WHO Medical Devices July 2021 Newsletter

Dear colleagues: Access, Availability, Affordability and Appropriate use of medical devices for COVID-19 are essential:

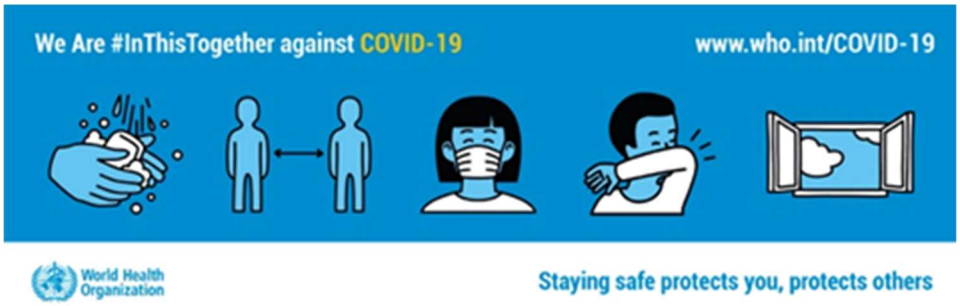
In vitro diagnostics, Personal protective equipment and Oxygen sources, delivery and monitoring systems.

Please continue to support in every way you can!

WHO July news:

Globally, as of **7:21pm CEST, 16 July 2021**, there have been **188,655,968 confirmed cases** of COVID-19, including **4,067,517 deaths**, reported to WHO.

As of **15 July 2021**, a total of **3,402,275,866 vaccine doses** have been administered.



Find below the following information and please disseminate in your networks

1. Medical devices and other technologies for COVID-19.

2. WHO List of Priority medical devices for cardiovascular diseases and diabetes and MeDevIS e-platform

3. Nomenclature of medical devices

1. Medical technologies for COVID-19 :

1.1. Oxygen, Oxygen, Oxygen, continues to be the medicine most needed for COVID-19 and for other diseases and conditions, work by ACT-A: Access to COVID-19 Tools and many other organizations is ongoing.

https://www.who.int/initiatives/act-accelerator

https://www.who.int/initiatives/oxygen-access-scale-up

https://www.who.int/teams/health-product-and-policy-standards/assistive-and-medical-technology/medical-devices

1.2 Oxygen task force ACT-A Therapeutics

https://unitaid.org/news-blog/unprecedented-cooperation-global-oxygen-suppliers-june-2021/#en

Unprecedented cooperation with global oxygen suppliers paves way to increase access for low- and middle-income countries to address COVID-19 crisis.

1.3 International pharmacopeia, open for open consultation for GMP medical gases and Oxygen 93%

We invite you to review the following draft working document which will be posted on the WHO Medicines website under "Monographs and general texts under review/revision for inclusion in The International Pharmacopoeia

(https://www.who.int/teams/health-product-and-policy-standards/standards-and-specifications/pharmaceuticals/current-projects):

Medicinal Oxygen

Draft proposal for revision in The International Pharmacopoeia

qas20_867_rev2_medicinal_oxygen.pdf (who.int)

It is intended to revise the monograph on Oxygen in The International Pharmacopoeia:

- to clarify that WHO Member States, considering options for increasing the supply of medicinal oxygen to treat COVID-19 and other patients, can safely apply oxygen generated by:
    - o Oxygen Generation Plants and concentrators, which use Pressure Swing Adsorption (PSA) or Vacuum Swing Adsorption (VSA) technologies to generate 90 to 96% pure

oxygen, referred to in the draft revision as "Oxygen 93%"; and/or

o Air Separation Units, which use cryogenic technology to generate 99% 51 pure oxygen, referred to in the draft revision as "Oxygen 99%"; and 52

• to define quality requirements for these products.

Send email to schmidth@who.int by 10th September, 2021

WHO good manufacturing practices for medicinal gases.

Please send your comments to Dr Steve Estevao Cordeiro, Technical Officer, Norms and Standards for Pharmaceuticals, Technical Standards and Specifications (estevaos@who.int), with a copy to Ms Sinéad Jones (jonessi@who.int) before 31 August 2021.

