
Briefing Seminar (TBS) on Medicines and Health Products
WHO Headquarters, Geneva, Switzerland
08 – 12 May 2023

Prioritizing Medical Devices: Update on the global situation and sourcing for information

Adriana Velazquez Berumen
Team Lead Medical Devices



Medical devices are indispensable to provide health for all

Core message:

COVID has given us a lesson: Medical devices are indispensable to test, treat patients and protect health care workers.

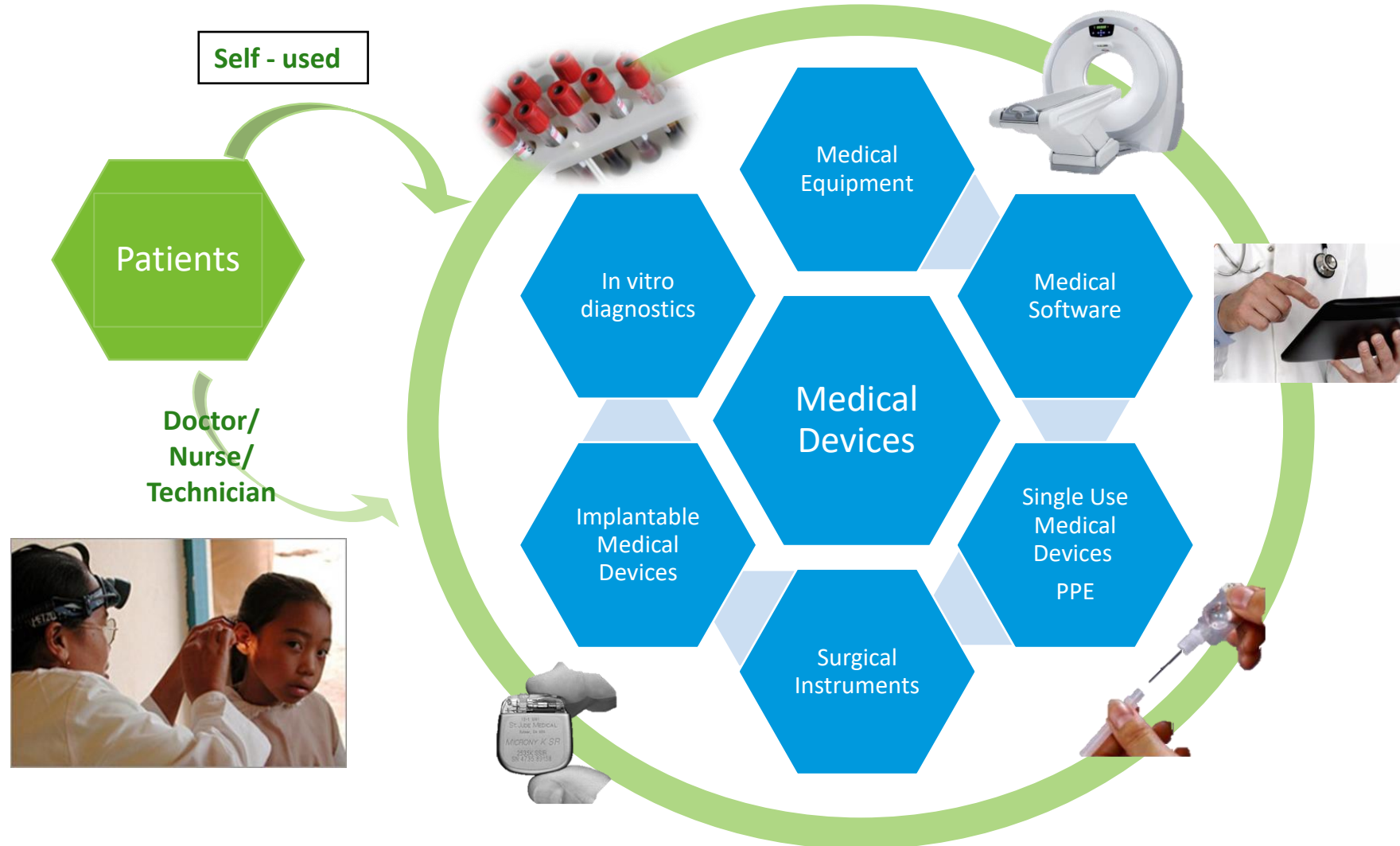
Biomedical Engineers are professionals responsible of them.



ICU equipment, In vitro diagnostics and personal protective equipment



Medical Devices include more than 10,000 types
in vitro and non in vitro:



WHO TRIPLE BILLION

The Triple Billion targets



Universal health coverage

One billion more people benefitting from universal health coverage, tracked via 15 indicators.



Health emergencies

One billion more people better protected from health emergencies, tracked via six indicators.



Healthier populations

One billion more people enjoying better health and well-being, tracked via 14 SDG indicators.



World Health
Organization

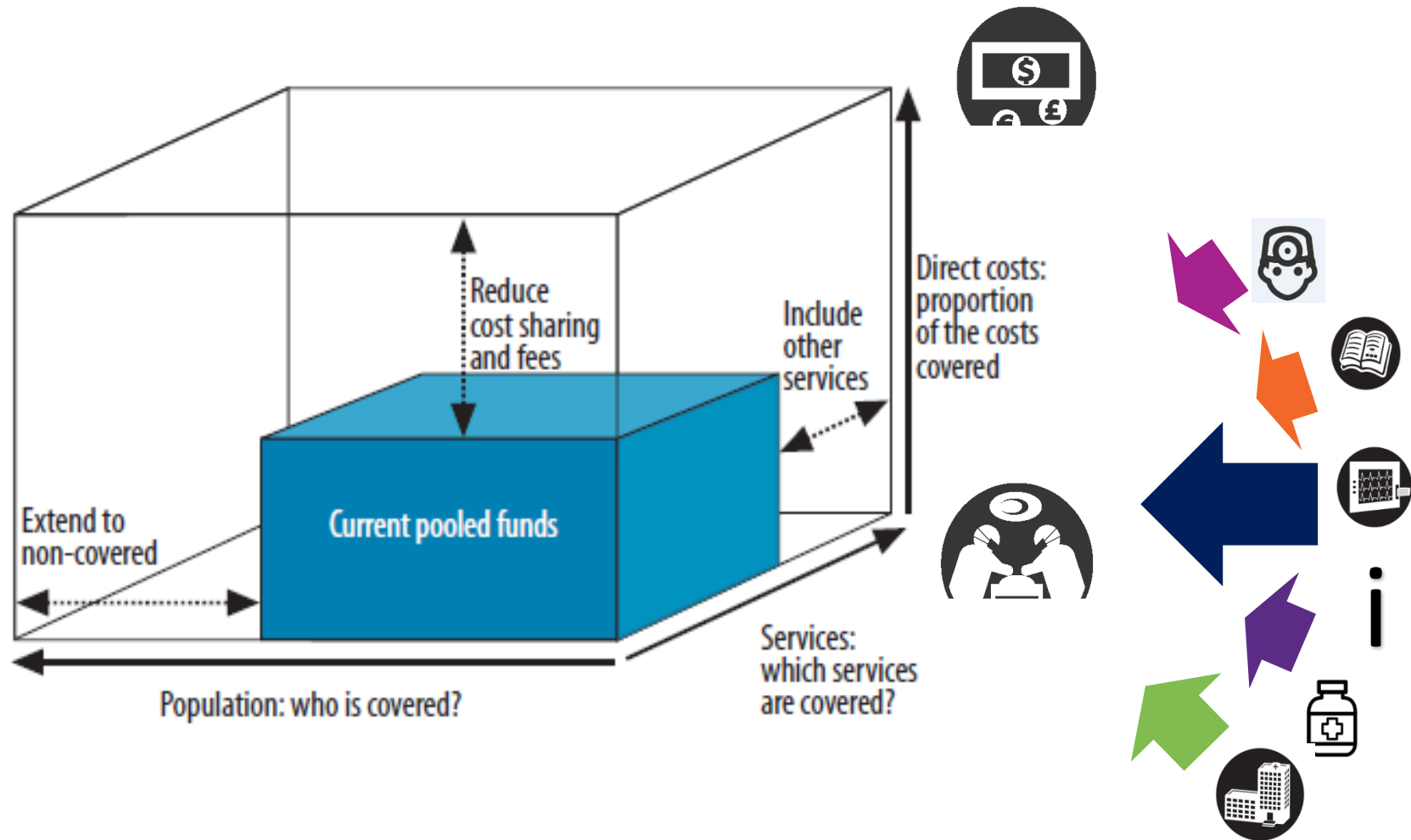
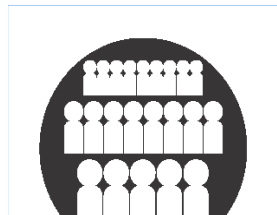
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HEALTH
FOR ALL

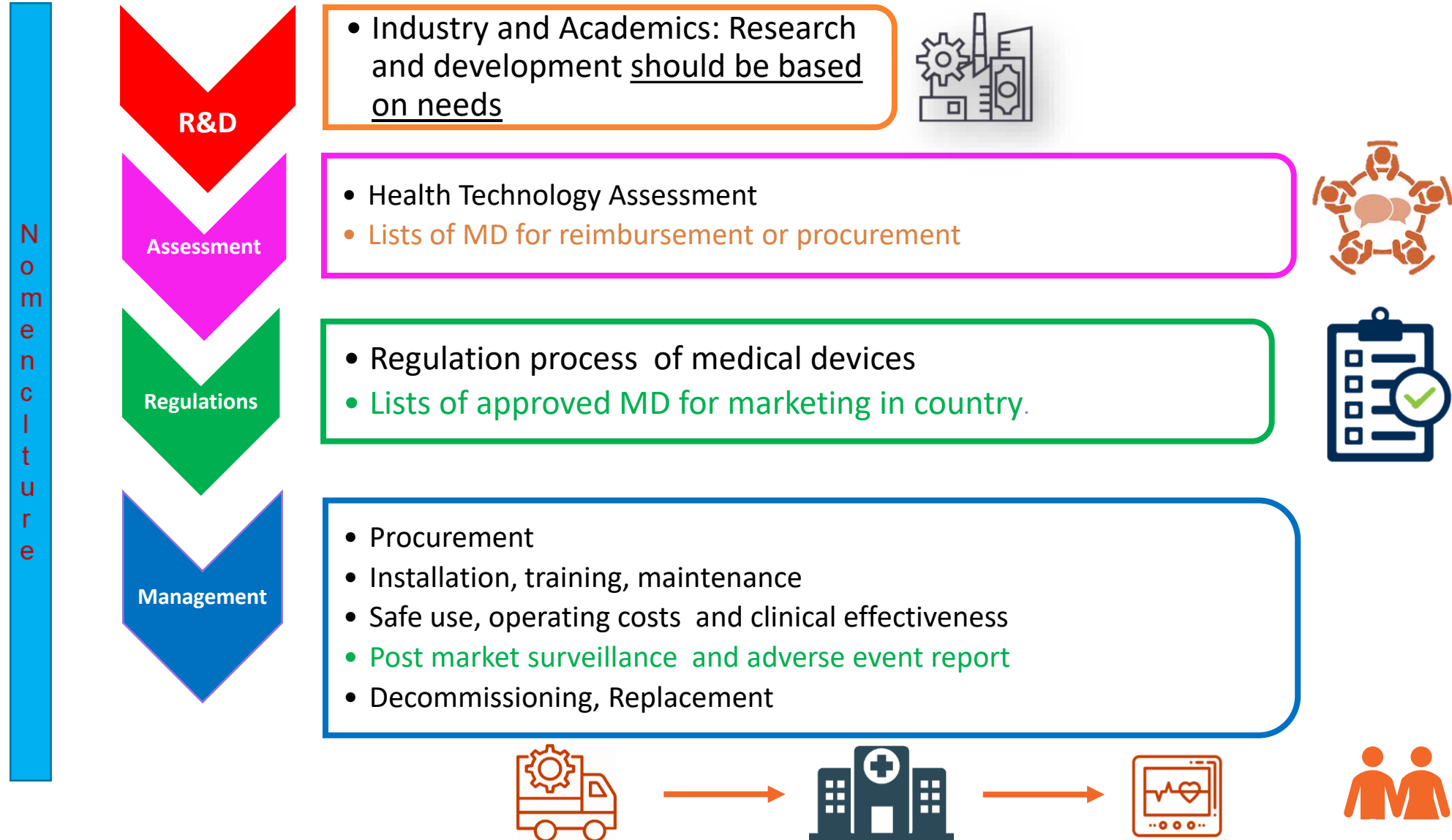
Our work includes selecting, assessing, managing medical devices that will support local, regional and global health to support patients everywhere.



