WHO Lists to select health products for benefit packages in countries.

Adriana Velazquez Berumen,

Senior advisor on medical devices and IVDs 2020.

World Health Organization

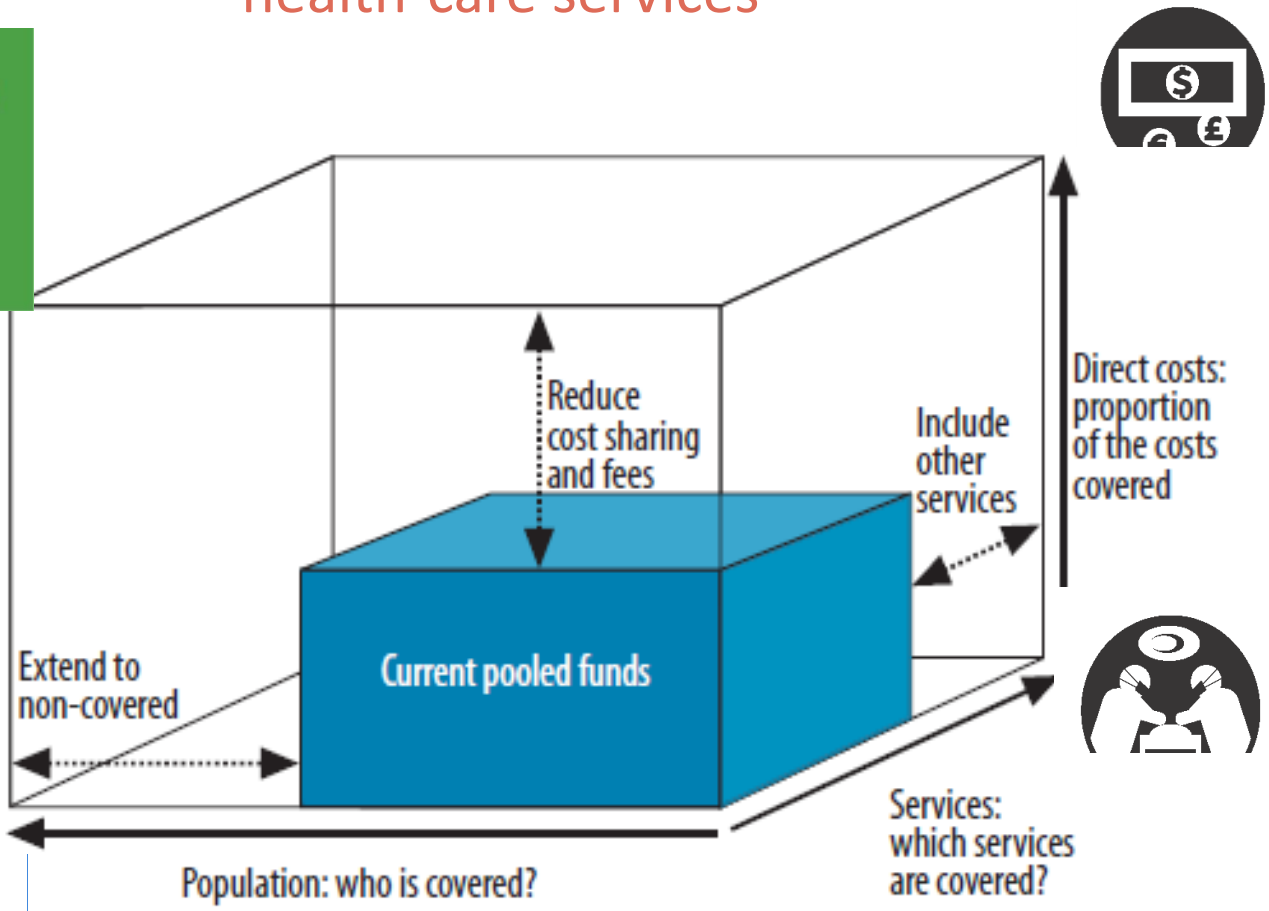
World Health Organization

Goal 3. Good health and well being

SDG3: Achieve universal health coverage, including financial risk protection, access to quality essential health-care services

World Health Organization

3 GOOD HEALTH AND WELL-BEING



Agenda

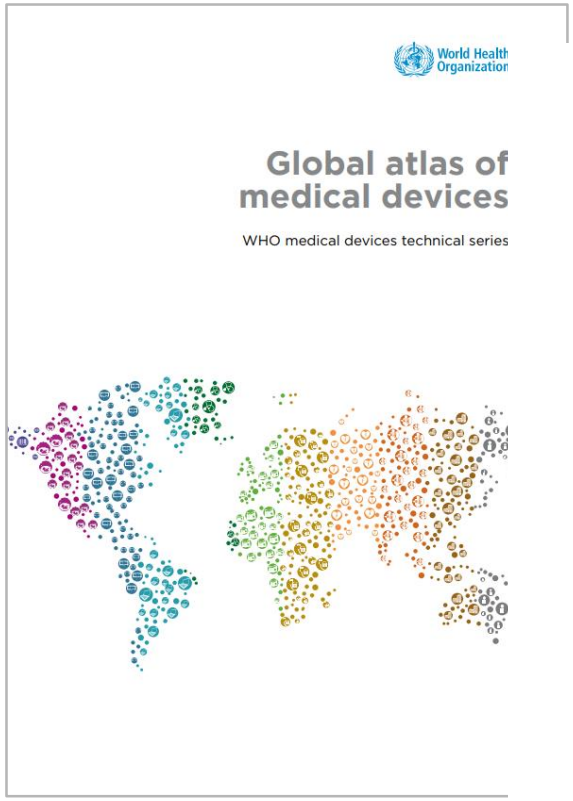
World Health Organization

WHO ESSENTIAL AND PRIORITY LISTS to inform development of National lists to increase access.

- **Medical devices**
- **In vitro diagnostics**
- **The COVID situation**

Priority Medical Devices and Essential in vitro
Aim to inform national lists for procurement / reimbursement/ UHC coverage

World Health Organization



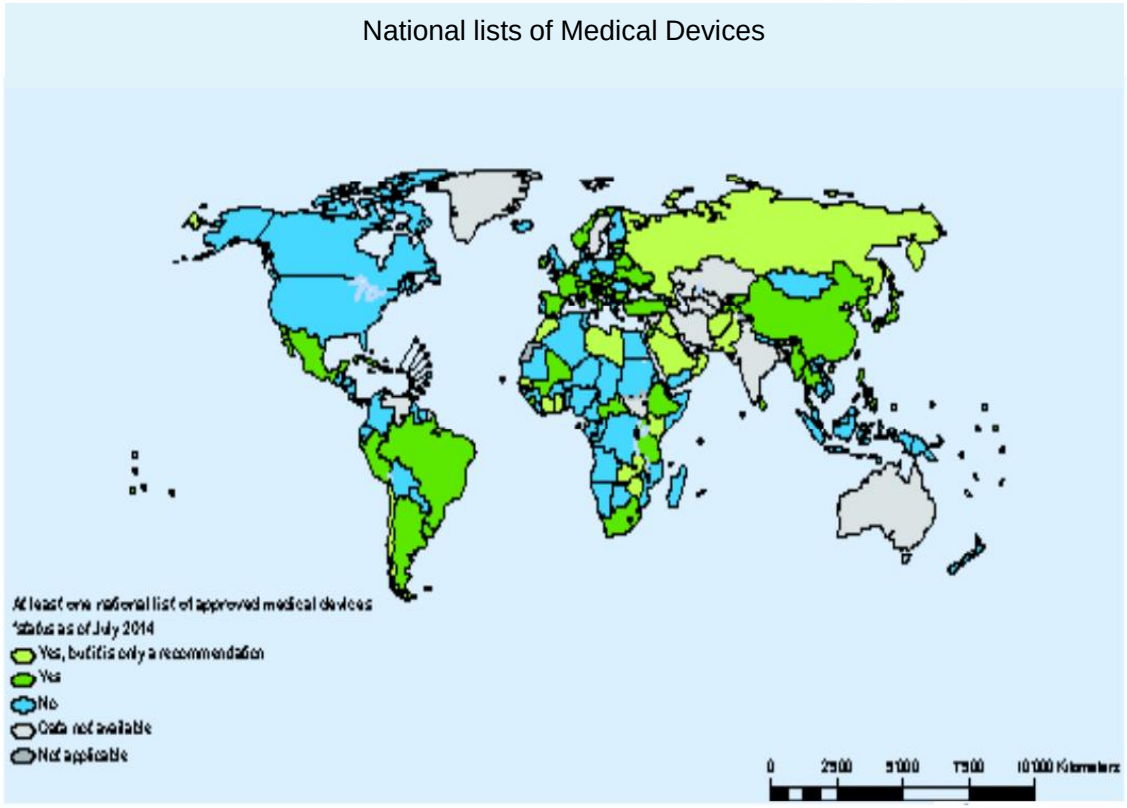


Fig. 3.6-1: Available national standards or recommended lists of medical devices for public procurement or reimbursement.

https://www.who.int/medical_devices/publications/global_atlas_meddev2017/en/

The Global Atlas is being updated December 2020!

Medical Devices scope:

World Health Organization

Self –used

Patients

Doctor/ Nurse/ Technician

Medical Equipment

IVDs

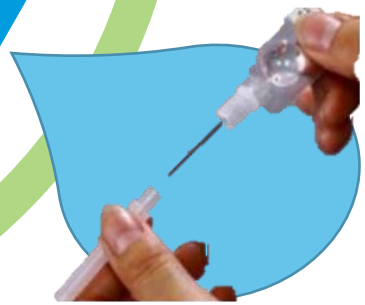
Medical Software

Medical Devices

Implantable Medical Devices

Single Use Medical Devices PPE..

Surgical Instruments



Sequence of process to ensure access to appropriate and safe health technologies

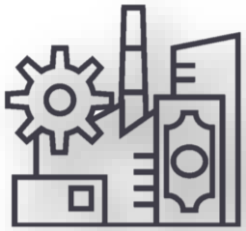
World Health Organization

Value chain To ensure improved access of safe, quality medical devices

World Health Organization

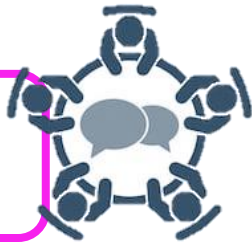
R&D

- Industry and Academics: Research and development <u>should be based on needs</u>



Assessment

- Health Technology Assessment
- Priority and Essential Lists of MD for reimbursement or procurement



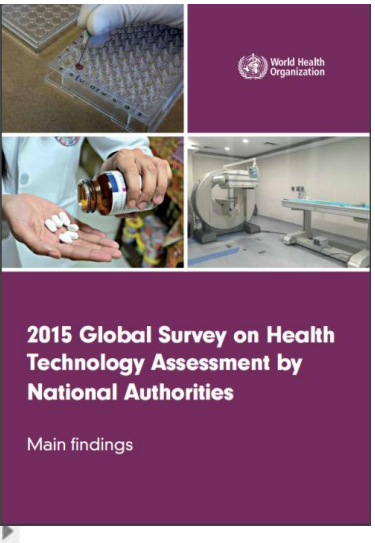
Regulations

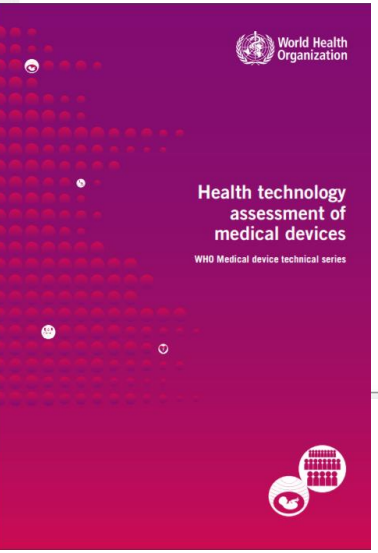
- Regulation process of medical devices
- Lists of approved MD for marketing in country.