Arising from an increased demand for medicinal gases, in particular the use of oxygen in the treatment of patients with Coronavirus disease 2019 (COVID-19), the World Health Organization (WHO) Health Products Policy and Standards Department and other departments involved in the supply of oxygen and the inspection of production sites of medicinal gases, raised the urgency for the preparation of the WHO good manufacturing practices for medicinal gases guidance text.

qas21_875_gmp_for_medical_gases.pdf (who.int)

1.4 PSA Plants and Oxygen Concentrators that need repair, Lists:

Every Breath Counts LMIC Oxygen Plant "FIX LIST" - Google Sheets

https://fdunn8.wixsite.com/website

Maintenance
Challenge: https://drive.google.com/file/d/18URm59O_12t6ymjNqQ4pqxMvm0_YGv3I/view Email to connect: will@d-prize.org

WHO, UNICEF and other partners are working to support the repair of PSA plants, and increase availability of oxygen at country level

1.5 NGOs very active on oxygen support

- Every breath counts https://stoppneumonia.org/latest/covid-19/
- PATH https://www.path.org/programs/market-dynamics/covid-19-oxygen-needs-tracker/
- Clinton health access initiative https://www.clintonhealthaccess.org/our-programs/oxygen/

1.6 Global Fund

The Global Fund has opened another window for sending funding proposals in September!

COVID-19 Response Mechanism to support countries to procure:

in vitro Diagnostics, Personal Protective Equipment, Treatment and Oxygen Equipment. They have authorized funds for 540 PSA plants.

1.7 C-TAP

Medical devices industry, academia, innovators are invited to share knowledge, IP or data, join C-TAP: The technology access pool, to increase access of technologies globally.

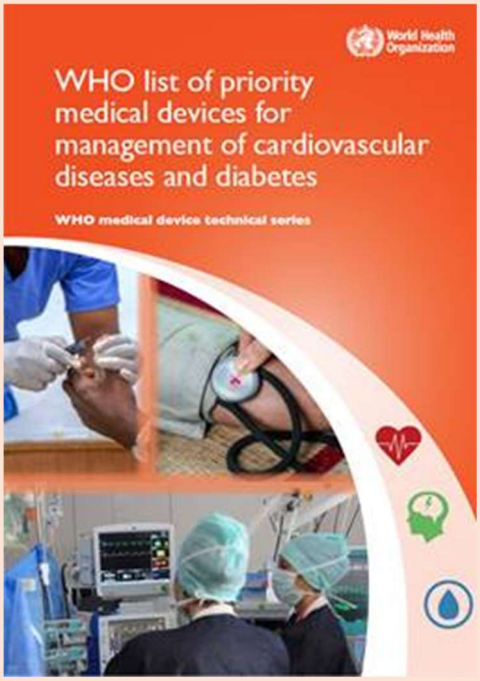
1.8 Clinical management course

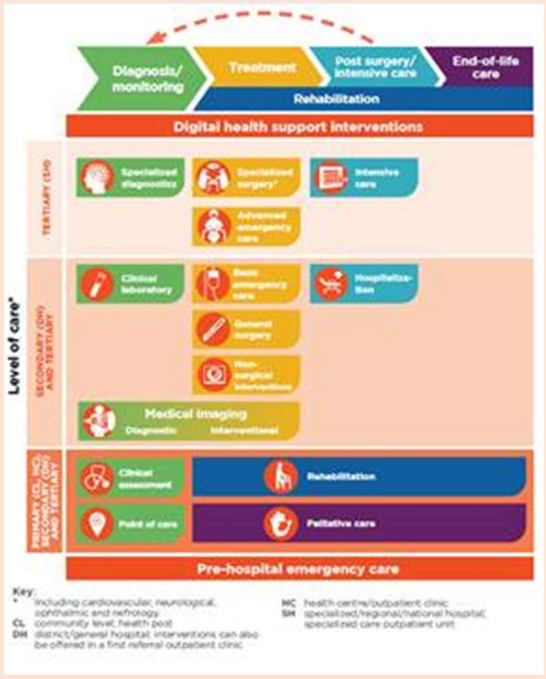
The Clinical management course is now live on OpenWHO: https://openwho.org/courses/clinical-management-COVID-19-mild-mod-severe

