

Statement on Access to Quality and Safe Medical Oxygen

Version 02 MAY 2023



World Health
Organization

Introduction

It is estimated that fewer than half of all health facilities in low- and middle-income countries (LMICs) have uninterrupted access to medical oxygen, contributing to preventable deaths, particularly during the COVID-19 pandemic (1, 2). The lack of access to reliable supplies of quality-assured and safe medical oxygen can be due to limited production, distribution, unreliable power supply, lack of equipment, condition of storage facilities, inadequate funding, or lack of technical expertise and guidance related to the installation, maintenance and use of oxygen systems when it is available (3). A holistic approach is required to address these shortcomings, such as appropriate policies at the country level; the inclusion of oxygen in national essential medicines lists; a regulatory framework with the appropriate technical specifications and guidance on medical oxygen and oxygen systems; training of healthcare workers; sustainable energy solutions in health facilities; financing; and effective maintenance programmes.

The World Health Organization (WHO) is committed to strengthening the supply of quality-assured medical oxygen. To achieve this, WHO provides recommendations and tools to facilitate the production, distribution, storage and use of quality-assured, safe medical oxygen. This statement summarizes the current WHO recommendations and tools related to the quality assurance of medical oxygen systems.

Medical oxygen is oxygen of a distinct quality intended for use in patients and it is produced, distributed and stored according to applicable health regulatory requirements for patient use. Medical oxygen should be sourced from approved suppliers, meet defined quality standards and be used appropriately under the oversight of qualified health professionals.

Clinical use of oxygen

Oxygen is an essential medicine included in the WHO Model List of Essential Medicines (EML) since 1979¹ and it was added to the the first WHO Model List of Essential Medicines for Children (EMLc) in 2007. Clinical indications for oxygen treatment to reverse or prevent hypoxaemia include surgical anaesthesia and treatment of acute and chronic respiratory conditions such as COVID-19 and pneumonia. Medical oxygen is essential for optimal patient care in various medical disciplines such as surgery, obstetrics, neonatal care and emergency and critical care. Therapeutic uses require concentrations of 24% volume fraction and upwards – often requiring the mixing of oxygen of defined concentration or quality with air or other gases. The COVID-19 pandemic exacerbated the global demand for medical oxygen, raising concerns about the critical shortages, limited supply options and the quality of available oxygen, especially in LMICs.

Delivery at the point of care

The administration of oxygen at the point of care requires a combination of different devices to produce, store, transport and deliver. Oxygen may be delivered to the patient by medical devices such as face masks and nasal cannulas that are interconnected to bedside oxygen concentrators, high-pressure gas oxygen cylinders or wall outlet terminals. The concentration or percentage of oxygen administered to patients is adjusted with a combination of medical air and oxygen depending on the respective patient's therapeutic need. Depending on each case, the stream of medical oxygen could come from any on-site oxygen source: oxygen generator plant (either with Pressure Swing Adsorption (PSA) and/or Vacuum Swing Adsorption (VSA) technologies), vacuum insulated evaporator (VIE) system, cryogenic liquid oxygen (LOX) cylinder, high-pressure gas oxygen cylinder, or a mixture thereof, as long as the source is certified for medical use. Effective oxygen supply systems should be a universal standard of care and be made more widely available.

¹ <https://list.essentialmeds.org/files/trs/D9GThPSnias5fEHbYKtzasG6vrq4VAyOisH7lyJN.pdf>

Production and quality control of medical oxygen

The quality standards for medical oxygen are defined by pharmacopoeias or are approved by national regulatory authorities. Only medical oxygen of a defined quality which has been tested and meets the authorized specifications for its identity, purity and content, produced and stored and distributed according to good practices, should reach the patient. Uncertainties regarding the content of oxygen intended for industrial purposes due to the possible occurrence of particulate and microbial contamination and production, storage and distribution processes that may not be planned, performed and controlled in accordance with good practices that reflect healthcare needs, can result in unacceptable risks for patients.

Manufacturers and distributors of medical oxygen should comply with the relevant parts of WHO good manufacturing practice (GMP) guidelines and recently adopted guidelines on GMP for medicinal gases.

These guidelines provide recommendations on the production, control, storage and distribution of medical gases, including medical oxygen, to ensure that gases for medicinal use are of an assured quality when they reach the patients.

The revised monograph on Medicinal Oxygen, published in the 11th edition of *The International Pharmacopoeia*, cover oxygen produced by distillation and single-stage pressure/vacuum swing adsorption (PSA/VSA). It does not cover oxygen produced by double-stage or multi-stage PSA/VSA as information about its critical control attributes currently available in the public domain was insufficient to establish a public standard. However, if approved by the appropriate national or regional regulatory authority, other oxygen qualities may also be considered as medicinal oxygen.

