

MS information session

23 September 2021



Standardization of medical devices nomenclature

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Consultants: Eunice Lourenco, Olga Pineda and Teresa Reed.

Agenda 23rd September, MS information session



- Message from Assistant Director General: Dr Simao
- Requests from Member States and results from ongoing consultations
- Nomenclature agencies
- WHO IT platforms: ICD-11 and MeDevIS
- Feasibility study
- Stakeholder statements
- Open discussion from Member States
- Conclusions

Background: EB145, 148, WHA74 ... towards EB150 February 2022.

Standardization of medical devices nomenclature, the way forward



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,

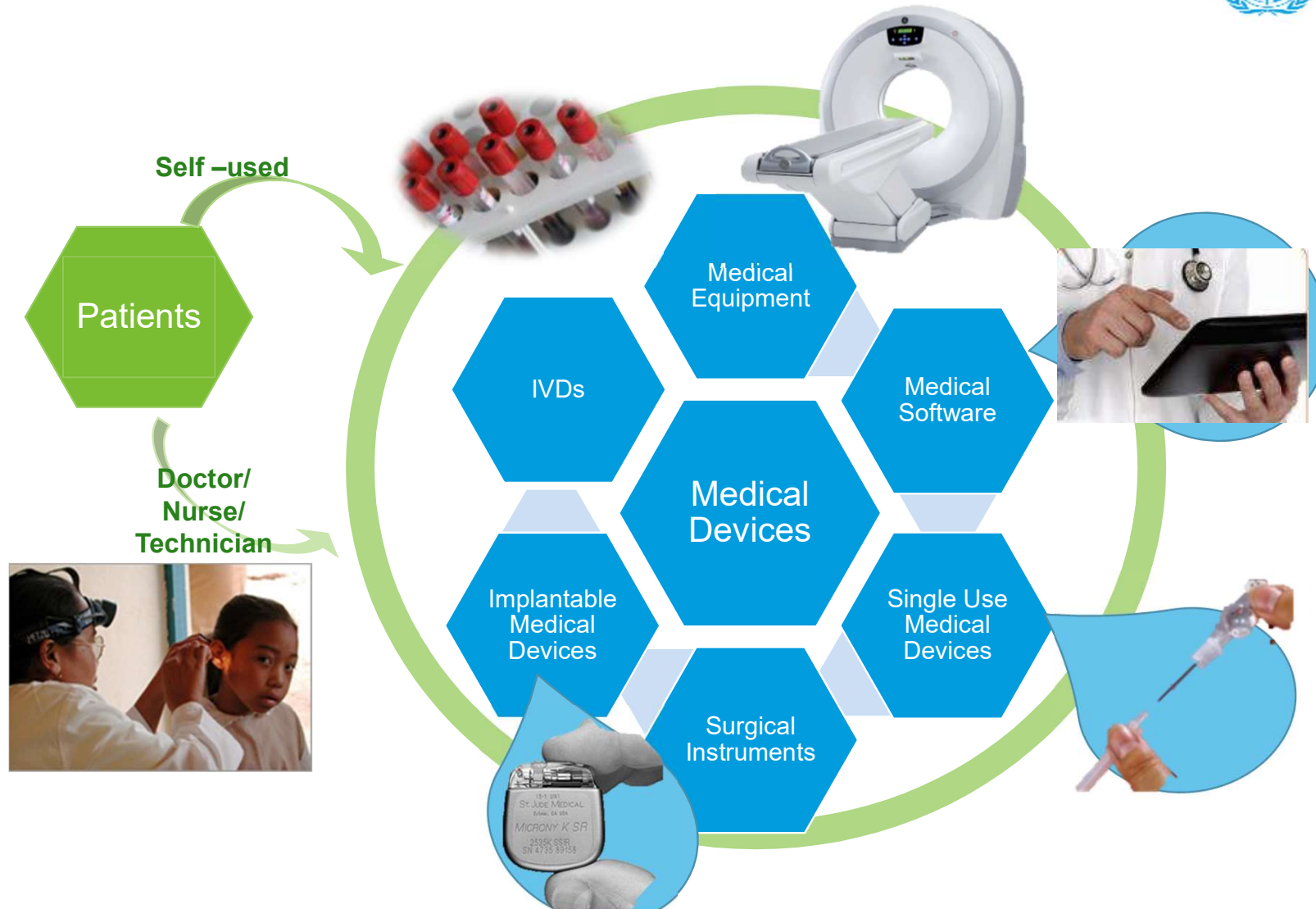
access to medical devices for universal health coverage,