More information: https://www.who.int/emergencies/diseases/novel-coronavirus-2019

2 WHO List of Priority medical devices for cardiovascular diseases and diabetes and MeDevIS e-platform

2.1 New publication: WHO List of Priority medical devices for cardiovascular diseases and diabetes

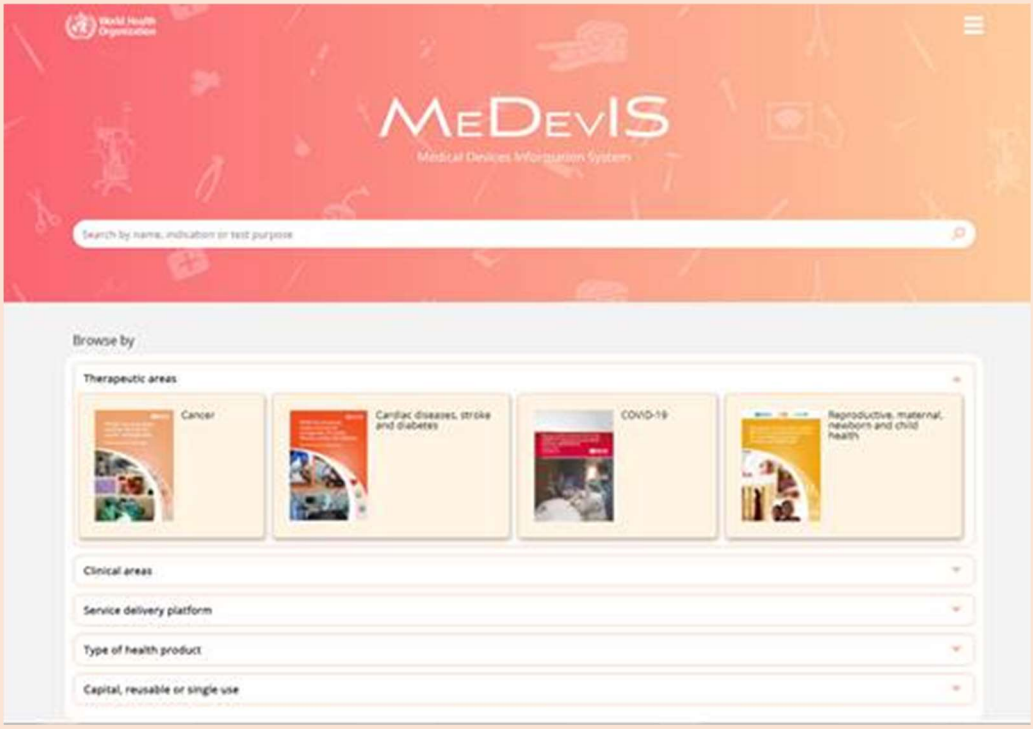




The book was launched on JUNE 30, you can download it here: WHO List of Priority medical devices for management of cardiovascular diseases and diabetes

It includes more than 500 medical devices, listed by clinical interventions, clinical areas of the hospital, includes diabetes and complications of diabetes, for cardiac disease and stroke.

2.2 WHO Priority Medical Devices Information System: MeDevIS



The beta version was released 30th of June. It includes all the priority medical devices listed in 4 WHO publications: for cancer management, for COVID, for cardiovascular and diabetes for reproductive, maternal , new born and child care.

