Briefing Seminar (TBS) on Medicines and Health Products
WHO Headquarters, Geneva, Switzerland
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Prioritizing Medical Devices: Update on the global situation and sourcing for information

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Team Lead Medical Devices

World Health Organization

75 HEALTH FOR ALL

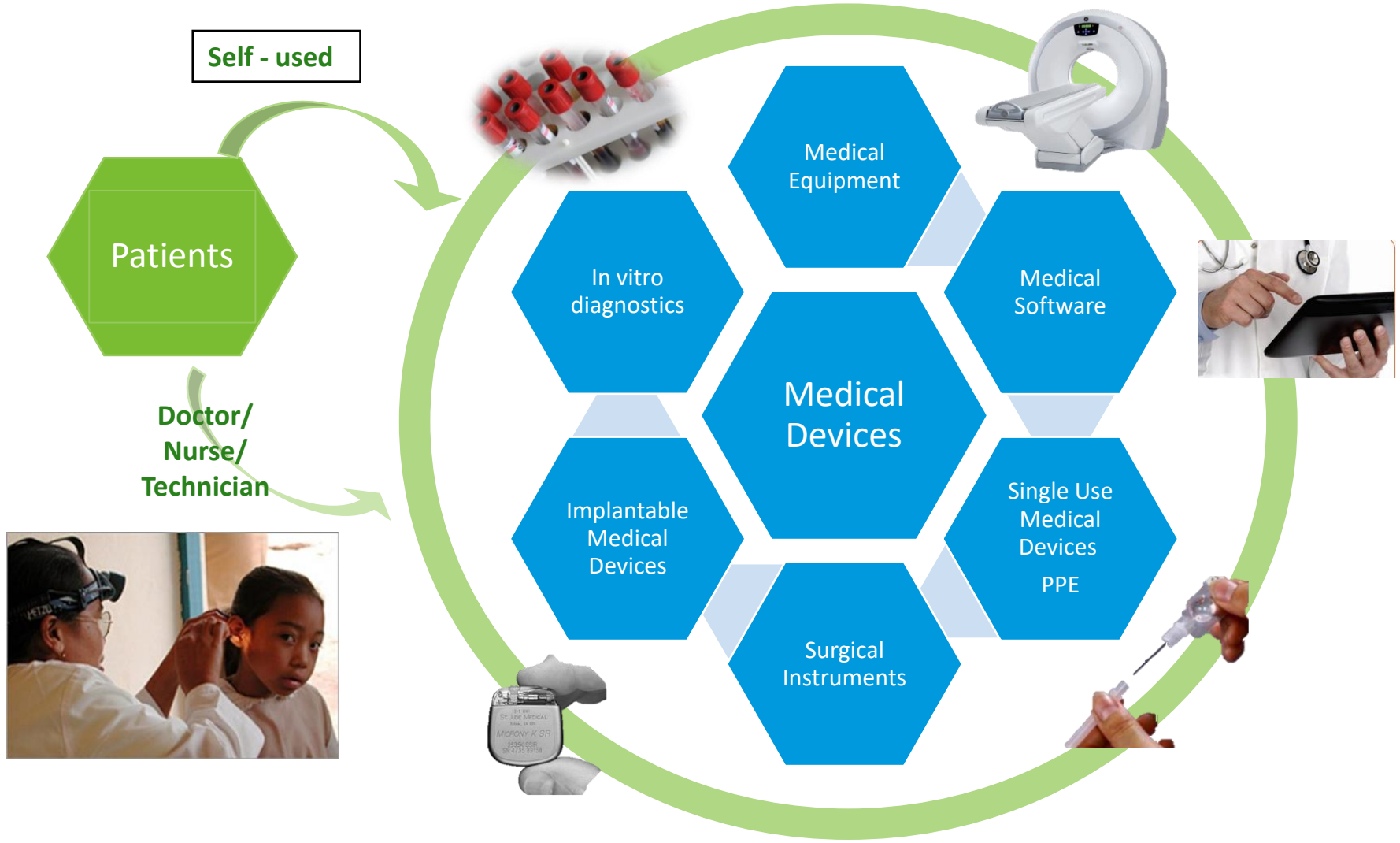
Medical devices are indispensable to provide health for all

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 then 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.

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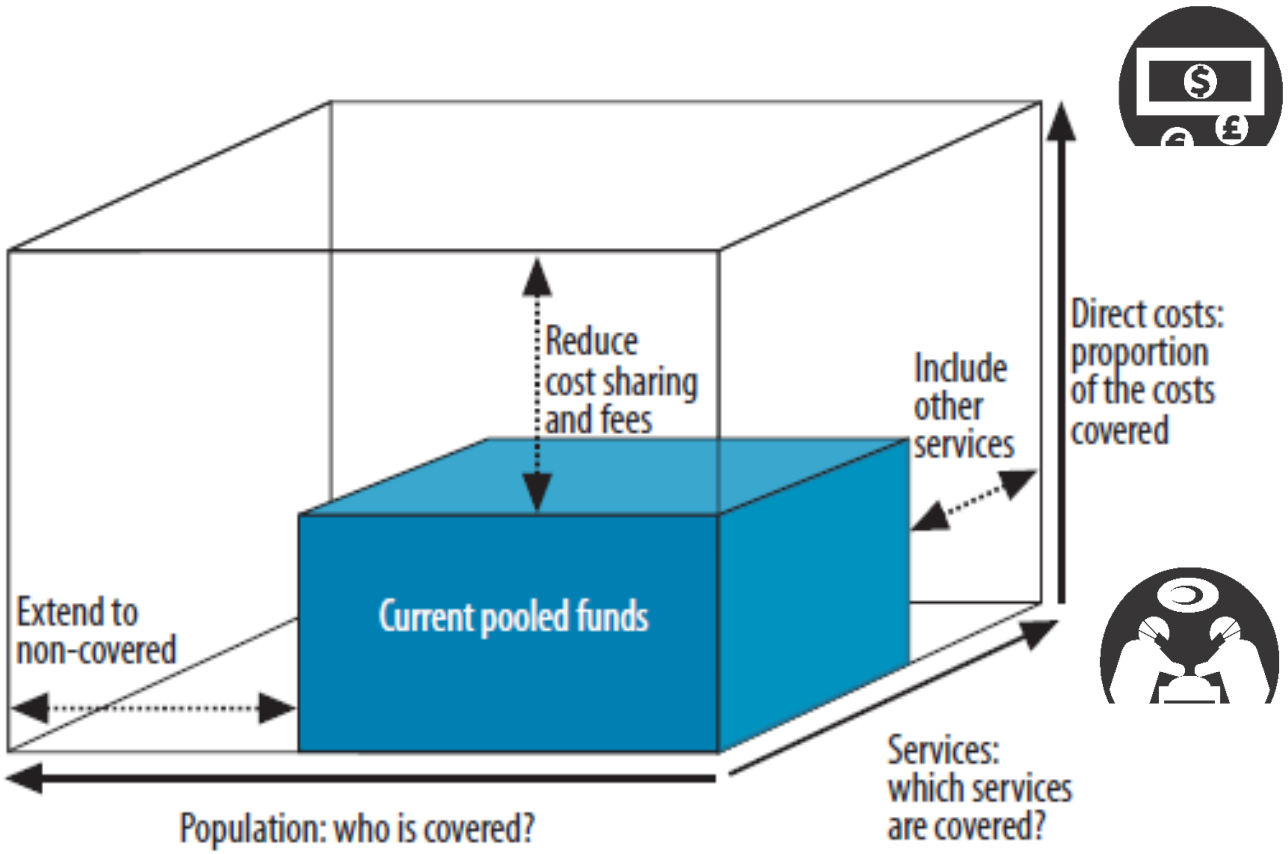
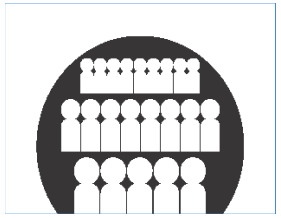
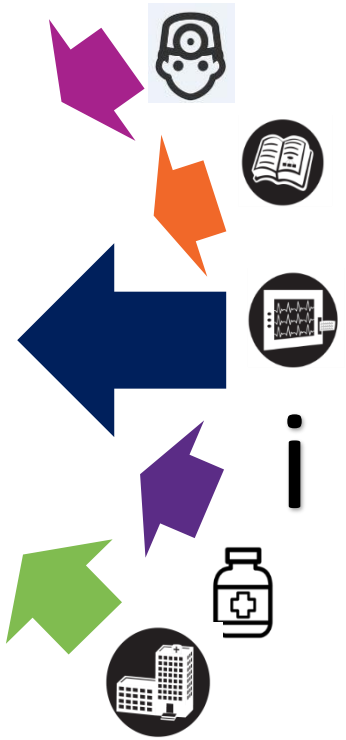
Our work includes selecting, assessing, managing medical devices that will support local, regional and global health to support patients everywhere.

