AHWP Oman
14 November 2019

Regulation of medical devices to improve Global Health. WHO update

Adriana Velazquez, Senior advisor on medical devices, 8 October, 2019.

World Health Organization

Goal 3. Good health and well being

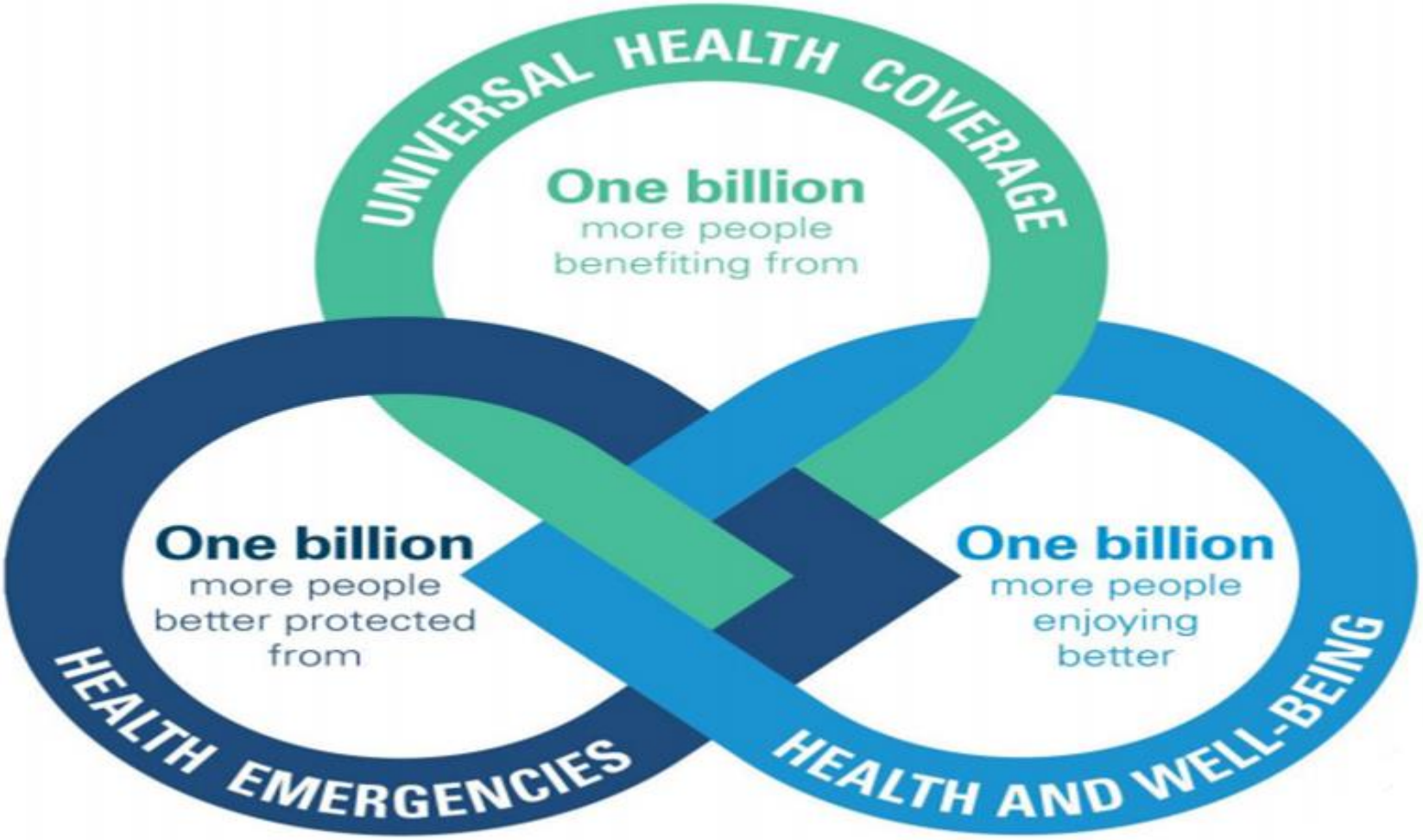
World Health Organization

Global health problems

13th WHO Global Programme of Work:

"Triple Billion" targets

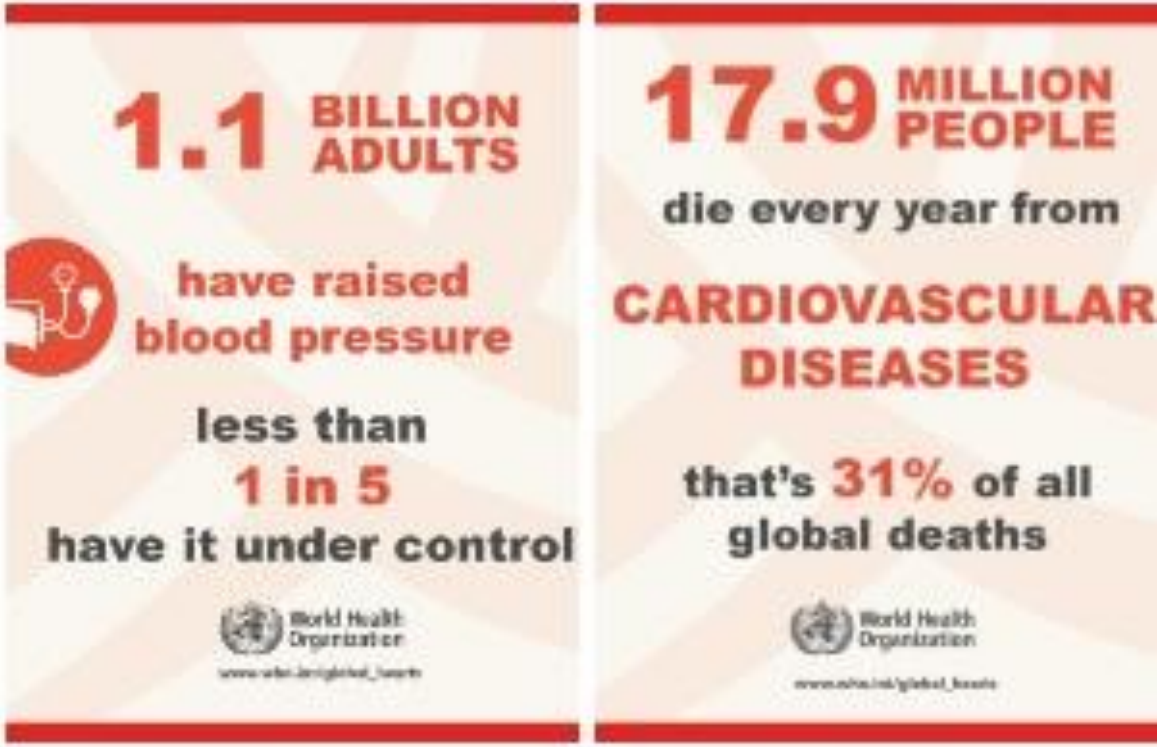
World Health Organization



Hypertension

Selecting affordable, effective, Technologies to tackle NCDs

Facts



WHO work under development

5 billion people lack access to safe and affordable surgery

Lancet commission on Global Surgery

Emergency and essential surgical care

Five billion people lack access to safe and affordable surgery

In 2015, The Lancet Commission on Global Surgery produced a report – Global Surgery 2030 – which outlines five key approaches for improving universal access to safe and affordable surgical and anaesthesia care. Review the report overview below and learn more about other key findings, too.