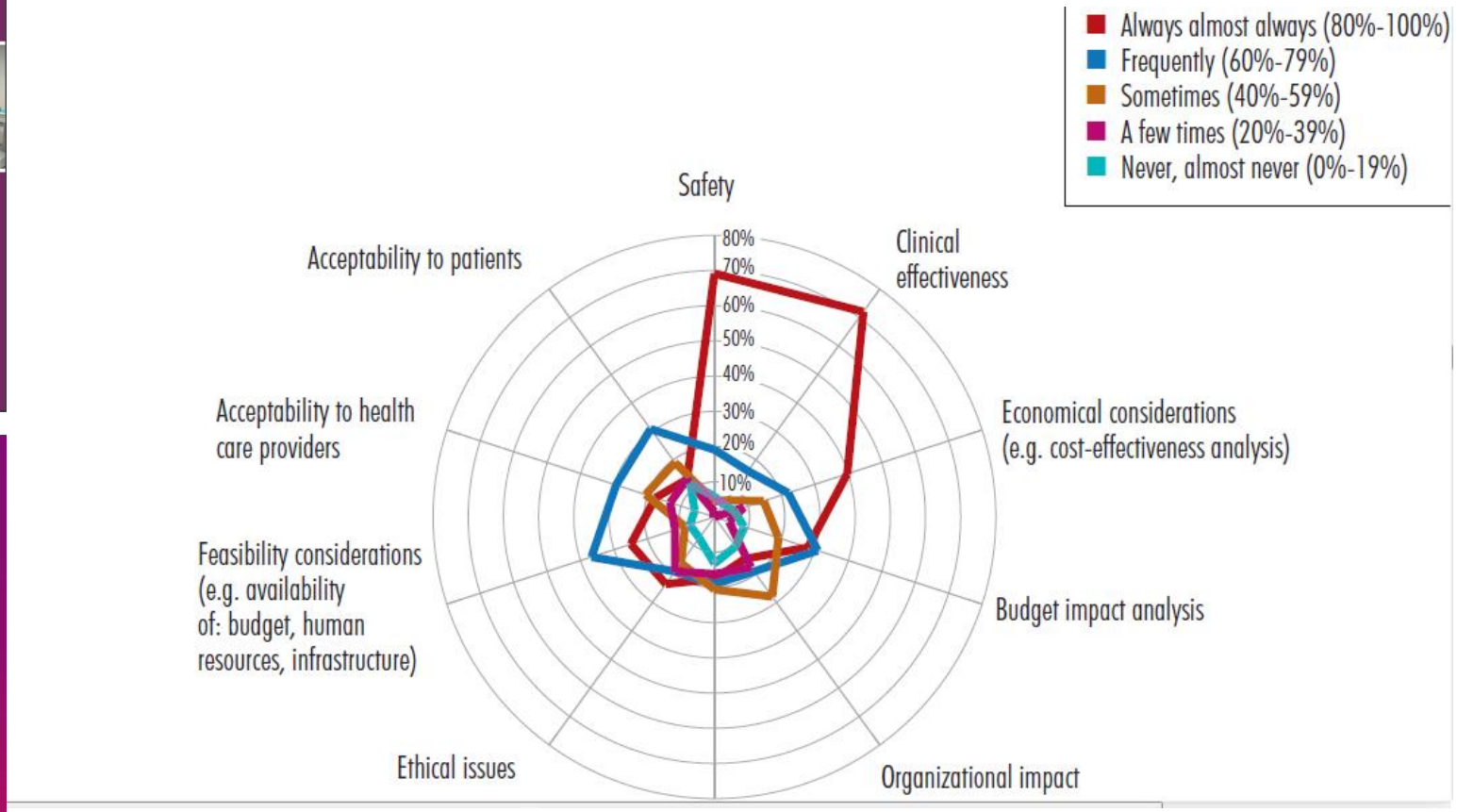
Management

- Procurement
- Installation, training, maintenance
- Safe use, operating costs and clinical effectiveness
- Post market surveillance and adverse event report
- Decommissioning, Replacement

2015 WHO survey on national authorities on HTA indicated mostly clinical effectiveness and safety of product are assessed in the case of medical devices. (WHA60.23)

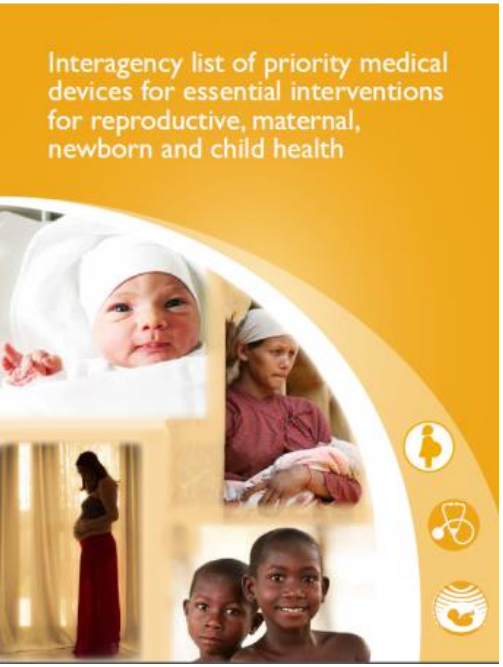




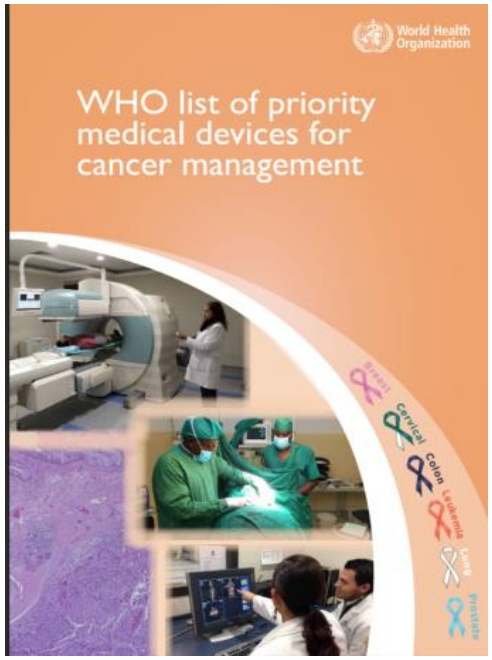


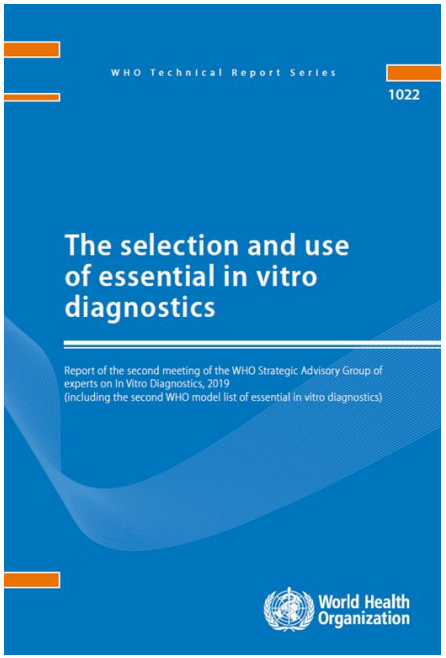
Priority medical devices by interventions and levels of care

2015



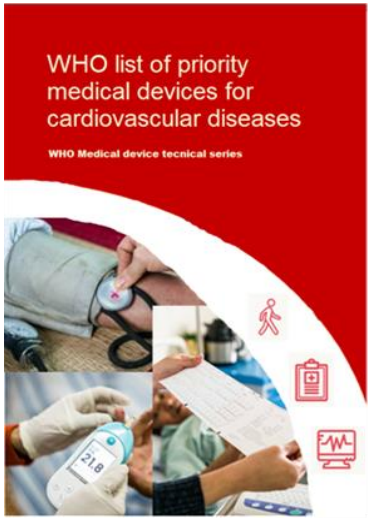
2017





2020

In development: 2017-2020 to include also Stroke and Diabetes.



The WHO Model List of Essential In Vitro Diagnostics (EDL)

World Health Organization

Department of Essential Medicines and Health Products

JOINT UNICEF – UNFPA – WHO MEETING WITH MANUFACTURERS AND SUPPLIERS

November 2020

EDL scope and oversight

Scope :

Test categories - **No brand names:**

- Disease-specific tests (infectious and NCDs)
- General tests

Oversight:

Strategic Advisory Group of Experts on IVDs (SAGE IVD)

Review:

Annual review by SAGE IVD

First meeting April 2018

Second meeting 18 – 22 March 2019

Third virtual meeting June - July 2020.