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

Nomenclature

R&D

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

Assessment

- Health Technology Assessment
- Lists of MD for reimbursement or procurement

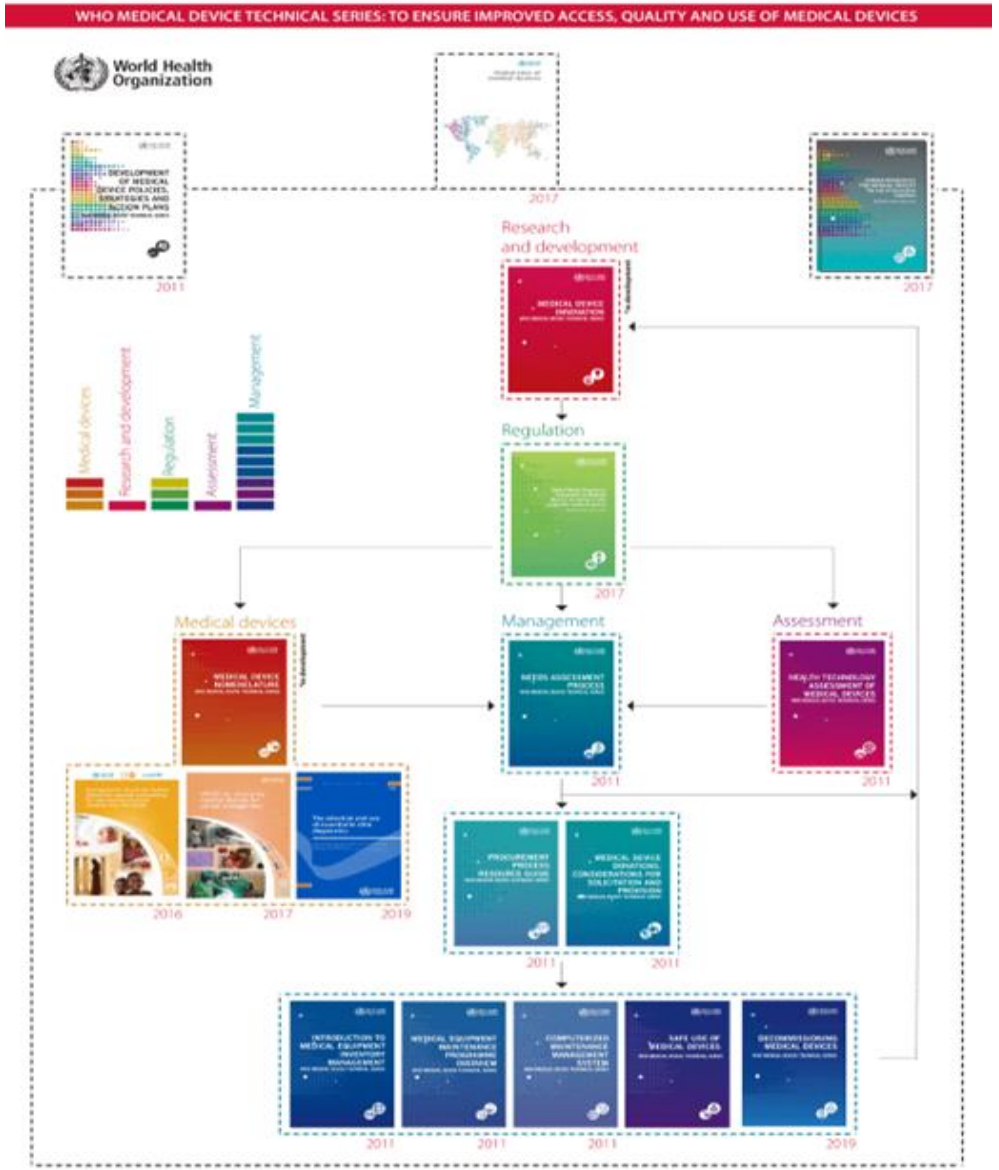
Regulations

- 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

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

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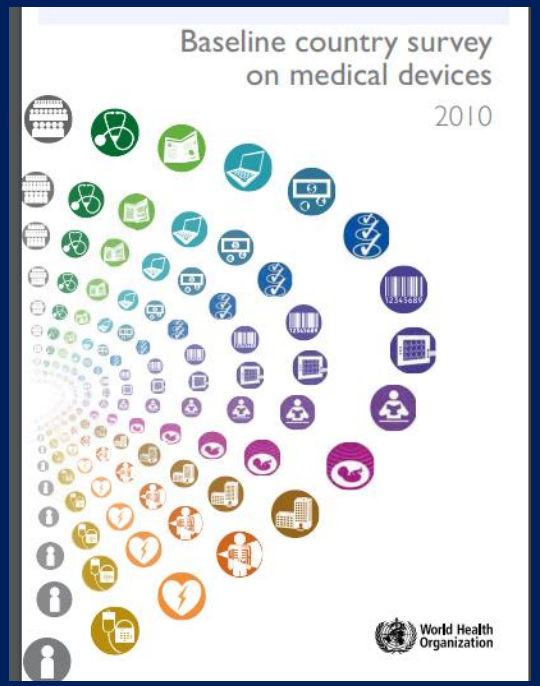
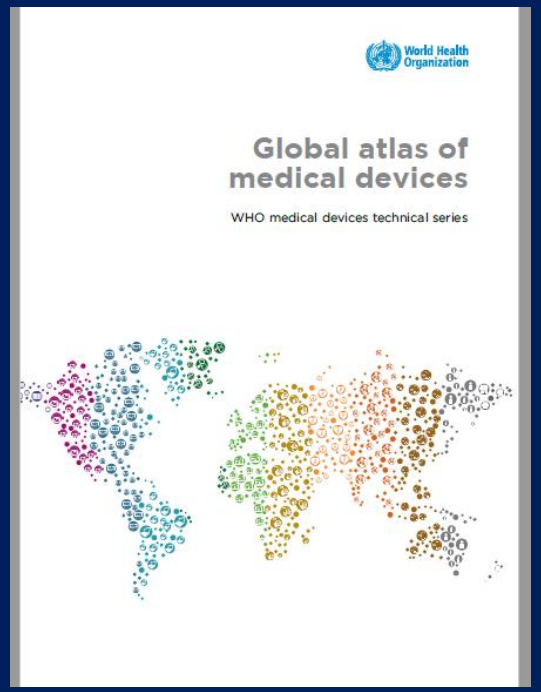
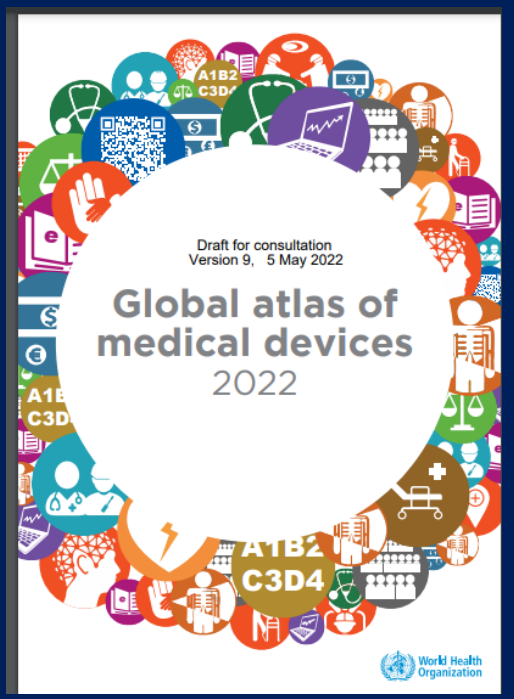
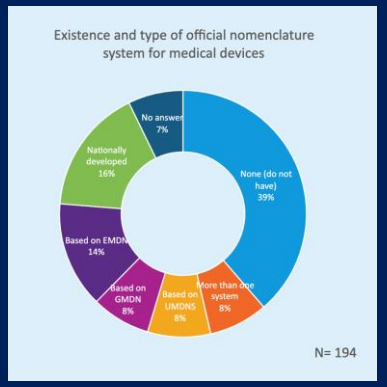
Global Atlas of Medical devices

Country profiles and data in Global Health Observatory









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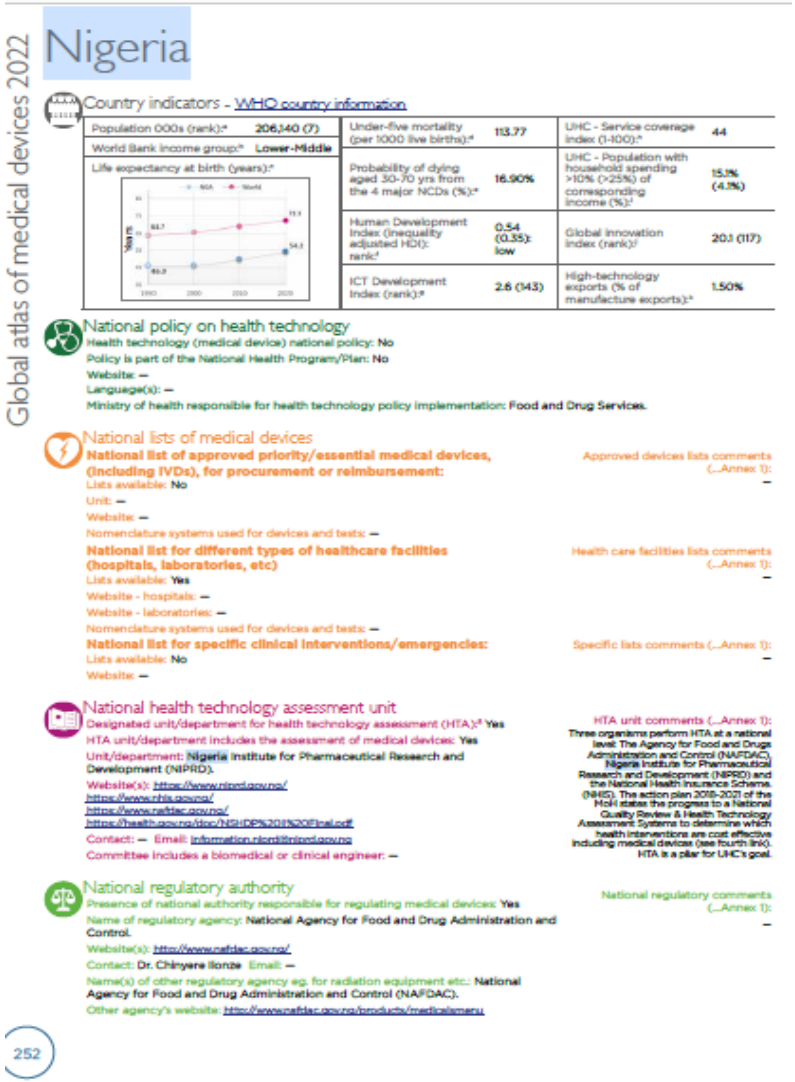

Global atlas of medical devices 2022

Nigeria

Country indicators - WHO country information

Population 000s (rank):[a]	206,140 (7)	Under-five mortality (per 1000 live births):[d]	113.77
World Bank income group:[b]	Lower-Middle	UHC - Service coverage index (1-100):[e]	44
Life expectancy at birth (years):[c]		Probability of dying aged 30-70 yrs from the 4 major NCDs (%):[e]	16.90%
		UHC - Population with household spending >10% (>25%) of corresponding income (%):[f]	15.1% (4.3%)
		Human Development Index (inequality adjusted HDI): rank:[g]	0.54 (0.35): low
		Global innovation index (rank):[h]	20.1 (117)
		ICT Development Index (rank):[i]	2.6 (143)
		High-technology exports (% of manufacture exports):[a]	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: –

Approved devices lists comments (...Annex 1): –

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: –

Health care facilities lists comments (...Annex 1): –

National list for specific clinical interventions/emergencies:
Lists available: No
Website: –

Specific lists comments (...Annex 1): –

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[a] Yes
HTA unit/department includes the assessment of medical devices: Yes
Unit/department: Nigeria Institute for Pharmaceutical Research and Development (NIPRD).
Website(s): https://www.nipnl.gov.ng/
https://www.nhis.gov.ng/
https://www.nafdac.gov.ng/
https://health.gov.ng/doc/NSHDP%202018%20Final.pdf
Contact: – Email: information.nipnl@nipnl.gov.ng
Committee includes a biomedical or clinical engineer: –

HTA unit comments (...Annex 1): Three organisms perform HTA at a national level: The Agency for Food and Drugs 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 MoH states the progress to a National Quality Review & Health Technology Assessment Systems 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/products/medicalimeru

National regulatory comments (...Annex 1): –

WHO African Region

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
Publically 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
Mammograph:**	n/a	n/a
Radiotherapy:β	9	0.04

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

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. Esan Bukola Emmanuel Contact email: bukolaesan2000@yahoo.com
Website with publically 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:[a] 280

Contacts

National officer(s):
Name: Mr. Esan Bukola Emmanuel
Email: bukolaesan2000@yahoo.com

Name: –
Email: –

WHO Country officer(s):
Name: Dr. Walter Kazadi Mulombo
Email: kazadim@who.int

Name: –
Email: –

General comments (...Annex 1): –

a UN WPP 2019, POP (data year: 2020)
b WB FY23 (data year: 2021)
c UN WPP 2019, MORT (data year: 1990-2020)
d UN IGME, SDG 3.2.1 (data year: 2020)
e WHO GHO, SDG 3.4.1 (data year: 2019)
f UNDP HDR 2019/20, HCI and IHDI (data year: 2019)
g ITU IDI 2017 (data year: 2017)
h WHO GHO, SDG 3.8.1 (data year: 2019)
i WHO GHO, SDG 3.8.2, 10% or 25% (data year: latest 2010-18)
j WIPO GII (data year: 2020)
k UN-WB HSE (data year: latest 2017-19)
δ WHO HTA&HSP 2021 survey, HTA 2015, CSoHD2.1 (data year: latest 2015 or 2021)
α WHO GHO, HS, OECD, HS, CSoHD2.1 (data year: latest 2013-21)
β WHO GHO, RLI, IAEA, DIRAC, CSoHD2.1 (data year: latest 2013-21)
γ WHO GHO, HW, CSoHD2.1 (data year: latest 2017-2021)
n/a not applicable/not available

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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).