Global Surgery 2030: Report Overview

The Lancet Commission on Global Surgery

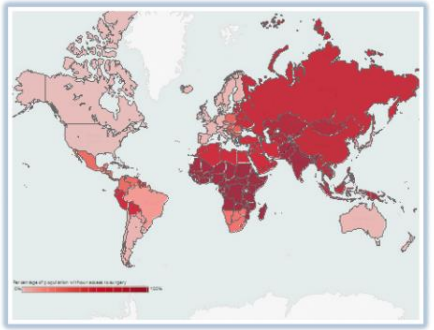
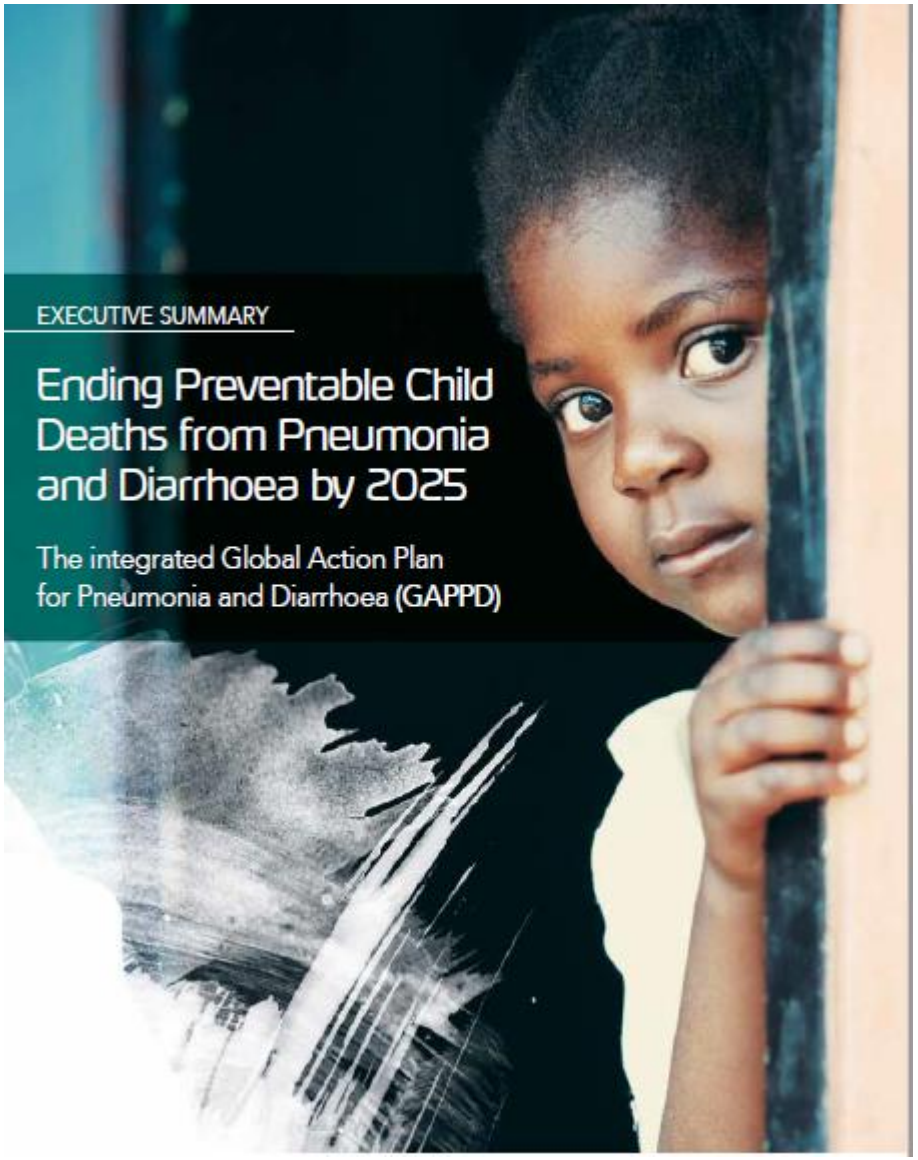


Figure 1. Proportion of the population without access to safe, affordable surgery and anaesthesia by region

https://www.who.int/surgery/en/ and http://media.wix.com/ugd/346076_713dd3f8bb594739810d84c1928ef61a.pdf Lancet commission

Pneumonia

Number 1 killer for less then 5 years old.



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Patient Safety

Magnitude

4 out of 10

Up to 4 out of 10 patients are harmed in primary and ambulatory care settings

Incidence

134 million

134 million adverse events occur each year in hospitals in LMICs, contributing to 2.6 million deaths annually due to unsafe care

Speak up for patient safety!

No one should be harmed in health care

World Health Organization

World Patient Safety Day 17 September

World Health Organization

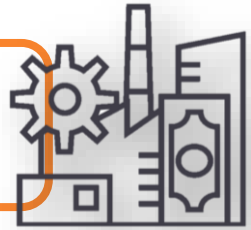
WHO has developed guidance for you on medical devices

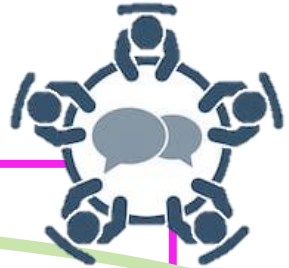
To ensure improved access of safe, quality medical devices

World Health Organization

R&D

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





Assessment

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

Common elements in dossier

Regulations

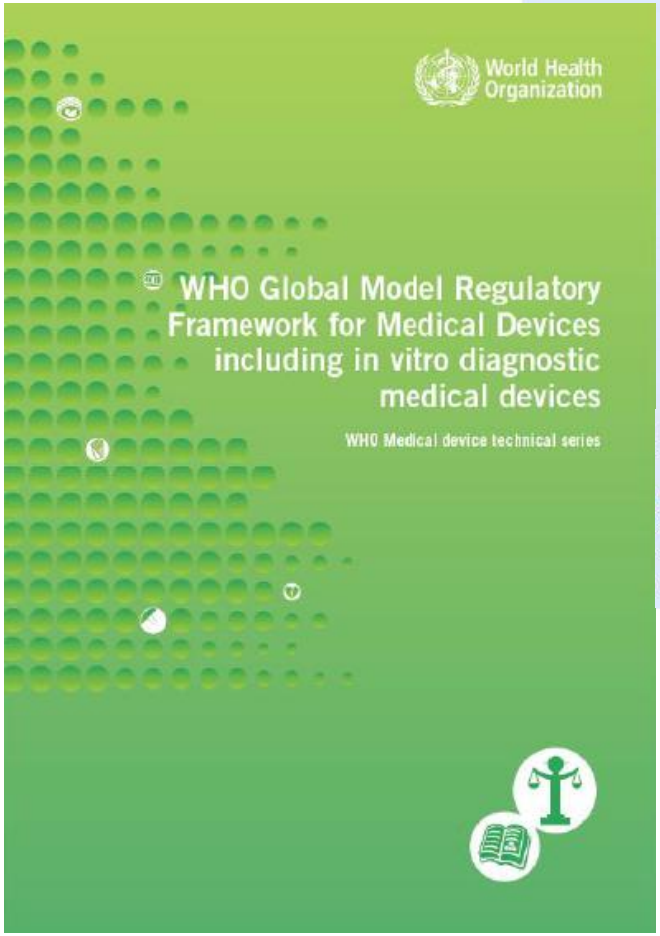
- Regulation process of medical devices
- Lists of approved MD for marketing in country.