Source: Image from iStock.com

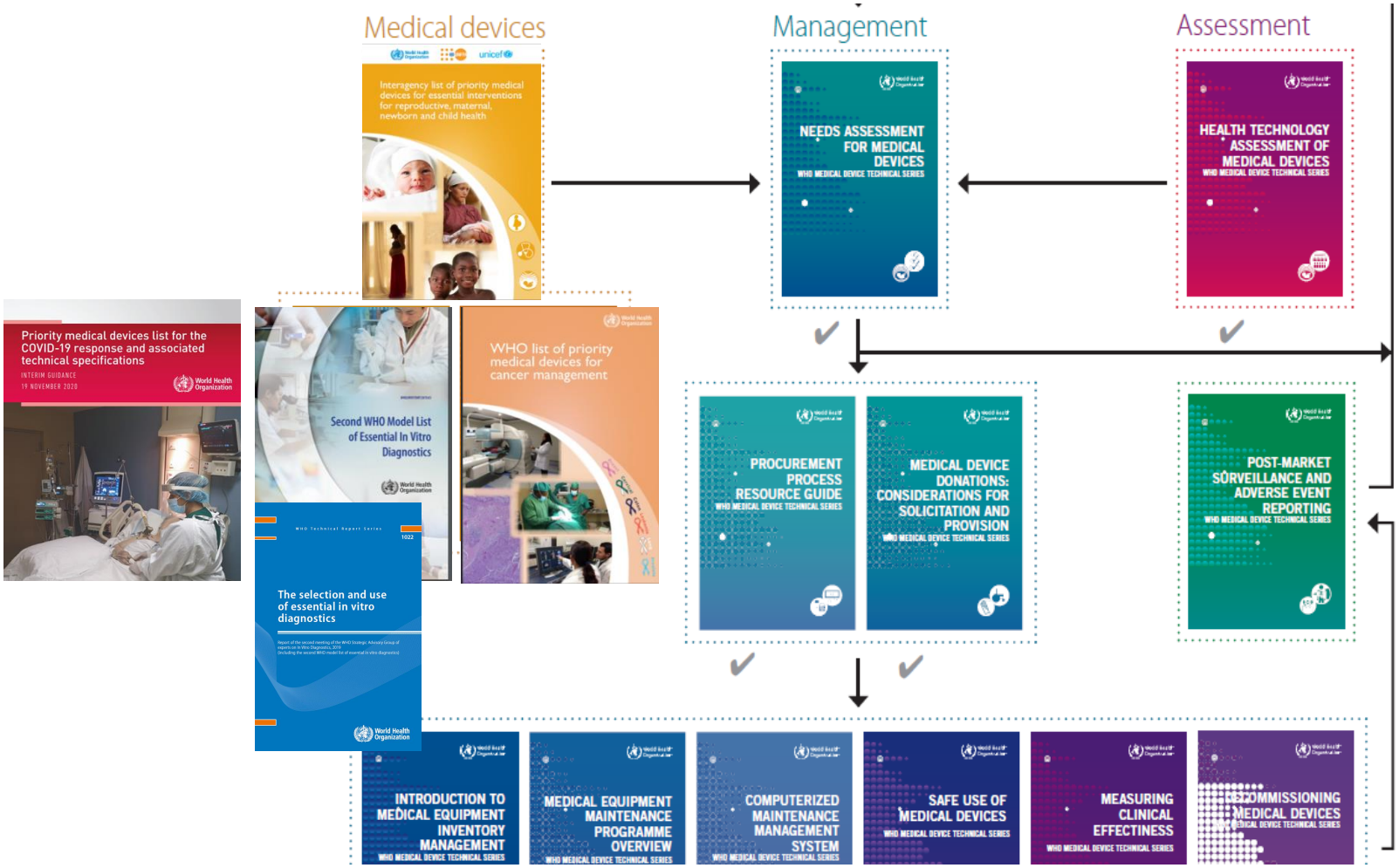
Medical devices are indispensable to test, treat patients and protect health care workers

World Health Organization

Personal protective equipment, in vitro diagnostics and medical equipment

Health technology Assessment, Health technology management and lists of priority medical devices and essential IVDs.

World Health Organization



Priority medical devices list for the COVID-19 response and associated technical specifications

World Health Organization

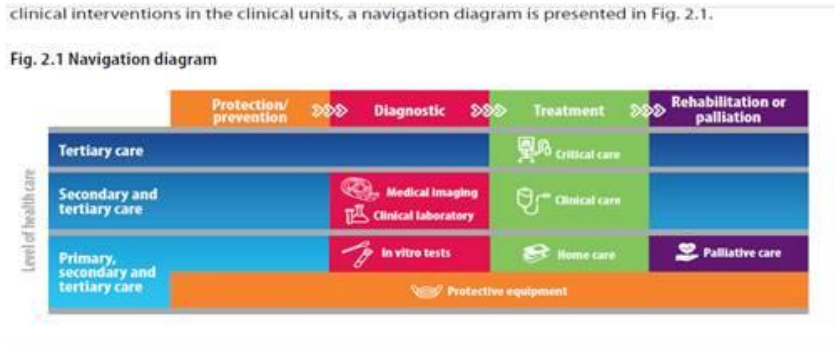
https://www.who.int/publications/i/item/WHO-2019-nCoV-MedDev-TS-O2T.V2

Link to the clinical interventions

Table 2.1 Interventions by clinical area

Clinical area	Intervention	Triage	Severe patients	Critical patients	1st level	2nd level	3rd level
Clinical assessment	Body temperature assessment	●	●	●	●	●	●
	Oxygen saturation assessment	●	●	●	●	●	●
Medical imaging	Ultrasound scan		●	●		●	●
	CT scan		●	●		●	●
	X-ray scan, chest		●	●		●	●
Clinical laboratory	Blood gas analysis		●	●		●	●
	RT-PCR test	●	●	●	○	●	●
	Antigen test	●	●	●	●	●	●
Clinical care	Multiparametric monitoring		●	●		●	●
	Oxygen therapy		●	●	●	●	●
	Airway management and intubation		●	●		●	●
	Non-invasive ventilation		●	●		●	●
	Invasive ventilation			●		●	●
	Infusion therapy		●	●		●	●
	Intensive care treatment			●		●	●
	Central venous catheter placement			●			●
	Gastrometrical feeding			●			●
	Urine collection			●		●	●
Protective equipment	General	●	●	●	●	●	●
	Personal protection	●	●	●	●	●	●
	Sterilization	●	●	●	●	●	●

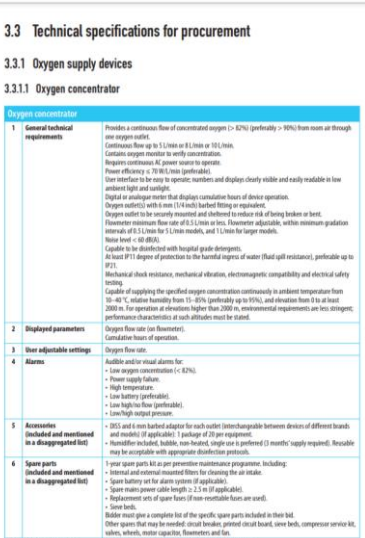
Devices for protection, diagnose, treatment and palliation



clinical interventions in the clinical units, a navigation diagram is presented in Fig. 2.1.

Fig. 2.1 Navigation diagram

Technical specifications description



3.3 Technical specifications for procurement

3.3.1 Oxygen supply devices

3.3.1.1 Oxygen concentrator

Oxygen concentrator		
1	General technical requirements	Provides a continuous flow of concentrated oxygen (> 82%) (preferably > 90%) from room air through one oxygen outlet. Continuous flow up to 5 L/min or 8 L/min or 10 L/min. Contains oxygen monitor to verify concentration. Requires continuous AC power source to operate. Power efficiency ≤ 70 W/L/min (preferable). User interface to be easy to operate; numbers and displays clearly visible and easily readable in low ambient light and sunlight. Digital or analogue meter that displays cumulative hours of device operation. Oxygen outlet(s) with 6 mm (1/4 inch) barbed fitting or equivalent. Oxygen outlet to be securely mounted and sheltered to reduce risk of being broken or bent. Flowmeter minimum flow rate of 0.5 L/min or less. Flowmeter adjustable, within minimum gradation intervals of 0.5 L/min for 5 L/min models, and 1 L/min for larger models. Noise level < 60 dB(A). Capable to be disinfected with hospital grade detergents. At least IP11 degree of protection to the harmful ingress of water (fluid spill resistance), preferable up to IP21. Mechanical shock resistance, mechanical vibration, electromagnetic compatibility and electrical safety testing. Capable of supplying the specified oxygen concentration continuously in ambient temperature from 10–40 °C, relative humidity from 15–85% (preferably up to 95%), and elevation from 0 to at least 2000 m. For operation at elevations higher than 2000 m, environmental requirements are less stringent; performance characteristics at such altitudes must be stated.
2	Displayed parameters	Oxygen flow rate (on flowmeter). Cumulative hours of operation.
3	User adjustable settings	Oxygen flow rate.
4	Alarms	Audible and/or visual alarms for: • Low oxygen concentration (< 82%). • Power supply failure. • High temperature. • Low battery (preferable). • Low high/no flow (preferable). • Low/high output pressure.
5	Accessories (included and mentioned in a disaggregated list)	• DISS and 6 mm barbed adaptor for each outlet (interchangeable between devices of different brands and models) (if applicable): 1 package of 20 per equipment. • Humidifier included, bubble, non-heated, single use is preferred (3 months' supply required). Reusable may be acceptable with appropriate disinfection protocols.
6	Spare parts (included and mentioned in a disaggregated list)	1-year spare parts kit as per preventive maintenance programme. Including: • Internal and external mounted filters for cleaning the air intake. • Spare battery set for alarm system (if applicable). • Spare mains power cable length ≥ 2.5 m (if applicable). • Replacement sets of spare fuses (if non-resettable fuses are used). • Sieve beds. Bidder must give a complete list of the specific spare parts included in their bid. Other spares that may be needed: circuit breaker, printed circuit board, sieve beds, compressor service kit, valves, wheels, motor capacitor, flowmeters and fan.

Priority list of PPE and technical specifications including QA and standards recognition

https://www.who.int/publications/i/item/WHO-2019-nCoV-PPE_specifications-2020.1

List of PPE

WHO Priority medical devices for COVID-19 :

