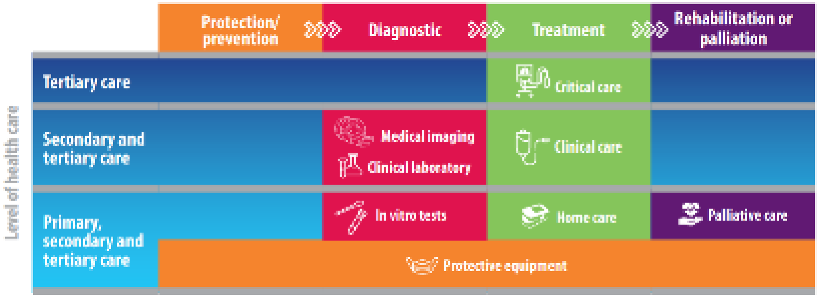


PRIMARY SYSTEM

SOURCE (production and reserve) + DISTRIBUTION (piped network or trolleys) + DELIVERY (regulation and conditioning)



Bedside delivery & monitoring medical devices



Pulse Oximeter

		
O_2 dose 1–5 L/min (initiate @ 5 L/min)	Initial O_2 dose 6–10 L/min (can increase to 10-15 L/min)	O_2 dose 10–15 L/min
FiO_2 0.25–0.40	FiO_2 0.44–0.60	FiO_2 0.60–0.95
Nasal cannula	**Venturi face mask**	**Face mask with reservoir bag**

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

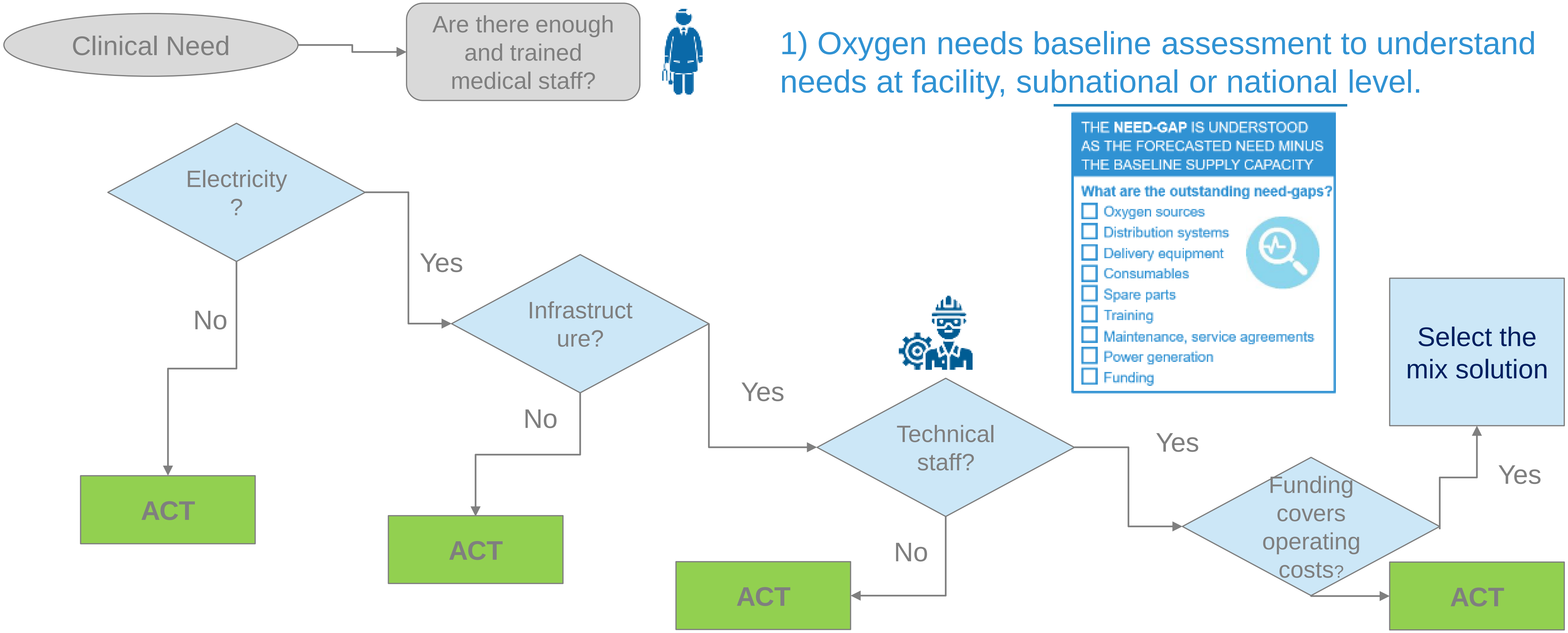
- Preparation of site (including infrastructure, human resources, power supply and other ancillary services).

Phase 3: Sustainability of the project

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

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.