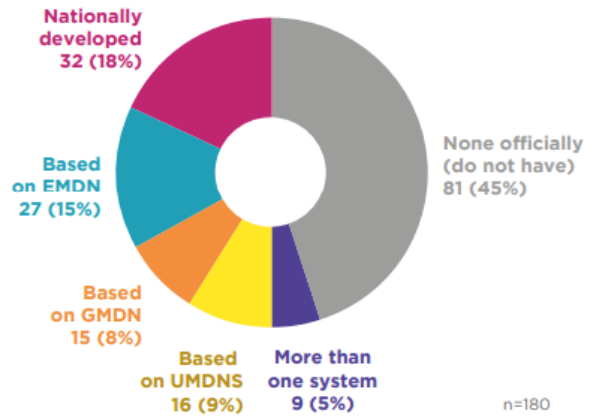
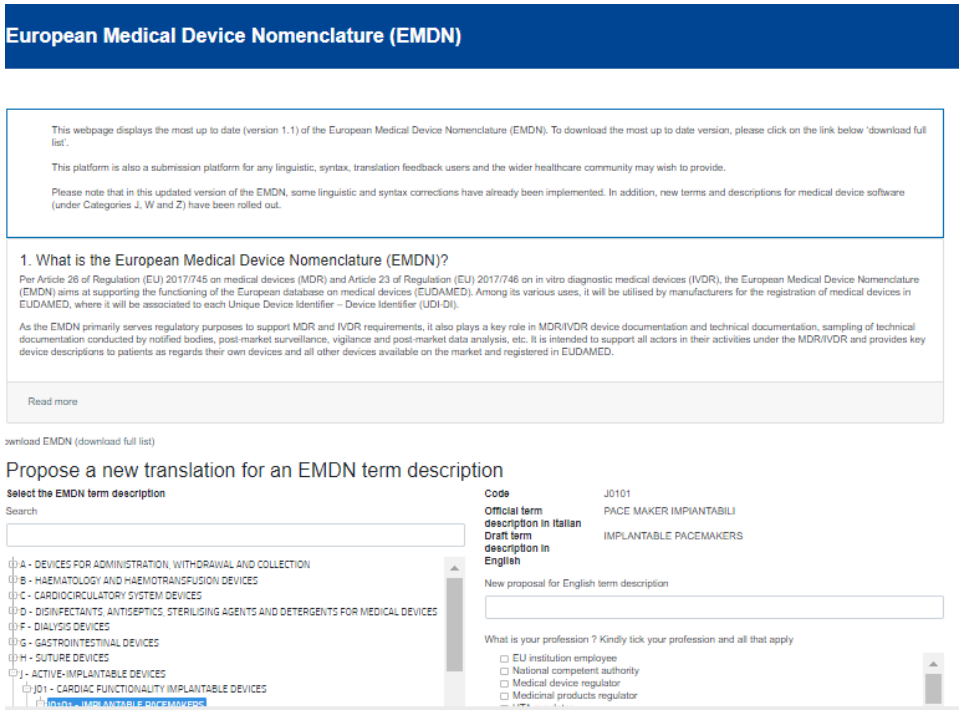
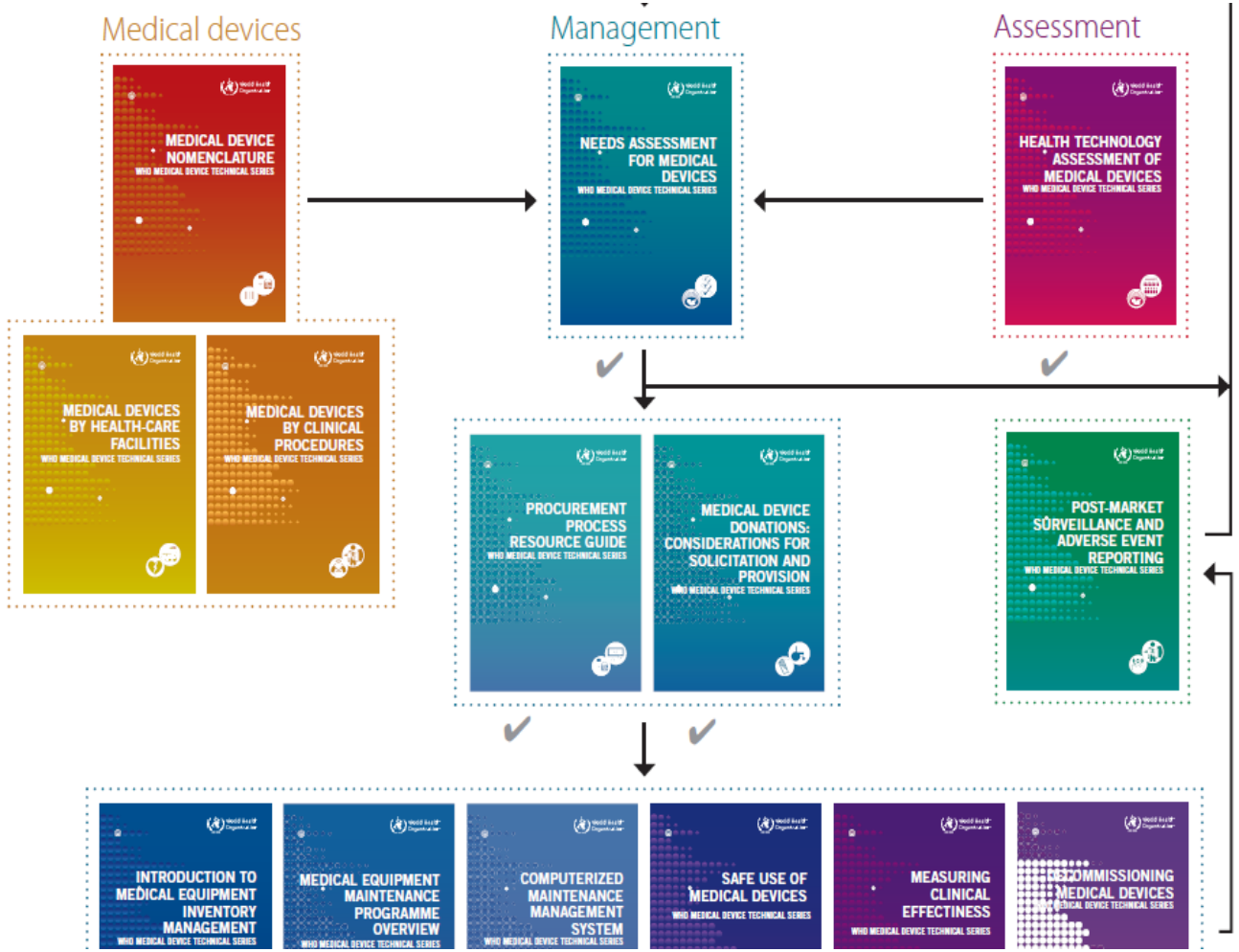


Figure 2. Type of an official nomenclature system for medical devices (data from the 2020 Country survey and the 2021-2022 Nomenclature consultations)



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



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

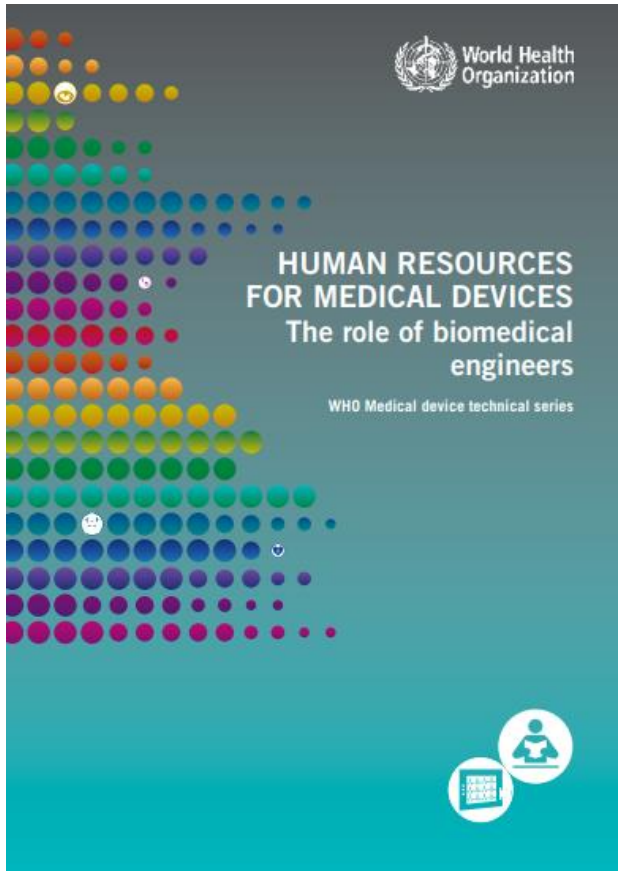
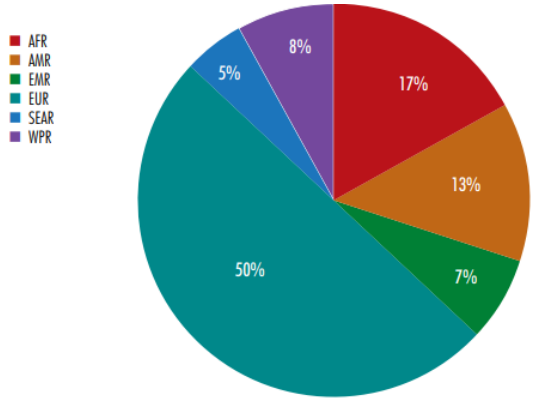


Figure 1.1 Density of biomedical engineers per 10 000 population globally (as at January 2016)

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

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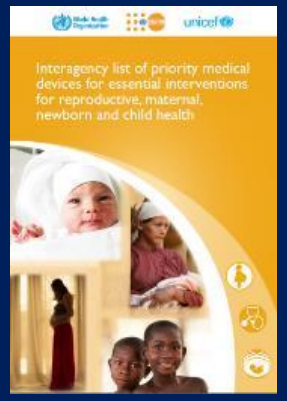
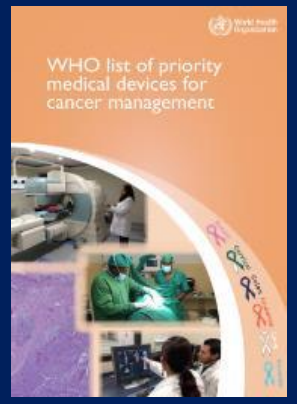
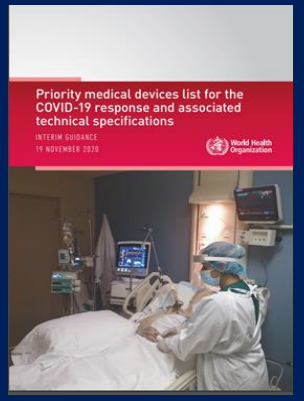
Priority medical devices

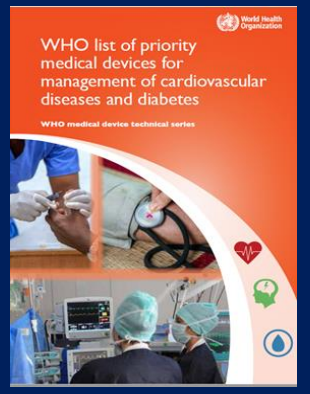
List of essential/ priority

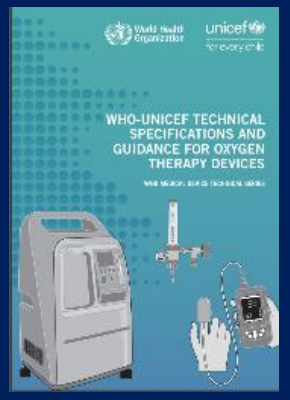
Technical specifications

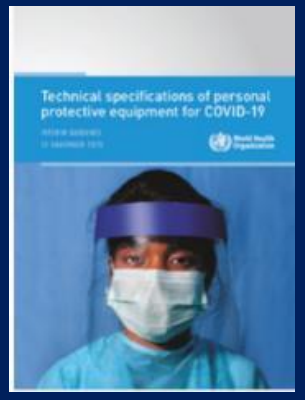


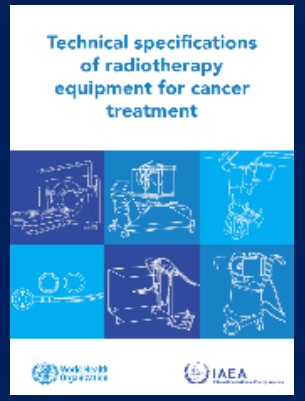




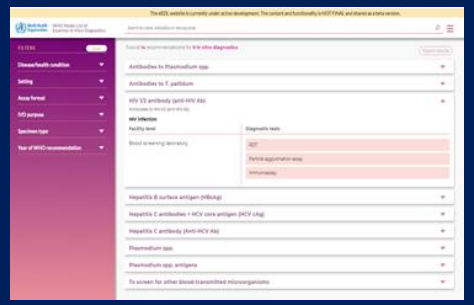








Essential in vitro diagnostics



https://www.who.int/health-topics/medical-devices
https://medevis.who-healthtechnologies.org/