Surgical Masks

Non Surgical Masks

N95 masks

Googles

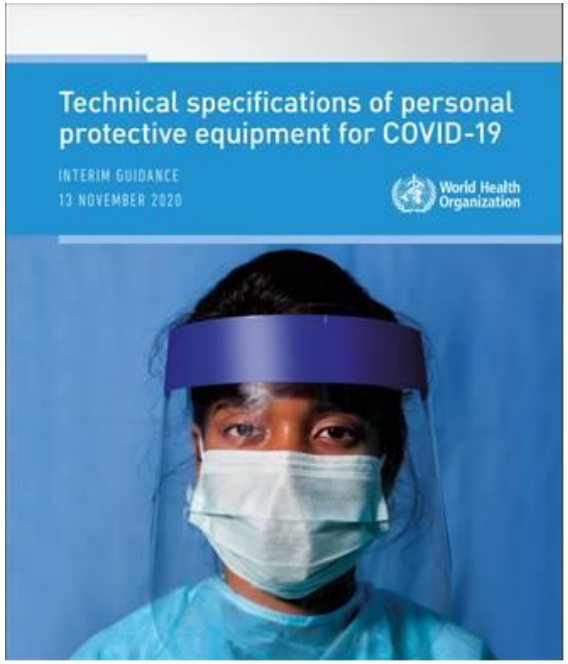
Faceshields

Gloves

Gowns

…

New publication

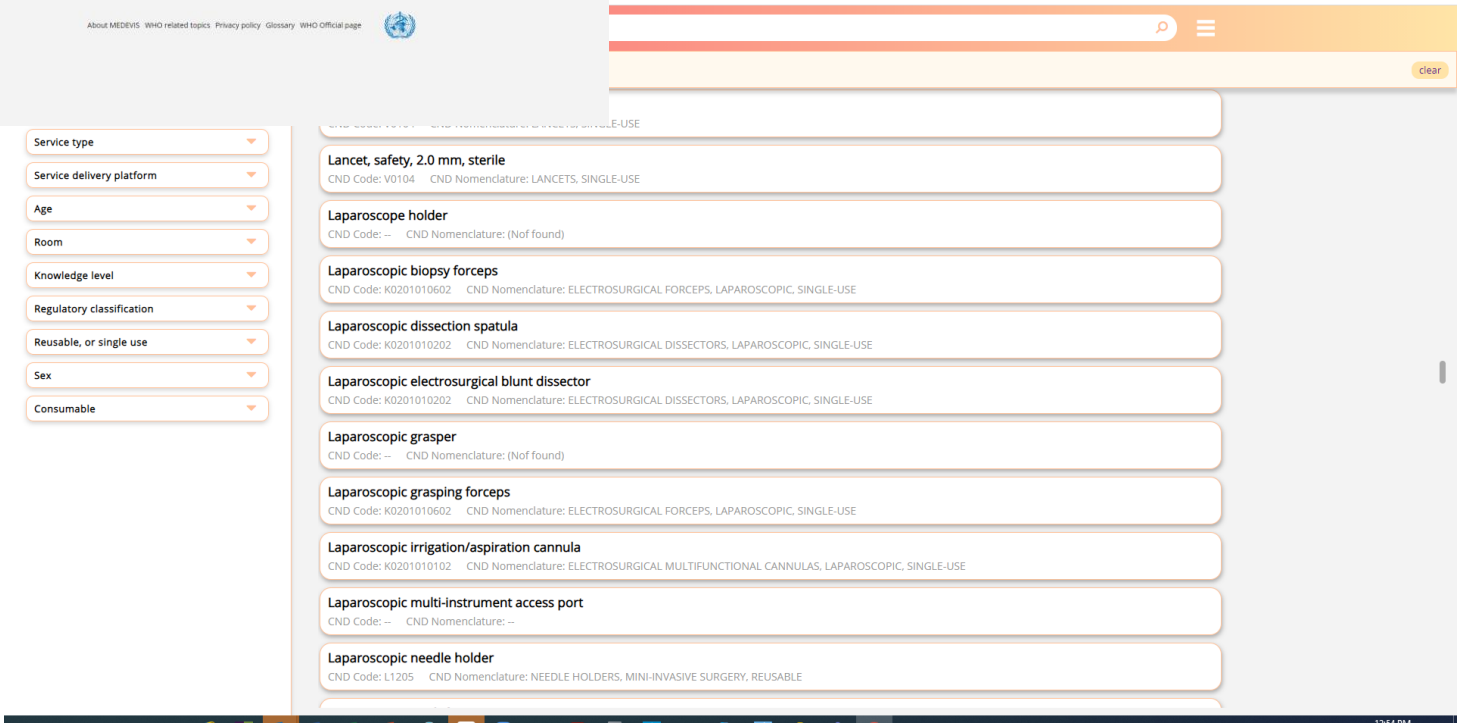


Description of tech specif for procurement

4. Technical specifications for procurement

Item	Characteristics	Performance standards (or alternative equivalent standard)
Gloves, medical examination (non-sterile)	Gloves, examination, nitrile (preferable), latex, polychloroprene or PVC, powder-free, non-sterile (e.g. minimum 230 mm total length). Minimum thickness 0.05 mm. Sizes S, M, L.	EN 455 EN 374, optional additional: ASTM D6319, D5578, D5250, D6977 Or alternative equivalent set of standards
Gloves, surgical (sterile)	Gloves, surgical, nitrile (preferable), latex, polyisoprene or polychloroprene, sterile, powder-free, single use. Gloves should have long cuffs, reaching well above the wrist, ideally to mid-forearm. Minimum thickness 0.10 mm. Sizes ranging 5.0–9.0.	EN 455 ASTM D3577 Sterility: United States Pharmacopeia EN ISO 11607 Or alternative equivalent set of standards
Goggles, glasses protective	Good seal with the skin of the face, flexible PVC frame to easily fit with all face contours with even pressure, enclose eyes and the surrounding areas, accommodate wearers with prescription glasses, clear plastic lens with fog- and scratch-resistant treatments. Adjustable band to secure firmly so as not to become loose during clinical activity. Indirect venting to avoid fogging. May be reusable (provided appropriate arrangements for decontamination are in place) or disposable.	EN 166 ANSI/ISEA Z87.1 Or alternative equivalent set of standards
Face shield	Made of clear plastic and providing good visibility to both the wearer and the patient. Adjustable band to attach firmly around the head and fit snugly against the forehead. Fog resistant (preferable). Completely cover the sides and length of the face. May be reusable (made of robust material which can be cleaned and disinfected) or disposable.	EN 166 (if reusable) ANSI/ISEA Z87.1 (if reusable) Or alternative equivalent set of standards
Fit test kit	To evaluate effectiveness of seal for tight fitting respiratory protection devices.	OSHA 29 CFR 1910.134 Appendix A
Particulate respirator	Good particle filtration (minimum 94% or 95%), good breathability with design that does not collapse against the mouth (e.g. duckbill, cup-shaped). May be tested for fluid resistance (NIOSH/FDA surgical N95, EN 149 FFP2 + Type IIR, GB 19083 Grade/Level 1).	Fluid-resistant respirator: • Minimum NIOSH approved (42 CFR Part 84) and FDA cleared "surgical N95" • EN 149, minimum "FFP2" and EN 14683 Type IIR • GB 19083, minimum "Grade/Level 1" • Or alternative equivalent standard Non-fluid resistant respirator: • Minimum NIOSH approved "N95" according to 42 CFR Part 84 • EN 149, minimum "FFP2" • GB 2626, minimum "KN95" • Or alternative equivalent standard

Priority medical devices information system MeDevIS …Q4 2020, 1500 types



Objectives of the EDL

The EDL is intended to support IVD policy development, to support patients having diagnostics-informed treatment.

The EDL lists a set of priority IVD categories for use at various levels of the healthcare system.

The EDL:

1. Provides evidence-based guidance to Member States for the development of local/national essential in vitro diagnostics lists
2. Informs United Nations (UN) agencies and non-governmental organizations (NGOs) who support selection, procurement, supply, donations or provision of in vitro diagnostics
3. Provides guidance to the medical technology private sector on diagnostics priorities needed to address global health issues

Benefits of an EDL…

- Support countries to prioritize their testing and infrastructure needs
- Support outbreak preparedness
- Facilitate the development of high priority new IVDs by industry and funders
- Availability of diagnostics will ensure safe and rational use of medicines in the EMLs
- Increase affordability by facilitating bulk and advanced purchasing

Source: Image from iStock.com

Contents of 2nd edition of EDL

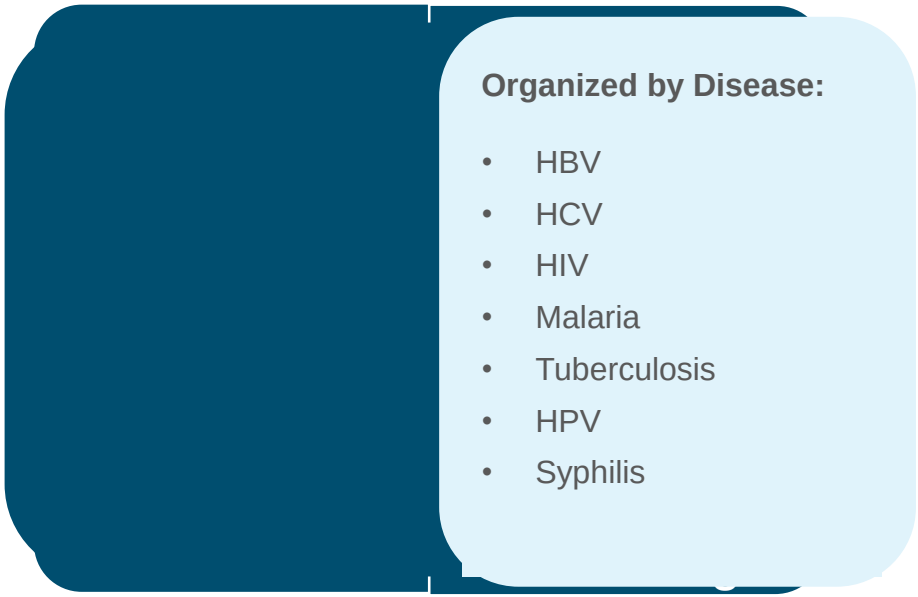
September 2019

Section I
Community and health settings without laboratories

Section II
Health care facilities with clinical laboratories

Section I.a & II.a
General IVDs

Section I.b, II.b, II.c
Disease Specific IVDs



Stepwise summary of submission review process for the EDL

World Health Organization

Step 1	• Pre-submission reviewed by EDL Secretariat submission in close collaboration with relevant departments at WHO and invites a full submission if appropriate.
Step 2	• Full submission/change request/additional evidence reviewed for completeness by EDL Secretariat
Step 3	• Each submission is peer-reviewed by at least two members of the SAGE IVD, who formulate draft recommendations for consideration by the full committee during the meeting
Step 4	• The evidence provided in each full submission is reviewed and assessed for strength and quality by a methodologist
Step 5	• All reviews are published on the WHO website for full transparency and public comment at least one month prior to the SAGE IVD meeting
Step 6	• Peer reviewers and methodologists present their recommendations for each application to the full SAGE IVD for discussion
Step 7	• The SAGE IVD reaches a decision for each submission by consensus, documents the reasons for the decision and makes its recommendation to the Director-General.
Step 8	• The Director-General approves the list.

EDL 3 update (in process)

SAGE IVD meeting held as a series of WebEx sessions over 6 weeks to review:

- 28 applications received
- 26 changes suggested (non editorial)
- 5 sets of additional data to lift conditional listings

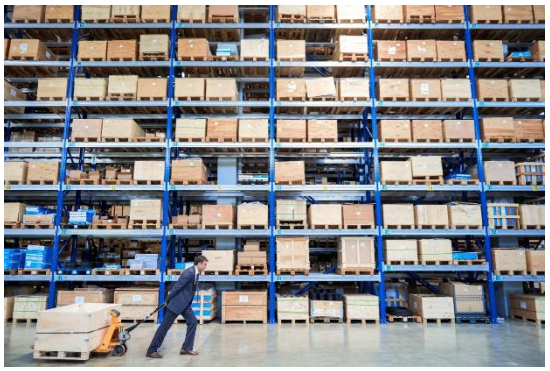
EDL 3 includes:

- 13 additional infectious disease test categories including SARS CoV NAT and antigen tests and 9 additional tests for NCDs
- New section on endocrine disorder tests
- Re-organization of general tests

Launch expected January 2021.