Quality assurance of medical oxygen systems

Medical oxygen requires a holistic and integrated system of technologies to properly detect hypoxemia and ensure a continuous supply of quality and safe medical oxygen at the point of care. Medical oxygen systems consist of an oxygen source, storage, distribution, regulation and conditioning, delivery and patient monitoring. The pressurized vessels should comply with safety management and transport regulations. The electrical equipment requires a reliable and continuous power supply to operate as well as effective maintenance programmes. The reusable medical devices require good reprocessing practices for cleaning, disinfection and/or sterilization. All the devices and equipment should be of medical grade and meet the technical specifications as established by national, regional or international standards organizations.

Glossary

Fraction of inspired oxygen (% FiO₂) is the oxygen concentration that is inspired by the patient, usually a result of mixing the oxygen source and medical air, and can range from 0.21–1.0 (21–100%). This varies depending on the delivery device and the respective patient's respiratory drive.

Medicinal Oxygen is oxygen of a distinct quality intended for use in patients and is produced, distributed and stored according to the applicable health regulatory requirements for patient use. Medicinal oxygen and Medical oxygen are used interchangeably.

References

1. Bakare AA, Graham H, Ayede AI, Peel D, Olatinwo O, Oyewole OB, et al. Providing oxygen to children and newborns: a multi-faceted technical and clinical assessment of oxygen access and oxygen use in secondary-level hospitals in southwest Nigeria. *Int Health*. 2020;12(1):60-8.
2. Mangipudi S, Leather A, Seedat A, Davies J. Oxygen availability in sub-Saharan African countries: a call for data to inform service delivery. *The Lancet Global Health*. 2020;8(9):e1123-e4.
3. Graham H, Tosif S, Gray A, Qazi S, Campbell H, Peel D, et al. Providing oxygen to children in hospitals: a realist review. *Bull World Health Organ*. 2017;95(4):288-302.

Further reading

GMP requirements

- WHO good manufacturing practices for medicines gases In WHO Expert Committee on Specifications for Pharmaceutical Preparations; fifty-sixth report. WHO Technical Report Series No 1044, 2022. Annex 5. <https://www.who.int/publications/m/item/trs1044-annex5>

Quality control

- International Pharmacopoeia, 11th edition. Geneva: World Health Organization; 2022 (<https://digicollections.net/phint/2022/index.html#p/home> (accessed 2 May 2023)).

Technical guidance on medical oxygen systems

- WHO Foundation for medical oxygen systems (in press), World Health Organization: Geneva.
- WHO technical consultation on oxygen access scale-up for COVID-19. 14 July 2021. World Health Organization: Geneva. <https://www.who.int/publications/i/item/9789240031517>
- World Health Organization and United Nations Children's Fund, WHO-UNICEF technical specifications and guidance for oxygen therapy devices, in WHO medical devices technical series. 2019: Geneva. <https://apps.who.int/iris/handle/10665/329874>
- World Health Organization, (2020). Priority medical devices list for the COVID-19 response and associated technical specifications, World Health Organization: Geneva <https://www.who.int/publications/i/item/WHO-2019-nCoV-MedDev-TS-O2T.V2>
- World Health Organization, Technical specifications for oxygen concentrators. 2015, World Health Organization: Geneva. <https://apps.who.int/iris/handle/10665/199326>
- World Health Organization. (2020). Technical specifications for pressure swing adsorption (PSA) oxygen plants: interim guidance, 2020, World Health Organization: Geneva. <https://apps.who.int/iris/handle/10665/332313>

Clinical use of oxygen therapy

- World Health Organization, Clinical care for severe acute respiratory infection: toolkit, update 2022. COVID-19 adaptation. 2022: Geneva. <https://apps.who.int/iris/handle/10665/352851>
- World Health Organization, COVID-19 clinical management: living guidance, 25 January 2021. 2021: Geneva. <https://apps.who.int/iris/handle/10665/338882>
- World Health Organization, Oxygen therapy for children. 2016: Geneva. <https://apps.who.int/iris/handle/10665/81170>
- World Health Organization, Pocket book of hospital care for children: Guideline for the management of common childhood illnesses. 2013: Geneva. <https://apps.who.int/iris/handle/10665/81170>
- World Health Organization, Updated guideline: paediatric emergency triage, assessment and treatment Care of critically ill children. 2016, World Health Organization: Geneva. <https://apps.who.int/iris/handle/10665/204463>