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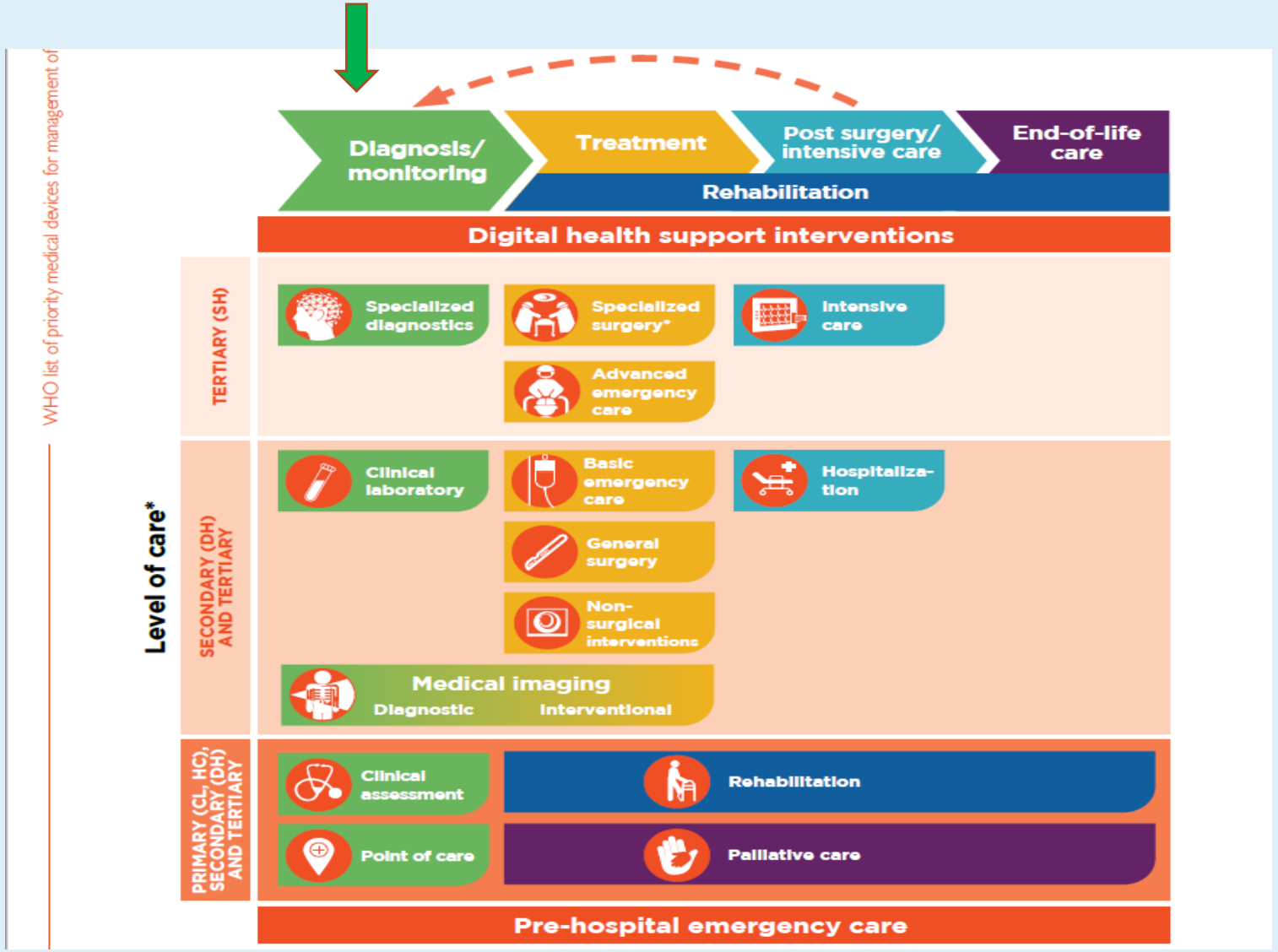
Priority Medical Devices can be used for:

Prevention,
Diagnosis,
Treatment,
Rehabilitation,
Palliation.

Should be available at different levels of care.



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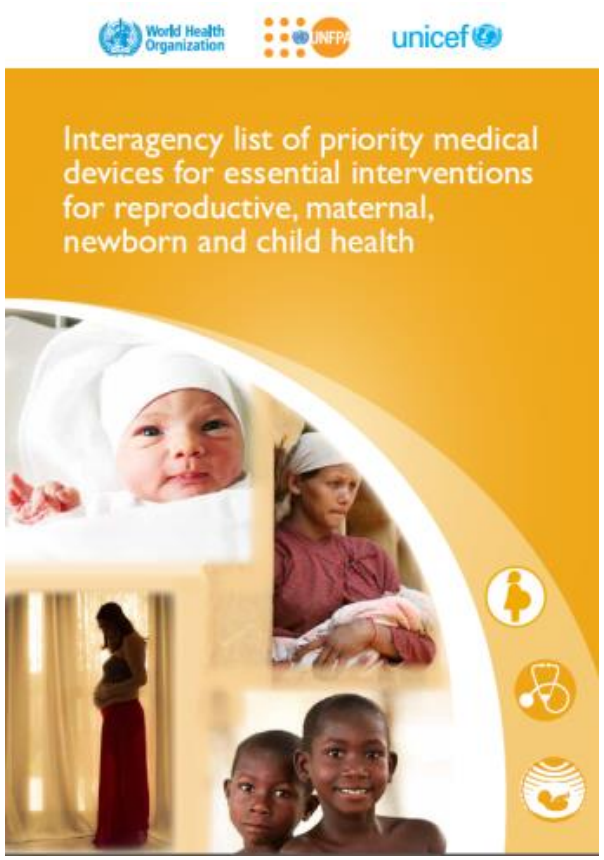
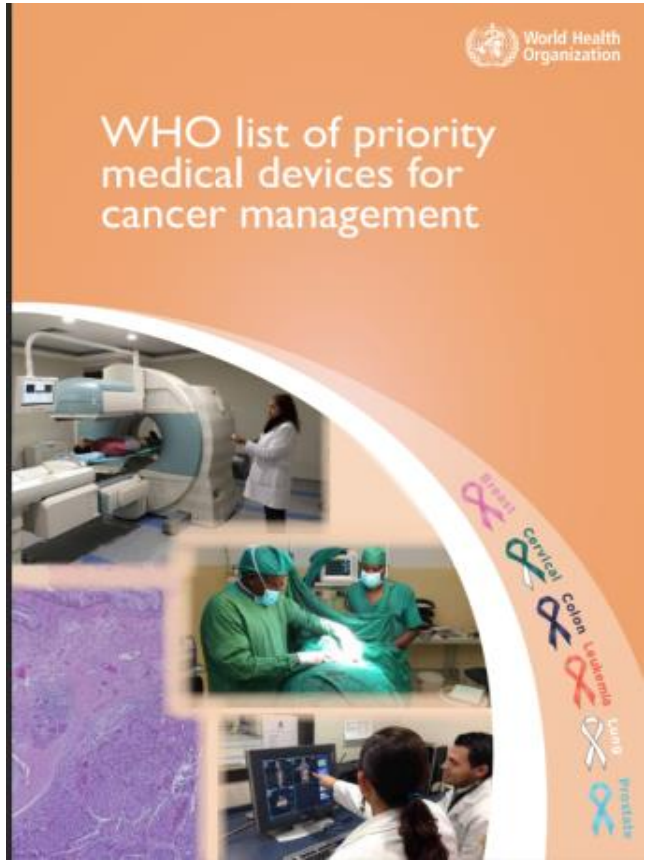
WHO Lists of Priority medical devices by interventions and levels of care

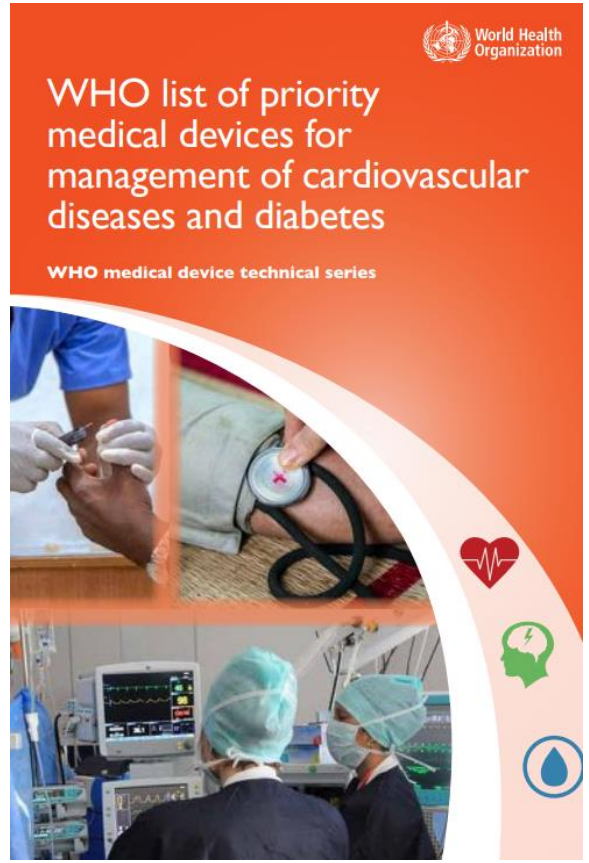
2015



2017



2021



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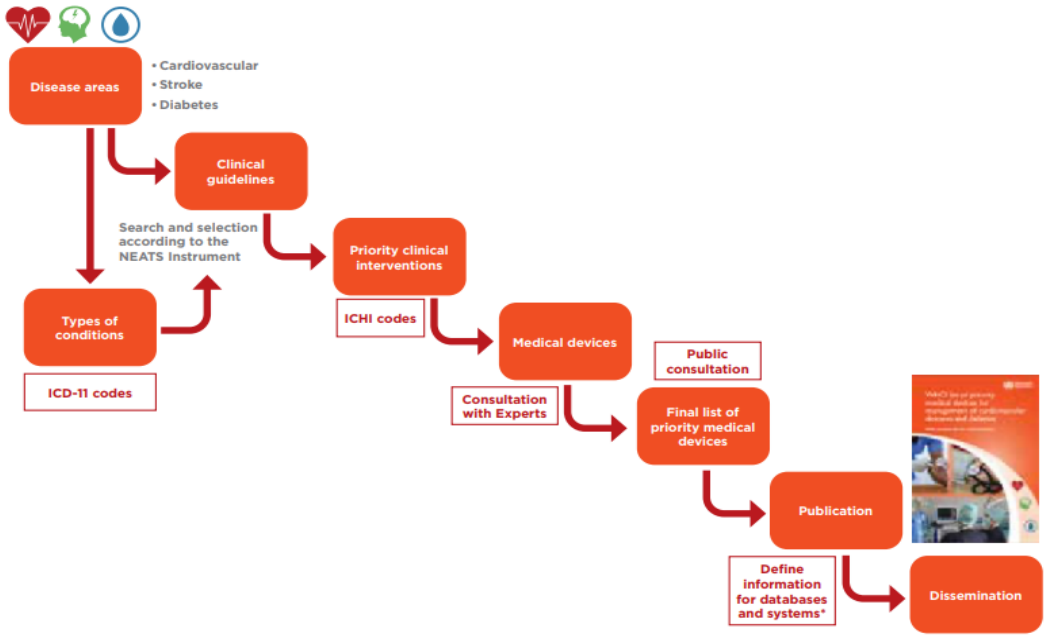
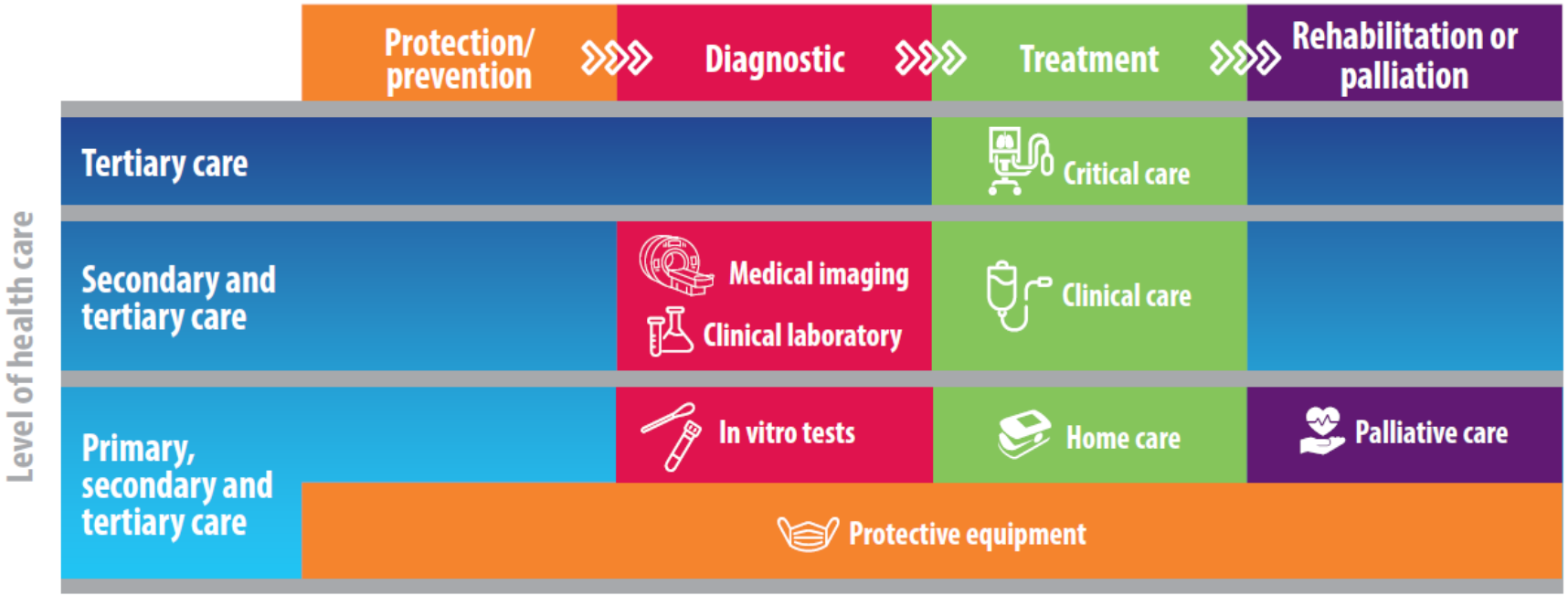
II. Methodology