Additional tools to support implementation of the EDL

1. Technical specifications to support procurement
   - Generic specifications that can be used by countries as a guide to procure commercially available products
2. Guidance on development of a national EDL
3. Global nomenclature for IVDs
   - Supporting regulatory bodies, procuring entities, testing sites
4. e-EDL: electronic version of the EDL
   - A more user-friendly, comprehensive approach to use the EDL which includes cross-referencing, history of the listing, caveats and statements made at the time of listing



Differences between the WHO EDL and WHO IVD prequalification

The EDL is policy oriented and PQ lists quality assessed individual products.

Model list of Essential IVDs

- **Evidence based selection for policy**
- **Product categories by type:** no manufacturer names, no brand names.
- **Larger scope**: Infectious, Non Communicable diseases and general laboratory tests.
- **Outcome**. List of types of tests to be considered essential for UHC, emergencies and wellness.
- Note: EDL includes references to WHO guidelines, WHO documents and Prequalified products that correspond to certain categories of test.

List of WHO Prequalified IVDs

- **Specific product assessment**
- **Specific IVDs** assessed for quality, safety and performance, listed by product manufacturer, model, brand name.
- **Limited scope**: HIV, malaria , syphilis, G6PD, HPV, HCV, HBV, cholera.
- **Outcome:** a list of quality assured branded products that are eligible for procurement by UN agencies, NGOs, donors or Member States.
- PQ by product is time bound to assessment performed to the specific brand/model.

WHO Essential in vitro diagnostic list: 2018, 2019, 2020 @200 diagnostic tests in 3 tiers

World Health Organization

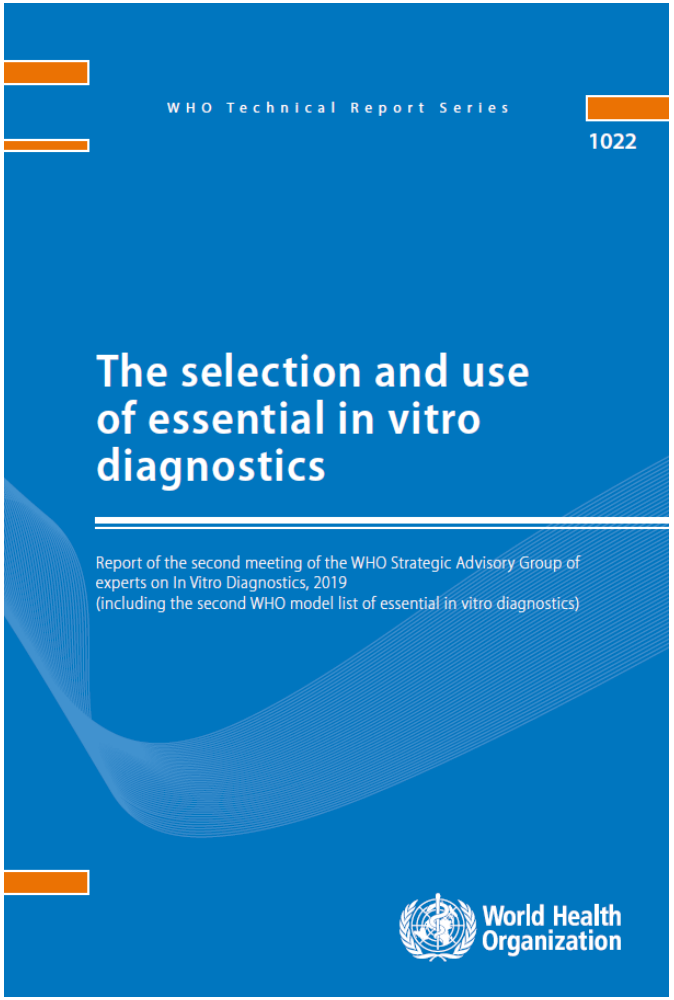
Basic test characteristics

- Test purpose
- Test format
- Specimen types
- Equipment required
- Regulatory status
- Global availability
- Price per test range
- Instrument price range

Ethics, equity and human rights issues

Evidence for clinical usefulness and impact

Evidence for economic impact and/or cost–effectiveness

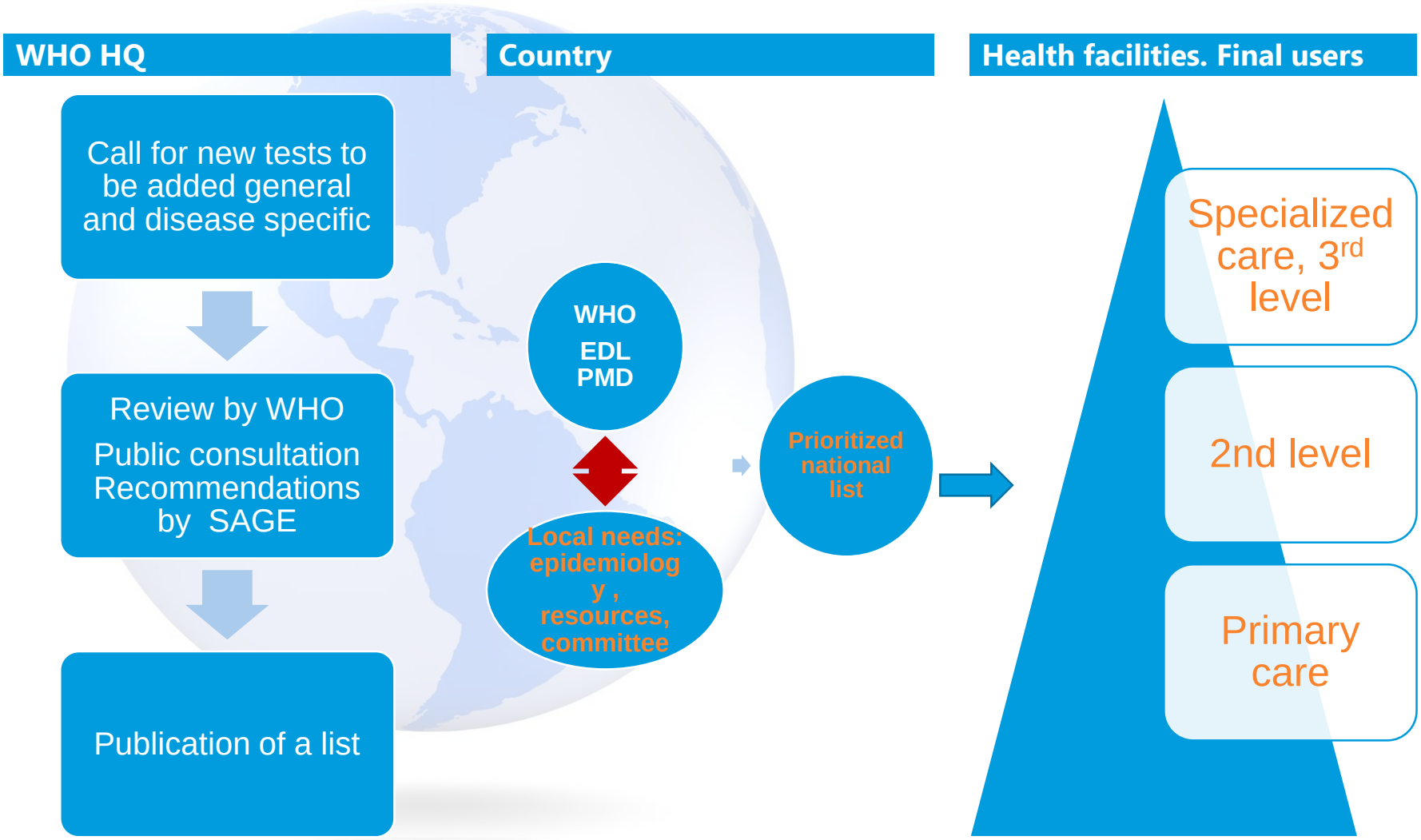


E-EDL … Q4 2020

World Health Organization

EDL secretariat

Global Implementation:
From WHO tools: EDL & PMD to access of MD & IVDs at country level

