IFMBE Clinical Engineering Division

World Health Organization

WHITE PAPER

Oxygen Delivery Systems

WHO-CED Townhall Summary, May 5, 2020 – V1, 8 June 2020

Content

- In response to the quest for reliable and timely information regarding healthcare technology challenges during these abnormal times, IFMBE CED - in partnership with the World Health Organization Medical Device Unit - initiated twice weekly topic based ***COVID19 Critical Issue virtual Townhall*** broadcasts in May 2020. Their purpose was to provide a virtual meeting hall for identifying solutions, proven methodologies, and answers on subjects of importance for clinical engineers, biomedical engineers, technologists, technicians, HTM managers, and other stakeholders facing challenging situations where wider knowledge and expertise from successfully implemented solutions can help others. Both those who are willing to share their expertise and those who are facing challenges were invited to join the townhalls.
- See/Download References at https://ced.ifmbe.org/blog/who-ced-covid19-townhalls.html.
- Listen to YouTube of Townhall: https://www.youtube.com/playlist?list=PLhnffEvoohI0kuRHd6mgxZaJ2RCh001wC

Panelist Bios:

- Adriana Velazquez (WHO) https://www.linkedin.com/in/adrianavelazquezberumen/
- Alejandra Velez (WHO) https://www.linkedin.com/in/laura-alejandra-v%C3%A9lez-8794911b/
- Ashenafi Hussein (Ethiopia), LMIC Presenter https://www.linkedin.com/in/ashenafi-hussein-00955237/
- Mohammad Ameel (India), Facilitator https://www.linkedin.com/in/mohammad-ameel-59662722/
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1. World Health Organization (WHO) Input

1. Medical Device Unit - https://www.who.int/medical_devices/en/

2. Low-Middle-Income-Country (LMIC) & Panelist Input:

A. Clinical & Technical requirements
B. Supply of necessary equipment & accessories, and operation/support
C. Availability of support/maintenance materials,
   i. eg, Operator and Service Manuals in correct language,
   ii. including related donation issues, language, accessories, etc.
D. Training for operation and support
E. Coordination of various Critical Topic activities at care delivery & national levels
F. Systems approach and safety management for all of the above

3. Q&A Review

4. Figures

1. COVID19 Key Oxygen Delivery System Links (WHO)
2. Oxygen Delivery Equipment List for COVID19 (WHO)
3. Key Oxygen Topics for LMICs to address (WHO & CED)
4. LMIC & Panelist Input (Various)
5. Oxygen System Components (WHO)
6. Priority Medical Devices for COVID19 Oxygen Systems (WHO)
7. Description & Comparison of Oxygen Sources and Storage (WHO)
8. Typical Oxygen System delivery configuration (Sloane)

5. References – at end, https://ced.ifmbe.org/blog/who-ced-covid19-townhalls.html

6. CED Contact Information – at end

7. Closing Comments, Polls & Registrants

Fig. 1 WHO COVID-19 Technical specifications for O2 delivery systems, ventilators, PSA plants:
https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/covid-19-critical-items
WHO Medical Device Site for COVID19
https://www.who.int/medical_devices/priority/COVID-19/en/
WHO Inventory Tool for COVID19
The survey can be accessed through a web browser using link:
https://o2therapy.surveycto.com/collect/who_covid_oxygen_therapy_scto_open?caseid=
Username: biomedequipment Password: facilityoxygen20
WHO Medical Device Innovation:
https://www.who.int/medical_devices/innovation/compendium/en/

Fig. 2. WHO Oxygen Delivery Equipment List for COVID19

physiological monitor multiparameter for ICU
Infusion pumps / giving sets
Oxygen concentrator
Pulse oximeter
Patient ventilator, for critical care
Flow-splitter, for oxygen supply
Flowmeter, Thorbe tube
Humidifier, non-heated
Nasal prongs
Catheter
Oxygen mask
Venturi mask
Laryngoscope, adult/child
Laryngoscope, neonate
Endotracheal tube
Endotracheal tube introducer, Bougie
Endotracheal tube introducer, Stylet
Colorimetric end tidal CO2 detector
Resuscitator, adult
Resuscitator, child
Oropharyngeal airway, Guedel, sterile, single use
Nasopharyngeal airway
Suction devices
Infusion giving set