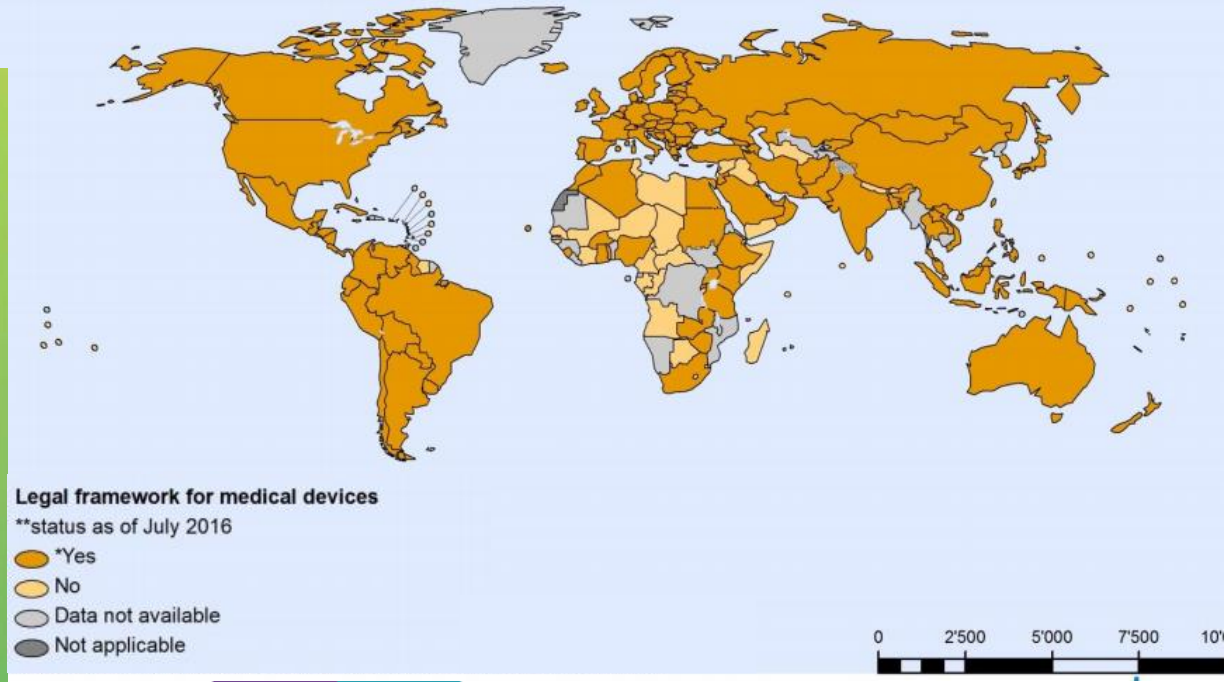
Management

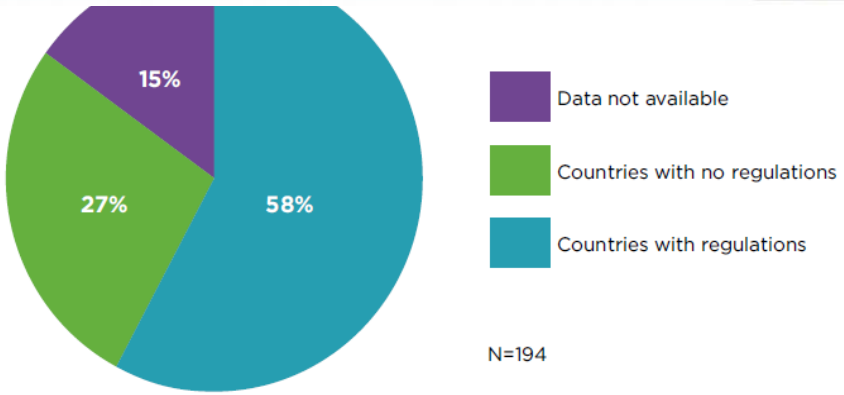
- 1. Needs Assessment 2.Selection 3. Incorporation: (procurement, donations, loan…)
- Installation, inventories, training, maintenance, operations
- Safe use, operating costs and clinical effectiveness
- Post market surveillance and adverse event report
- Decommissioning, Replacement

National regulatory authorities in the governments decide which medical devices can enter the local market (WHA67.20)

World Health Organization







Human Resources (Biomedical Engineers)

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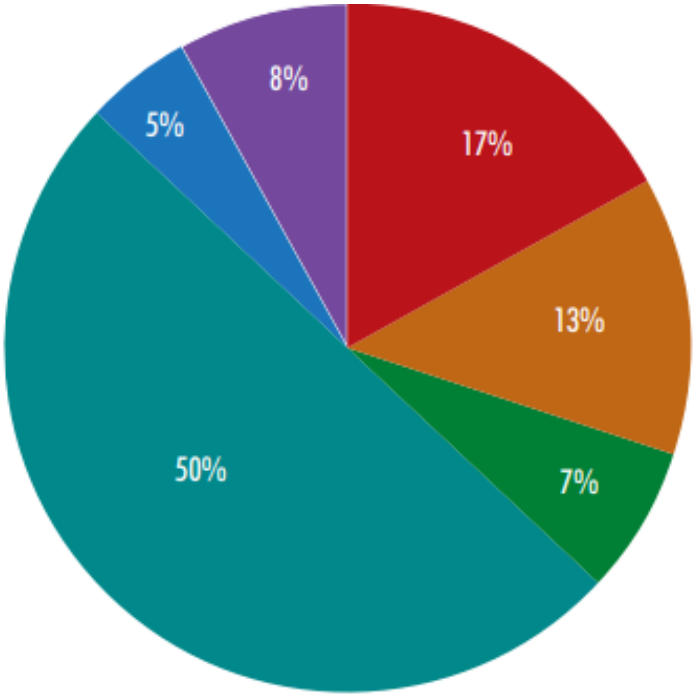
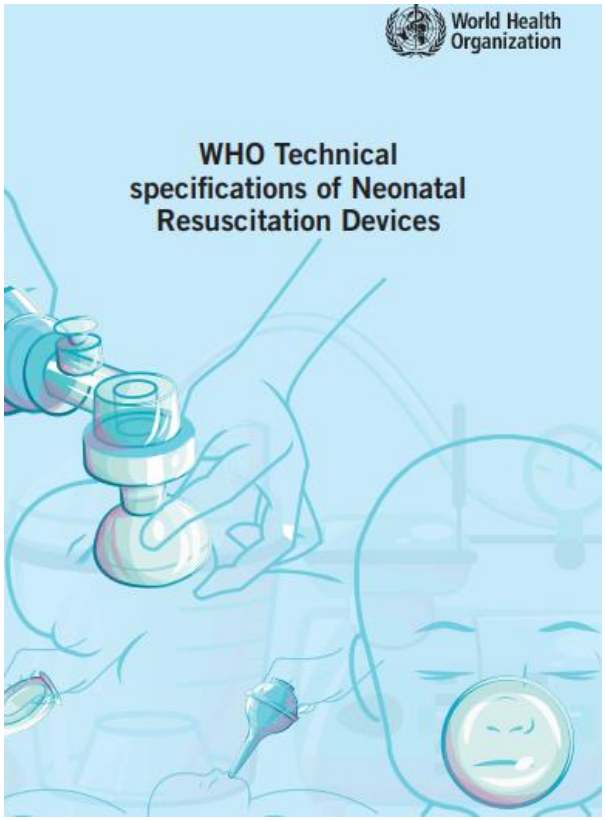
Countries with at least one BME professional association by WHO region