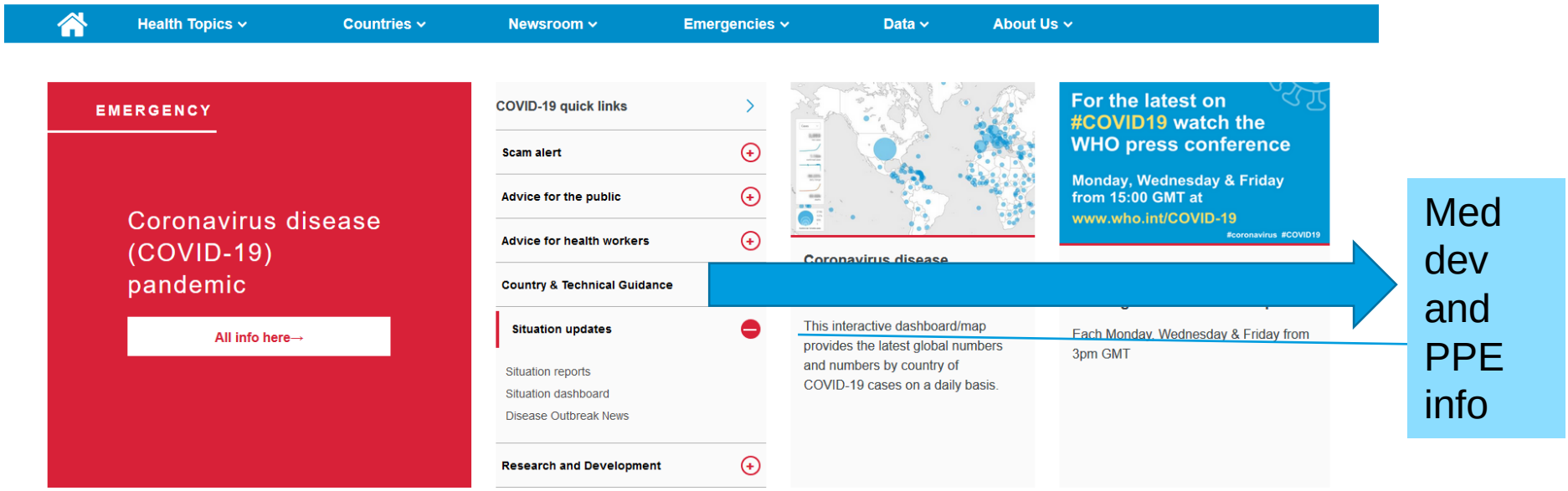


World Health Organization

COVID situation

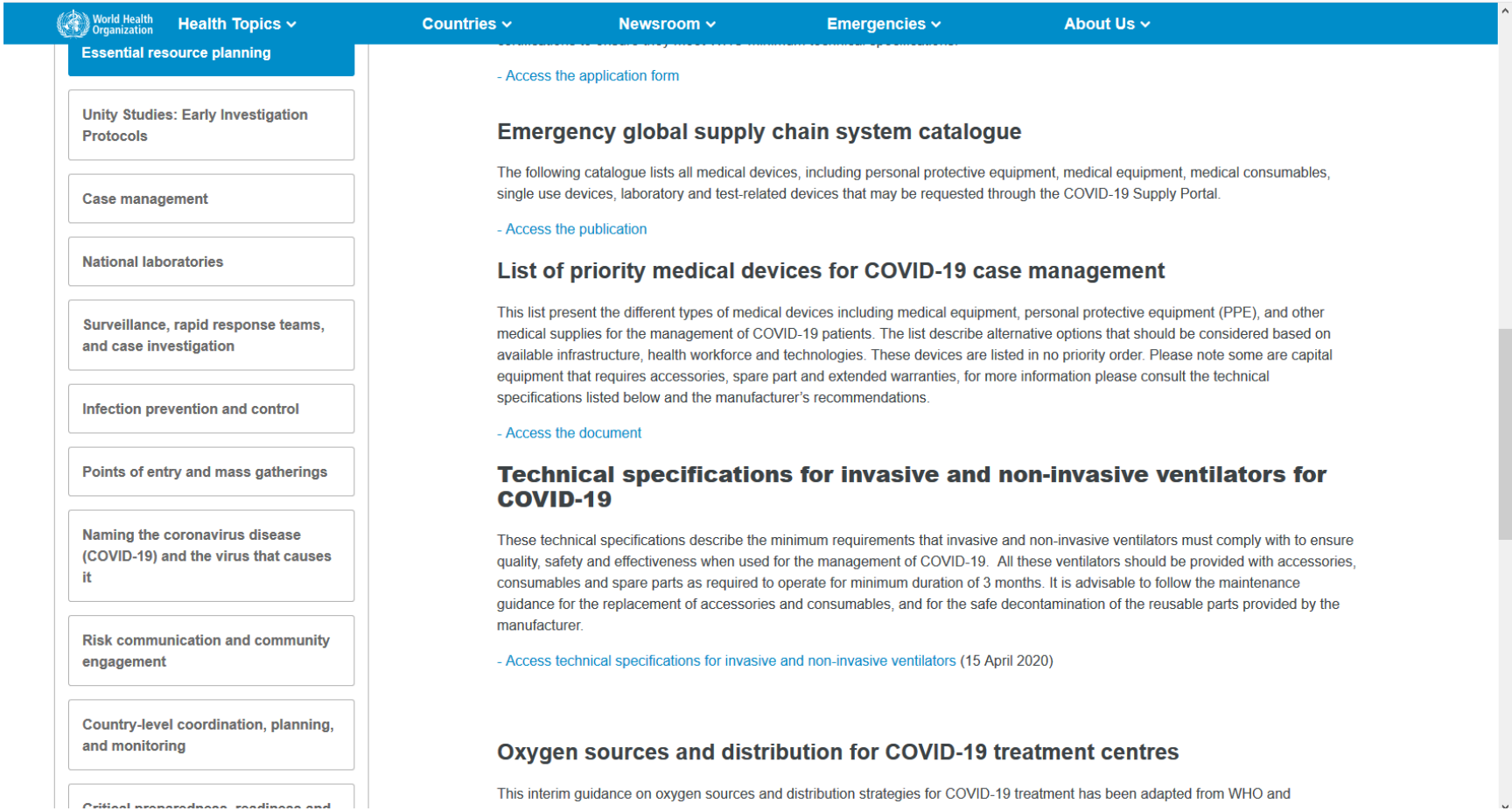
Information

https://www.who.int/



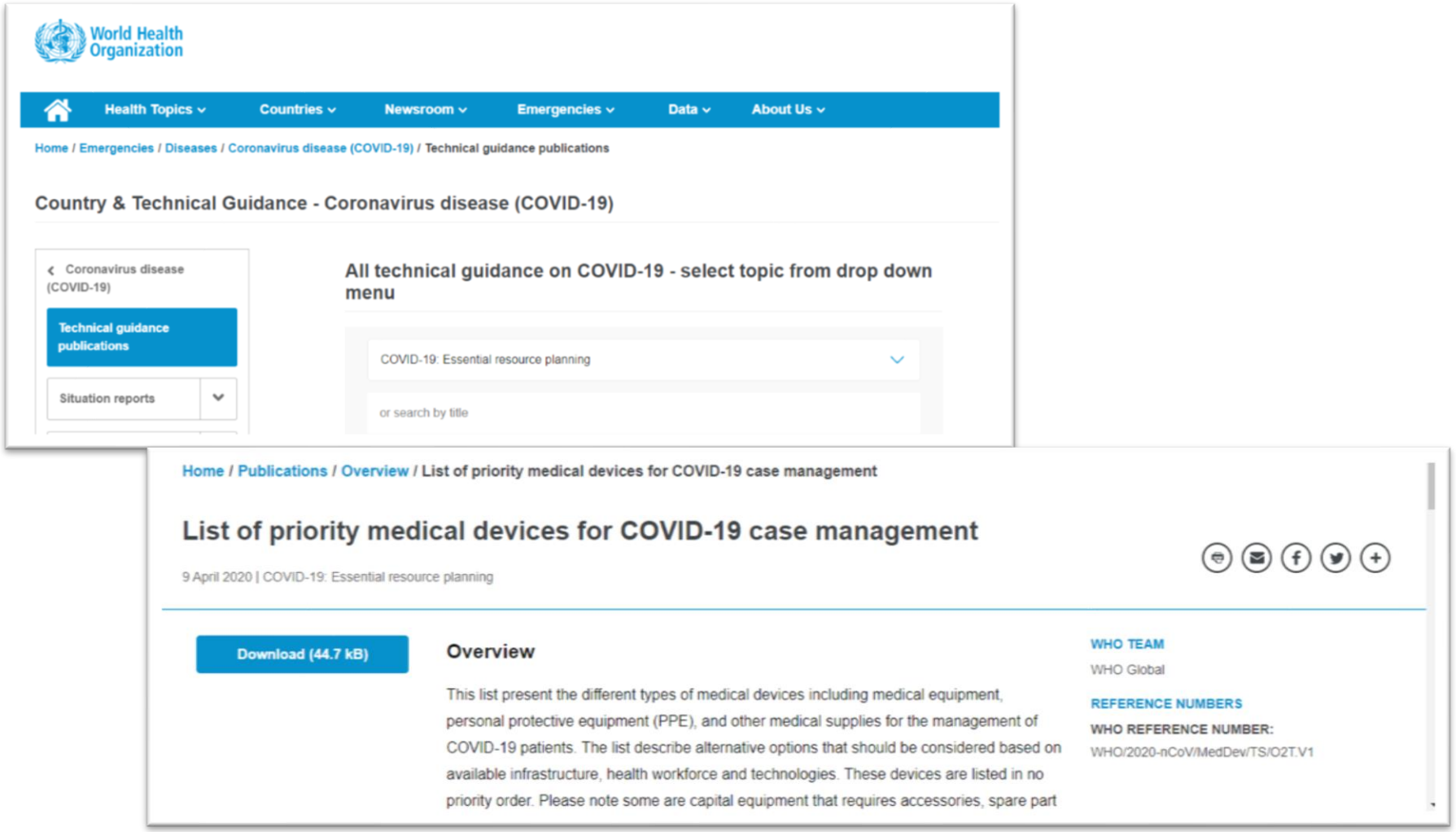
COVID CRITICAL ITEMS PUBLISHED IN COVID SITE

World Health Organization



https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/covid-19-critical-items

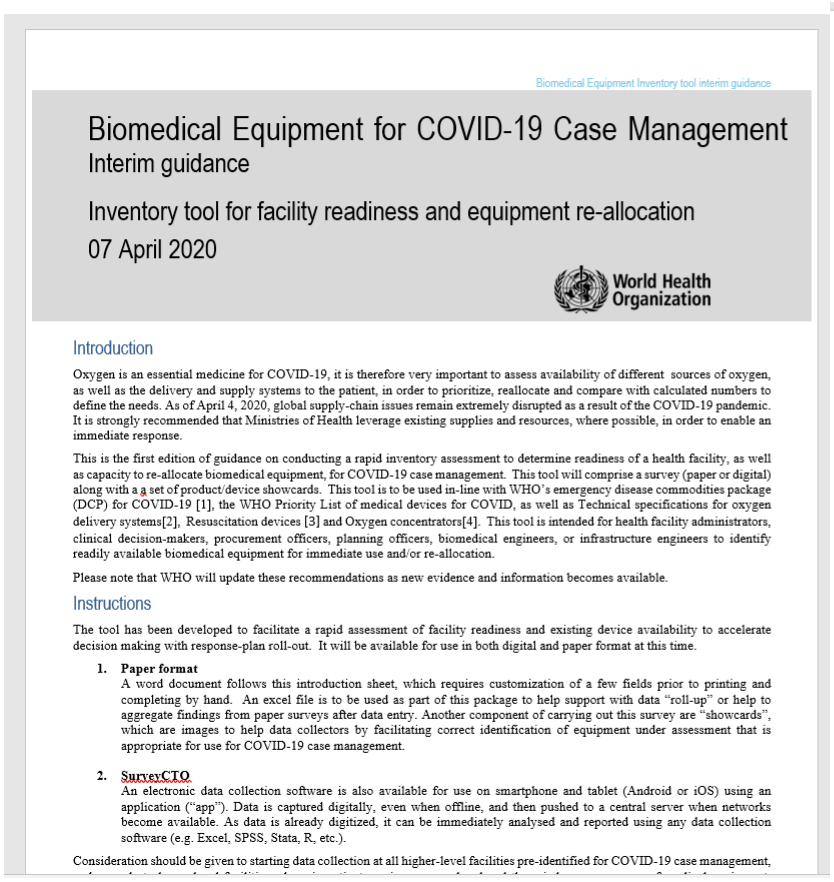
Technical guidance for decision making



https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance-publications?publicationtypes=3621862b-3c59-4efc-93f2-9c68d6a424ea

Inventory tool for COVID 19

In 6 languages.



Biomedical Equipment Inventory tool interim guidance

Biomedical Equipment for COVID-19 Case Management
Interim guidance

Inventory tool for facility readiness and equipment re-allocation
07 April 2020

World Health Organization

Introduction

Oxygen is an essential medicine for COVID-19, it is therefore very important to assess availability of different sources of oxygen, as well as the delivery and supply systems to the patient, in order to prioritize, reallocate and compare with calculated numbers to define the needs. As of April 4, 2020, global supply-chain issues remain extremely disrupted as a result of the COVID-19 pandemic. It is strongly recommended that Ministries of Health leverage existing supplies and resources, where possible, in order to enable an immediate response.