1. WHO Input

1. Adriana Velazquez & Alejandra Velez
   Listen to YouTube segments: https://www.youtube.com/watch?v=OJTk--J95xQ&list=PLhnffEvoohI0kuRHd6mgxZaJ2RCh001wC&index=4&t=0s & https://www.youtube.com/watch?v=2R5o-laDk34&list=PLhnffEvoohI0kuRHd6mgxZaJ2RCh001wC&index=6&t=43s
   i. Addresses Clinical & Technical requirements noted in Fig. 3
   ii. See Reference 2 & Figures 1-3, 5-7

Fig. 3. Key Oxygen Topics for LMIC to address:

1. Clinical & Technical requirements
2. Supply of necessary equipment & accessories, and operation/support
3. Availability of support/maintenance materials,
   A. eg, Operator and Service Manuals in correct language
   B. including related donation issues, language, accessories, etc.
4. Training for operation and support
5. Coordination of various Critical Topic activities at care delivery & national levels
6. Systems approach and safety management for all of the above

2. LMIC Input

1. Ashenafi Hussein (Chair, IFMBE Working Group on Africa Activities)
   Listen to YouTube segment; see Reference 4:
   https://www.youtube.com/watch?v=MIwOQII35Ps&list=PLhnffEvoohI0kuRHd6mgxZaJ2RCh001wC&index=5&t=0s
   i. Challenges for Supply, Operation, Maintenance (Fig 3, Fig 4a)
   ii. Recommendations for Supply, Operation, Maintenance (Fig 3, Fig 4b)

Fig 4a

- **Supply**
  - Lack of Funding
  - Lack of Policies (Nigeria and Ethiopia have National Oxygen policy roadmap)
  - Very Long and interrupted supply chain system
- **Operation**
  - Lack of Capacity and Resources to manage (Personnel, material…)
  - Problem with Administering Medical Oxygen (With SOP)
  - Issues with Measuring the purity level of Medical Oxygen
- **Maintenance**
  - Lack of Tools and Trained personnel,
  - Lack of Spare parts,
  - Calibration of devices (important with the amount of medical oxygen administration)

Fig 4b

- **Supply**
  - Strengthening Financial Capacity (Local and International Funding , The use of REVOLVING FUND)
  - Special Supply system (DIRECT purchase , FRAME WORK Contract) of Medical Grade Oxygen with Cylinders, Oxygen Concentrators
  - Large scale Oxygen production as a policy- Long Term - Using Revolving Fund
- **Operation**
  - Intensive training - Online about SOP, How to administer and Manage Medical Oxygen
  - Followup and Continuous support
- **Maintenance -**
  - Strengthening Inhouse Maintenance
  - Online Training and support from Vendors
  - Availing spare parts asap
  - increasing the National Capacity to develop easy spare parts e.g for Oxygen gauges and some fittings with humidifiers,
  - Confirmation of Medical Grade Oxygen after maintenance

2. **Anwar Hossain (Bangladesh):** Ministry of Health Plan for Supply & Storage in Ref. 6, https://ced.ifmbe.org/blog/who-ced-covid19-townhalls.html

3. **Elliot Sloane (Panelist, USA)**: see more details in Reference 1

i. Oxygen is NOT trivial; it must be understood to be managed and used safely!
   a. Oxygen as a drug
   b. Oxygen as a compressed gas
   c. Oxygen as a fire accelerator
   d. Oxygen as a life-critical resource
      i. If a patient has Acute Respiratory Distress Syndrome from COVID-19, their life DEPENDS on sufficient supplemental oxygen!
      ii. Failure/exhaustion of the O2 supply can cause death
      iii. Monitoring and planning is needed to assure sufficient installed and back-up capacity to support all patients' and devices' O2 consumption!
      iv. Alarms, automatic shut-off systems, and pulse oximetry are required for anesthesia devices that could continue to administer anesthetic without sufficient oxygen to prevent suffocation of the helpless patient! See Figure 8.