Phase 1: Assessment of oxygen need-gap (2)

Holistic and "tiered" approach

2) Select and bundle solutions to estimate costs.

Contextualise plan for compatibility with…

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

Holistic and “tiered” approach

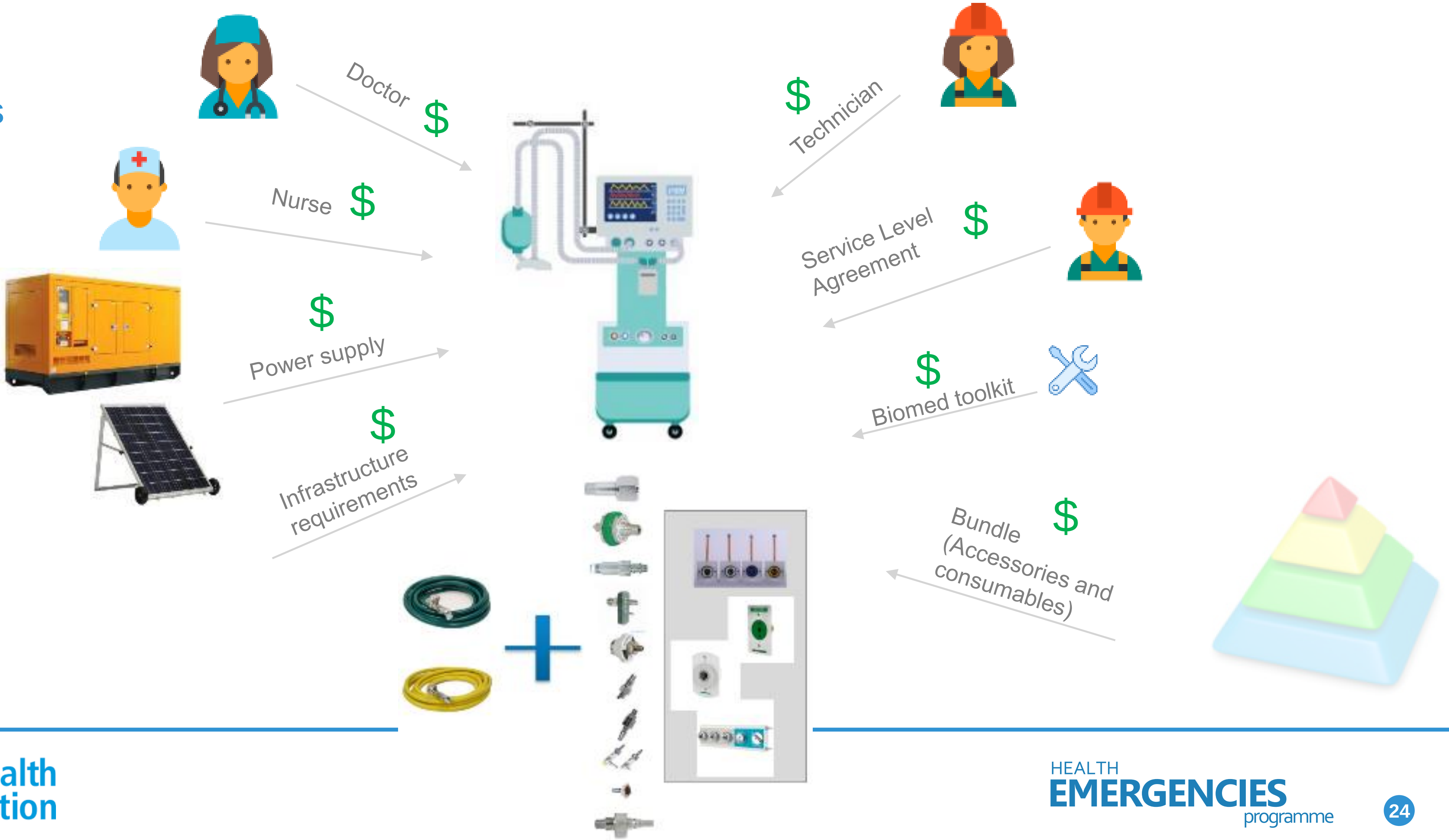
2) Select and bundle solutions to estimate costs.

CAPEX & OPEX

Phase 1: Assessment of oxygen need-gap (4)

Holistic and “tiered” approach

2) Select and bundle solutions to estimate costs.



E.g. of equipment bundles:

BiPAP		HFNC	
			
Resmed/ Lumis 150 VPAP ST-A	YUWELL/ YH-830	F&P/ AIRVO2	MASIMO/ TN1 softFlow 50
Adult, Paediatric (patients weighing more than 13 kg)	Adult, Paediatric (patients weighing more than 30 kg)	Adult, Paediatric	Adult, Paediatric
S, ST, T, PAC, iVAPS, CPAP	S, ST, T, VGPS, CPAP	Target temperature settings: 37, 34, 31 ˚C	Target temperature settings: 30 – 37 ˚C
Up to 15 L/min	Up to 15 L/min	Up to 60 L/min (Low pressure inlet)	Up to 50 L/min (Low pressure inlet)

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.