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 *or* Video-laryngoscope, with blades and accessories	Compressible self-refilling ventilation bag for adult, capacity > 1500 mL, with masks (small, medium, large) 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 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 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	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	
Non-invasive ventilation	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			
Invasive ventilation	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			
Infusion therapy	Electronic drop counter, IV fluids			
	Infusion pump, with accessories			
Intensive care treatment	Electrocardiograph, portable, with accessories			
	Suction pump	Electrical, with accessories		
		Manual		
Central venous catheter placement	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

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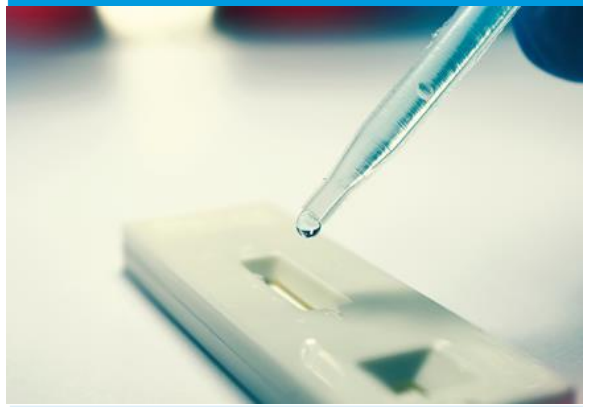
Presentation of the EDL 3

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

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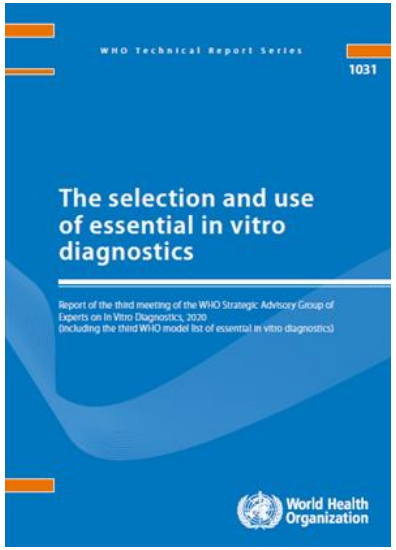
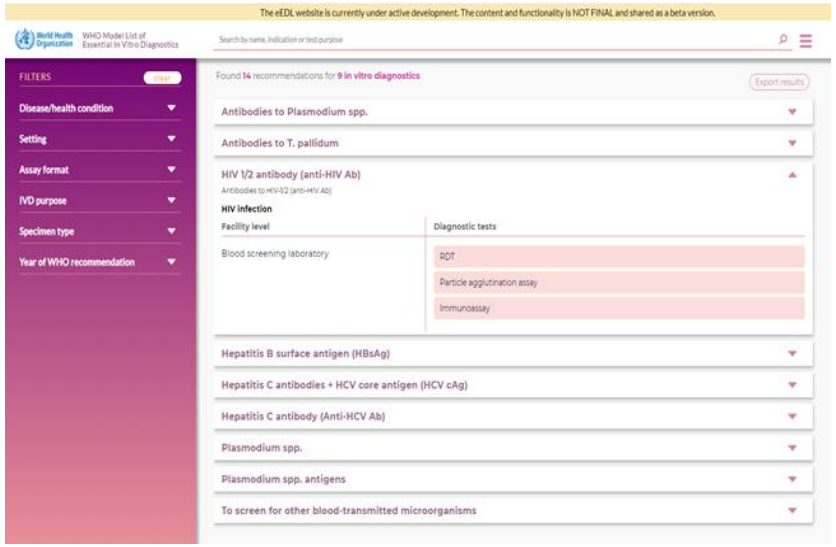
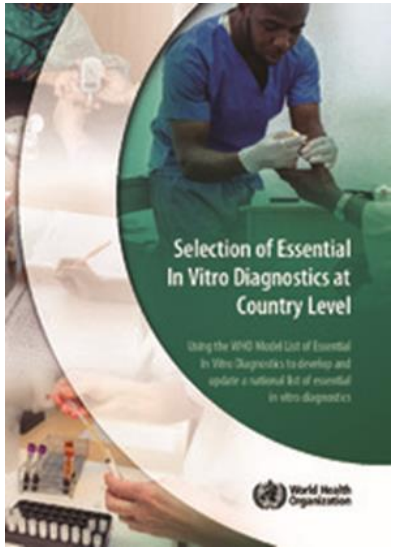
Tools to support countries

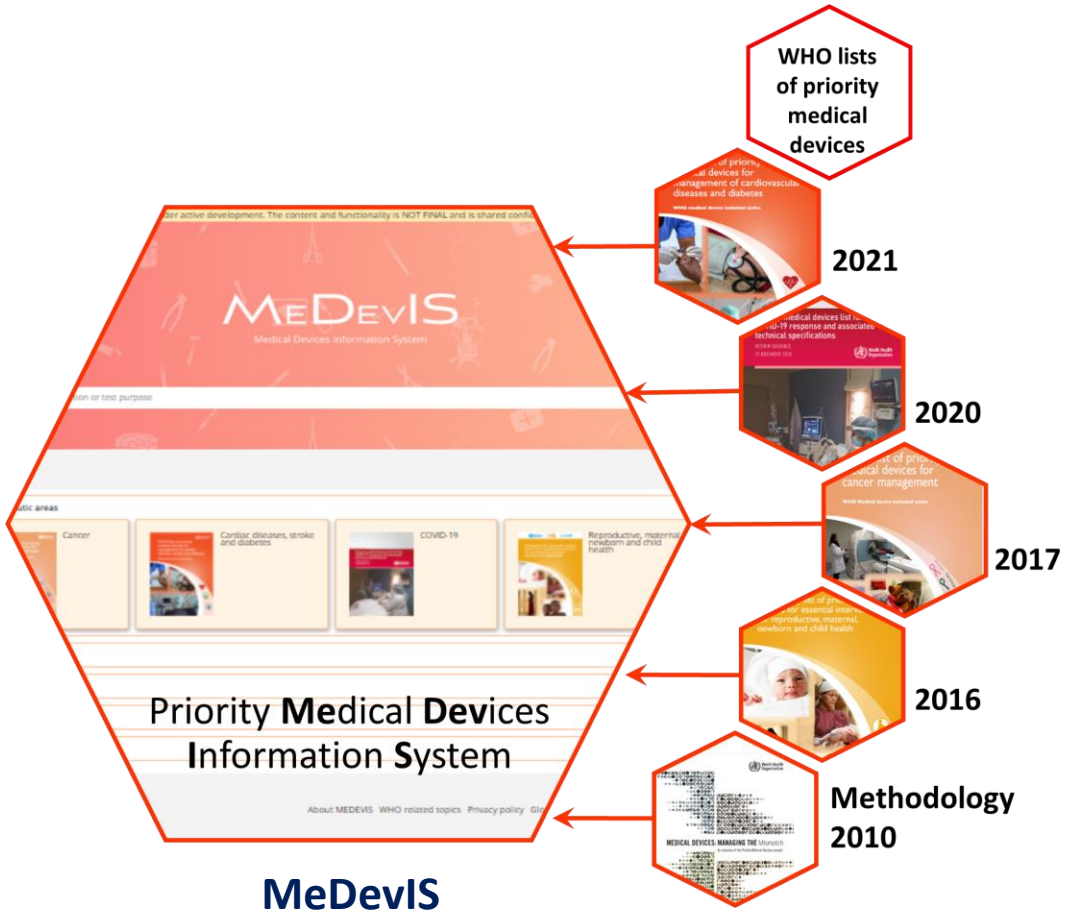
- 1.WHO Technical Report Series: The selection and use of essential IVDs
- 2.Electronic EDL (eEDL)
- 3.Selection of essential in vitro diagnostics at country level: using the WHO Model List of Essential In Vitro Diagnostics to develop and update a national list of essential in vitro diagnostics
- 4.Technical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