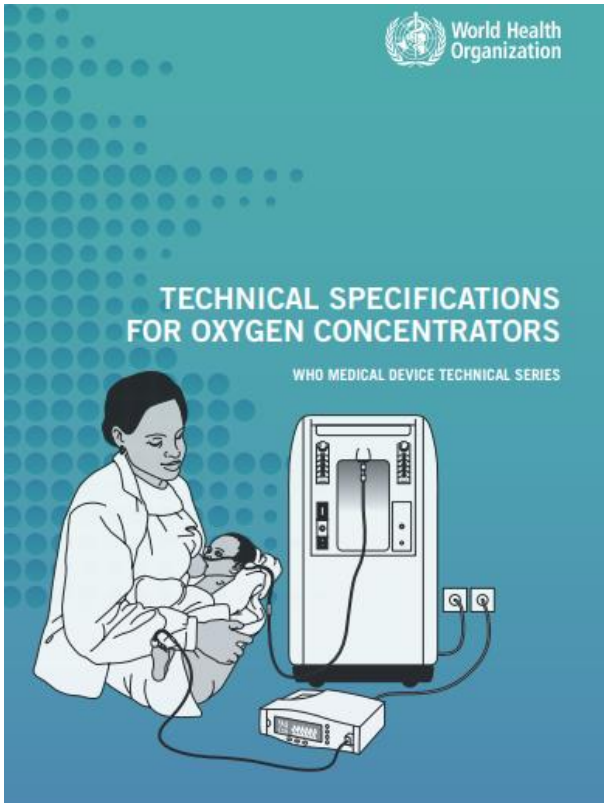


Source: Data was reported in surveys launched by WHO from 2009–2015.

Guide & Technical specifications for different Devices

World Health Organization





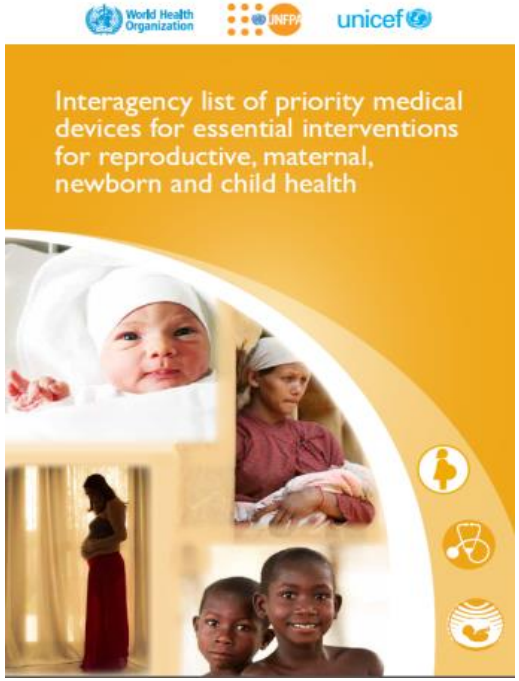
- Blood pressure measurement
- Radiotherapy equipment
- Oxygen delivery systems
- Devices for screening and treatment of precancerous lesions

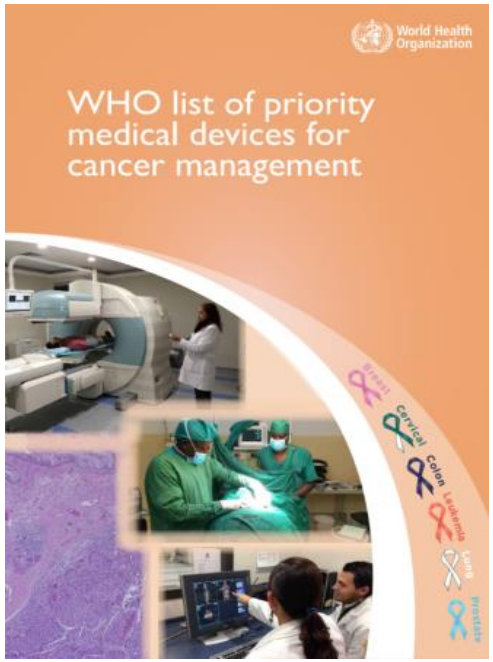
2019

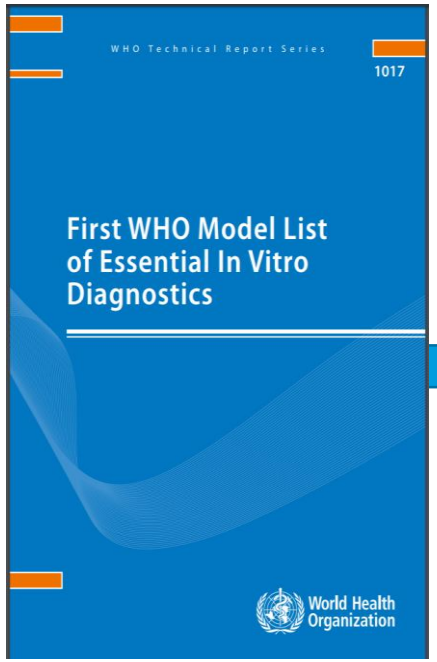
WHO has been selecting and publishing: Priority Medical Devices (PMD) and essential in vitro diagnostics (EDL)

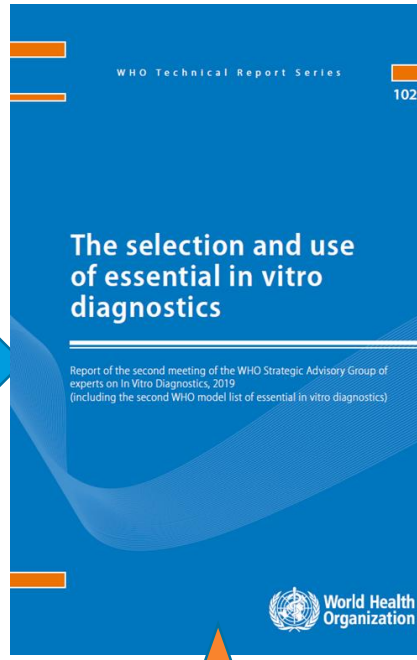
World Health Organization

2015, 2017, 2018, 2019 …..