ii. Further commentary by Elliot Sloane (USA); see also ***NFPA, JCI/TJC, other oxygen system standards and fire safety,*** **Ref. 13**

1. Rapid, safe scaling up oxygen supplies is NOT trivial. Ventilators, masks, anesthesia, and CPAP consume huge quantities of O2 .
2. High pressure tanks and large volumes of oxygen can present huge fire hazards (see OR fires and photos at TheMedicalDetective dot com **https://imgur.com/97HXF0p)** or severe physical injury risks.
3. Inadequate O2 capacity causes low/no O2 concentration for patients' oxygen-starved tissues & organs, leading to further damage and death.
4. Colleagues around the world - & WHO - are working to gather and share life-saving clinical engineering documentation to safely design, install, and maintain O2 systems at the scale needed for COVID-19 patients.
5. Some examples that sourced from friends in Italy, Geneva, UK, US, and elsewhere: **https://imgur.com/xEyhjqn** and **https://imgur.com/yCchttz**. WHO just published this tech document: **https://lnkd.in/eih5TwF**. A US O2 company, BeaconMedas, just published a special COVID-19 bulletin and worksheet for O2 planning: **https://lnkd.in/eFei5MH**. Kudos: Hacking COVID-19 one breath at a time! **https://imgur.com/6m60F57**. **#hackingcoronavirus #oneworldcoronavirus #clinicalengineering #notgoingdownwithoutafight**

iii. **ECRI Institute (USA)**

1. COVID19 Resources: https://www.ecri.org/covid-19-resources-clinical-care
2. HTM: https://www.ecri.org/components/HDJournal/Pages/COVID-19-Technology-Management-Resources.aspx?tab=1
3. Oxygen Supply Alert: https://www.ecri.org/EmailResources/Health%20Devices/ECRI_COVID-19_Alert_S0396.pdf
4. Resources provided as examples – see References 9-12:
   a. Oxygen Monitors & Oxygen Concentrators – two (2) product comparisons (ECRI)
   b. Two (2) Protocols for User Maintenance for Oxygen Concentrators (other than ECRI)

3. Q&A Review

Samples from Ref. 7; listen to this portion of the Townhall at Q&A part 1: https://www.youtube.com/watch?v=bOhH3lUAIc8&list=PLhnffEvoohI0kuRHd6mgxZaJ2RCh001wC&index=7&t=0s; and Q&A part 2 https://www.youtube.com/watch?v=8GvwA9LzY9Q&list=PLhnffEvoohI0kuRHd6mgxZaJ2RCh001wC&index=8&t=0s