An interactive session on MeDevIS will take place Wednesday 21 July 2021 14:00 CEST (Geneva time) .

https://www.who.int/news-room/events/detail/2021/07/21/default-calendar/webinar-an-interactive-session-on-medevis

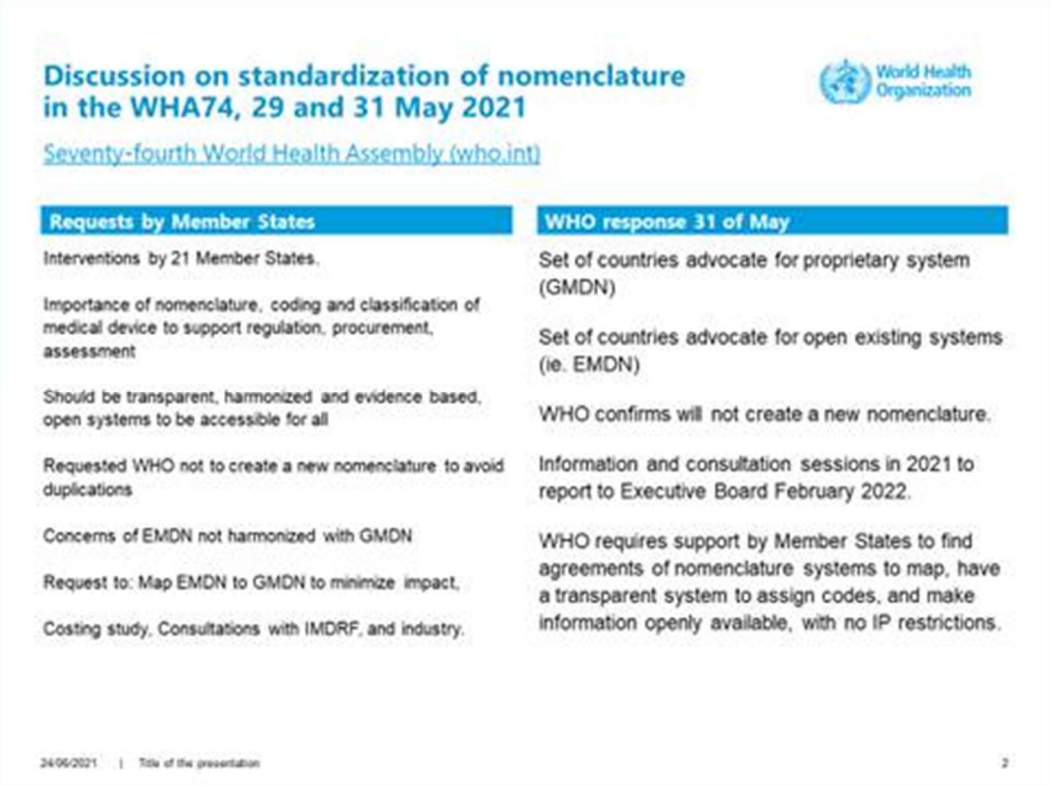
3 Nomenclature of medical devices consultations.

The WHA74 took place virtually from 24 May to 1 June 2021, in light of the ongoing COVID-19 pandemic. You will be able to listen to all the discussions [Seventy-fourth%20World%20Health%20Assembly%20(who.int)]here.

Topic WHA74.7 Standardization of medical device nomenclature discussions took place 29 and 31 of May.

WHO will be conducting information sessions and consultation with various stakeholders as indicated in the timeline of events here below.

More information can be found here



Draft dates to be confirmed	Activity	Expected outcome
May-June	WHA74 and EB149	----------
24 June	IMDRF teleconference	Briefing of WHA and next steps
16, 20 July	WHO HQ	
19 July	WHO Regional advisors	Status, plan and their input
22 July	Medical devices industry	GMTA, DITTA,
28 July	UN agencies	Nomenclature and tech specs
July, August TBC	Nomenclature agencies	Willingness to map, one to one, WHO and agency
21-27 July	Biomedical and Clinical engineers, procurement and supply	Use of nomenclature in health care facilities
6,7,8,9,10, September	Regional regulators networks	Nomenclature uses and challenges
2x September, TBC	Member States information session	Report on the consultation sessions with various stakeholders
September	IMDRF meeting	Briefing and next steps
1 October	Report for EB150	Discussion of the report
1 February 2022	EB150.	Presentation to the Executive Board

For more information contact: medicaldevices@who.int and visit our website about https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices/nomenclature

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WHO medical devices website,