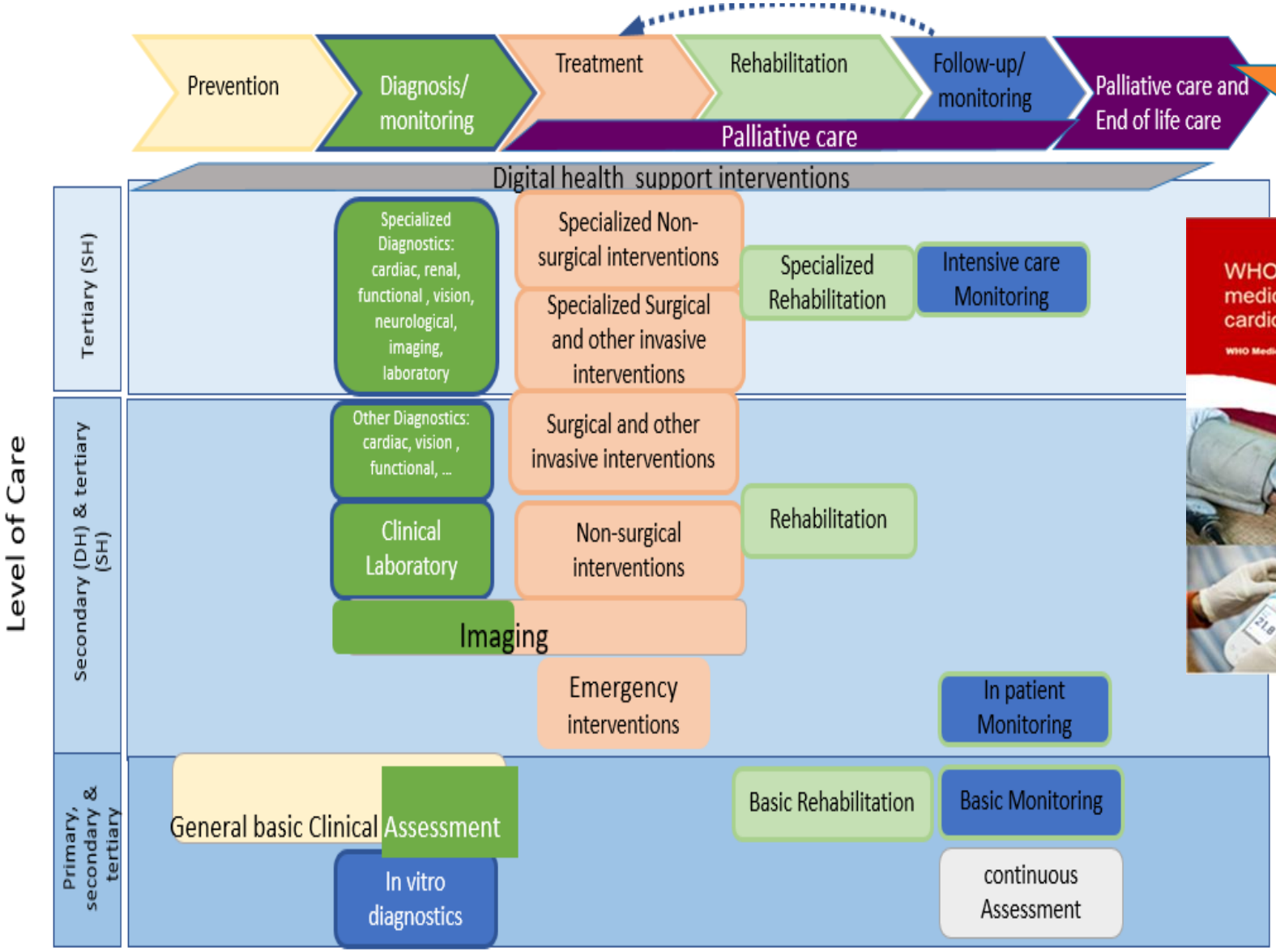


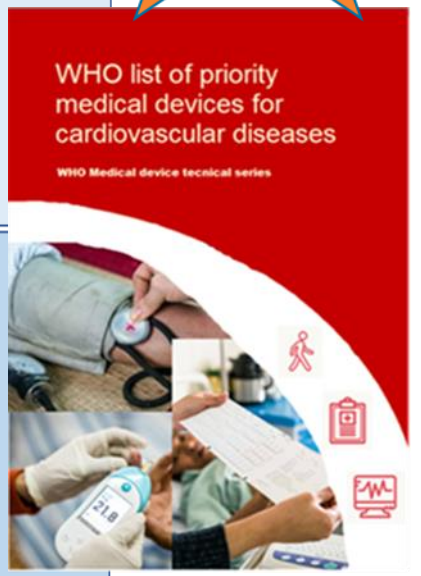


2019

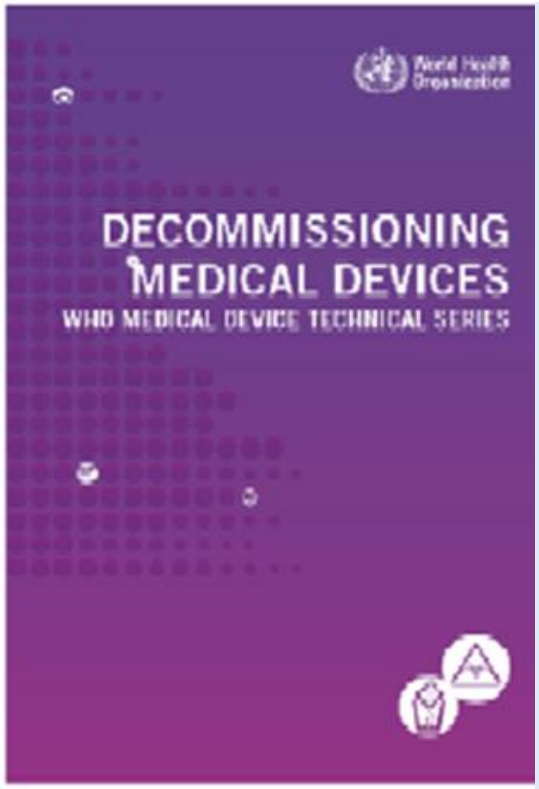
End 2019: Priority Medical devices for cardiac, stroke and diabetes