1. I have been reading about patients reporting to hospital with alarmingly low oxygen saturation levels, as low as 50%, called "silent hypoxia". Shouldn't COVID-19 screening involve pulse oximetry measurements rather than temperature measurement? (MSF, Spain)	My answer is yes! Pulse oximetry is a very important diagnostic tool. However, there are potential patient cross-contamination, and it is sometimes difficult to purchase them given the high demand for them. They can be only "self-calibrated" by confirming high concentrations (98-100%) on one or more known healthy clinicians.
2. Ashenafi said Ethiopia and Nigeria are currently the only countries in Africa with a national oxygen policy roadmap. In the case of Nigeria, can Ashenafi please supply a point of contact for establishing wider discussions on this roadmap? (Nigeria)	Yes. Nigeria and Ethiopia are the one that have issued NATIONAL OXYGEN SUPPLY ROADMAP POLICY. Which actually means different oxygen plants, different oxygen sources and improve their health supply system in Safe surgery, ICU and overall health system. The point of contact is MOH.
3. Ashenafi said Ethiopia and Nigeria are currently the only countries in Africa with regards to the model presented by Alejandra, which costs have been included in the tentative estimated budget (i.e. installations, training, warranty, etc.)? Thanks (Italy)	Alejandra Velez to respond:
4. As MSF advisor, I received a lot of innovative technology to analyze. Can I submit this innovative technology instead of the primary manufacturer? (MSF, Spain)	Yes. Submit through the WHO COVID19 Medical Device Innovation portal: https://www.who.int/medical_devices/priority/COVID-19_innovations/en/
5. How to decide on when and where (what type of healthcare settings) to use oxygen cylinders vs oxygen plant? (MOH, Bhutan)	Firstly, it depends on the policy that the health service of the country has. Secondly both have their advantage and disadvantages, So the country need to do the analysis and come up with the proper one based on their country analysis. Funding issue, Infrastructure issue, HR issue?
6. PSA oxygen plants range from small (10 lpm) to large size (2000 lpm). This is recognized to be the most economical supply mode. (France)	Noted.
7. I have a question about the maintenance of oxygen concentrators. In many cases they fail because the zeolite cartridges need to be replaced. Can we develop a supply chain and a process for refilling zeolite cartridges, as replacement cartridges are very expensive and the supply chain for them is very slow. (Canada)	To be addressed
8. Uganda also launched a National scale up Plan to increase access to oxygen Nationally, this was done with MOH in conjunction with CHAI, launched last pneumonia day. (Uganda)	That is Great News from Uganda. Can you please share us if there is NATIONAL OXYGEN SUPPLY ROADMAP AS A POLICY?
9. I have few suggestions: 1. That WHO together with IFMBE CED to develop a quick guideline on oxygen supply and distribution. 2. There are more than 40,000 oxygen concentrators out of service in Africa / can manufacturers join hands to provide the spare parts and training? 3.to ensure availability can we design together with manufacturer a high flow oxygen concentrator at low cost + the multiple outlet flow such as ensuring flow with one inlet and 10 outlets ? (Rwanda)	1. WHO is conducting the COVID19 device inventory (see page 1 link) to determine availability and needed distribution. 2. CED is willing to help address this maintenance issue with manufacturers. 3. Adriana has addressed through the WHO Innovation link on page 1 how to best address this possibility.
10. I really see a big issue, especially in LMIC where Covid-19 has not hit yet, and where we cannot find any devices in the local market and where supply are slowed down and when manufacturer seemed to have reached their maximum production capacity. (MSF, Spain)	To be addressed through WHO Emergency Supply Chain Catalogue https://www.who.int/publications-detail/emergency-global-supply-chain-system-(covid-19)-catalogue
11. How many 'connectors' should be procured per machine (as per WHO specs). Are these separate pieces or usually connected to either the machine or tubing? - (This is referring to the oxygen/air connectors) (Fiji)	To be addressed.