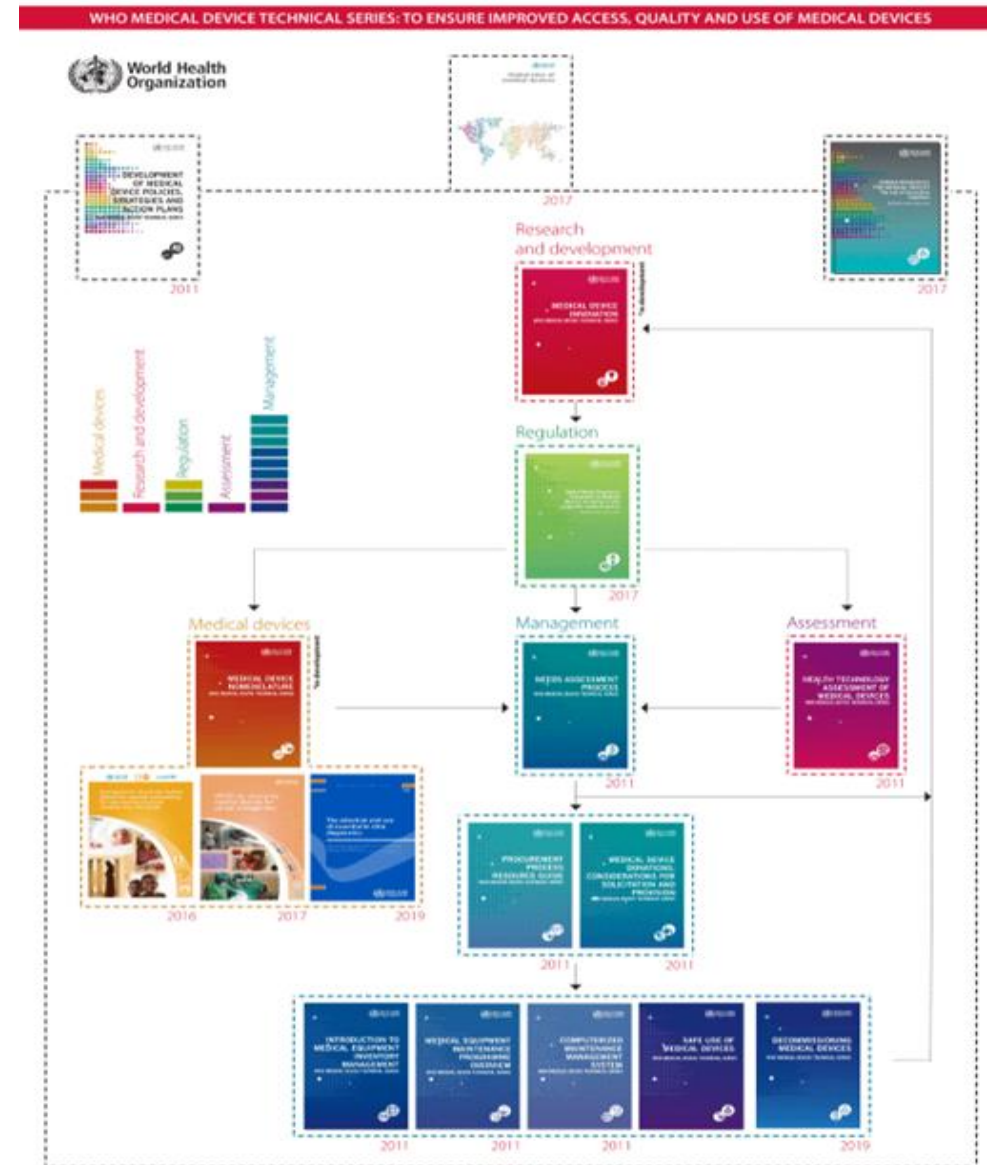
SDG3: Achieve universal health coverage, including financial risk protection, access to quality essential health-care services



To ensure improved access of safe, quality medical devices



WHO Medical Device Technical Series to ensure improved access, quality and use of medical devices



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



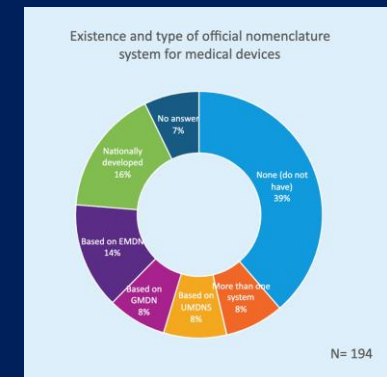
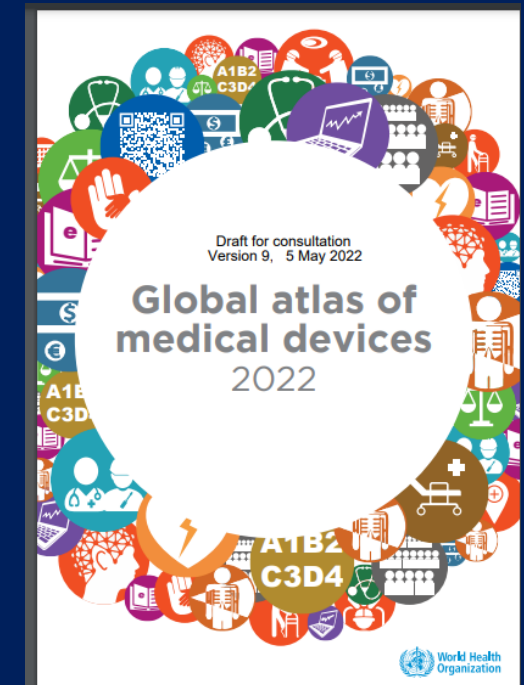
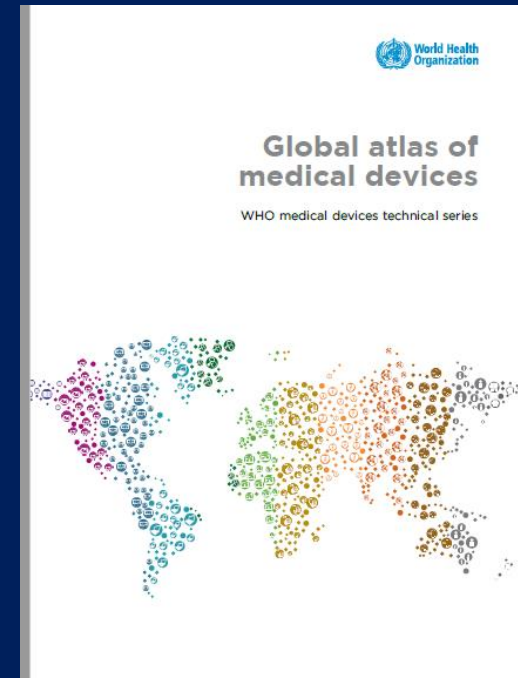
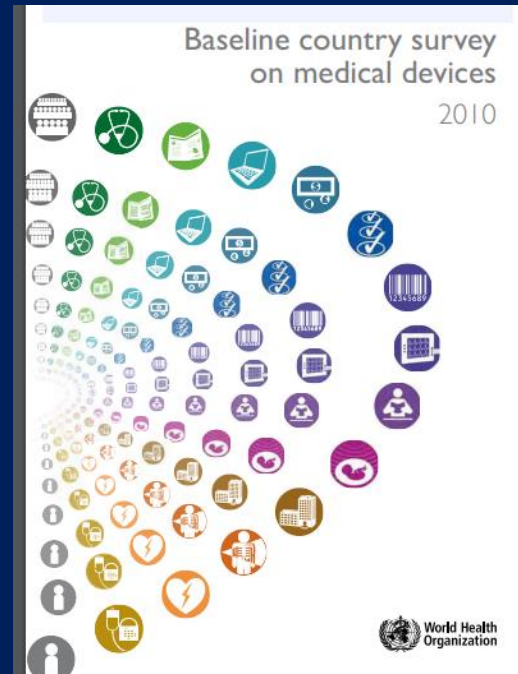
World Health
Organization



HEALTH
FOR ALL

Global Atlas of Medical devices

Country profiles and data in Global Health Observatory



Nigeria

Country indicators - WHO country information

Population (000s) (rank)*	206,140 (7)	Under-five mortality (per 1000 live births)*	113.77	UHC - Service coverage index (1-100)*	44
World Bank income group*	Lower-Middle	Probability of dying aged 30-70 yrs from the 4 major NCDs (%)**	16.90%	UHC - Population with household spending >10% (>25%) of corresponding income (%)†	15.1% (4.1%)
Life expectancy at birth (years)*	54.3	Human Development Index (inequality adjusted HDI): rank‡	0.54 (0.35): low	Global Innovation Index (rank)‡	201 (117)
		ICT Development Index (rank)*	2.6 (143)	High-technology exports (% of manufacture exports)*	1.50%

National policy on health technology

Health technology (medical device) national policy: No
 Policy is part of the National Health Program/Plan: No
 Website: —
 Language(s): —
 Ministry of health responsible for health technology policy implementation: Food and Drug Services.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - laboratories: —

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):* Yes

HTA unit/department includes the assessment of medical devices: Yes

Unit/department: Nigeria Institute for Pharmaceutical Research and Development (NIPRD).

Website(s): <http://www.niprd.gov.ng/>

<https://www.niprd.gov.ng/>

<https://healthtechnologyassessment.gov.ng/2019/02/01/final.pdf>

Contact: — Email: information@niprd.gov.ng

Committee includes a biomedical or clinical engineer: —

Approved devices lists comments (Annex 1): —

Health care facilities lists comments (Annex 1): —

Specific lists comments (Annex 1): —

HTA unit comments (Annex 1):

Three organisms perform HTA at a national level: The Agency for Food and Drug Administration and Control (NAFDAC), Nigeria Institute for Pharmaceutical Research and Development (NIPRD) and the National Health Insurance Scheme (NHIS). The action plan 2018-2021 of the NHIS states the progress to a National Quality Review & Health Technology Assessment System to determine which health interventions are cost effective including medical devices (see fourth link). HTA is a pillar for UHC's goal.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: National Agency for Food and Drug Administration and Control.

Website(s): <http://www.nafdac.gov.ng/>

Contact: Dr. Chinyere Ilonze Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc: National Agency for Food and Drug Administration and Control (NAFDAC).

Other agency's website: <http://www.nafdac.gov.ng/radiation/medical-devices>

National regulatory comments (Annex 1): —



Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: Not specified

Website: —

Nomenclature comments (Annex 1): —



Medical device incorporation

Procurement

Policy or guideline: No Website: —

National level procurement: No Website: —

Donations

Policy or guideline: No Website: —

Technical specifications

Technical specifications to support procurement or donations: No

Publicly available: —

Website: —

Medical device incorporation comments (Annex 1): —



Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging*	n/a	n/a
Computerized Tomography Scanner*	n/a	n/a
Positron Emission Tomography Scanner*	n/a	n/a
Gamma camera or nuclear medicine*	n/a	n/a
Mammography**	n/a	n/a
Radiotherapy*	9	0.04

* Density per 1,000,000 females aged from 50-69 yrs.



Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes

Unit/Department: Medical Devices Management and Standardization Unit. Unit website: —

Contact name: Mr. Ekan Bukola Emmanuel Contact email: bukolaemmanuel2000@yahoo.com

Website with publicly available technical specifications: —

Number of regional/state offices/units: —



Inventories and medical equipment management software

Type of inventories available: None

Website: —

Use of management software: No Software name: —

Software comments (Annex 1): —



Medical devices workforce

Number of biomedical/clinical engineers professionals in the country: 280



Contacts

National officer(s):

Name: Mr. Ekan Bukola Emmanuel

Email: bukolaemmanuel2000@yahoo.com

Name: —

Email: —

WHO Country officer(s):

Name: Dr. Walter Kazadi Mulombo

Email: wkazadi.mulombo@who.int

Name: —

Email: —



General comments (Annex 1): —

a. UNWFP 2019, POP (data year: 2020)

b. WB FY23 (data year: 2021)

c. UNWFP 2019, HORT (data year: 1990-2020)

d. UNWFP 2022, 1.1 (data year: 2020)

e. WHO QHQS, SDG 3.6 (data year: 2019)

f. UNDP/HRD 2019/2020, HCI and HCI (data year: 2019)

g. ITU ICT 2017 (data year: 2017)

h. WHO QHQS, SDG 3.6 (data year: 2019)

i. WHO QHQS, SDG 3.6, 10K or 25K (data year: latest 2010-18)

j. WHO QHQS, SDG 3.6 (data year: 2020)

k. UNWFP HSE (data year: latest 2017-19)

l. WHO HTA/HP 2021 survey, HTA 2015, CSoHDI (data year: latest 2015 or 2021)

m. WHO QHQS, HSE, CSoHDI, HSE, CSoHDI (data year: latest 2015-21)

n. WHO QHQS, HTA, HTA, HTA, CSoHDI (data year: latest 2015-21)

o. WHO QHQS, HTA, HTA, HTA, CSoHDI (data year: latest 2015-21)

p. WHO QHQS, HTA, HTA, HTA, CSoHDI (data year: latest 2015-21)

q. WHO QHQS, HTA, HTA, HTA, CSoHDI (data year: latest 2015-21)

r. not applicable/not available

Nomenclature for medical devices

WHO is using EMDN to refer to all priority medical devices because it is open access and anyone anywhere can use it, later if agreements, will refer to others

Global atlas of medical devices 2022

In addition, 105 member states use, at least, one nomenclature system with the following types: 18% a Nationally developed nomenclature system, 9% use the Universal Medical Device Nomenclature System (UMDNS), 8% use the Global Medical Device Nomenclature (GMDN), 5% use more than one system and 15% uses the European Medical Device Nomenclature (EMDN) (see Fig. 2).