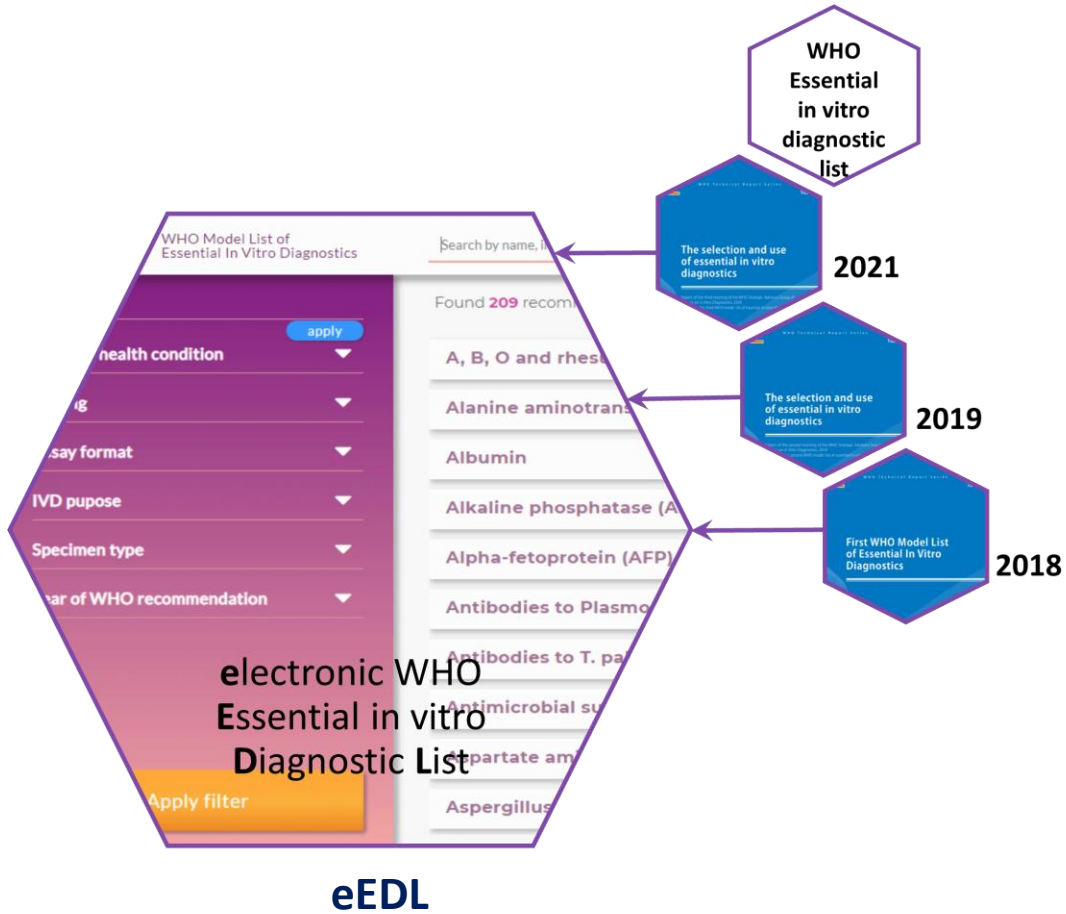




Moving toward electronic databases

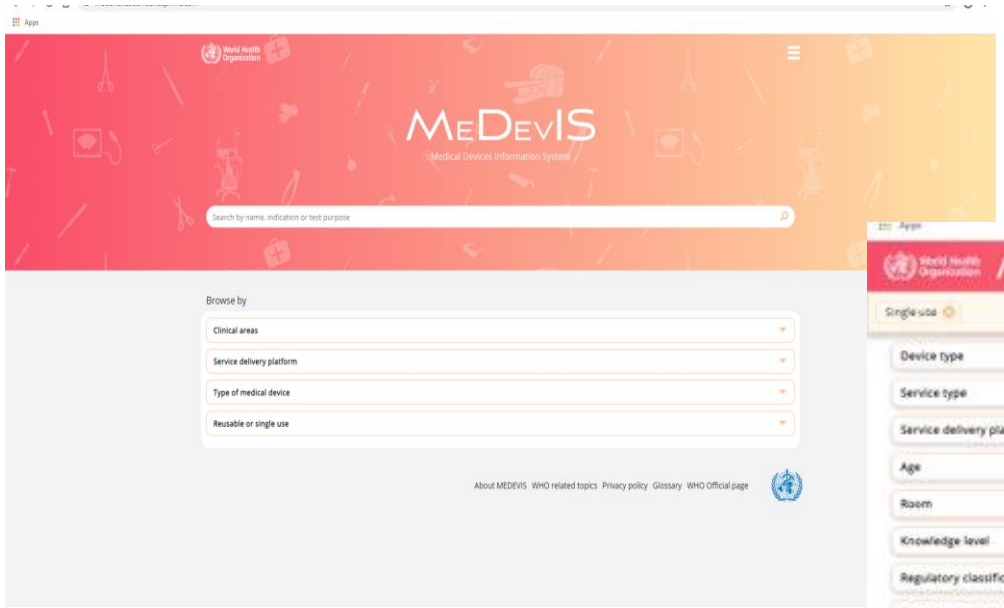


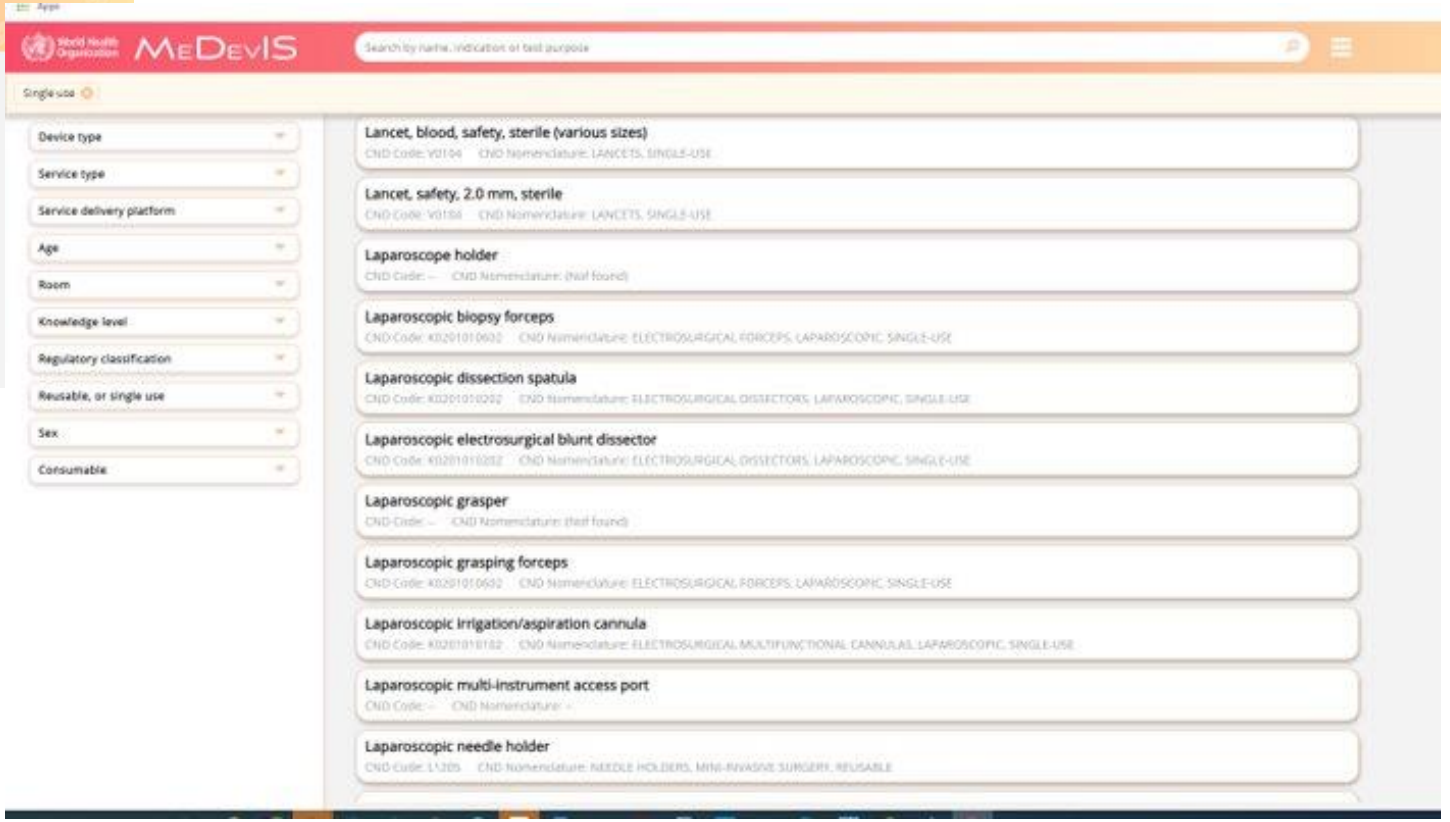
MeDevIS



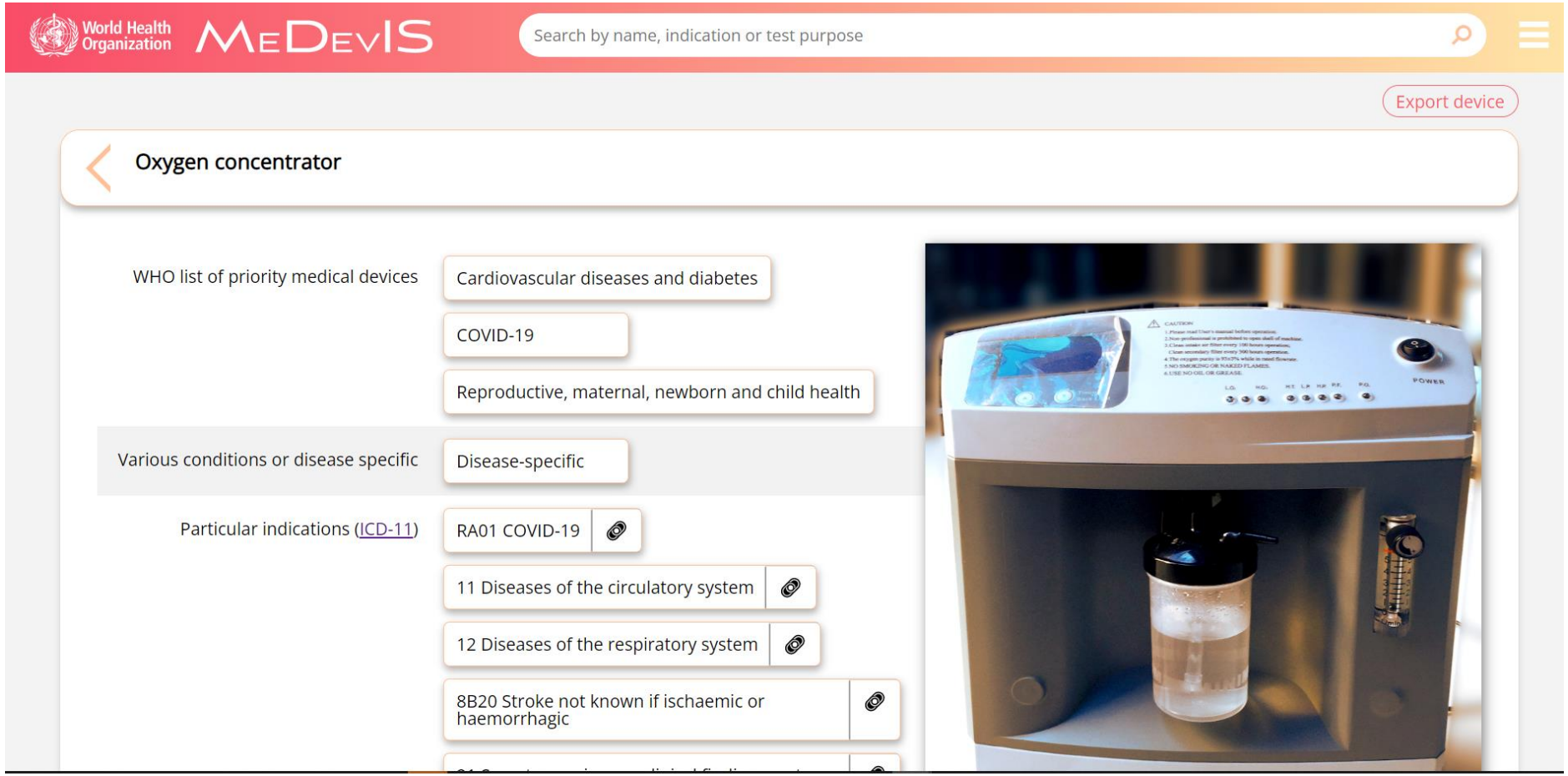
eEDL

Priority medical devices information system **MeDevIS**

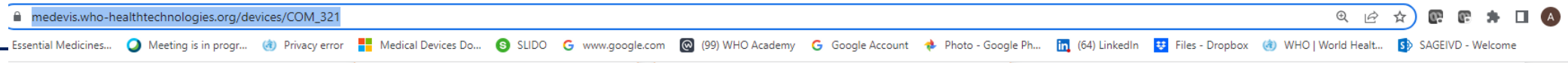




https://medevis.who-healthtechnologies.org/



https://medevis.who-healthtechnologies.org/devices/COM_321



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 © ECRI. All rights reserved			
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