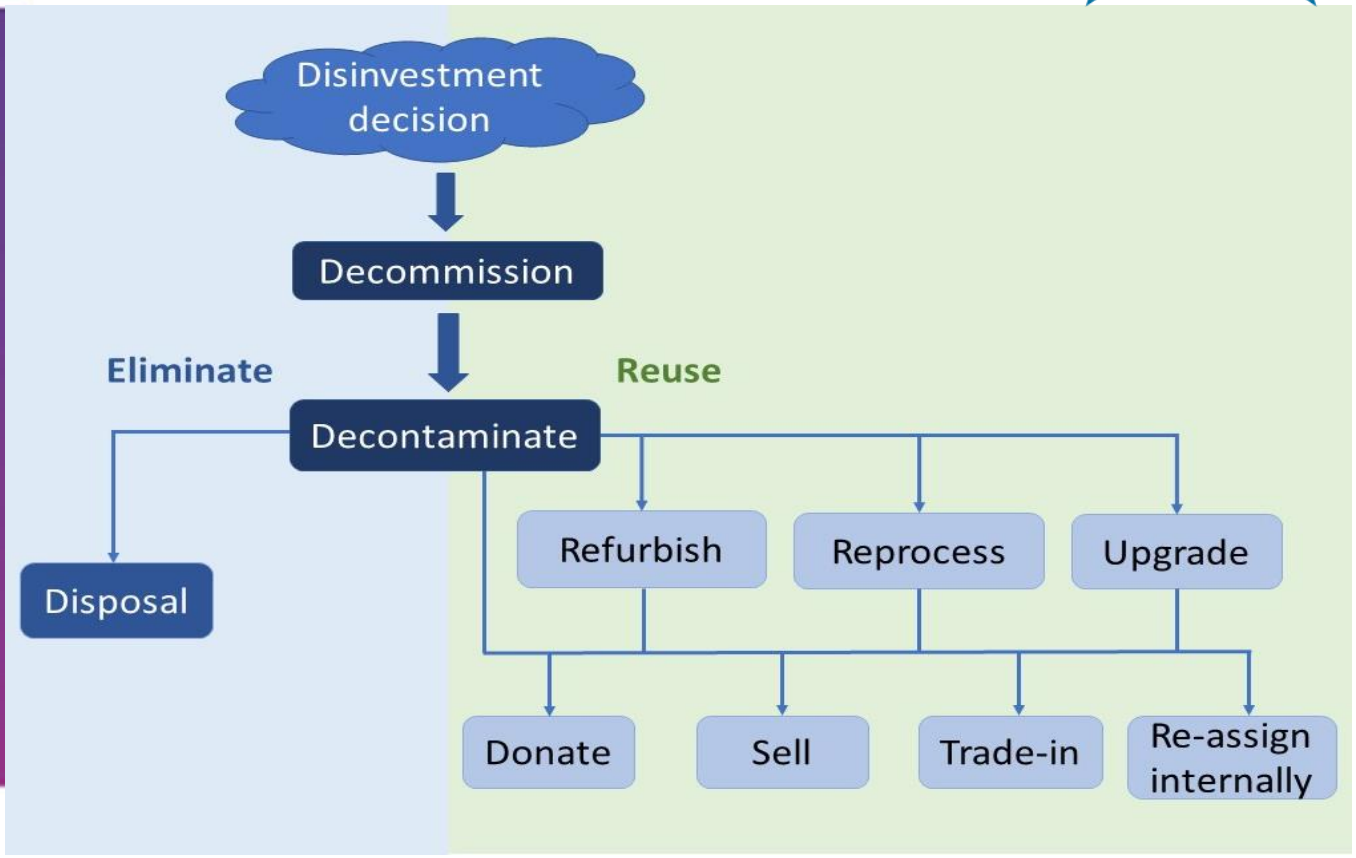
World Health Organization





End 2019:
Decommissioning of Medical Devices





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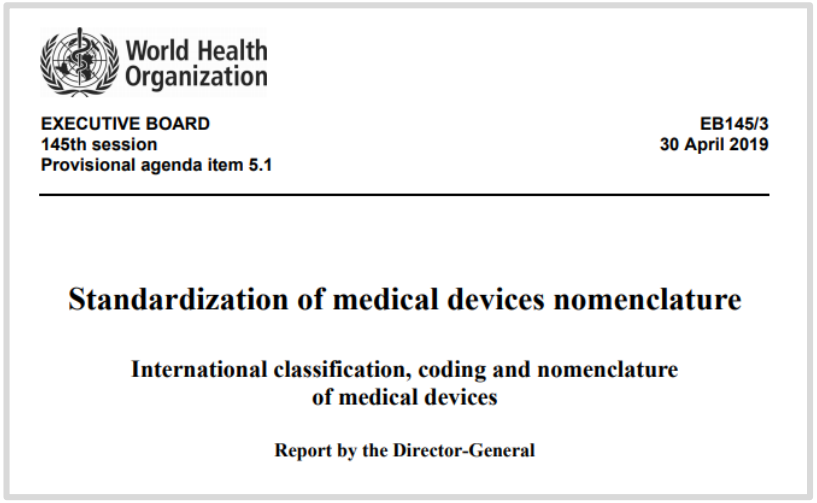
Nomenclature of medical devices.

WHO working on an international nomenclature of medical devices including IVDs for use by regulators, procurers, supply and use.

World Health Organization

Discussion on Nomenclature of Medical Devices
145th session of the Executive Board
May 2018



World Health Organization

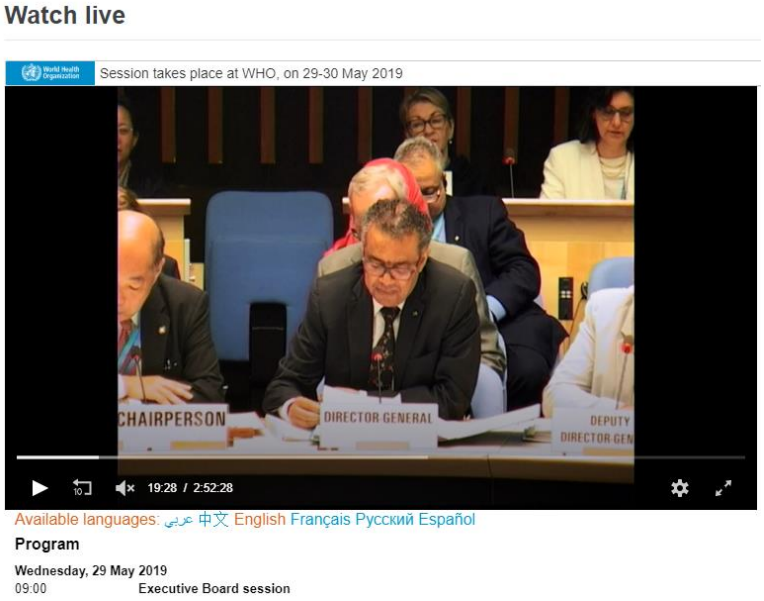
EXECUTIVE BOARD
145th session
Provisional agenda item 5.1

EB145/3
30 April 2019

Standardization of medical devices nomenclature

International classification, coding and nomenclature of medical devices

Report by the Director-General



Developing and adapting a global standard for naming medical devices is a perfect example of WHO's core normative standard-setting work

Tedros Adhanom Ghebreyesus

Standardization of medical devices nomenclature, the way forward

World Health Organization

Nomenclature to support all process : from development to use

"The goal is to have an international classification, coding and nomenclature for medical devices that would be available to all Member States and that would support: patient safety, access to medical devices for universal health coverage, quality of health care and achievement of Sustainable Development Goal 3 (Ensure healthy lives and promote well-being for all at all ages)"

Executive Board EB145/3. Report by Director General .

http://apps.who.int/gb/ebwha/pdf_files/EB145/B145_3-en.pdf?ua=1

Guiding principles for international nomenclature of Medical Devices, developed by WHO 2018 for consultation

World Health Organization

Governance

By WHO secretariat to Member states

Defined mechanism for stakeholder feedback

Reference group of experts to review new submissions/updates/

For public consultation, allowing public feedback.