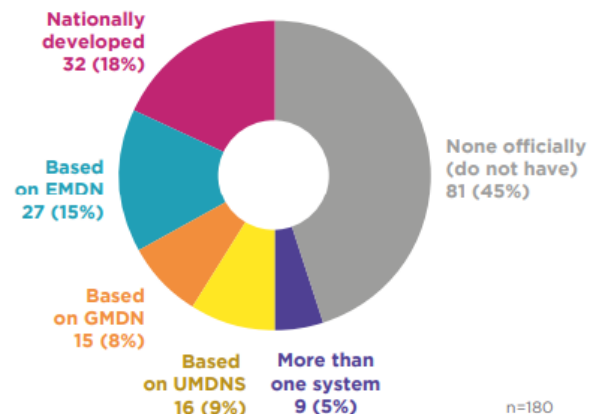


Figure 2. Type of an official nomenclature system for medical devices (data from the 2020 Country survey and the 2021-2022 Nomenclature consultations)

European Medical Device Nomenclature (EMDN)

This webpage displays the most up to date (version 1.1) of the European Medical Device Nomenclature (EMDN). To download the most up to date version, please click on the link below 'download full list'.

This platform is also a submission platform for any linguistic, syntax, translation feedback users and the wider healthcare community may wish to provide.

Please note that in this updated version of the EMDN, some linguistic and syntax corrections have already been implemented. In addition, new terms and descriptions for medical device software (under Categories J, W and Z) have been rolled out.

1. What is the European Medical Device Nomenclature (EMDN)?

Per Article 26 of Regulation (EU) 2017/745 on medical devices (MDR) and Article 23 of Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR), the European Medical Device Nomenclature (EMDN) aims at supporting the functioning of the European database on medical devices (EUDAMED). Among its various uses, it will be utilised by manufacturers for the registration of medical devices in EUDAMED, where it will be associated to each Unique Device Identifier – Device Identifier (UDI-DI).

As the EMDN primarily serves regulatory purposes to support MDR and IVDR requirements, it also plays a key role in MDR/IVDR device documentation and technical documentation, sampling of technical documentation conducted by notified bodies, post-market surveillance, vigilance and post-market data analysis, etc. It is intended to support all actors in their activities under the MDR/IVDR and provides key device descriptions to patients as regards their own devices and all other devices available on the market and registered in EUDAMED.

[Read more](#)

[Download EMDN \(download full list\)](#)

Propose a new translation for an EMDN term description

Select the EMDN term description

Search

- (A) - DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION
- (B) - HAEMATOLOGY AND HAEMOTRANSFUSION DEVICES
- (C) - CARDIOVASCULAR SYSTEM DEVICES
- (D) - DISINFECTANTS, ANTISEPTICS, STERILISING AGENTS AND DETERGENTS FOR MEDICAL DEVICES
- (E) - DIALYSIS DEVICES
- (F) - GASTROINTESTINAL DEVICES
- (G) - SUTURE DEVICES
- (H) - ACTIVE-IMPLANTABLE DEVICES
- (I) - CARDIAC FUNCTIONALITY IMPLANTABLE DEVICES
- (J) - IMPLANTABLE PACEMAKERS

Code

J0101

Official term

PACE MAKER IMPIANTABILI

Draft term

IMPLANTABLE PACEMAKERS

Draft term

IMPLANTABLE PACEMAKERS

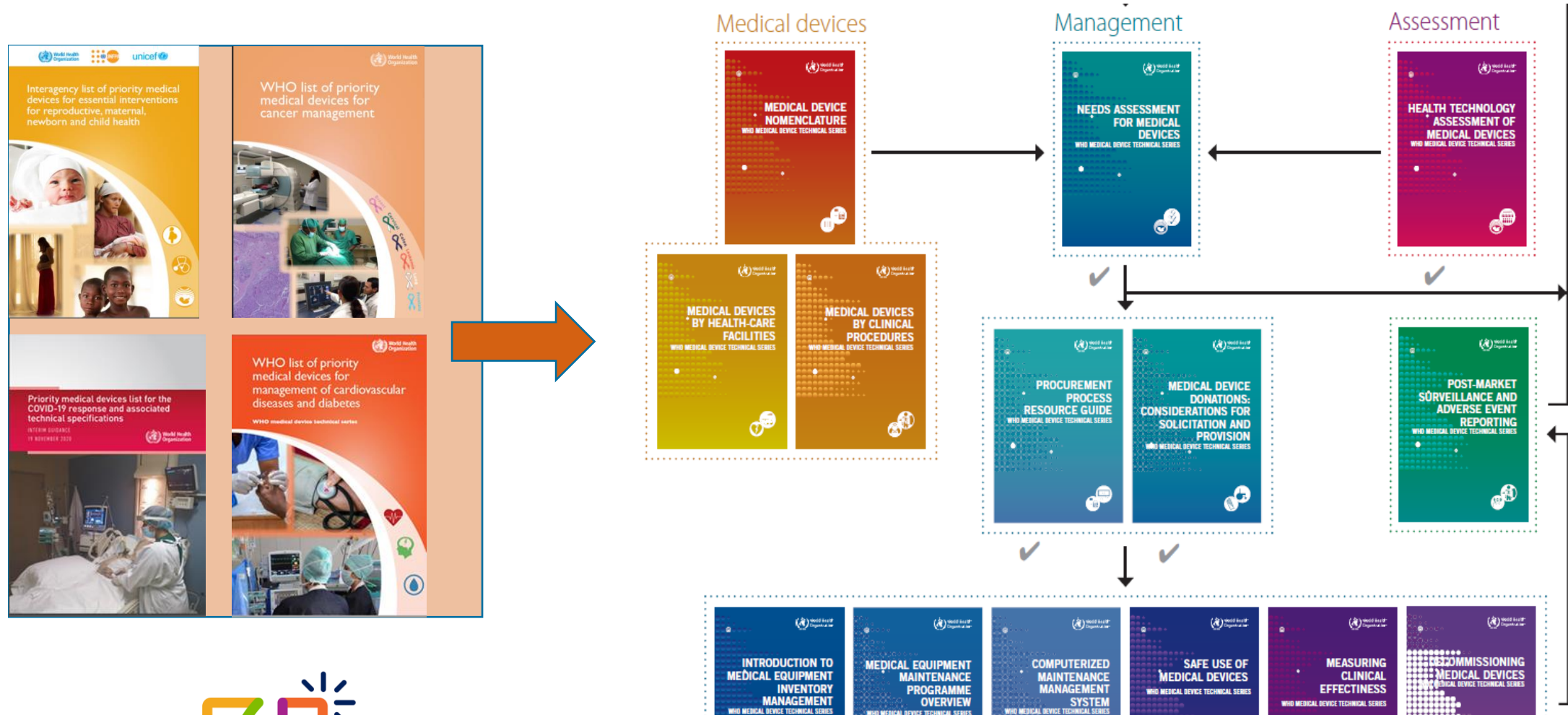
English

New proposal for English term description

What is your profession? Kindly tick your profession and all that apply

- ☐ EU institution employee
- ☐ National competent authority
- ☐ Medical device regulator
- ☐ Medicinal products regulator

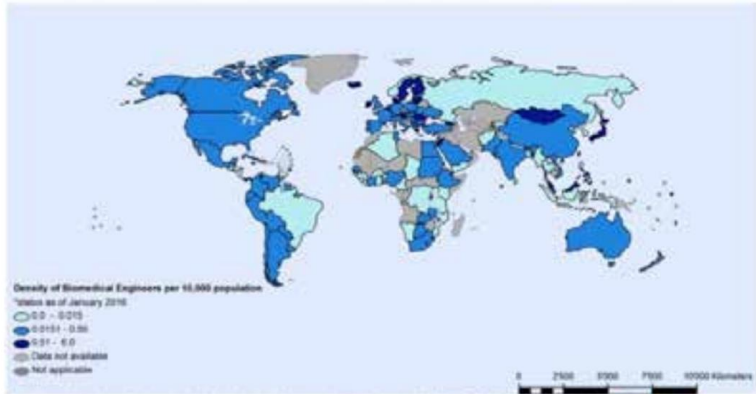
Health technology Assessment, Health technology management and lists of priority medical devices



Availability of biomedical engineers is increasing globally. They need to participate in decision making related to medical technologies

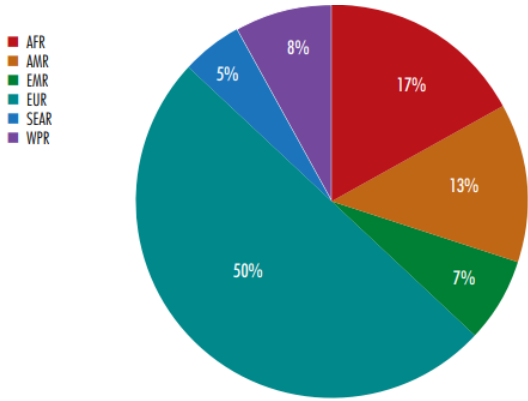


Figure 1.1 Density of biomedical engineers per 10 000 population globally (as at January 2016)



Source: Data was collected from three different sources: government offices and ministries of health (through surveys launched by WHO between 2010–2015); IFMBE; and universities offering BME programmes.

Countries with at least one BME professional association by WHO region



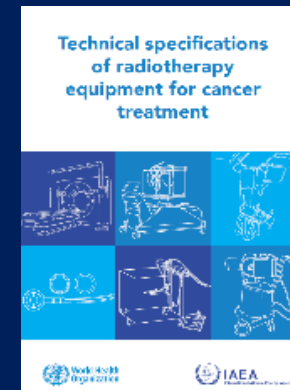
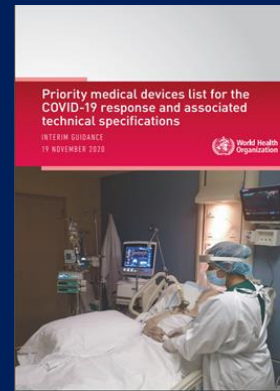
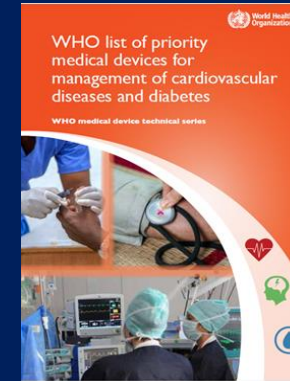
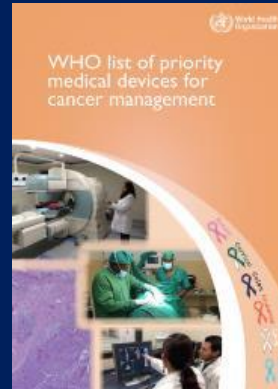
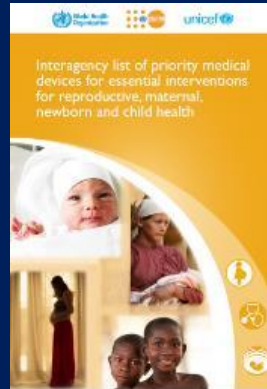
Source: Data was reported in surveys launched by WHO from 2009–2015.