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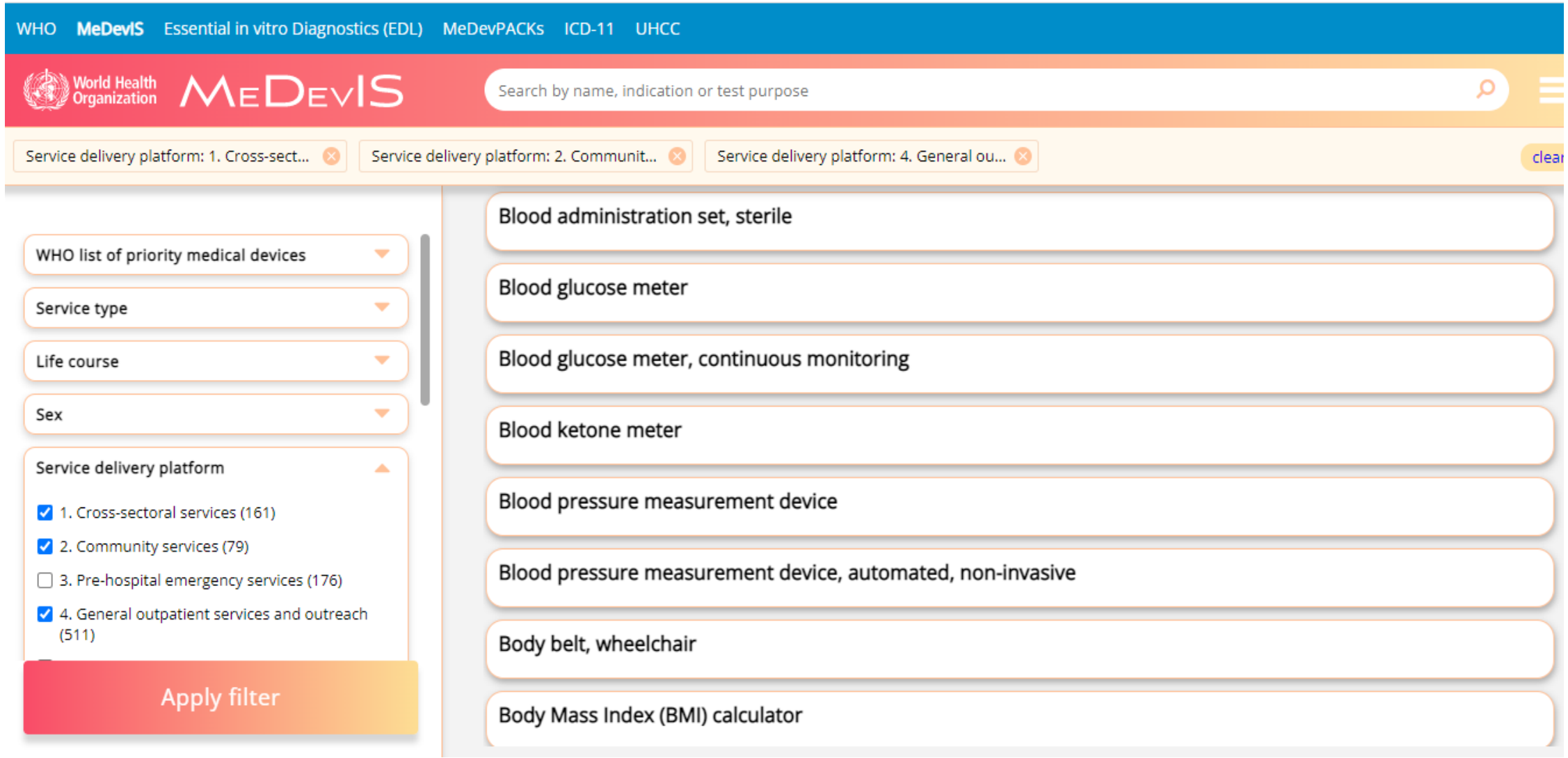
Links to WHO publications, technical specifications and training material

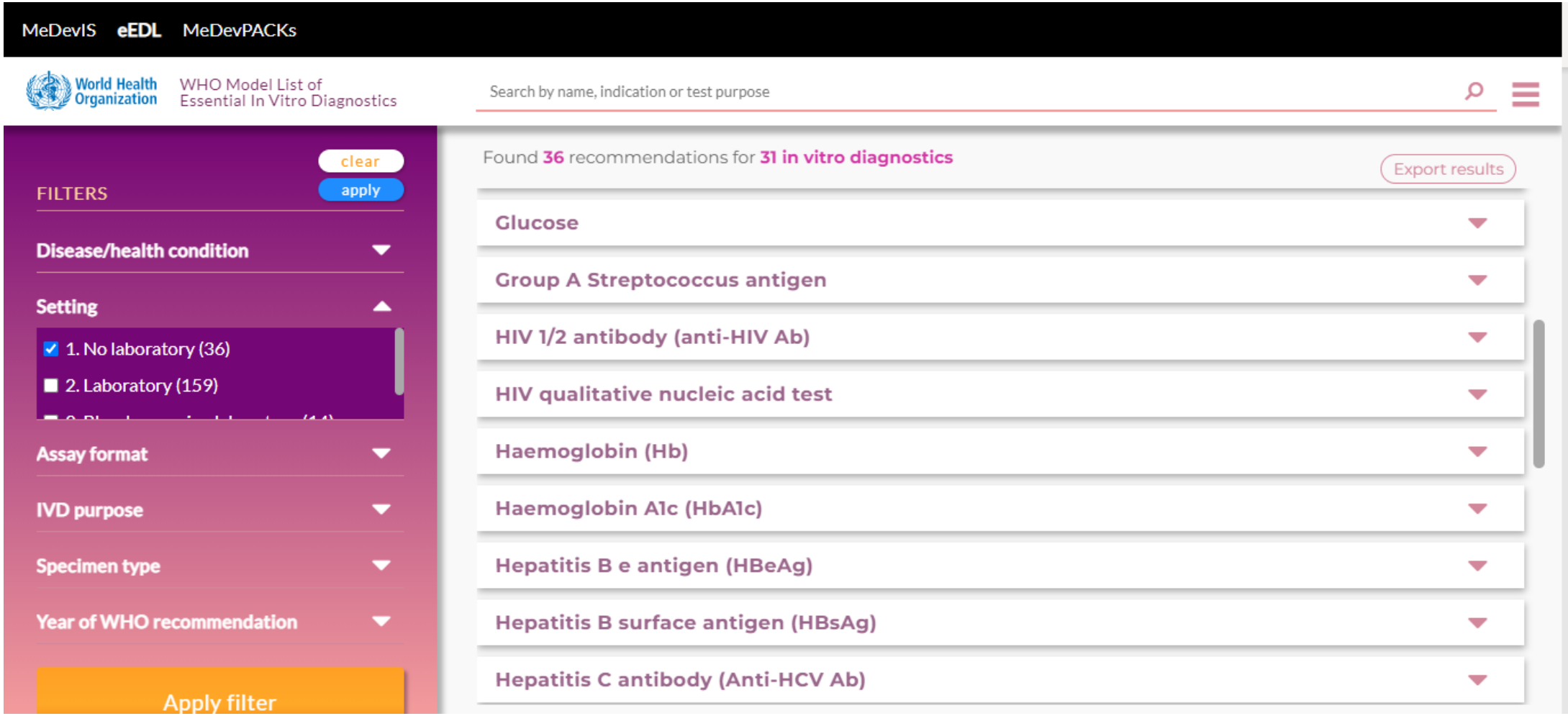
PMD books	Interagency list of priority medical devices for essential interventions for reproductive, maternal, newborn and child healt WHO list of priority medical devices for cancer management WHO List of Priority Medical Devices for management of cardiovascular diseases and diabetes WHO List of Priority 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	Basic Delivery room Commodity 1 Basic Freestanding Emergency Departments (Urgent Care) Commodity 1 Basic Intensive care Commodity 1 Basic Intensive care Commodity 1 Basic Obstetrics Commodity 1 Basic Obstetrics Commodity 1 Basic Pediatrics Commodity 1 Basic Pediatrics Commodity 1 BASIC Sub-acute care Set 2 Basic Surgical Units Commodity 1
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 60601-1-9:2013 ISO 13485:2003 ISO 14971:2007

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



e-EDL electronic platform

e-EDL: No laboratory settings



World Health Organization

Global Implementation:

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

WHO

Review of evidence, guidelines, types of medical devices for interventions

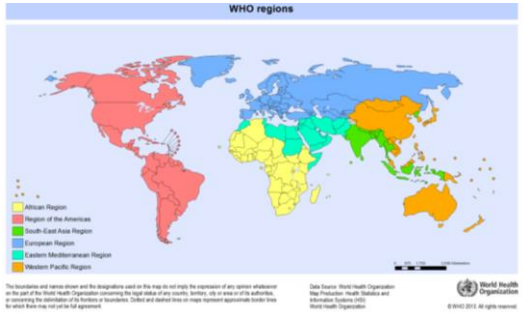
Expert input, Public consultation

Recommendations by SAGE IVD / STAG MEDEV

Publication of list and update e-EDL, MEDEVIS, UHCC, ICD

Country: National committee

WHO
EDL PMD



National lists prioritized

Local needs: epidemiology , resources, committee

Health facilities. Final users

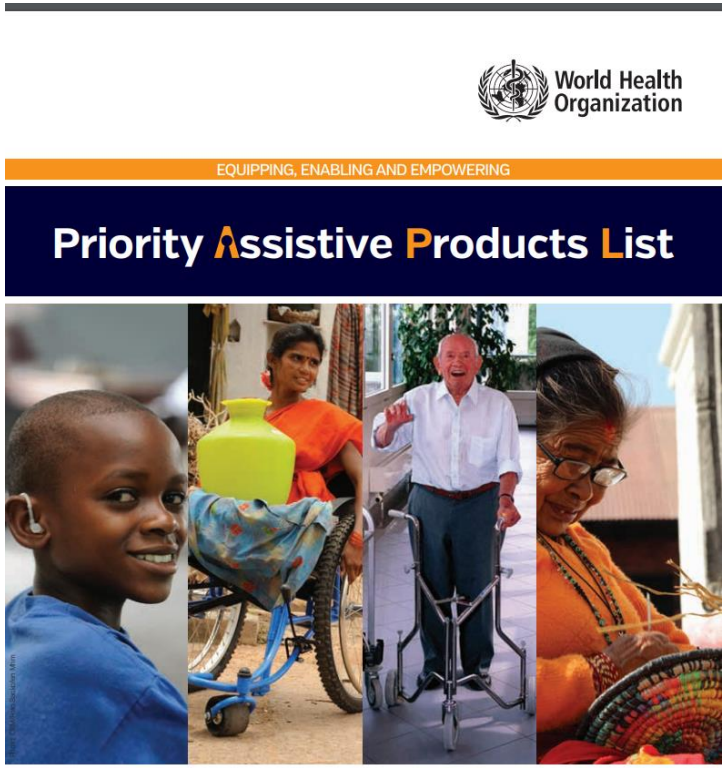
Specialized care, 3rd level

2nd level

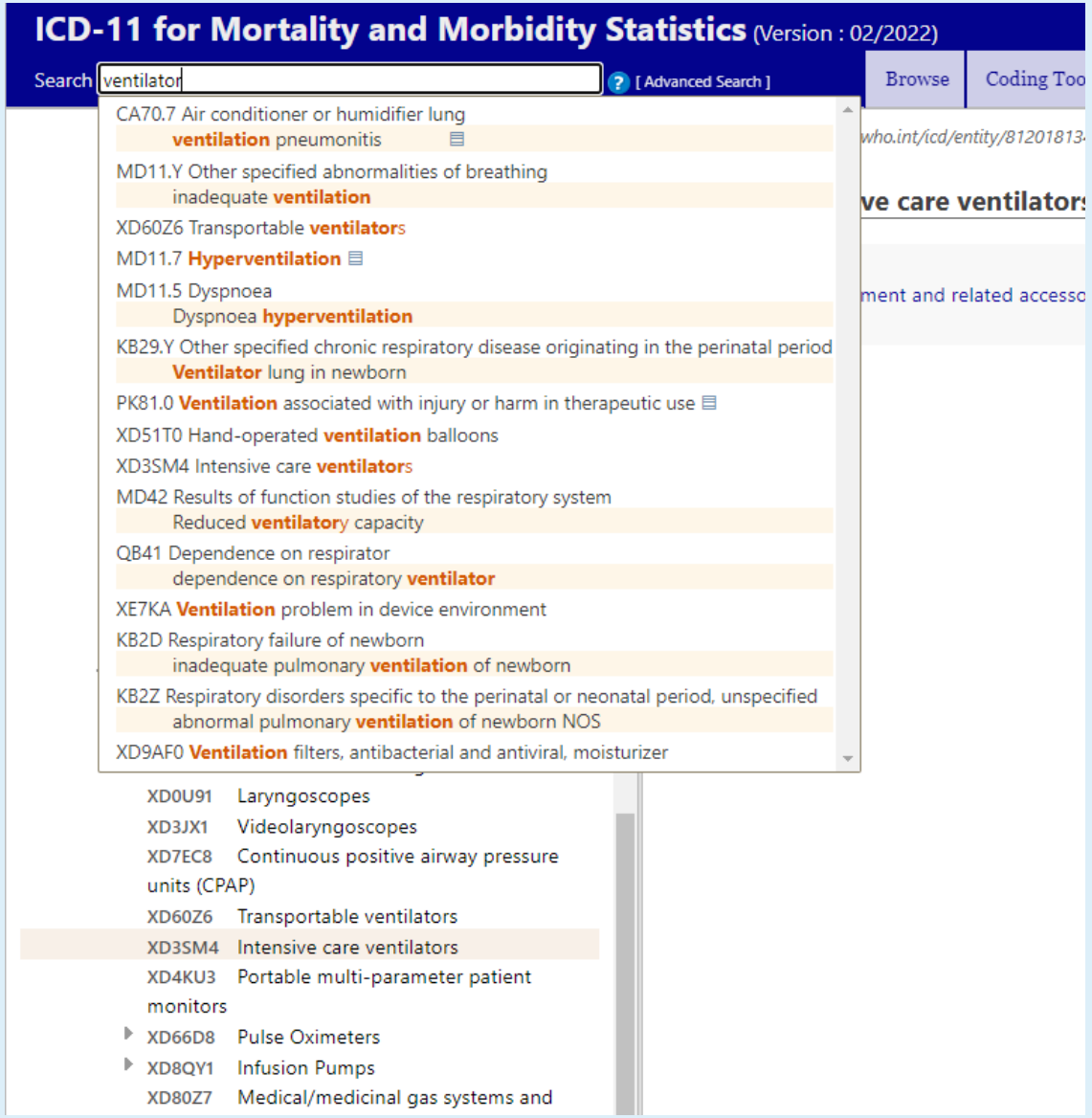
Primary care

Other complementary lists: Priority assistive products

2017: 50 types



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



Towards the 2023 compendium of innovative technologies for low resource settings

World Health Organization

75 HEALTH FOR ALL

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

World Health Organization 75 HEALTH FOR ALL

https://www.who.int/activities/accelerating-impact-for-innovations-for-health

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.