Fig 5

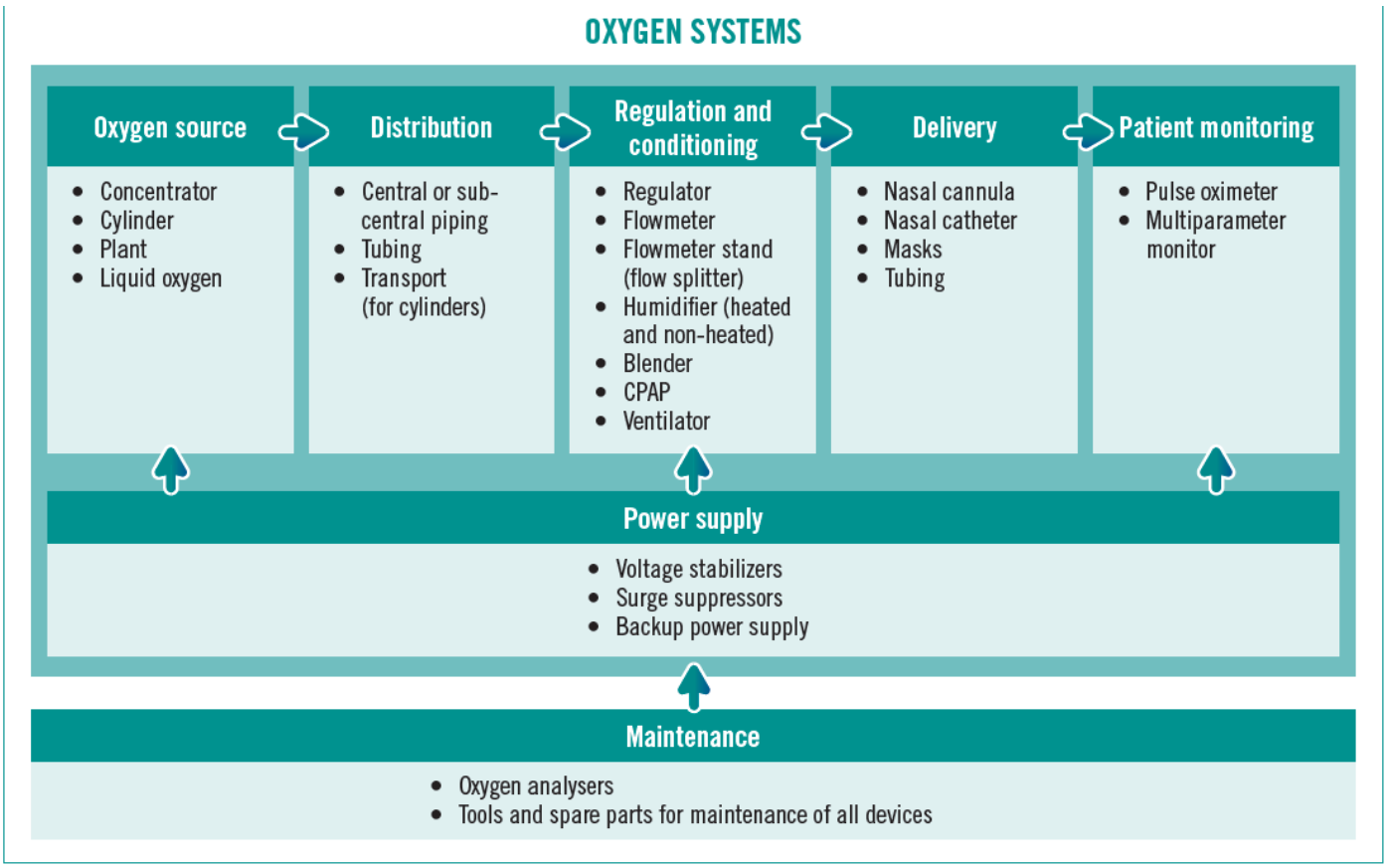


Fig 6

World Health Organization

WHO/2020-nCoV/MedDev/TS/O2T.V1 4/9/2020

Priority Medical Devices in the context of COVID-19

A. Medical Devices for Case Management

Objective

The list of priority medical devices in the context of COVID-19 provides descriptions for the management of patients with severe acute respiratory infection (SARI) when a COVID-19 virus infection is suspected at different levels of health care provision. The first level, for outpatient; second level includes general hospitals and laboratories; and third level, includes specialized hospitals with intensive care units and SARI units. The technologies listed are for the interventions and should be adapted to the health care workforce, infrastructure and technological resources available.

Target Audience

This document is recommended to support decision-making regarding the allocation and use of medical devices in the context of COVID-19 and is intended for healthcare providers, managers of SARI Units, procurement and regulatory agencies and Ministries of Health. Recommend to involve Biomedical Engineer in the selection and verification of installation of the equipment and ensure training of health care workforce.

Considerations

* An assessment of the health facility is required prior to choosing equipment from the list in order to have a fully functional unit. For more details consult the technical specifications per equipment.
* Accessories and consumables for starting operation are not disaggregated in this list. They should be provided with the purchase of the equipment for at least 3 months of operation.
* Extended warranty of at least one year and additional spare parts for maintenance should be also aggregated, according to the health care capacity.

Note: Training is indispensable for invasive ventilation.

Table 1. Medical Devices for Case Management of severe and critical patients by health facility level.