Selecting priority medical devices for national lists

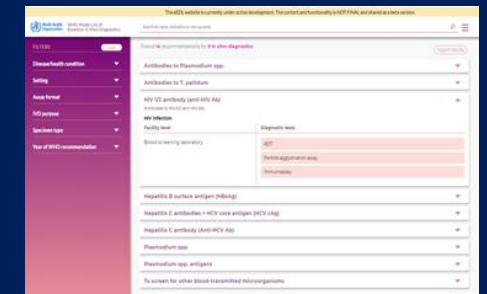
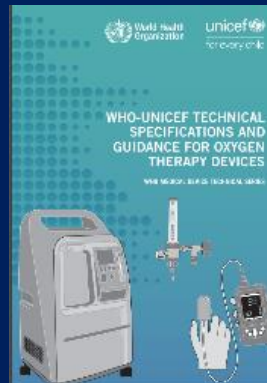
Priority medical devices

Essential in vitro diagnostics

List of essential/
priority



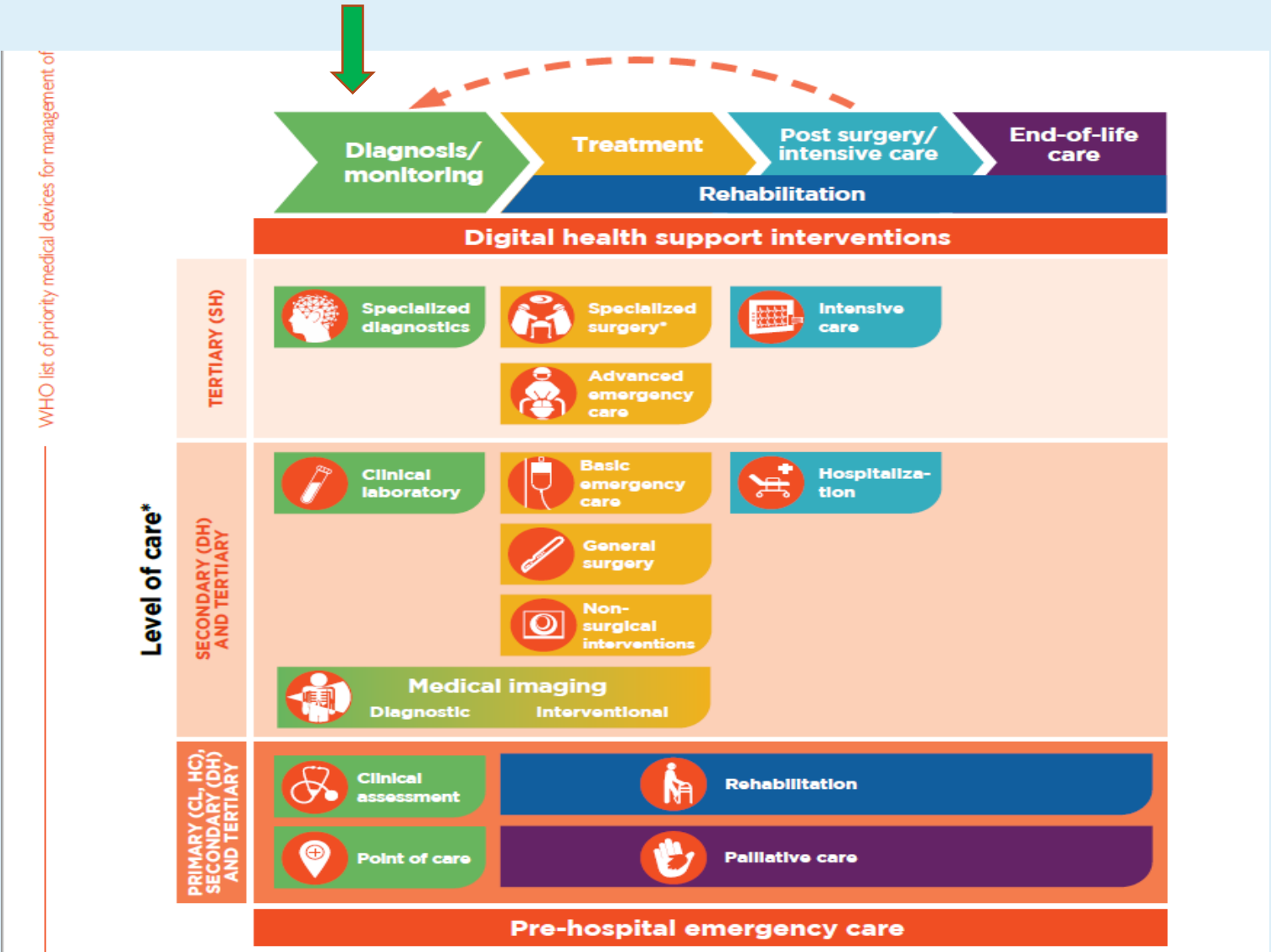
Technical specifications



Priority Medical Devices can be used for:

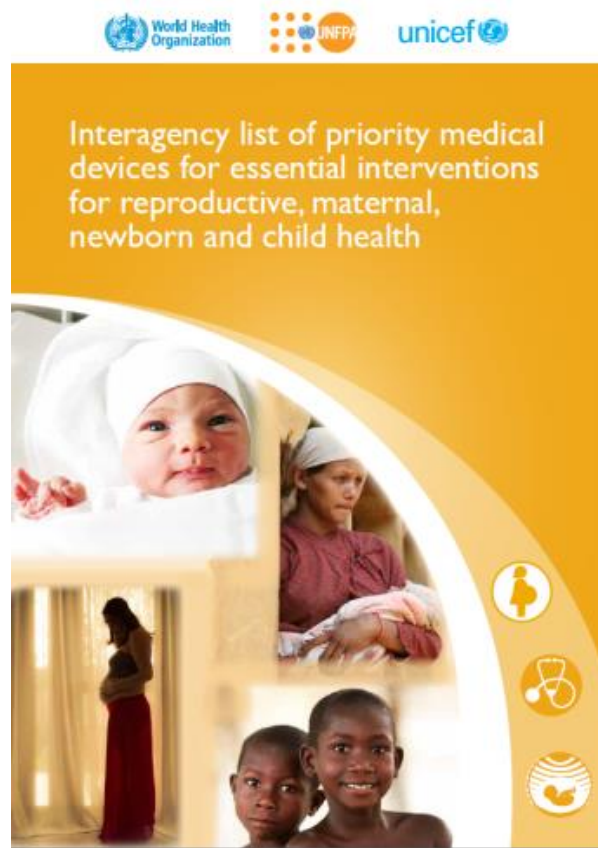
Prevention,
Diagnosis,
Treatment,
Rehabilitation,
Palliation.

Should be available at
different levels of care.

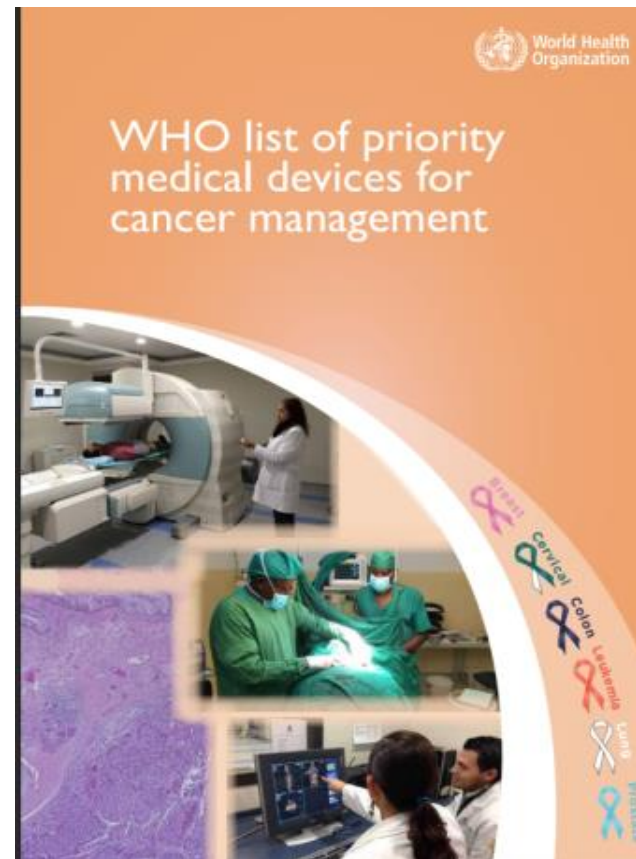


WHO Lists of Priority medical devices by interventions and levels of care

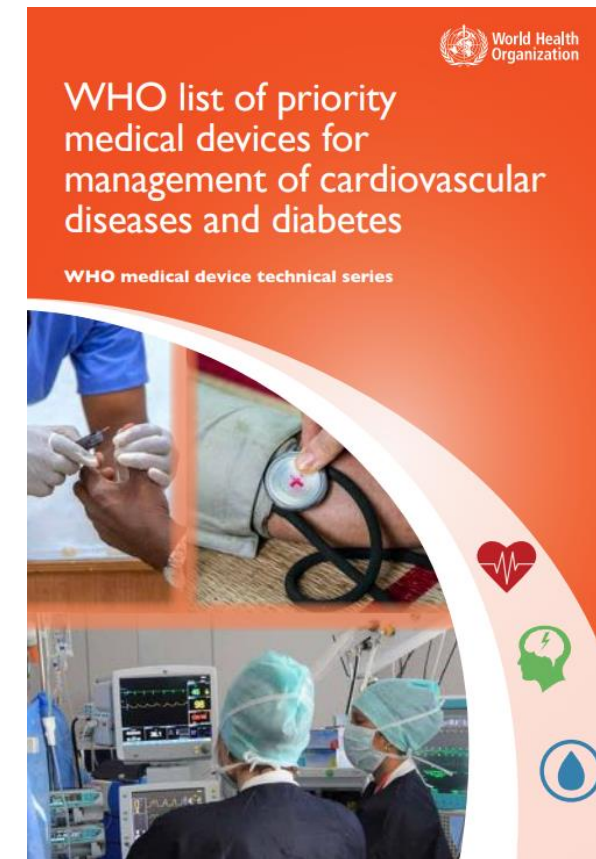
2015



2017



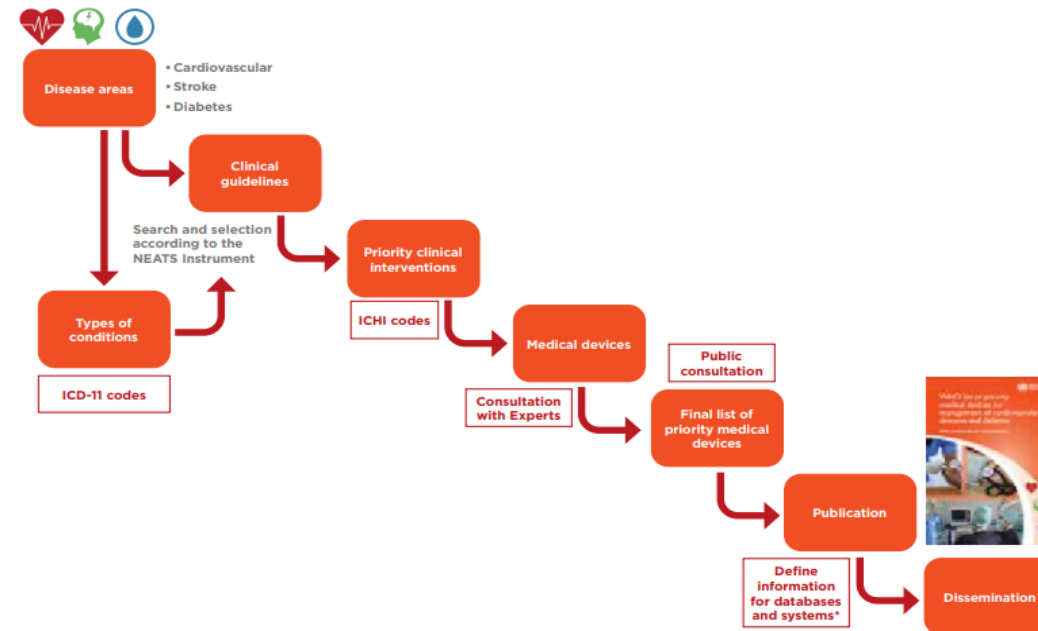
2021



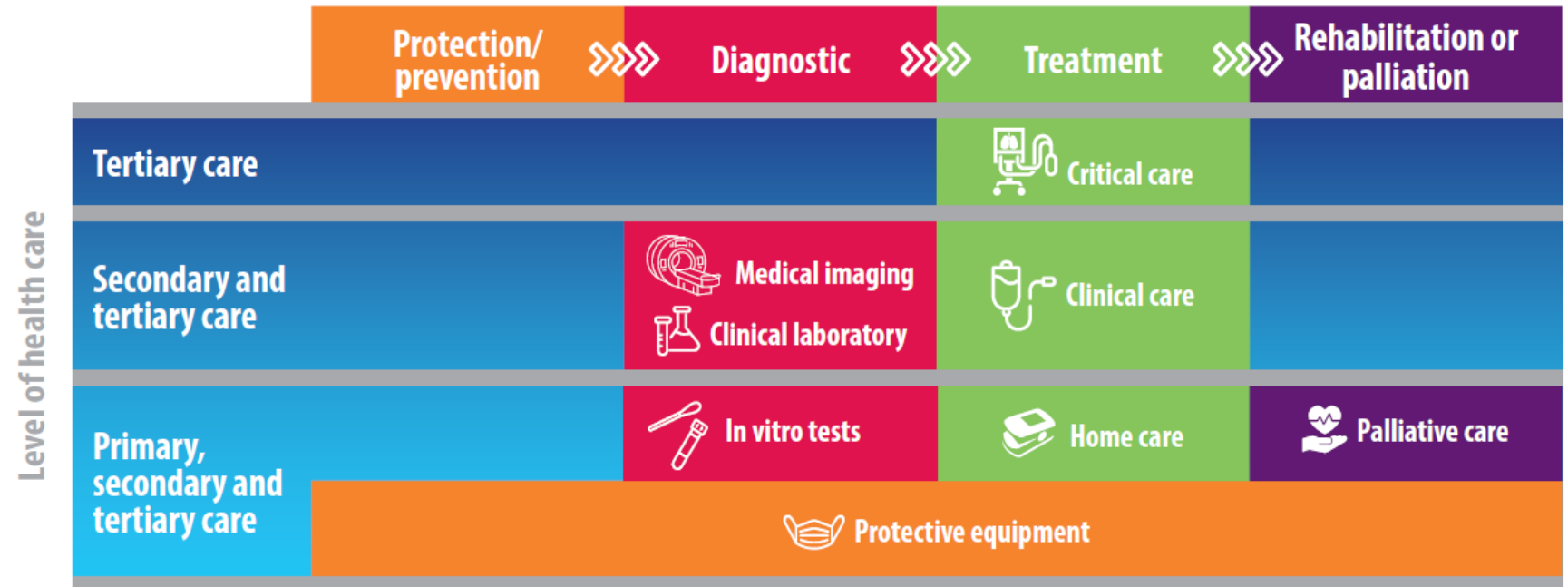
II. Methodology

The methodology used to select the priority medical devices for cardiovascular diseases and diabetes was based on the methodology defined by WHO to select the previously published lists of priority medical devices (30, 31). The process involves a review of clinical guidelines to define interventions and identification of medical devices required to perform each intervention by level of care. However, there were very few WHO guidelines available for the management of cardiovascular diseases and diabetes; the methodology therefore had to be modified accordingly. The following overview presents the milestones and the adaptation of the methodology throughout the process that led to the present publication.