quality of health care and

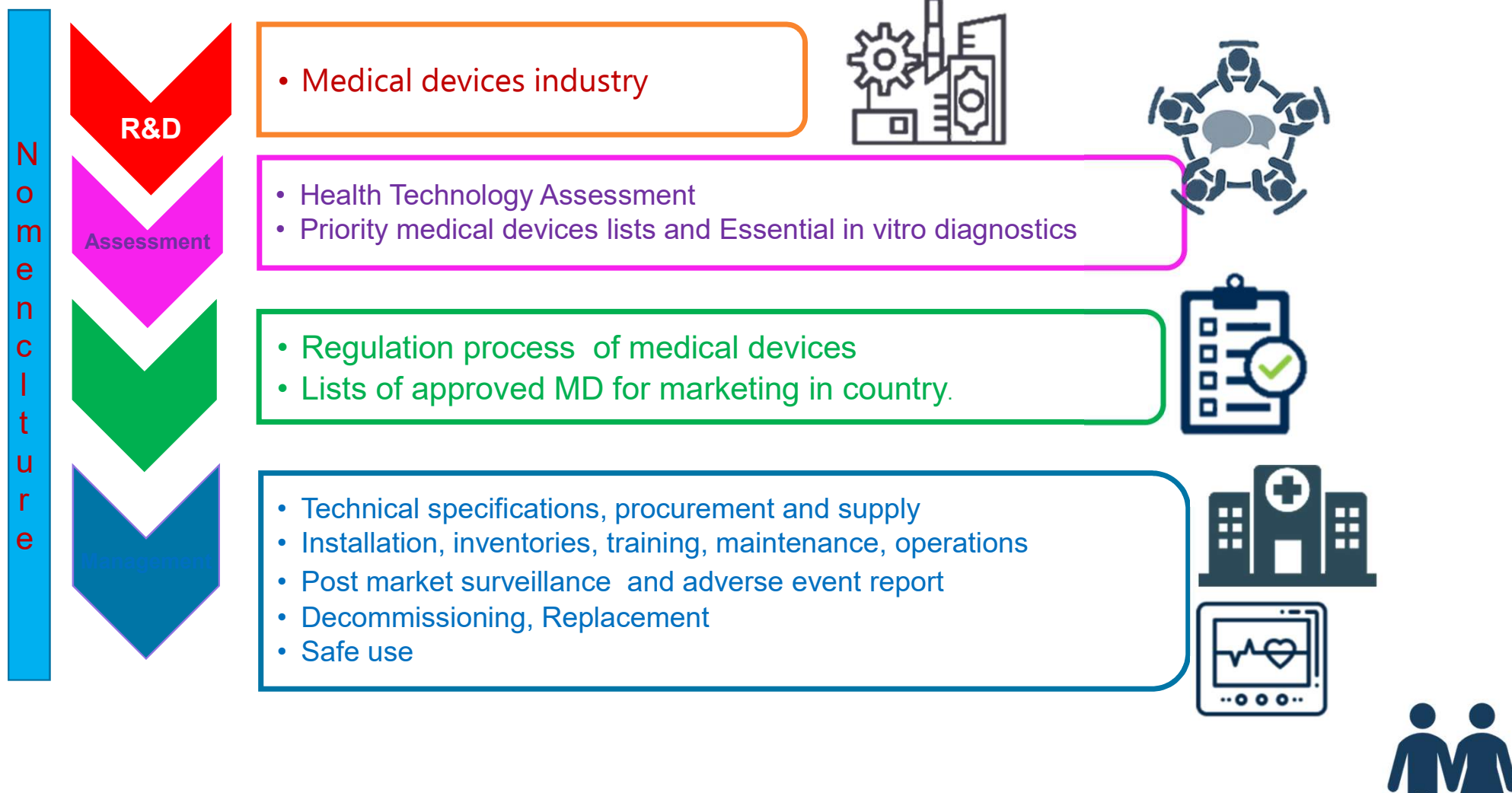
achievement of Sustainable Development Goal 3: Ensure healthy lives and promote well-being for all at all ages”