This is the first edition of guidance on conducting a rapid inventory assessment to determine readiness of a health facility, as well as capacity to re-allocate biomedical equipment, for COVID-19 case management. This tool will comprise a survey (paper or digital) along with a a set of product/device showcards. This tool is to be used in-line with WHO's emergency disease commodities package (DCP) for COVID-19 [1], the WHO Priority List of medical devices for COVID, as well as Technical specifications for oxygen delivery systems[2], Resuscitation devices [3] and Oxygen concentrators[4]. This tool is intended for health facility administrators, clinical decision-makers, procurement officers, planning officers, biomedical engineers, or infrastructure engineers to identify readily available biomedical equipment for immediate use and/or re-allocation.

Please note that WHO will update these recommendations as new evidence and information becomes available.

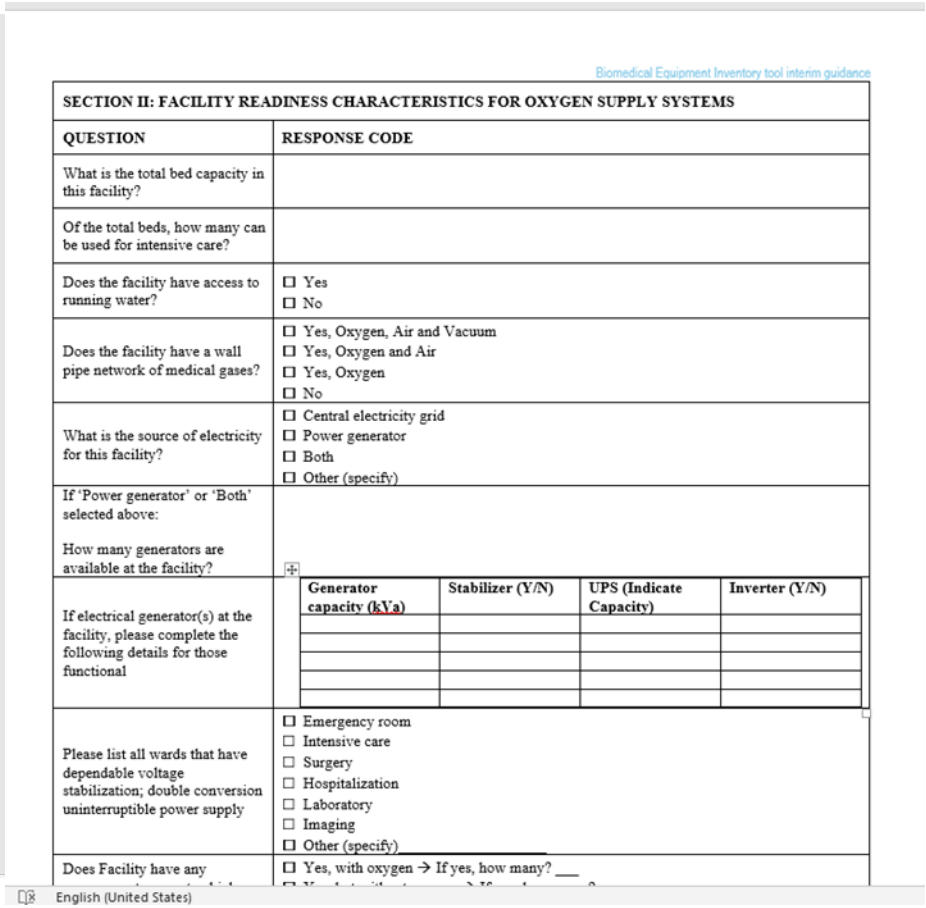
Instructions

The tool has been developed to facilitate a rapid assessment of facility readiness and existing device availability to accelerate decision making with response-plan roll-out. It will be available for use in both digital and paper format at this time.

1. **Paper format**
   A word document follows this introduction sheet, which requires customization of a few fields prior to printing and completing by hand. An excel file is to be used as part of this package to help support with data "roll-up" or help to aggregate findings from paper surveys after data entry. Another component of carrying out this survey are "showcards", which are images to help data collectors by facilitating correct identification of equipment under assessment that is appropriate for use for COVID-19 case management.

2. **SurveyCTO**
   An electronic data collection software is also available for use on smartphone and tablet (Android or iOS) using an application ("app"). Data is captured digitally, even when offline, and then pushed to a central server when networks become available. As data is already digitized, it can be immediately analysed and reported using any data collection software (e.g. Excel, SPSS, Stata, R, etc.).

Consideration should be given to starting data collection at all higher-level facilities pre-identified for COVID-19 case management,



Biomedical Equipment Inventory tool interim guidance

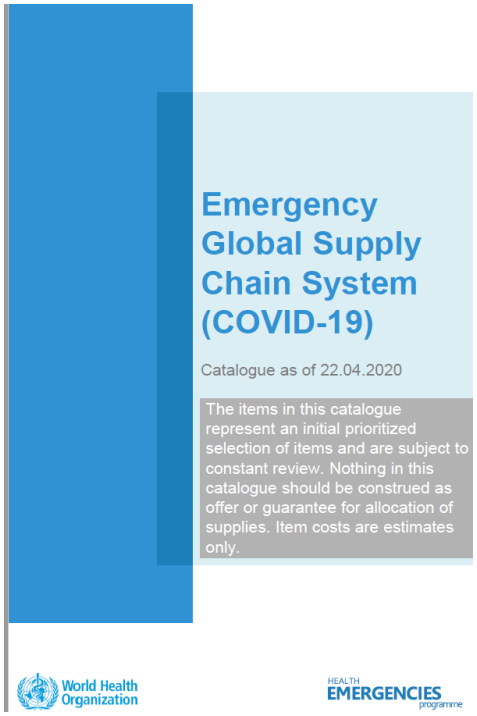
SECTION II: FACILITY READINESS CHARACTERISTICS FOR OXYGEN SUPPLY SYSTEMS	
QUESTION	**RESPONSE CODE**
What is the total bed capacity in this facility?	
Of the total beds, how many can be used for intensive care?	
Does the facility have access to running water?	☐ Yes ☐ No
Does the facility have a wall pipe network of medical gases?	☐ Yes, Oxygen, Air and Vacuum ☐ Yes, Oxygen and Air ☐ Yes, Oxygen ☐ No
What is the source of electricity for this facility?	☐ Central electricity grid ☐ Power generator ☐ Both ☐ Other (specify)
If 'Power generator' or 'Both' selected above: How many generators are available at the facility?	
If electrical generator(s) at the facility, please complete the following details for those functional	**Generator capacity (kVa)** / **Stabilizer (Y/N)** / **UPS (Indicate Capacity)** / **Inverter (Y/N)**
Please list all wards that have dependable voltage stabilization; double conversion uninterruptible power supply	☐ Emergency room ☐ Intensive care ☐ Surgery ☐ Hospitalization ☐ Laboratory ☐ Imaging ☐ Other (specify)_____
Does Facility have any	☐ Yes, with oxygen → If yes, how many? ___

English (United States)

Catalogue COVID products, include PPE, (for 120 LMI countries)

World Health Organization

On line supply portal to the catalogue



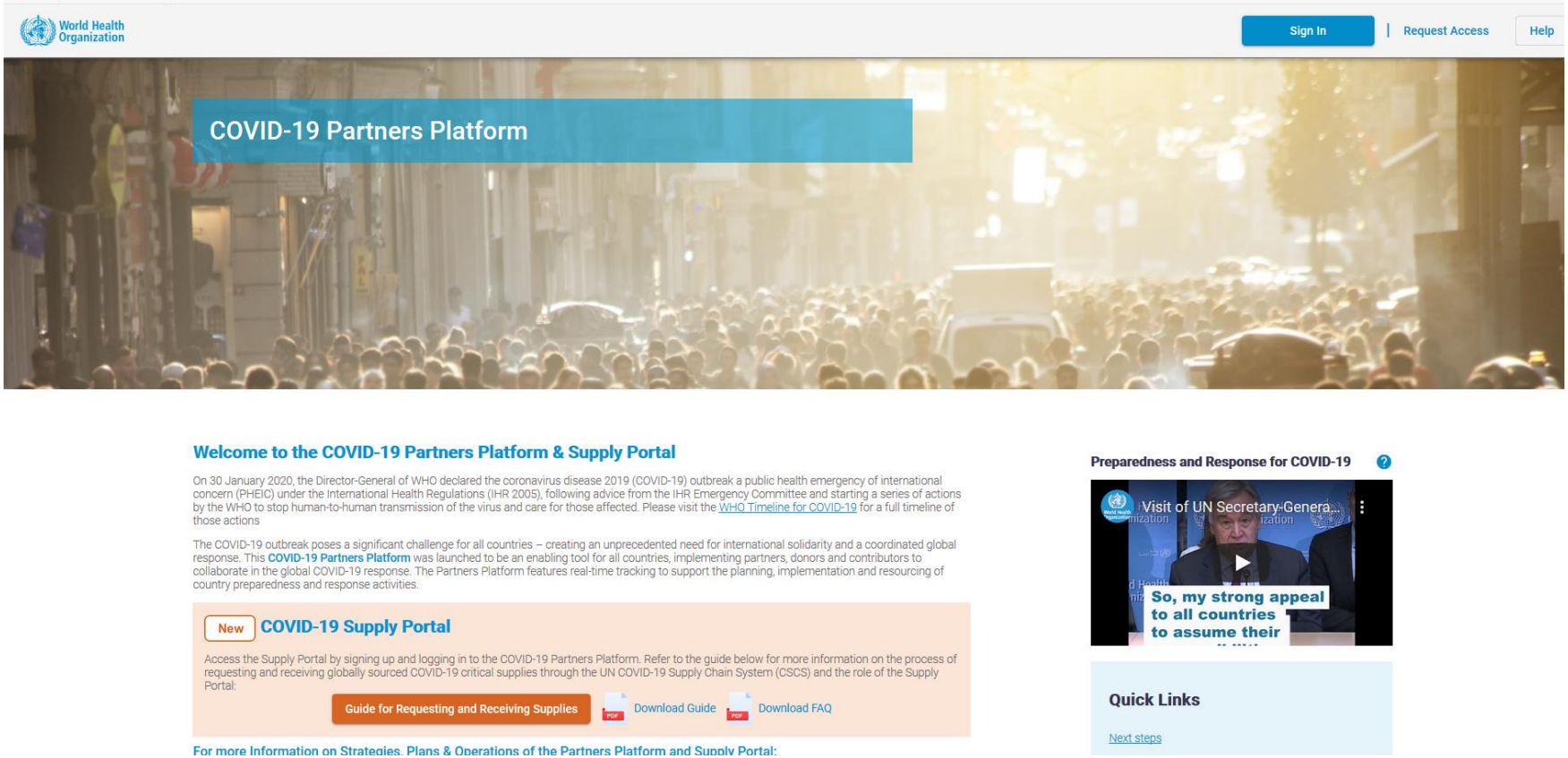
Personal protective equipment types

Emergency Global Supplies Catalogue(COVID-19)