Figure 12. Methodology: from disease identification to dissemination of information



Medical devices used along the care pathway



Interventions by clinical area

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			●			●
	Gastroenteral feeding			●			●
	Urine collection		●	●		●	●
Protective equipment	General	●	●	●	●	●	●
	Personal protection	●	●	●	●	●	●
	Sterilization	●	●	●	●	●	●

Clinical care (continued)

Intervention	Medical device generic name		Accessories/consumables/single-use devices
Airway management and intubation	Laryngoscope	Fibre optic, diameter 28 mm, with blades	Compressible self-refilling ventilation bag for adult, capacity > 1500 mL, with masks (small, medium, large)
		or	Airway, nasopharyngeal, sterile, single use, set with sizes of: 20 Fr, 22 Fr, 24 Fr, 26 Fr, 28 Fr, 30 Fr, 32 Fr, 34 Fr, 36 Fr
		Video-laryngoscope, with blades and accessories	Airway, oropharyngeal, Guedel, set with sizes of: No. 2 (70 mm), No. 3 (80 mm), No. 4 (90 mm), No. 5 (100 mm)
			Colourimetric end tidal CO ₂ detector, adult and paediatric, single use
			Cricothyrotomy, set, emergency, 6 mm, sterile, single use
Non-invasive ventilation			Syringe, Luer slip, 10 mL, sterile, single use
			Endotracheal tube introducer
			Stylet, sterile, single use, sizes: 10 Fr, 30 to 45 cm and 14 Fr, 30 to 45 cm
			Bougie, sterile, single use, sizes: 10 Fr, 60 cm and 15 Fr, 70 cm
			Tube, endotracheal
Invasive ventilation			No. 2, No. 2.5, No. 3, No. 3.5, No. 4, No. 5, without cuff, sterile, single use
			No. 4, No. 5, No. 6, No. 7, No. 8, No. 9, with cuff, sterile, single use
			Laryngeal mask airway (LMA), size 2, size 3, size 4, sterile, single use
			Lubricating jelly
			Forceps Magill, 24 cm
Infusion therapy			Continuous positive airway pressure (CPAP), for adult and paediatric, with accessories
			Bilevel positive airway pressure unit (BiPAP), for adult and paediatric, with accessories
			High-flow nasal cannula, with accessories
Intensive care treatment			Ventilator for intensive care unit, for adult and paediatric with accessories
			Ventilator for transport, for adult and paediatric with accessories
			Ventilator for sub-acute care, for adult and paediatric with accessories
Central venous catheter placement			Electronic drop counter, IV fluids
			Infusion pump, with accessories
			Electrocardiograph, portable, with accessories
			Suction pump
			Electrical, with accessories
			Manual
			Central venous catheters kit with: finder needle, syringe, wire dilator lidocaine, scalpel, needle

WHO Essential in vitro diagnostic list: 2018, 2019, 2021

Basic test characteristics

Test purpose

Test format

Specimen types

Equipment required

Regulatory status

Global availability

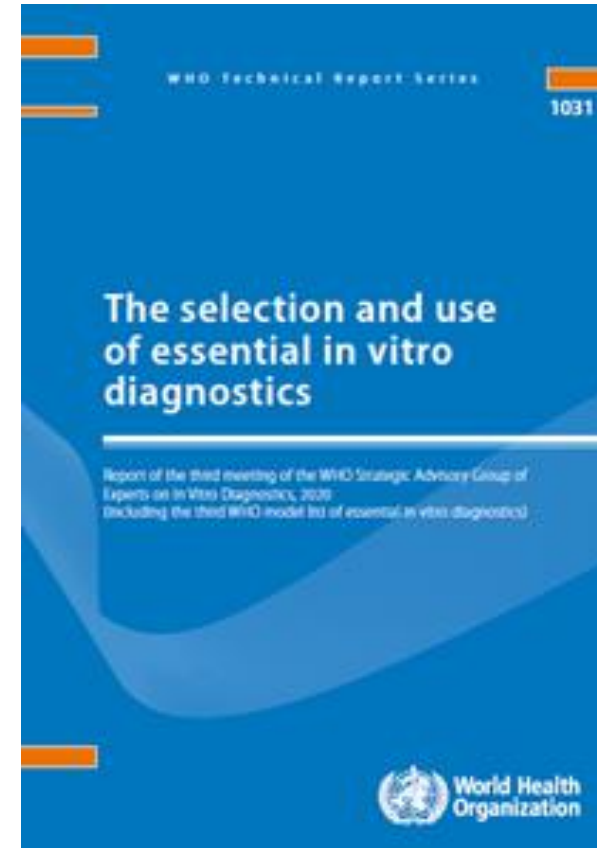
Price per test range

Instrument price range

Ethics, equity and human rights issues

Evidence for clinical usefulness and impact

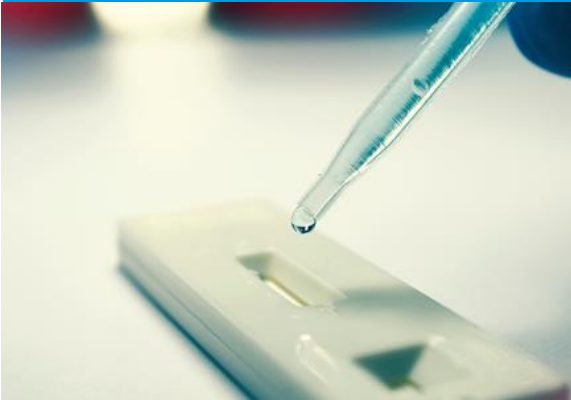
Evidence for economic impact and/or cost-effectiveness



Presentation of the EDL 3

The WHO EDL is presented by health-care facility level in **two tiers** and a Do Not Do recommendations section

Community settings and health facilities without laboratories



- I.a General tests (arranged by discipline)
- I.b Disease-specific tests (arranged by disease)

Health care facilities with clinical laboratories



- II.a General tests (arranged by discipline)
- II.b Disease-specific tests (arranged by disease)
- II.c Bloods screening tests

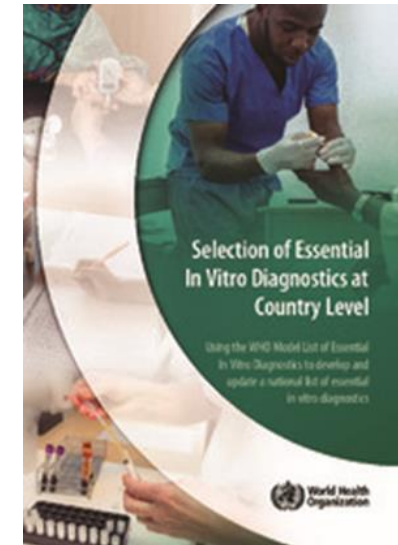
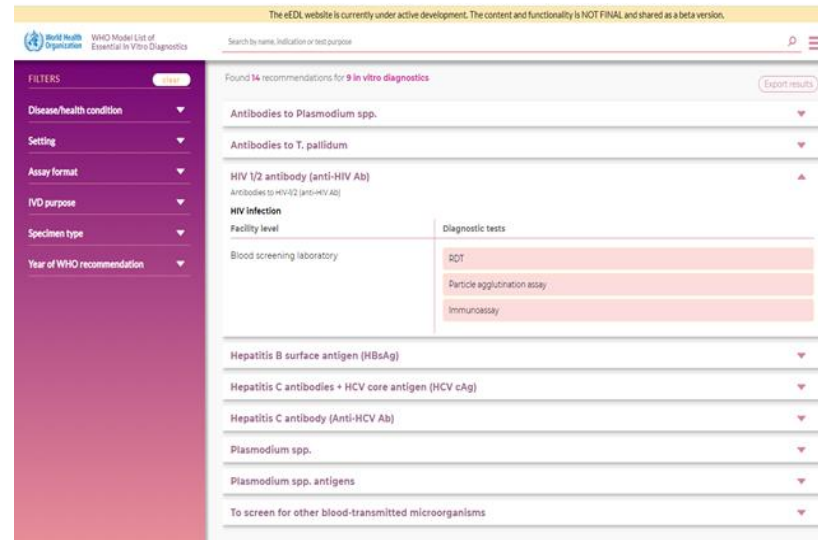
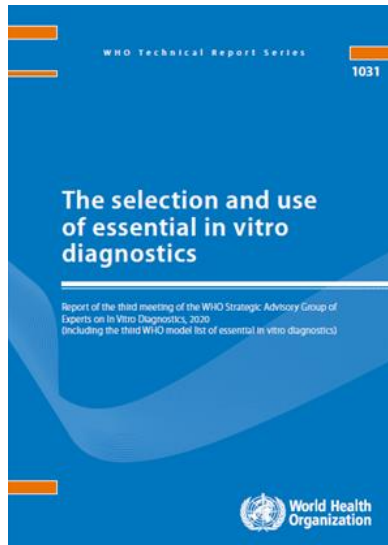
Do Not Do recommendations