Type	Medical Purpose	Remarks	Medical Device Generic Name	Triage	Treatment of severe patients	Treatment of critical patien	1st level	2nd Level	3rd Level
		-	**Infrared thermometer**	x			•		
	Monitoring	Option 1 - Desirable.	**Pulse oximeter - portable handheld, with cables and sensor**		x	x		•	•
		Option 2.	**Pulse oximeter - fingertip**	x	x	x	•	•	•
		Option 3.	**Pulse oximeter - table top, with cables and sensor**		x			•	•
		Option 1 - Desirable.	**Patient monitor, multiparametric, including EKG, non invasive blood pressure (NIBP), oxygen saturation (SpO2), respiratory rate (RR), temperature (TEMP), with sensors and cables**			x		•	•
		Option 2.	**Patient monitor, multiparametric, NIBP, SpO2, TEMP, respiratory rate (RR) with sensors and cables, (without EKG)**		x	x		•	•
	Oxygen therapy - Oxygen source to be selected according to capability of the health facility (i.e. power supply, pipeline oxygen network)	Option 1 - It is recommended that the device provides at least 5 to 6 L/min for adult patient. It is recommended that the device has electrical protection (power surge).	**Concentrator O2, 10 L, with accessories**		x	x	•	•	•
		Option 2 - Sizes, labelling and connections are, according to international regulations. Refilling and transport, according to manufacturer's quality procedures.	**Medical gas cylinder, portable, for oxygen, fitted with a valve and a pressure and flow regulator**		x	x	•	•	•

Fig 7

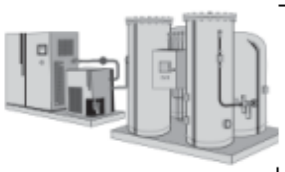
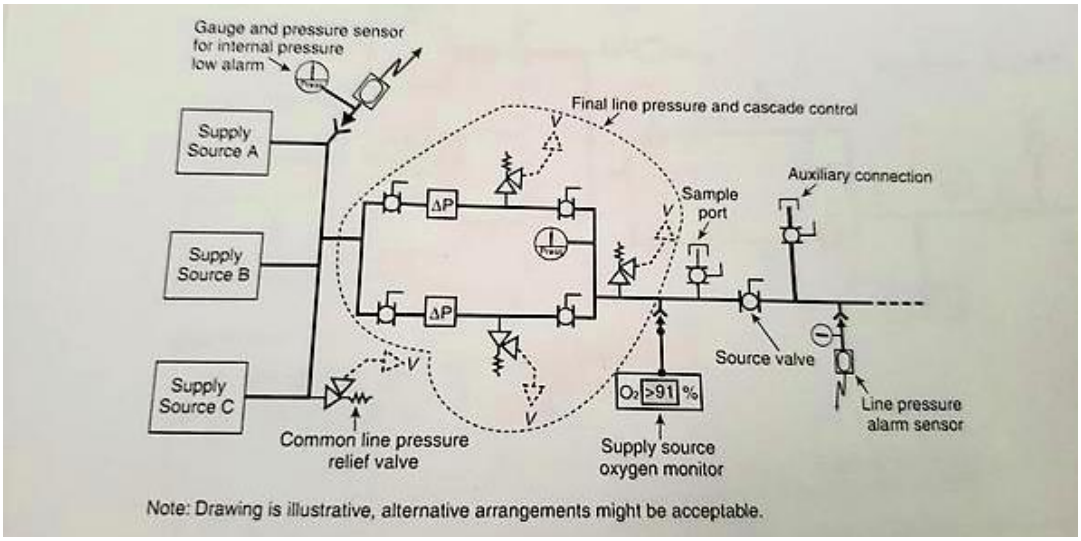
	Cylinders	Concentrators (PSA)	Oxygen plant (PSA)	Liquid oxygen
General characteristic				
Image				
Description	A refillable cylindrical storage vessel used to store and transport oxygen in compressed gas form. Cylinders are refilled at a gas generating plant and thus require transportation to and from the plant	A self-contained, electrically powered medical device designed to concentrate oxygen from ambient air, using PSA technology.	An onsite oxygen generating system using PSA technology, which supplies high-pressure oxygen throughout a facility via a central pipeline system, or via cylinders refilled by the plant.	Bulk liquid oxygen generated off-site and stored in a large tank and supplied throughout a health facility pipeline system. Tank requires refilling by liquid oxygen supplier.
Clinical application and/or use case	Can be used for all oxygen needs, including high-pressure supply and in facilities where power supply is intermittent or unreliable. Also used for ambulatory service or patient transport. Used as a backup for other systems.	Used to deliver oxygen at the bedside or within close proximity to patient areas. A single concentrator can service several beds with the use of a flowmeter stand to split output flow.	Can be used for all oxygen needs, including high-pressure supply.	Can be used for all oxygen needs, including high- pressure supply and in facilities where power supply is intermittent or unreliable.
Distribution mechanism	Connected to manifold of central/sub-central pipeline distribution system, or directly connected to patient with flowmeter and tubing.	Direct to patient with tubing or through a flowmeter stand.	Central/ sub-central pipeline distribution system, or can be used to refill cylinders that can be connected to manifold systems in the facility.	Central pipeline distribution system.
Electricity requirement	No	Yes	Yes	No
Maintenance requirement	Limited maintenance required by trained technicians.	Moderate maintenance required by trained technicians, who could be in-house.	Significant maintenance of system and piping required by highly trained technicians and engineers, can be provided as part of contract.	Significant maintenance of system and piping required by highly trained technicians and engineers, can be provided as part of contract.
User care	Moderate; regular checks of fittings and connections, regular checks of oxygen levels, cleaning exterior.	Moderate; cleaning of filters and device exterior.	Minimal; at terminal unit only.	Minimal; at terminal unit only.
Merits	– No power source.	– Continuous oxygen supply (if power available) at low running cost. – Output flow can be split among multiple patients.	– Can be cost-effective for large facilities. – Continuous oxygen supply.	– 99% oxygen obtained. – High oxygen output for small space requirement.
Drawbacks	– Requires transport/ supply chain. – Exhaustible supply. – Highly reliant upon supplier. – Risk of gas leakage. – Risk of unwanted relocation.	– Low pressure output, usually not suitable for CPAP or ventilators. – Requires uninterrupted power. – Requires backup cylinder supply. – Requires maintenance.	– High capital investments. – Requires uninterrupted power. Needs adequate infrastructure. – High maintenance for piping. – Requires backup cylinder supply. – Risk of gas leakage from piping system.	– Requires transport/ supply chain. – Exhaustible supply. – High maintenance for piping. – Needs adequate infrastructure. – Requires backup cylinder supply. – Risk of gas leakage from piping system.