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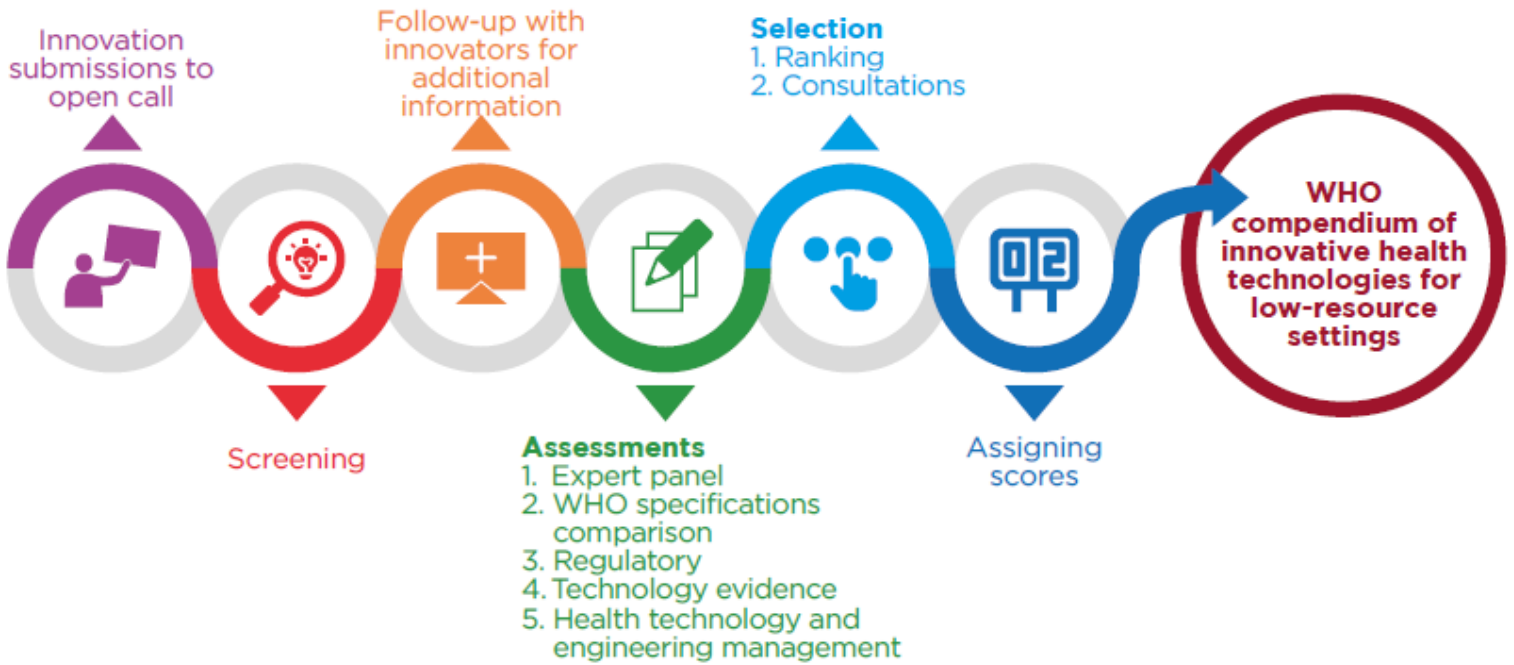
Methodology

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

	→	⚠	✕	N/A
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 appropriate-ness for low-resource settings	Moderate appropri-ateness for low-resource settings	Low appro-priateness for low-resource setting	Not Applicable

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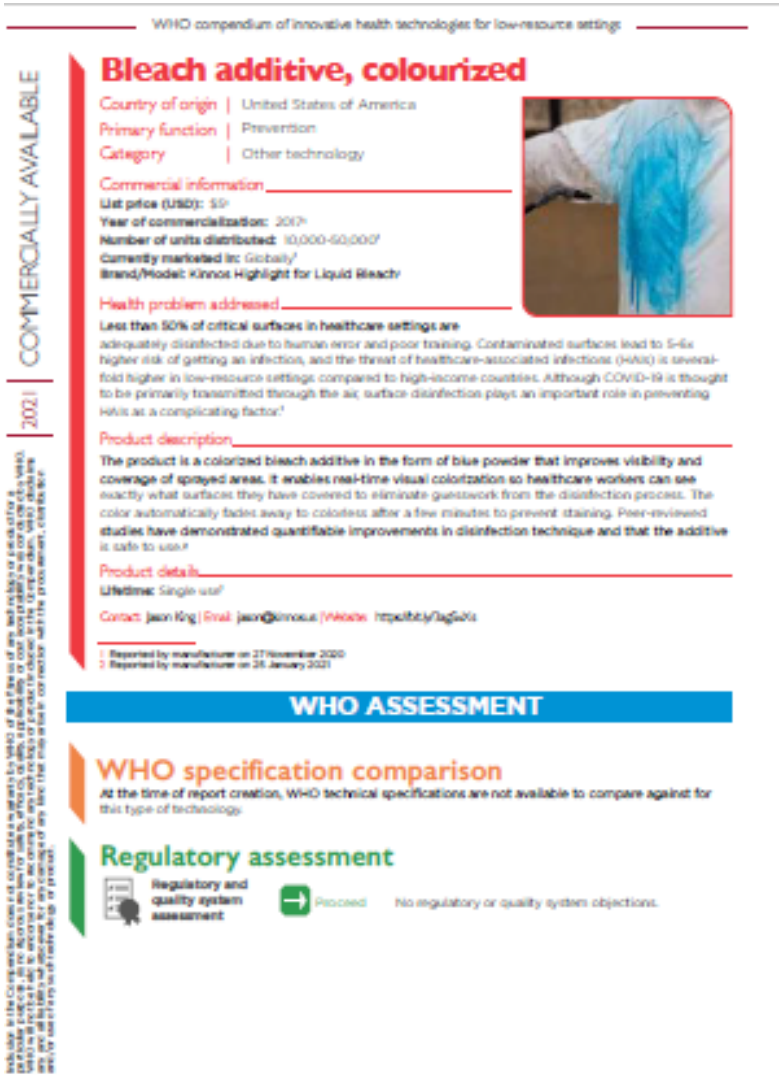
Example of a compendium page



WHO compendium of innovative health technologies for low-resource settings

COMMERCIALLY AVAILABLE | 2021

Bleach additive, colourized

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

Commercial information

List price (USD): $9[1]
Year of commercialization: 2017[1]
Number of units distributed: 10,000-50,000[1]
Currently marketed in: Globally[1]
Brand/Model: Kinnos Highlight for Liquid Bleach[1]

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 (HAIs) 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 HAIs as a complicating factor.[1]

Product description

The product is a colorized 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.[2]

Product details

Lifetime: Single use[1]

Contact: Jason King | Email: jason@kinnos.us | Website: https://bit.ly/3aGaXs

1 Reported by manufacturer on 27 November 2020
2 Reported by manufacturer on 26 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 — Proceed — No regulatory or quality system objections.

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

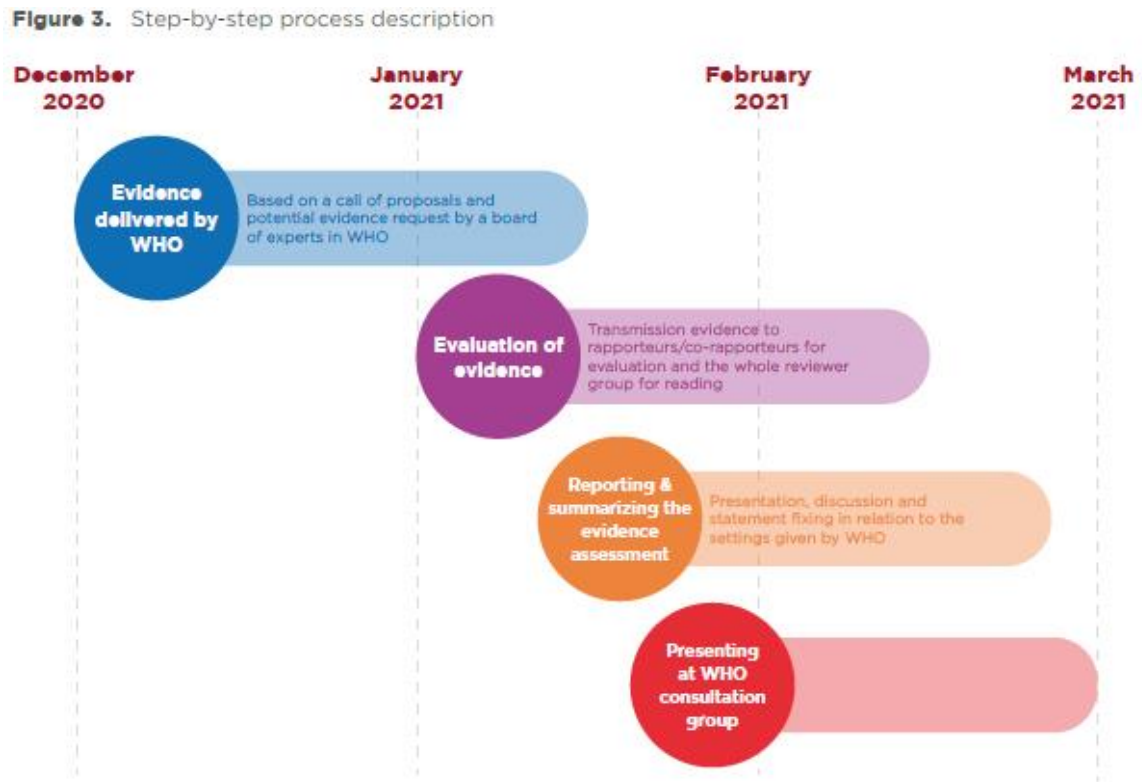
Domains	Appropriateness
Durability	!
Ease of Use	→
Positive impact on clinical outcomes	→
Affordability	→
Engineering resources minimization	→
Cultural and social acceptability	→
Environmental conditions	!

Domains	Appropriateness
Ease of maintenance	!
Infrastructure requirements	→
Local access to sales support	N/A
Local access to technical support	N/A
Local access to training	N/A
Local access to spare parts	N/A
Local production	→
Locations of	

Target setting: Public and home settings

The purpose of this product is to aid in infection prevention. It uses a patented colorized 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.

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



Process in 2021

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 75[1]

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**

(1) https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75_11Add1-en.pdf

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.

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

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/