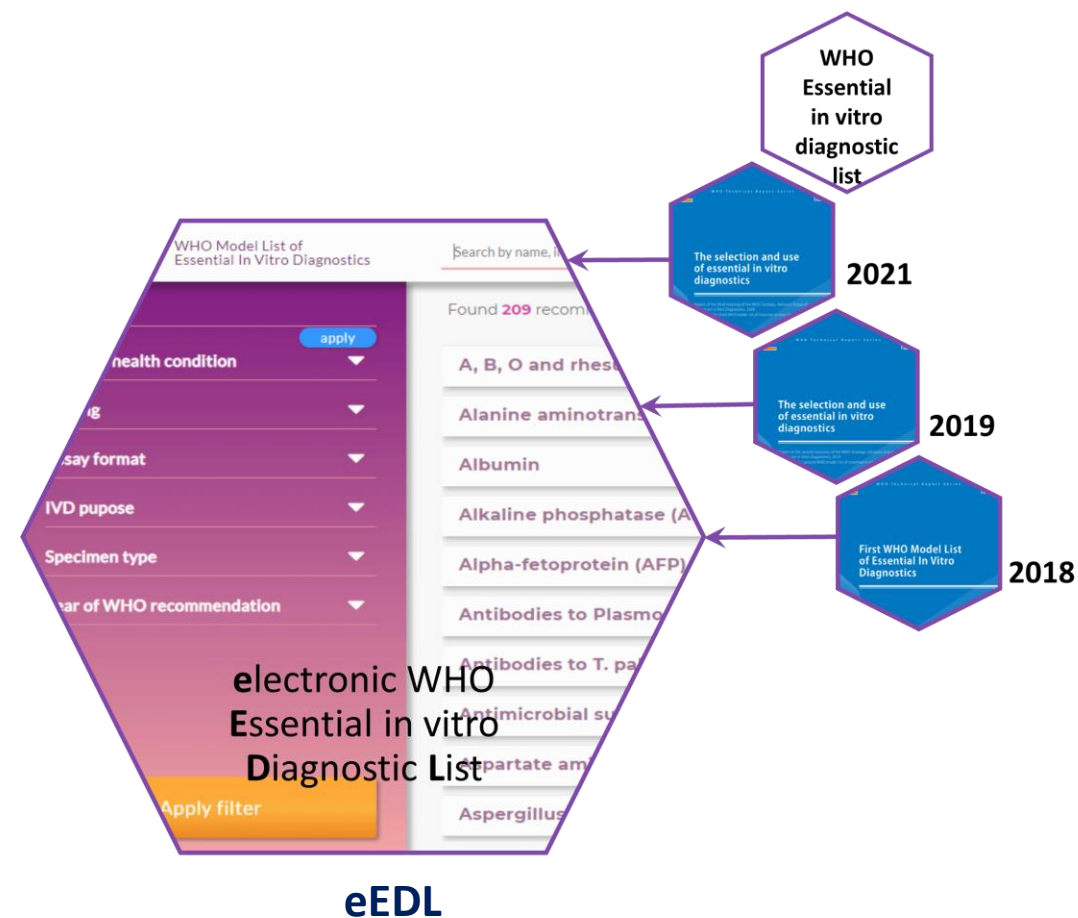
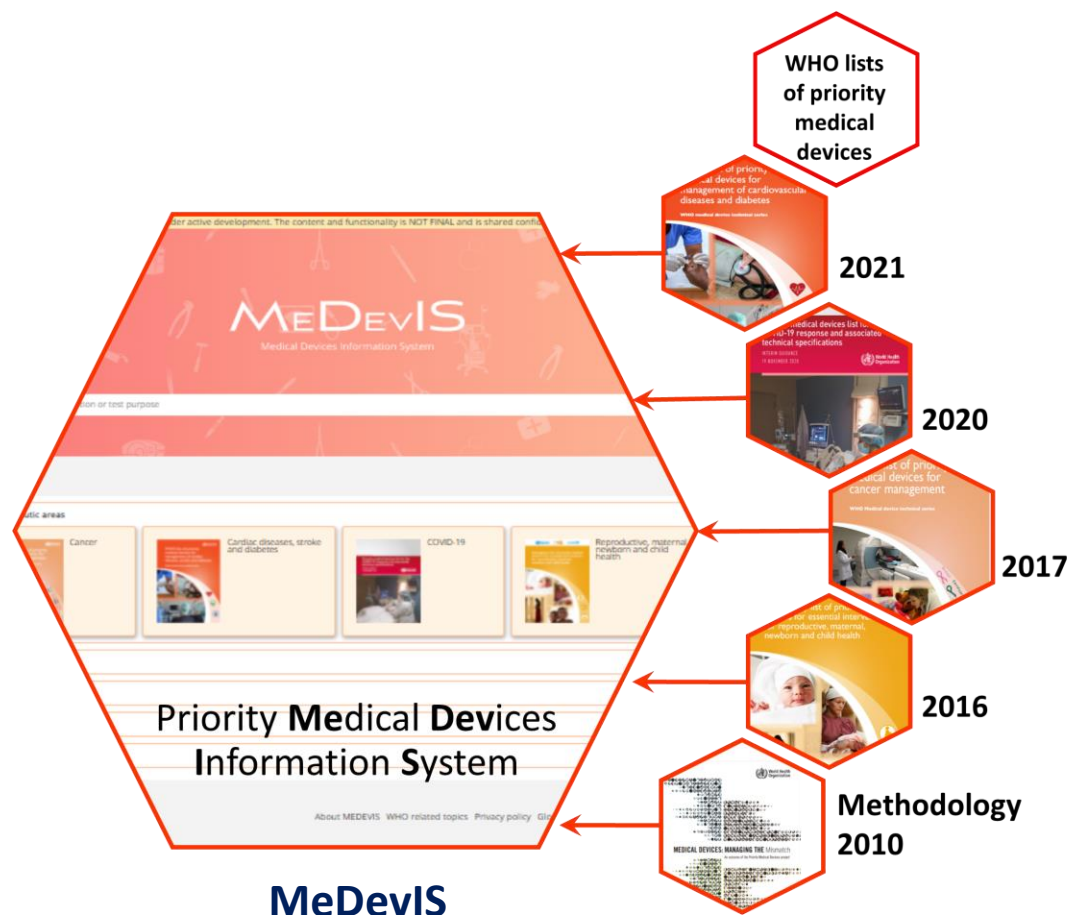
Refer to test categories that have been listed for discontinuation

Tools to support countries

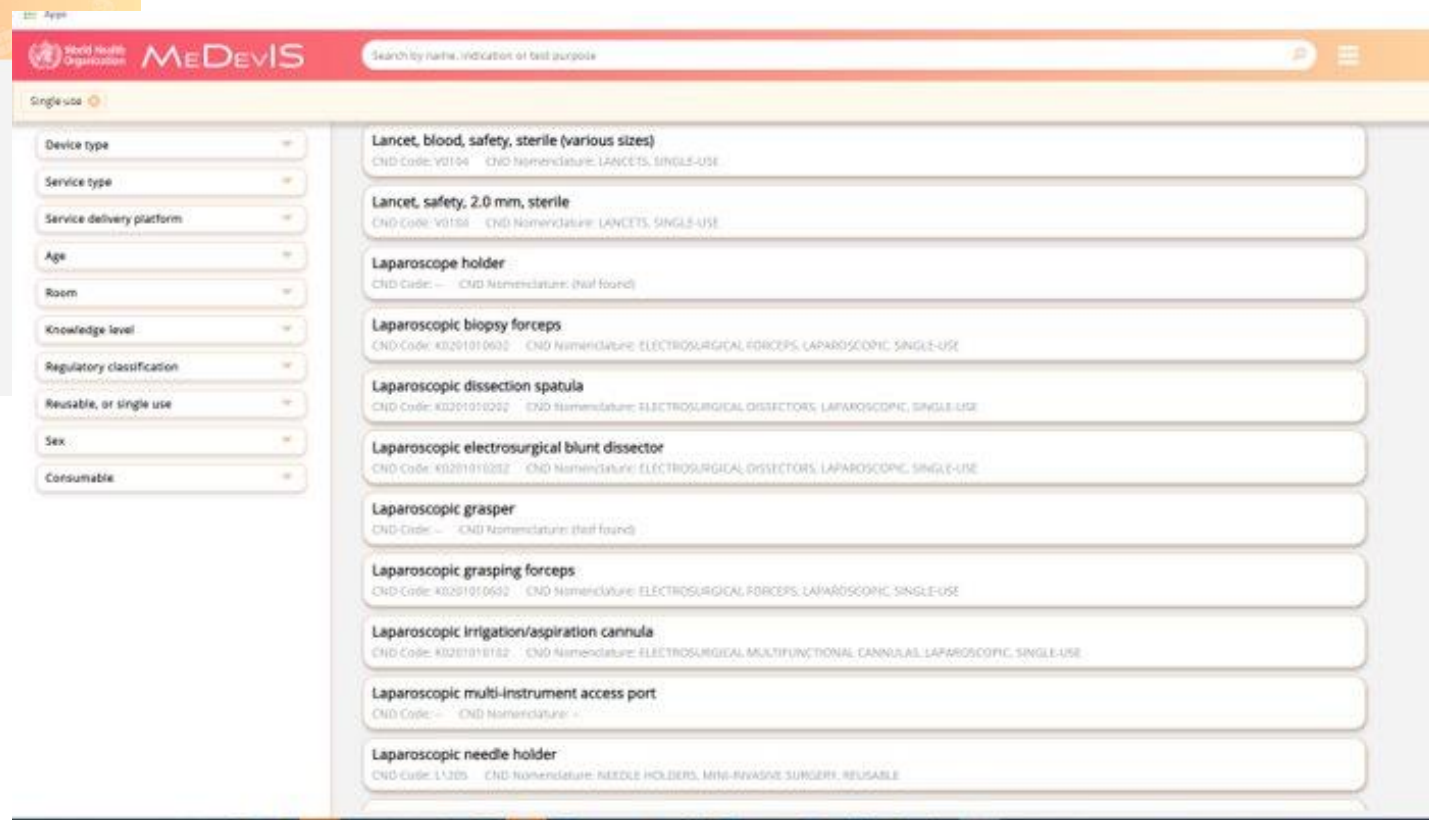
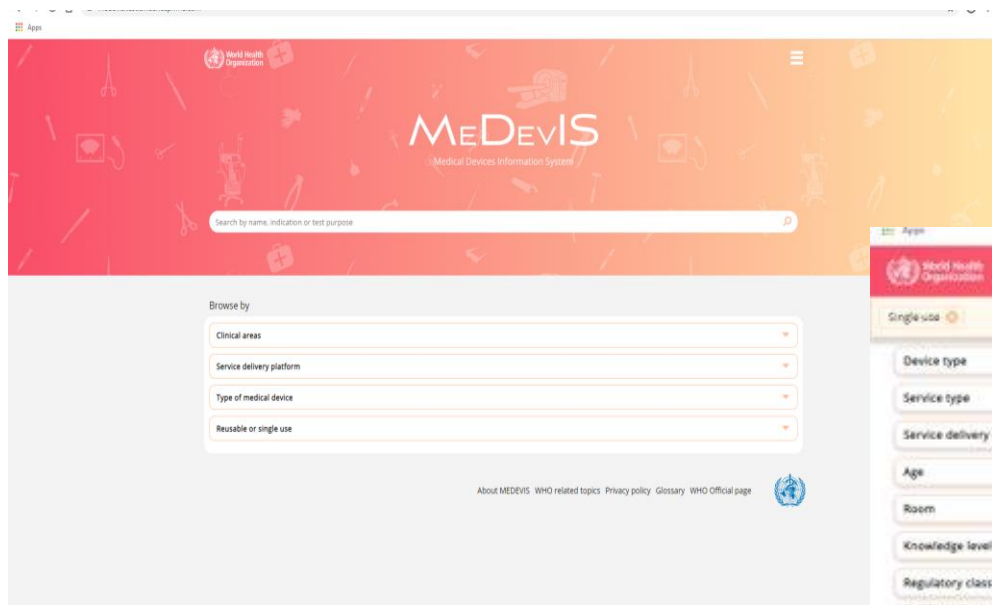
- 1. WHO Technical Report Series: The selection and use of essential IVDs
- 2. Electronic EDL (eEDL)
- 3. Selection of essential in vitro diagnostics at country level: using the WHO Model List of Essential In Vitro Diagnostics to develop and update a national list of essential in vitro diagnostics
- 4. Technical specifications to support selection and procurement of IVD products (work under development)



Moving toward electronic databases



Priority medical devices information system MeDeVIS





World Health
Organization





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<https://medevis.who-healthtechnologies.org/>


World Health Organization


MeDEVIS

Search by name, indication or test purpose

Export device

Oxygen concentrator

WHO list of priority medical devices

Cardiovascular diseases and diabetes

COVID-19

Reproductive, maternal, newborn and child health

Various conditions or disease specific

Disease-specific

Particular indications (ICD-11)

RA01 COVID-19

11 Diseases of the circulatory system

12 Diseases of the respiratory system

8B20 Stroke not known if ischaemic or haemorrhagic



Service delivery platforms

2. Community-based services

5. First referral level (District Hospital)

6. Second referral level and above (Regional or National hospital)

Healthcare unit

Emergency care

General surgery

Inpatient care

Intensive care

Long-term care

Pre-hospital care

Specialized surgery

Type of medical device

Medical gas equipment

EMDN related* code(s)

Z12159004 OXYGEN CONCENTRATORS

<https://webgate.ec.europa.eu/dyna2/emdn>

GMDN related* code(s)

31321 Mobile/portable oxygen concentrator

12873 Stationary oxygen concentrator

<https://gmdnagency.org>

© GMDN Agency 2005-2021

UMDNS related* code(s)

12873 Oxygen Concentrators

<https://www.ecri.org/solutions/umdns>

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UNSPSC related* code(s)

42271702 Oxygen concentrators

<https://store.unspsc.org/collections/codeset-downloads>

* The codes shown in this section were observed and retrieved from public databases and complemented with the input of Nomenclature Agencies. [More information](#)

Capital, reusable or single-use


Capital

Links to WHO publications, technical specifications and training material

PMD books	Interagency list of priority medical devices for essential interventions for reproductive, maternal, newborn and child health WHO list of priority medical devices for cancer management WHO List of Priority Medical Devices for management of cardiovascular diseases and diabetes WHO List of Priority medical devices list for the COVID-19 response and associated technical specifications WHO general medical devices WHO prioritizing medical devices
WHO resources	https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/patient-management https://www.who.int/publications/i/item/basic-emergency-care-approach-to-the-acutely-ill-and-injured https://www.who.int/emergencycare/systems/en/ https://www.who.int/publications/i/item/guidelines-for-essential-trauma-care
Modules	<div>Basic Delivery room Commodity 1</div> <div>Basic Freestanding Emergency Departments (Urgent Care) Commodity 1</div> <div>Basic Intensive care Commodity 1</div> <div>Basic Intensive care Commodity 1</div> <div>Basic Obstetrics Commodity 1</div> <div>Basic Obstetrics Commodity 1</div> <div>Basic Pediatrics Commodity 1</div> <div>Basic Pediatrics Commodity 1</div> <div>BASIC Sub-acute care Set 2</div> <div>Basic Surgical Units Commodity 1</div>
Kit or set	System: flow meter; mask
Training materials	https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices/management-use/trainings
WHO Tech Specs	Technical specification to download https://www.who.int/publications/i/item/WHO-2019-nCoV-MedDev-TS-O2T.V2 (CHAPTER 3) and https://www.who.int/publications/i/item/9789241516914
Quality product standards	ISO 80601-2-69:2014 – Part 2–69:IEC 60601-1:2012 – Part 1IEC 60601-1-2:2014 – Part 1–2IEC 60601-1-6:2013 – Part 1–6IEC 60601-1-8:2012 – Part 1–8IEC 60601-1-8:2013 ISO 13485:2003 ISO 14971:2007

MEDEVIS, PHC: cross sectorial, community and general outpatient.