Fig 8



5. References - May 5th, 2020 - Oxygen Systems (Recording)

1. Sloane IFMBE CED WHO Oxygen Systems Webinar
2. WHO Oxygen 5 05 Medical devices WHO for COVID
3. INSTALLATION OF OXYGEN GAS MANIFOLDS IN EMERGENCY CARE CENTRES - NEW
4. Kenya O2 Manifolds 0520
5. Oxygen System in Africa Ashenafi 050520
6. Leadership Accountability to Ensure Quality O2 Therapy in Bangladesh v2
7. Oxygen systems (May 5) - Q&A Report v3b
8. Oxygen Delivery Townhall References v1
9. ECRI PCS-Oxygen Concentrators
10. ECRI PCS-Oxygen Monitors
11. Protocol I User Maintenance - Oxygen Concentrator DeVilbiss
12. Protocol II Technical Maintenance - Oxygen Concentrator AirSep NewLife
13. NFPA, JCI/TJC, other oxygen system standards and fire safety

6. CED Contact Information

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IFMBE CED Website: info@ced.ifmbe.org
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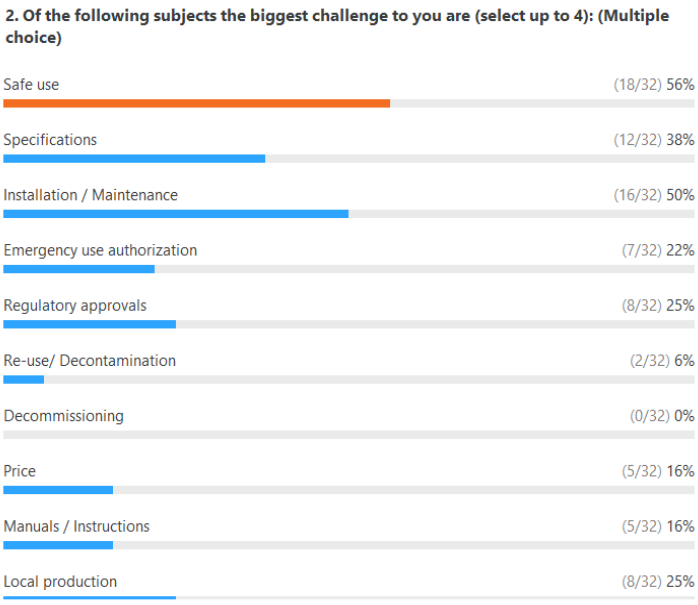
CED Webmaster & Clinical Engineer
CED COVID19 Resources: https://ced.ifmbe.org/blog/covid19-resources.html