Links to other WHO international nomenclatures

Characteristics

Transparent methodology to assign new terminology

Defined mechanism for updates

Hierarchical nomenclature with various levels of granularity as needed by product user

Classification, name and code generated for multiple levels

Supports translations

Access of Information

A referenced for all stakeholders

Free – a global public good

Compatible with UDI

Downloadable

Easy to search

API for exchange of information to other systems

Compatible with other international classifications

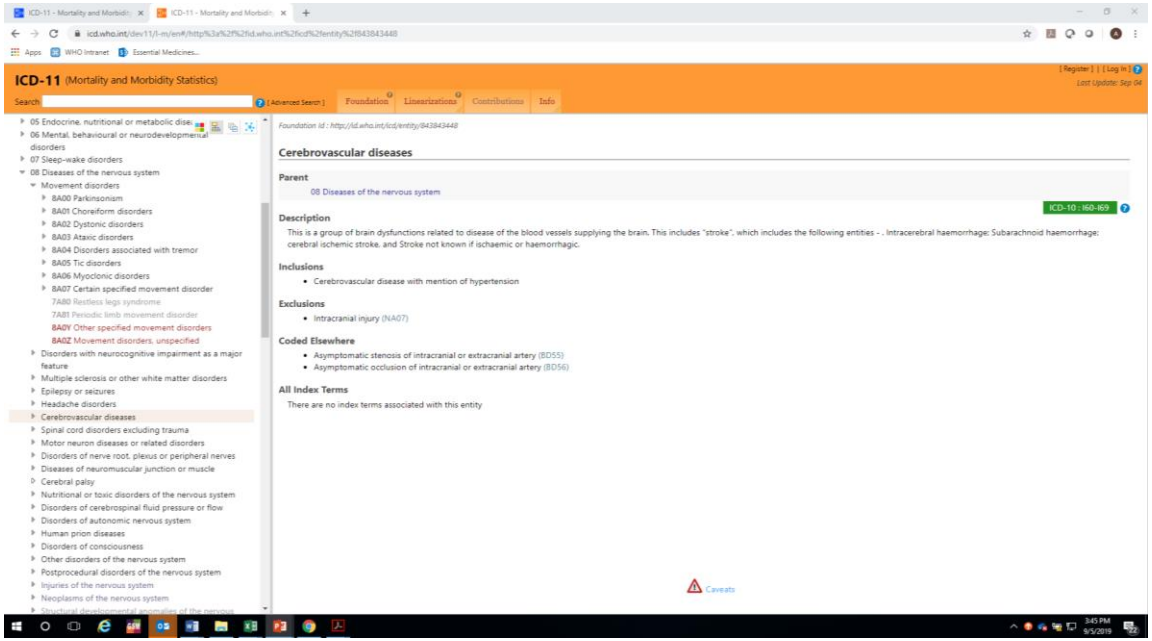
Using ontology platform which is used by ICD11 in WHO. Possibilities:

World Health Organization

https://icd.who.int/browse11/l-m/en#/http%3a%2f%2fid.who.int%2ficd%2fentity%2f1032688129

- Medical Devices
  - XD7QL5 Medical Equipment
  - XD23H7 Surgical Instruments
    - XD8JT7 Blades
      - XD8VY0 Blade, Hoitgrewe malleable
      - XD04A8 Blade, Tablet cutter, stainless steel
      - XD8PG2 Blades and handles, scalpel
      - XD4113 Blade, scalpel 10, handle 3, sterile, single use
      - XD75W9 Blade, scalpel 11, handle 3, sterile, single use
      - XD2J98 Blade, scalpel 15, handle 3, sterile, single use
      - XD3GG9 Blade, scalpel, 20, handle 4, sterile, single use
      - XD2W09 Blade, scalpel, 2, handle 4, sterile, single use
      - XD1RT2 Handle, scalpel number 3
      - XD27K4 Handle, scalpel, number 4
      - XD51M7 Handle, scalpel, number 7
      - XD1SU2 Handle, large, scalpel, number 7
      - XD2G88 Scalpel number 4 with blade
      - XD5LC5 Scalpel number 7 with blade
    - XD6MQ1 Surgical scissors
    - XD1BJ8 Dilators and probes
    - XD7JB1 Speculum
    - XD23W0 Basins/bowls
    - XD0WK5 Clamps and Clips
    - XD70Y9 Retractors
    - XD5KX4 Needle holder
  - XD3677 Medical Software
  - XD9HD1 Laboratory Equipment (non In-Vitro Diagnostic Devices)
  - XD82U5 Laboratory Supplies (non In-Vitro Diagnostic Supplies)
  - XD3WP8 Implantables

Possibilities to see: hierarchy, definitions, synonyms, exclusions, description, codes,



Governance of the nomenclature systems

Most of these receive input from the organization itself and it is not public comment.

	Universal Medical Device Nomenclature System (UMDNS)	Global Medical Device Nomenclature (GMDN)	Global Product Classifiation (GPC)	United Nations Standard Products and Services Code (UNSPSC)	Systematized Nomenclature of Medicine - Clinical Terms (SNOMED CT)	CND EUROPE
	ECRI Institute	**GMDN Agency**	**GS1 Global Office**	**GS1 US**	**SNOMED**	**EMDN**
Complies with WHO concept note: Global public good, freely available, to all stakeholders Transparent process code assignation, addition or removal Have organizational and review structures in place to ensure that all stakeholders (in particular experts, regulators, procurers and users) from different regions are able to regularly (at least annually) provide feedback. Downloadable for all CMMS systems, other international systems.	✘	✘	✘	✘	✘	✓

WHO process as requested by EB members:

Q3
- Develop comparative analysis of different nomenclatures

Q4
- Develop a circular letter
- Invite to a missions briefing in WHO
- Do country web based consultation November

Q1
- Analyze results of consultation
- Provide results in report to EB
- To be discussed in EB

Timeline proposal on technical input

World Health Organization

WHO/ EU collaboration > Consultants to review 7,000 CND terms

Bulk upload or ICMD terms to the WHO ICMD platform

WHO does analysis and country consultation to report to EB

ICMD goes live on the ICD-11 platform for e EDL and MEDEVIS for EUDAMED

EU Decision to use CND to develop EU nomenclature

EU to map CND to GMDN

Dissemination of the first version

Presentation at IMDRF

Teleconference with NGOs, WHO collaborating centres (CC) and other stakeholders
13 May