[WHO](#) [MeDevIS](#) [Essential in vitro Diagnostics \(EDL\)](#) [MeDevPACKs](#) [ICD-11](#) [UHCC](#)

 **MeDevIS**

Service delivery platform: 1. Cross-sect... ×

Service delivery platform: 2. Communit... ×

Service delivery platform: 4. General ou... ×

clear

WHO list of priority medical devices ▼

Service type ▼

Life course ▼

Sex ▼

Service delivery platform ▲

☒ 1. Cross-sectorial services (161)

☒ 2. Community services (79)

☐ 3. Pre-hospital emergency services (176)

☒ 4. General outpatient services and outreach (511)

Apply filter

Blood administration set, sterile

Blood glucose meter

Blood glucose meter, continuous monitoring

Blood ketone meter

Blood pressure measurement device

Blood pressure measurement device, automated, non-invasive

Body belt, wheelchair

Body Mass Index (BMI) calculator



e-EDL electronic platform



Search by name/indication


[go back to list](#)

Table of content

Details

Summary of evidence and Expert Committee recommendations

Indication - HIV infection **ICD11 code: 1C62.Z**

Combined HIV antibody/p24 antigen (antiHIV/p24 Ag)

Essential In Vitro Diagnostic ✓

Facility level: 1. No laboratory


Assay formats	RDT
Status history	First added in 2018
Purpose type	Diagnosis
Purpose	For the diagnosis of HIV infection: adults, adolescents, children and infants > 18 months of age
Specimen types	Capillary whole blood, Venous whole blood
WHO prequalified or recommended products	Public reports of WHO prequalified IVDs http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-rdts/public_report
WHO supporting documents	Guidelines on HIV self-testing and partner notification (2016) https://apps.who.int/iris/handle/10665/251655 ; Consolidated guidelines on HIV testing services (July 2015) https://apps.who.int/iris/handle/10665/179870 ; WHO implementation tool for pre-exposure prophylaxis (PrEP) of HIV infection, module 10 for testing providers (2017) http://www.who.int/hiv/pub/prep/prep-implementation-tool ; Consolidated guidelines on HIV testing services (2015) https://apps.who.int/iris/handle/10665/179870

Summary of evidence and Expert Committee recommendations



The selection of the disease specific diagnostics tests for the EDL took into account the relevant priority diseases for the WHO such as HIV infection, tuberculosis, malaria, viral hepatitis B and C, syphilis and HPV infection. For these diseases there are WHO guidelines and technical reports, including recommendations for the appropriate IVDs. These documents are the result of significant evidence review and formed the basis for the

e-EDL: No laboratory settings

MeDevIS eEDL MeDevPACKs

 WHO Model List of Essential In Vitro Diagnostics

Search by name, indication or test purpose



FILTERS

clear

apply

Disease/health condition

▼

Setting

▲

☒ 1. No laboratory (36)

☐ 2. Laboratory (159)

☐ 3. Both (11)

Assay format

▼

IVD purpose

▼

Specimen type

▼

Year of WHO recommendation

▼

Apply filter

Found 36 recommendations for 31 in vitro diagnostics

Export results

Glucose

▼

Group A Streptococcus antigen

▼

HIV 1/2 antibody (anti-HIV Ab)

▼

HIV qualitative nucleic acid test

▼

Haemoglobin (Hb)

▼

Haemoglobin A1c (HbA1c)

▼

Hepatitis B e antigen (HBeAg)

▼

Hepatitis B surface antigen (HBsAg)

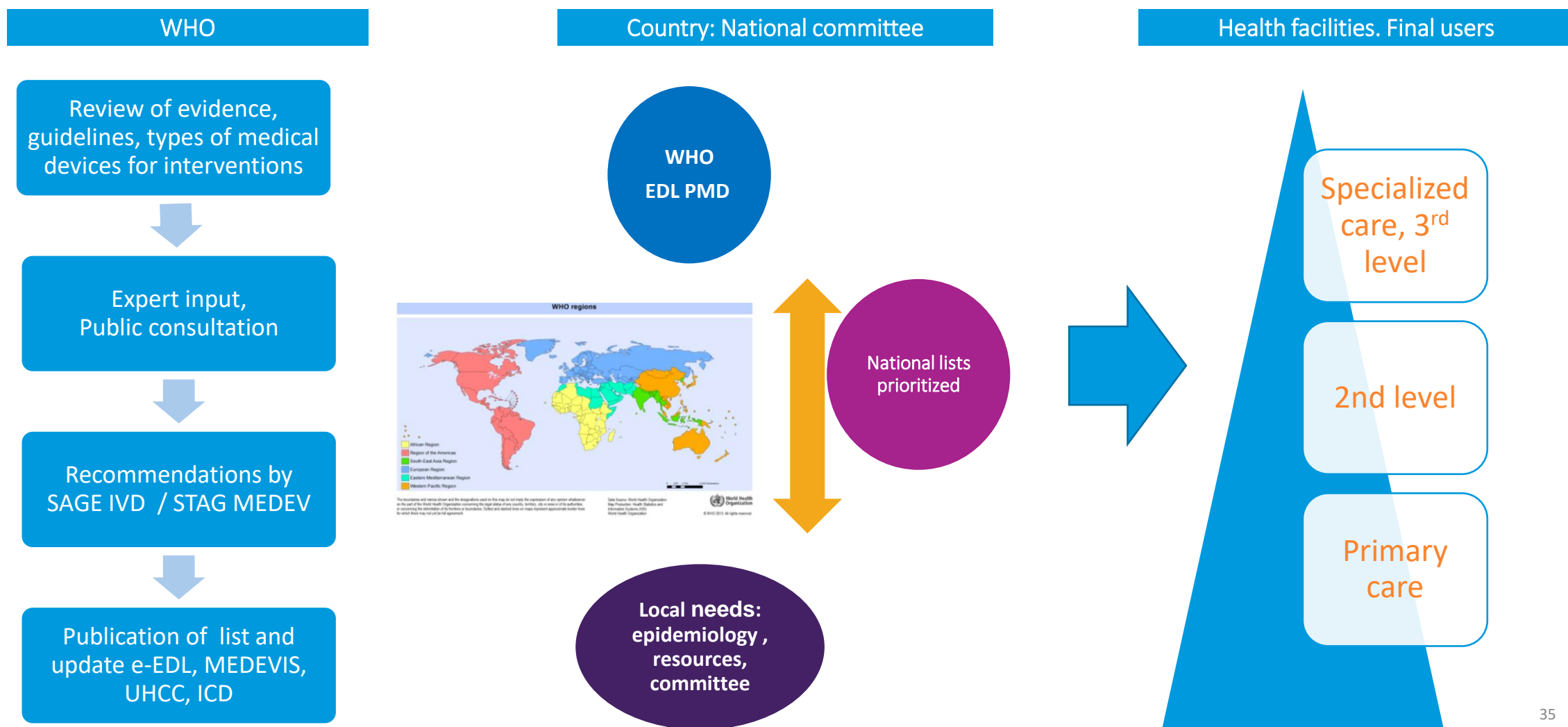
▼

Hepatitis C antibody (Anti-HCV Ab)

▼

Global Implementation:

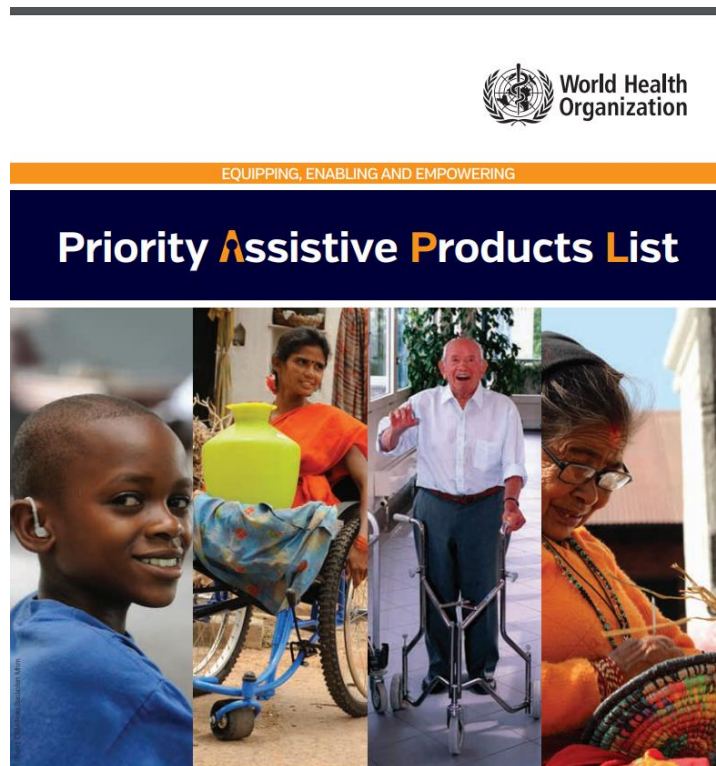
WHO lists (EDL & PMD) to be used for development or update of national lists, to increase access at country level



Other complementary lists:

Priority assistive products

2017: 50 types



Priority Assistive Products List		
1	Alarm signalers with light/sound/vibration	
2	Audioplayers with DAISY capability	
3	Braille displays (note takers)	
4	Braille writing equipment/braillers	
5	Canes/sticks	
6	Chairs for shower/bath/toilet	
7	Closed captioning displays	
8	Club foot braces	
9	Communication boards/books/cards	
10	Communication software	
11	Crutches, axillary/elbow	
12	Deafblind communicators	

Links with other WHO platforms i.e., ICD-11 relation to diseases, health conditions.

ICD-11 for Mortality and Morbidity Statistics (Version : 02/2022)

Search ventilator [Advanced Search] Browse Coding Tool

CA70.7 Air conditioner or humidifier lung
ventilation pneumonitis

MD11.Y Other specified abnormalities of breathing
inadequate **ventilation**

XD60Z6 Transportable **ventilators**

MD11.7 **Hyperventilation**

MD11.5 Dyspnoea
Dyspnoea **hyperventilation**

KB29.Y Other specified chronic respiratory disease originating in the perinatal period
Ventilator lung in newborn

PK81.0 **Ventilation** associated with injury or harm in therapeutic use

XD51T0 Hand-operated **ventilation** balloons

XD3SM4 Intensive care **ventilators**

MD42 Results of function studies of the respiratory system
Reduced **ventilatory** capacity

QB41 Dependence on respirator
dependence on respiratory **ventilator**

XE7KA **Ventilation** problem in device environment

KB2D Respiratory failure of newborn
inadequate pulmonary **ventilation** of newborn

KB2Z Respiratory disorders specific to the perinatal or neonatal period, unspecified
abnormal pulmonary **ventilation** of newborn NOS

XD9AF0 **Ventilation** filters, antibacterial and antiviral, moisturizer

XD0U91 Laryngoscopes
XD3JX1 Videolaryngoscopes
XD7EC8 Continuous positive airway pressure units (CPAP)
XD60Z6 Transportable ventilators
XD3SM4 Intensive care ventilators
XD4KU3 Portable multi-parameter patient monitors
XD66D8 Pulse Oximeters
XD8QY1 Infusion Pumps
XD80Z7 Medical/medicinal gas systems and



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Towards the 2023 compendium of innovative technologies for low resource settings



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Preparing the 2023 Call for the Compendium of innovative health technologies for low resources settings



WHO assessment of innovative health technologies for The Compendium

It requires the input of all STAG MEDEV working groups.