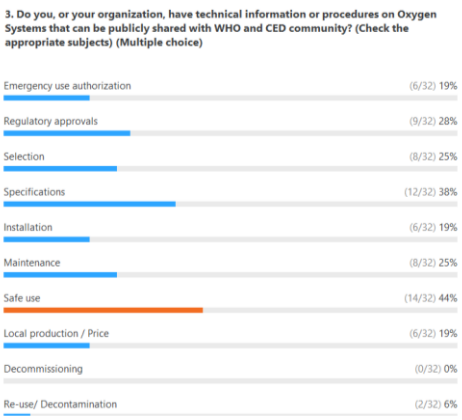
7. Closing Comments, Polls, & Registrants

Mohammad Ameel (Facilitator):

- We discussed how do you quantify oxygen demand and identify oxygen sources that are available and select appropriate surge sources to best respond to COVID19 patient needs, especially in LMIC.
- We initially reviewed data from China suggesting that majority of patients (80%) will have mild moderate illnesses and that only 15% of them will have severe illnesses requiring oxygen therapy and only 5% will be critically ill and requiring ICUs. For the 5% requiring ventilatory support, we discussed the oxygen flow needs for children and for adults. For adults we reviewed the primary sources of oxygen for non-invasive and for invasive ventilation systems.
- We also discussed how oxygen generating plants were a self-sufficient and reliable mode of generating oxygen and that they were only dependent on power and not dependent on any supplier or supply chain issues that we generally have. Then we reviewed liquid oxygen through cryogenic tanks which is not power dependent but certainly supply dependent and a bit costly as compared to oxygen generator plants; then in the smaller units you have oxygen concentrators and oxygen cylinders. So primarily we have two strategies: one - to generate and supply the oxygen generators and concentrator or two – to store and supply that is oxygen cylinders or liquid oxygen cryogenic tanks.
- We also discussed how oxygen storage and inter-hospital distribution happens within oxygen cylinders you had two strategies to supply: one was near to the patient within the ICU (within the wards) but then the challenge is that this oxygen cylinders carries a lot of infection with itself so what we discussed was that a pipeline for intra-hospital distribution network is a very important critical element which in current scenario lacks and a lot of LMICs, but this would be the next focus area if we want to have more sustainable oxygen systems.
- Additionally some of the oxygen needs estimations that we have which were primarily bifurcated amongst the severely ill patient and the critically ill patient. The severely ill patient which will have raw oxygen therapy at 10 litres per minute (l/min) and critically ill patients 30 l/min; however countries were requested to reassess their needs based on the equipment specific changes and other parameters. (And to fill out WHO's Inventory on-line tool as best they can.)
- We also discussed the oxygen surge plan, how do you ensure that various sources of oxygen are used at its best and developing an option search plan requires you to actually look into 'what capabilities do you currently have', 'whether you have spaces for various oxygen generator plants or the liquid oxygen tanks', 'whether you have power backup or not', 'whether you have sufficient supplies or not' and whenever we are planning for a robust oxygen systems we have to look at the overall oxygen system.
- It's always good to look at the air pipeline, the pipeline for nitrous oxide as well look for various distribution systems, regulations and conditioning around it, delivery mechanisms, patient monitoring, pulse oximeters, power supply; all these are very critical components.
- In the case you do not have pipelines, you're looking at oxygen cylinders alone; please look at how do you disinfect them so that handlers of these cylinders use it very safely.

Polls





Registrants

- There were 240 registrants from 60 countries.