Presentation at 4th Global Forum on Medical Devices, India
13 Dec

WHO-EU meeting
12 Apr

144th Executive Board session
29 May

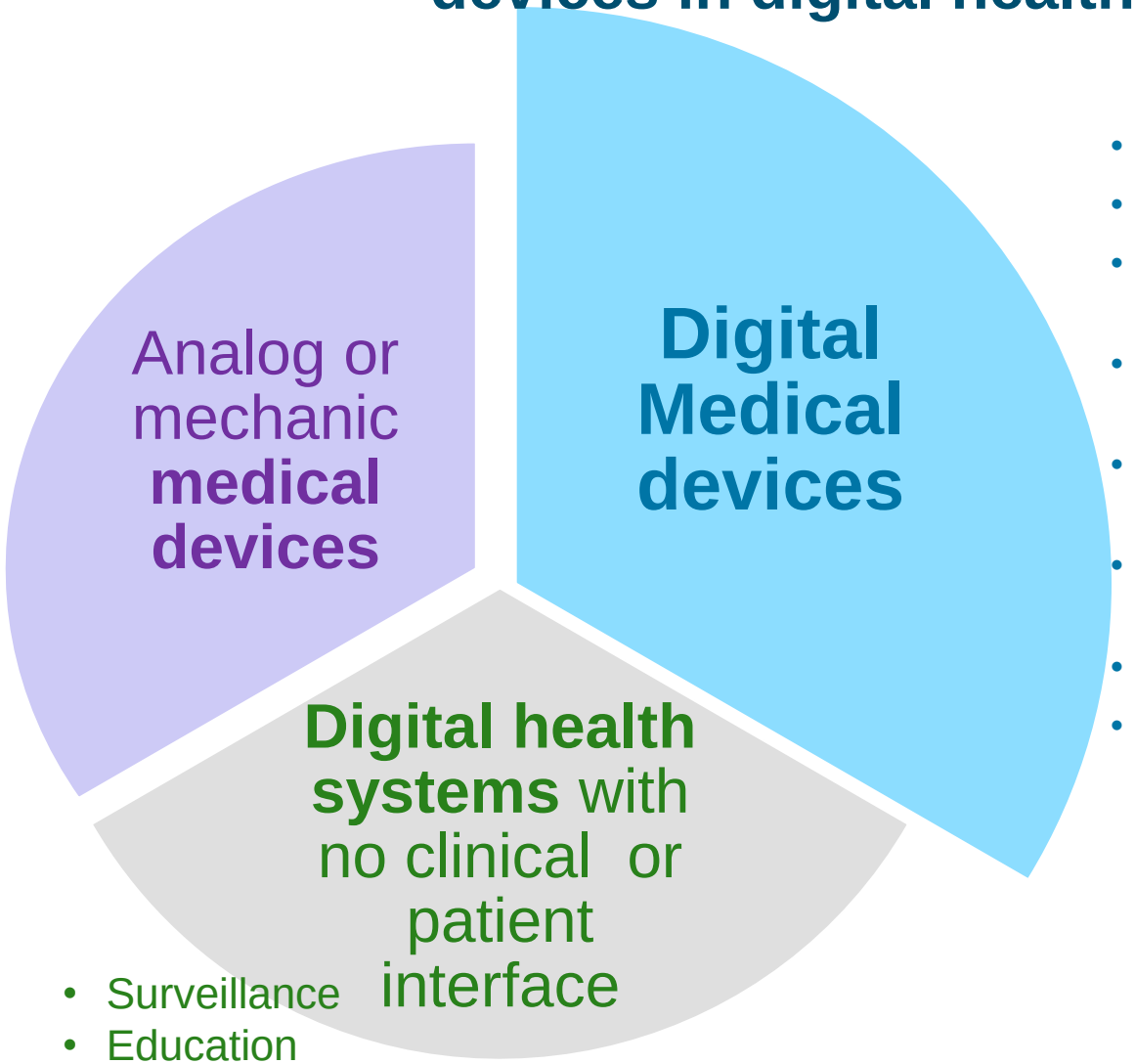
Presentation at IMDRF

Continuous maintenance with reference group

2018 | Dec | 2019 | Apr | Jun | Aug | Oct | Dec | Feb | 2020

Defining assessment protocols for medical devices in digital health

World Health Organization



- Surgical instruments
- Most single use devices
- Implantable prothesis

- Wearables
- all that use ICT
- Systems under digital health
- Clinical decision support systems
- Software as medical device
- Personalized medicine
- CADx
- AI

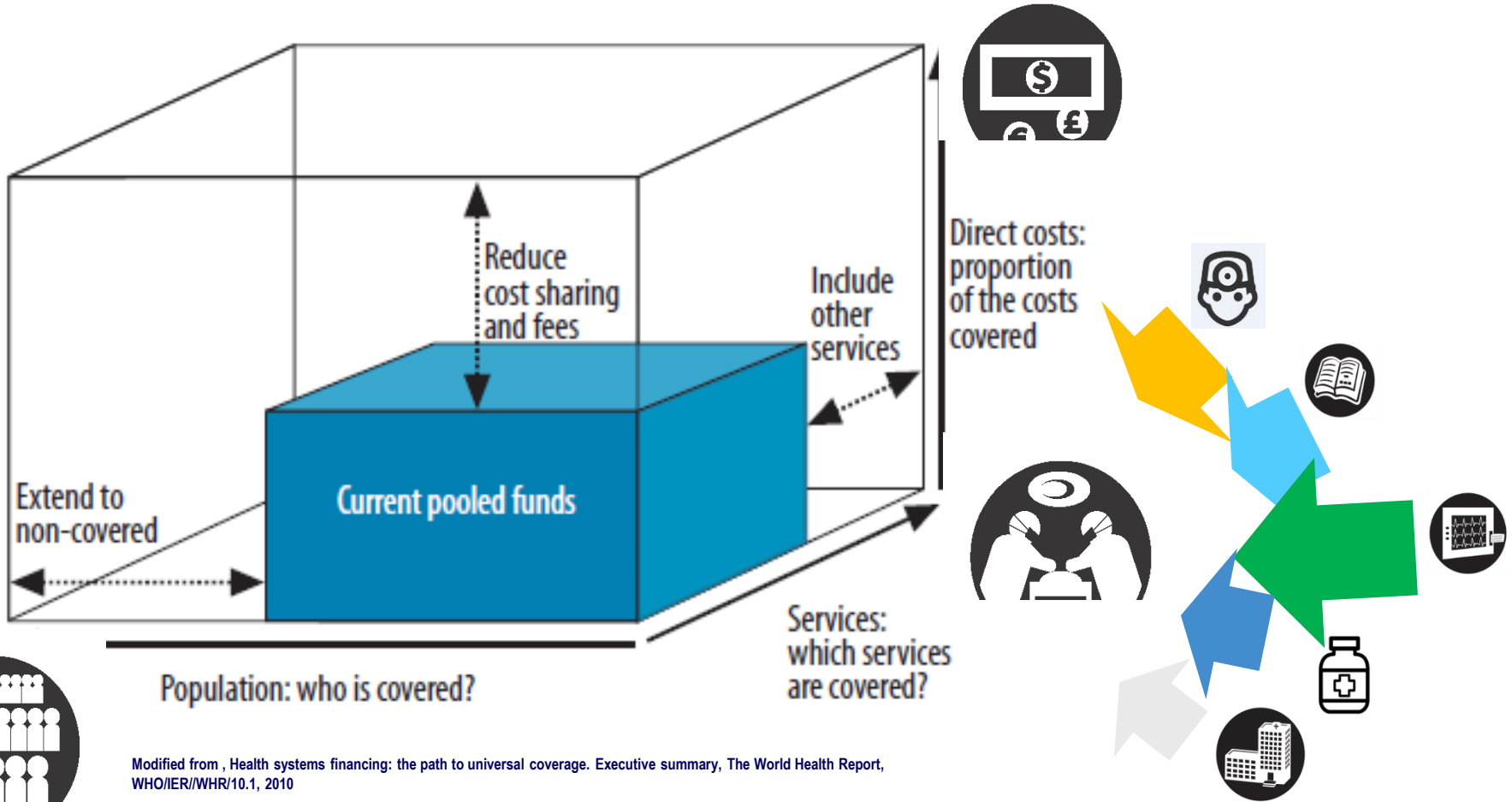
- Surveillance
- Education
- Public health

3 GOOD HEALTH AND WELL-BEING

World Health Organization

Goal: to ensure population coverage with appropriate medical devices

universal health coverage, including financial risk protection, access to quality essential health-care services .



Modified from , Health systems financing: the path to universal coverage. Executive summary, The World Health Report, WHO/IER//WHR/10.1, 2010

Remember a patient is at the end of all our activities, they deserve our:

World Health Organization

- **Technical knowledge**
- Passion
- Transparency
- Hard work
- **Collaboration**

WHO

20, Avenue Appia
1211 Geneva

Switzerland

Adriana Velazquez Berumen

velazquezberumena@who.int

www.who.int/medical_devices

World Health Organization