	Medical Purpose	Sample picture (not exhaustive)	Name	Covid19 Item Code	Indicative price[1] (USD / unit)	UOM[2]
Biomed	Oxygen therapy - Mechanical Ventilation accessories		Filter, heat and moisture exchanger (HMEF), high efficiency, with connectors, for adult, single use	BIOFILT001	4.0	EA
			Filter, heat and moisture exchanger (HMEF), high efficiency, with connectors, for pediatric, single use	BIOFILT002	4.1	EA
			Compressible self-refilling ventilation bag for adult, capacity > 1500 mL, with masks (small, medium, large)	BIOBAGV001	62	EA
	Oxygen therapy - Non-Invasive Ventilation		BiPAP, with tubing and patient interfaces for adult and pediatric, with accessories	BIOBIPA001	1,800	EA
			CPAP, with tubing and patient interfaces for adult and pediatric, with accessories	BIOCPAP001	5,606	EA
			High Flow Nasal Cannula, with accessories	BIOCAHF001	0.4	EA
PPE	Healthcare providers protection		APRON PROTECTION, plastic, disposable	PPEAPRO001	0.2	EA
			GLOVES, SURGICAL, s.u., sterile, size 6.5, pair	PPEGLOS001	0.4	PAIR
			GLOVES, SURGICAL, s.u., sterile, size 7, pair	PPEGLOS002	0.4	PAIR
			GLOVES, SURGICAL, s.u., sterile, size 7.5, pair	PPEGLOS003	0.4	PAIR
			GLOVES, SURGICAL, s.u., sterile, size 8, pair	PPEGLOS004	0.4	PAIR
			GLOVES, SURGICAL, s.u., sterile, size 8.5, pair	PPEGLOS005	0.4	EA
			GLOVE EXAMINATION, nitrile, pf, size S	PPEGLOE001	0.1	EA
			GLOVE EXAMINATION, nitrile, pf, size M	PPEGLOE002	0.1	EA
			GLOVE EXAMINATION, nitrile, pf, size L	PPEGLOE003	0.1	EA
			GLOVE EXAMINATION, nitrile, pf, size XL	PPEGLOE004	0.1	EA
			GLOVE EXAMINATION, nitrile, pf, size XXL	PPEGLOE005	0.1	EA
			FACE SHIELD, clear plastic, disposable	PPEFACE001	1.0	EA

Supply portal COVID-19, includes all priority medical devices: Dx. Tx, PPE

https://covid-19-response.org/



Screening and Diagnostic steps and technical specifications w IAEA

Need an HTA special process by case

Use of chest imaging in COVID-19

A rapid advice guide

11 June 2020 | COVID-19: Clinical care

Overview

This rapid advice guide examines the evidence and makes recommendations for the use of chest imaging in acute care of adult patients with suspected, probable or confirmed COVID-19. Imaging modalities considered are radiography, computed tomography and ultrasound. This guide addresses the care pathway from presentation of the patient to a health facility to patient discharge. It considers different levels of disease severity, from asymptomatic individuals to critically ill patients. Accounting for variations in the benefits and harms of chest imaging in different situations, remarks are provided to describe the circumstances under which each recommendation would benefit patients. The guide also includes implementation considerations for different settings, provides suggestions for impact monitoring and evaluation and identifies knowledge gaps meriting further research.

Corrigendum 01 July 2020

WHO TEAM

Radiation and health

NUMBER OF PAGES

56

REFERENCE NUMBERS

WHO REFERENCE NUMBER:

WHO/2019-nCoV/Clinical/Radiology_imaging/2020.1

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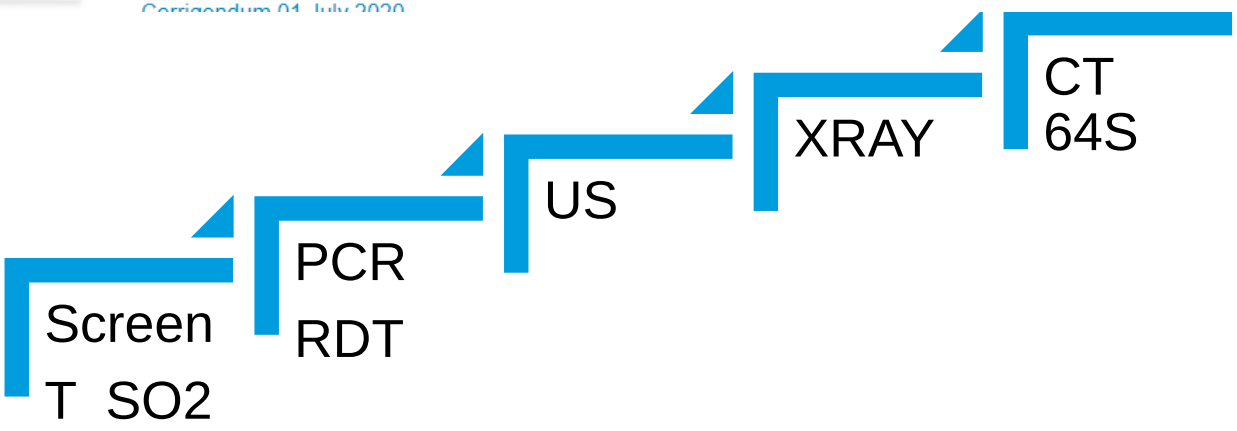
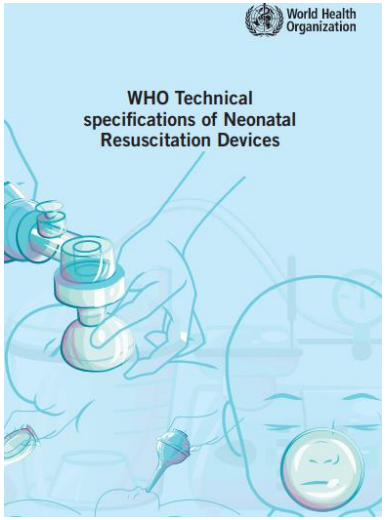
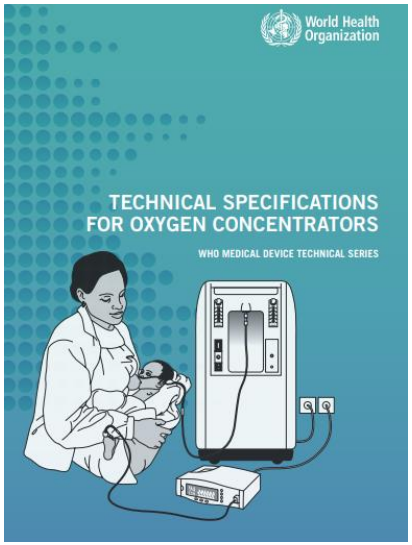


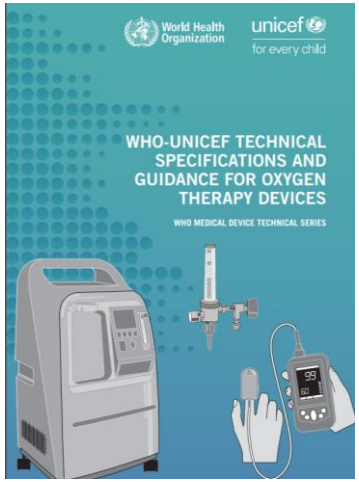
Technical specifications for procurement

World Health Organization





2019



Oxygen delivery systems
Ventilators, pulse oximeters
EKG, infusion pumps, monitors all consumables

Technical specifications for invasive and non-invasive ventilators for COVID-19

Interim guidance

15 April 2020

World Health Organization

These technical specifications describe the minimum requirements that invasive and non-invasive ventilators must comply with to ensure quality, safety and effectiveness when used for the management of COVID-19.

All these ventilators require a source of air and oxygen to operate their internal blenders. Some of the equipment includes an internal air compressor, but all these pieces of equipment require either a low-flow oxygen source (e.g. oxygen concentrator) or a high-flow oxygen source (e.g.

Definitions and intended use

1.1 Invasive ventilators

1.1.1 Patient ventilators for intensive care unit: Designed to provide temporary ventilatory and respiratory assistance to adult and paediatric patients who cannot breathe on their own or who require assistance to maintain adequate ventilation. This equipment is usually connected to a 50-psi gas supply. Some ventilators have their own air compressor but still need

WHO IAEA
Technical specification under development (Aug 2020)
US, XRAY, CT

Selecting innovative technologies for COVID-19 response.
WHO call opened in March: 174 received,
Types of technologies: oxygen delivery, ventilators, PPE, digital health, others.

World Health Organization

Innovator submits prototype or available product to international innovators call

Funding agency selected product

Or

independent innovators

submit for WHO assessment

WHO review dossier.

Expert panel and external review from LMIC

Pitch presentation to expert panel

Feedback to developer

Voting for approval

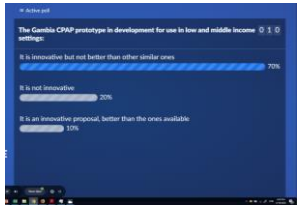
If approved:

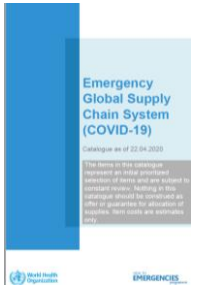
published in WHO compendium, clearinghouse

Even procurement by WHO or other partners

Grand Challenges Canada
Grands Défis Canada

IsDB
البنك الإسلامي للتنمية
Islamic Development Bank





R & D and TAP

World Health Organization

Home / Emergencies / Diseases / Coronavirus disease (COVID-19) / Global research on coronavirus disease (COVID-19) / COVID-19 technology access pool

https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov

Medical devices are indispensable to test, treat patients and protect health care workers

Agenda 30 November

time	topic	Participants
16.00	Training	Bill and Tobey
16.10	Nomenclature	Eunice
16:20	Priority medical devices, MEDEVIS	Mario, Antonio and Francesco
16:40	Prequalification	Stefano, Alison, Laurence, Riad, Mohid, Sasikala
17:00	Innovation	Gaby, Kim, Cesar, Carolyne; Jani; Tom , Yadin; Hans Peter,
17:20	Local production and tech transfer	Rainer, Einstein, Mohid, (X IVD)
17:40	Country data, facility assessments, global atlas	Valeria, Heike, Ricardo, Barun, Thierry, Joshua,
17:50	Donations	Dinsie; Humatem,
18:00	Website	Daniela and Adriana

Conclusions

1. WHO has methodologies to select essential and priority health products:

   medicines, vaccines,

   assistive and medical devices and in vitro diagnostics

   Based on evidence and expert groups.

2. The objective is that these lists serve as a reference for Member States so that can be adapted and adopted locally.

3. These lists should be used to support universal health coverage, emergencies and well being of local population.

Gracias
Thank you
Merci
Shokran
Xie xie
Spasiva

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Switzerland

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EDL website:
http://www.who.int/medical_devices/diagnostics/Selection_in-vitro_diagnostics/en/