Item	Quantity per equipment total	Category	Brand specific	Timeframe (approximate consumption)
Patient monitor multiparametric with ECG, non-invasive blood pressure (NIBP), oxygen saturation (SpO_2), respiratory rate (RR), and temperature (TEMP) sensors	**1**	Equipment	Brand: XXX; Model: XXX	N/A
ECG electrodes adult	**5**	Consumable	No	6 months
ECG electrodes paediatric	**5**	Consumable	No	6 months
3 leads ECG cable	**2**	Accessory	Yes	1 year
5 leads ECG cable	**2**	Accessory	Yes	1 year
Reusable SpO_2 probes adult	**3**	Accessory	Yes	1 year
Reusable SpO_2 probes paediatric use	**3**	Accessory	Yes	1 year
Paediatric blood oxygen probe extension wire	**2**	Accessory	Yes	1 year
Blood pressure – non-invasive: adult reusable cuffs	**3**	Accessory	Yes	1 year
Blood pressure – non-invasive: paediatric reusable cuffs	**3**	Accessory	Yes	1 year
Blood pressure extension tube	**2**	Accessory	Yes	1 year
External skin temperature probes	**2**	Accessory	Yes	1 year
Ground wire	**1**	Accessory	No	1 year
European standard power cord	**1**	Accessory	No	1 year
American standard power cord	**1**	Accessory	No	1 year
United Kingdom standard power cord	**1**	Accessory	No	1 year
Battery	**1**	Spare parts	Yes	1 year

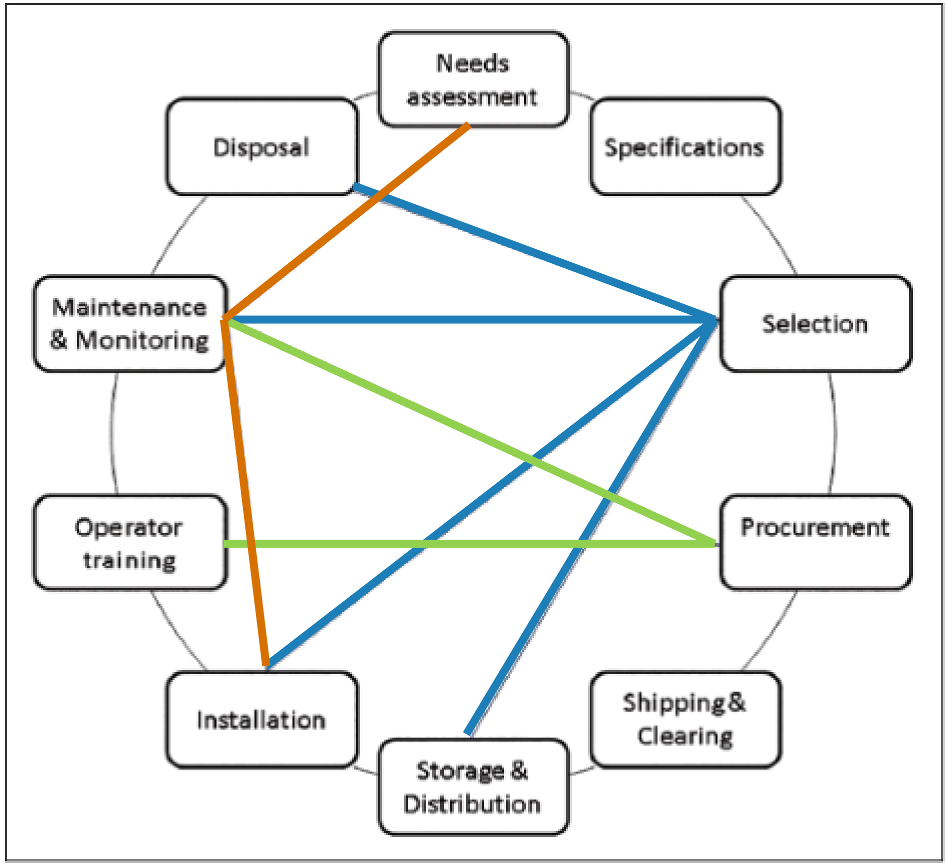
Phase 1: Assessment of oxygen need-gap (5)

Holistic and “tiered” approach

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



Multi-disciplinary team engagement.

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 O_2-related partners and activities (website here)
- C19RM - Operational recommendations resource package from BHI/PIH
- PATH Oxygen Delivery Toolkit

Ripple effect: Each act has better impact when coordinated in a collective.

Is an essential and common good.