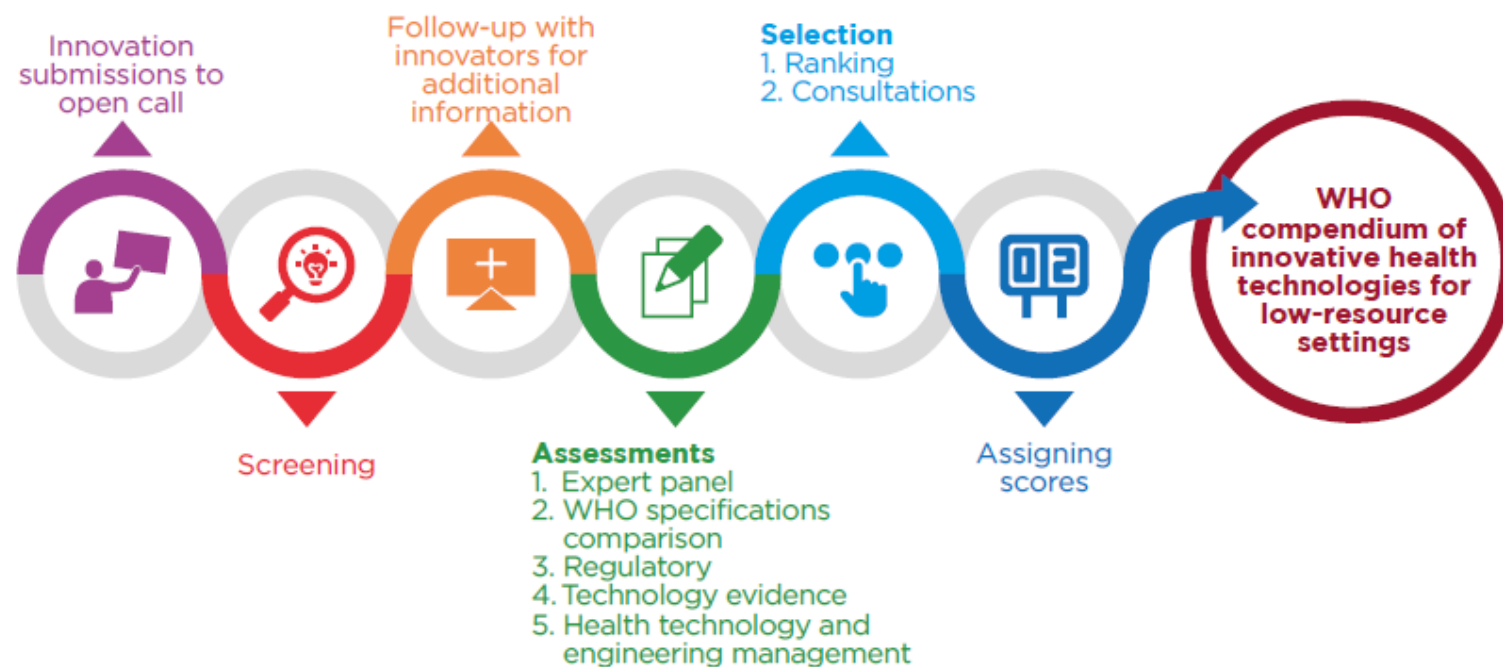
1. Revision and detailed feedback of the material for the call by the **Innovation working group**. The material includes the submission form and list of requirements.
2. Consolidation of the material by the STAG MEDEV.








Methodology

The overall evaluation and selection process is shown in Figure 1. The stages include innovation submissions to an open call, initial screening, varied assessments, selection, and scoring.

Figure 1. Overall evaluation process



Assessment

				
Regulatory assessment	Proceed	Proceed with caution	Not acceptable	
Technology evidence assessment - risk/benefit ratio	High	Medium	Low	
Technology evidence assessment - Impact	High	Medium	Low	
Innovation		Innovation aspect in the domain		
Summary:				
Transferability	Fully transferable	Partly transferable	Not transferable	
Evidence (according to GRADE)	High	Medium	Low	
Technology evidence assessment	Recommended	Recommend with caution	Not recommended	
Health technology and engineering management	High appropriateness for low-resource settings	Moderate appropriateness for low-resource settings	Low appropriateness for low-resource setting	Not Applicable

Example of a compendium page


WHO compendium of innovative health technologies for low-resource settings

2021 | COMMERCIALY AVAILABLE

Bleach additive, coloured

Country of origin | United States of America
Primary function | Prevention
Category | Other technology

Commercial information
List price (USD): \$5
Year of commercialization: 2017
Number of units distributed: 10,000-50,000
Currently marketed in: Globally
Brand/Model: Kinnox Highlight for Liquid Bleach



Health problem addressed
Less than 50% of critical surfaces in healthcare settings are adequately disinfected due to human error and poor training. Contaminated surfaces lead to 5-6x higher risk of getting an infection, and the threat of healthcare-associated infections (HAI) is several-fold higher in low-resource settings compared to high-income countries. Although COVID-19 is thought to be primarily transmitted through the air, surface disinfection plays an important role in preventing HAI as a complicating factor.

Product description
The product is a colored bleach additive in the form of blue powder that improves visibility and coverage of sprayed areas. It enables real-time visual colorization so healthcare workers can see exactly what surfaces they have covered to eliminate guesswork from the disinfection process. The color automatically fades away to colorless after a few minutes to prevent staining. Peer-reviewed studies have demonstrated quantifiable improvements in disinfection technique and that the additive is safe to use.

Product details
Lifetime: Single use
Contact: Jason King | Email: jason@kinnox.us | Website: <http://bit.ly/2ag5u6s>


1. Reported by manufacturer on 27 November 2020
2. Reported by manufacturer on 25 January 2021

WHO ASSESSMENT

















WHO specification comparison

At the time of report creation, WHO technical specifications are not available to compare against for this type of technology.

Regulatory assessment



Regulatory and quality system assessment:  Passed. No regulatory or quality system objections.

Indicate in the Compendium does not constitute a grant to WHO of the right of any technology or product for a particular purpose, nor does it constitute a grant to WHO of the right of any technology or product for a particular purpose. The Compendium is a public good and its use is encouraged. The Compendium is a public good and its use is encouraged. The Compendium is a public good and its use is encouraged.

















Domains	Risk/benefit ratio	Impact
Medical		
Safety		
Economy		
Organizational		
Legal		
Social		
Ethical		
Green environment		

This substance reduces the use of toxic (chlorine based) material. The product helps inform citizens about how to correctly use disinfection materials, thus reducing contamination and improving safety. It is an additive and therefore does not require extra infrastructure. It can be handled by trained people.

Summary

Transferability  Technology readiness level **9**
Evidence (according to GRADE)  Technology evidence assessment **Recommended**

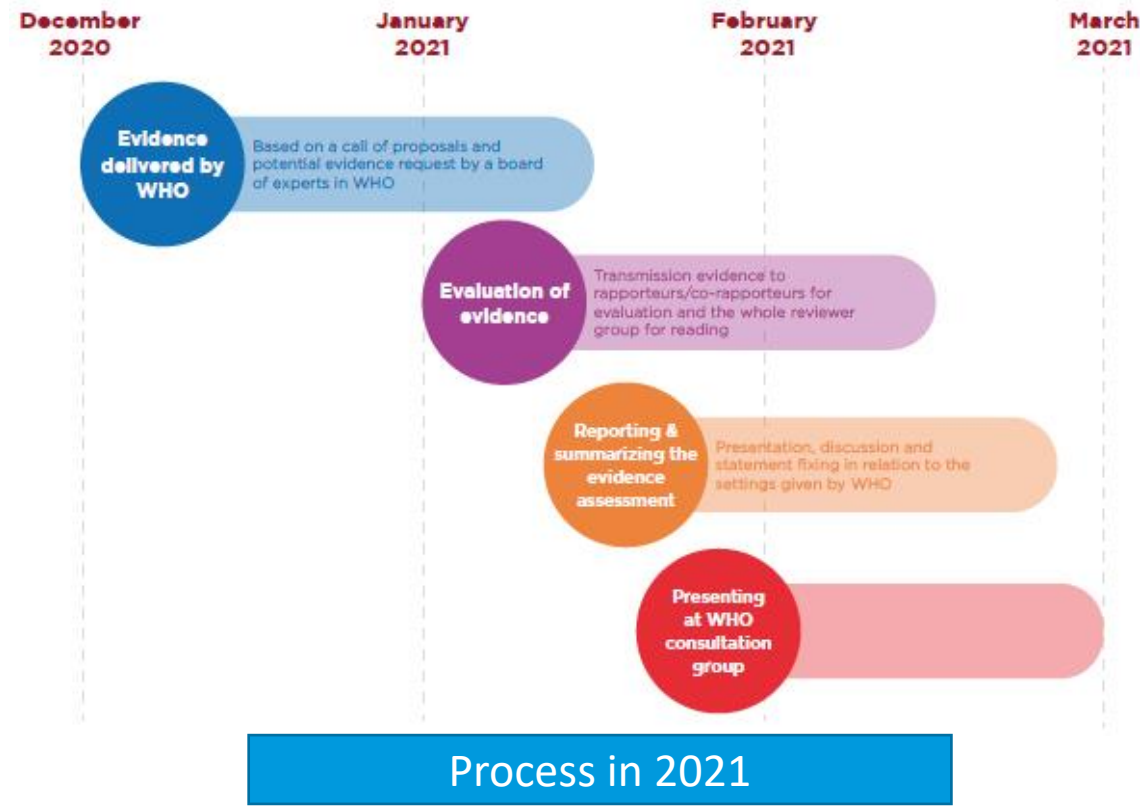
Health technology and engineering management

Domains	Appropriateness	Domains	Appropriateness	Target setting: Public and home settings 
Durability		Ease of maintenance		The purpose of this product is to aid in infection prevention. It uses a patented colored bleach additive that combines with standard bleach and thus enables real-time visualization of surfaces where the disinfectant was already applied. The user combines the color additive to the bleach and chlorine disinfectant. The product has a shelf life of up to 2 years and does not require any additional resources. The manufacturer provided study outcomes demonstrating that surface coverage is improved. However, there is no evidence that cleaning efficiency improves when using the product.
Ease of Use		Infrastructure requirements		
Positive impact on clinical outcomes		Local access to sales support		
Affordability		Local access to technical support		
Engineering resources minimization		Local access to training		
Cultural and social acceptability		Local access to spare parts		
Environmental conditions		Local production		
		Locations of		

Propose:

The Call in June, evaluations Sept-Oct, publication December 2023

Figure 3. Step-by-step process description



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STAG MEDEV: Strategic and technical advisory group of experts on medical devices.

• Areas of expertise :

Biomedical Engineering	Materials Engineering	Health Economics
Health technology Assessment	Health Technology Management	Medicine and Surgery
Medical Physics	Global Public Health	Public Policy
Regulation medical devices	Marketing devices	Law

• Originating from:

Albania	Australia	Austria	Bangladesh	Canada
China	Ethiopia	France	Greece	India
Kenya	Lebanon	Malaysia	Nepal	Nigeria
Pakistan	Paraguay	Peru	Rwanda	Saudi Arabia
Senegal	Singapore	South Africa	Tunisia	Uganda
	United Kingdom	United States of America	Uruguay	

- [Advisory groups](#)

Working **together** with biomedical engineers to solve local, regional and global health problems World Health Organization



Decision approved in WHA 75¹

28 May 2022

- On standardization of medical devices nomenclature... Decided to request the Director General:
 - (1) to integrate **available** information related to medical devices, including **terms, codes, and definitions**, in the web-based database and clearinghouse established in line with resolution WHA60.29 (2007) and now available as the Medical Devices Information System (MEDEVIS); and to **link this to other WHO platforms**, such as the International Classification of Diseases, (ICD-11) to serve as a reference to stakeholders and Member States;
 - (2) to submit a substantive report on progress made in implementing this decision to the Executive Board at its 152nd session in January 2023, and **in January 2025**

WHO needs your expertise to ensure medical devices are safe, effective, appropriate, accessible, available and affordable by all that need them



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Conclusions

WHO continuously develops guidelines, norms and standards on medical devices and related technologies, to support implement at country level.

Biomedical engineers should get involved in selection, needs assessment, management, regulations of all types of medical devices.

Collaborative work with other health professionals is required, particularly medical doctors, nurses, technicians, biomedical scientists, pharmacists, health facility managers.

The goal is to save lives and increase quality of lives with medical devices that are accessible, safe and of assured quality.



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Gracias
Thank you
Merci
Shokran
Xie xie
Spasiva

WHO

20, Avenue Appia
1211 Geneva

Switzerland

Medical devices

Email: medicaldevices@who.int

website: https://www.who.int/health-topics/medical-devices#tab=tab_1



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Important links references

- Medical devices WHO website
- <https://www.who.int/health-topics/medical-devices#tab=tab>
- MEDEVIS
- <https://medevis.who-healthtechnologies.org/>
- Nomenclature
- <https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices/nomenclature>

- In vitro diagnostics WHO website
- https://www.who.int/health-topics/in-vitro-diagnostics#tab=tab_1
- eEDL
- <https://edl.who-healthtechnologies.org/>