Medical Devices thousands categories with no generic international name, classification and code



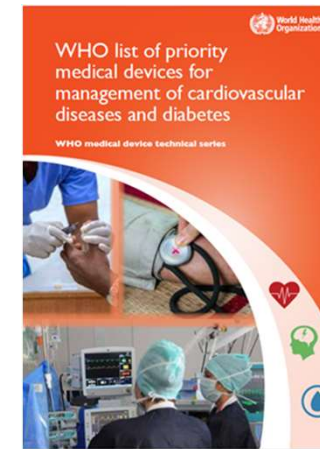
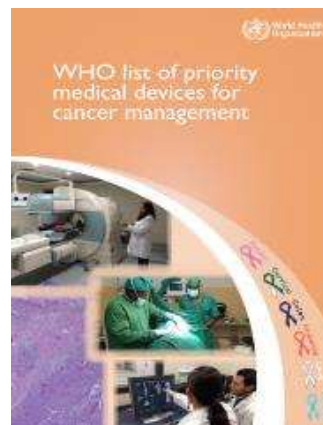
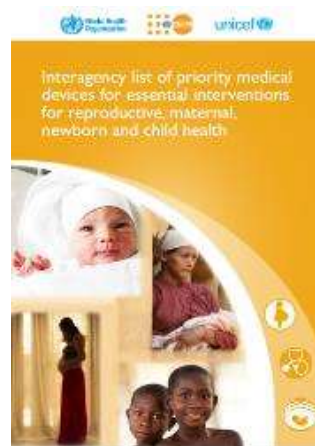
To ensure improved access of safe, quality medical devices, **standardized names are the backbone:**



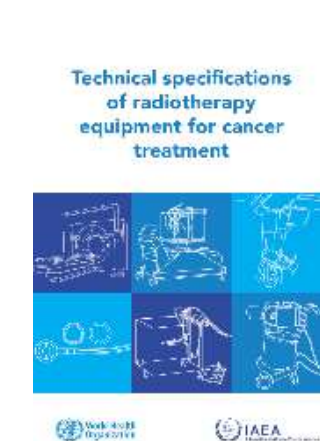
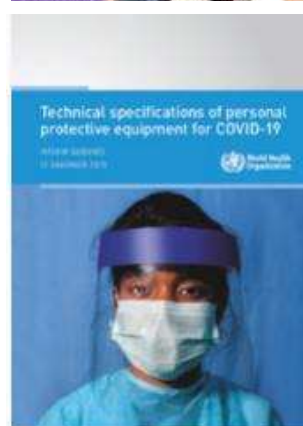
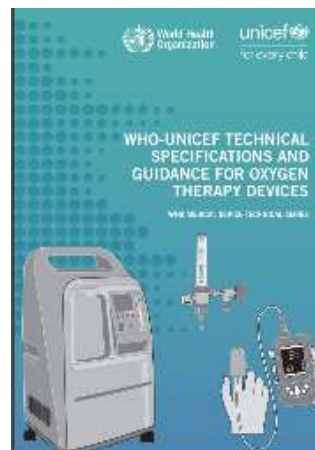
Examples of WHO Publications requiring nomenclature and coding to facilitate access



List of essential/
priority



Technical
specifications



Electronic WHO Essential in vitro diagnostic list, (e-EDL)



Beta version 29 January 2021, does not include any nomenclature yet, <https://edl.medevis.test.evidenceprime.com>.

The eEDL website is currently under active development. The content and functionality is NOT FINAL and shared as a beta version.

World Health Organization WHO Model List of Essential In Vitro Diagnostics

Search by name, indication or test purpose

Found 209 recommendations for 154 in vitro diagnostics

Export results

FILTERS

- Disease/health condition
- Setting
- Assay format
- IVD purpose
- Specimen type
- Year of WHO recommendation

Apply filter

Back

Alanine aminotransferase (ALT), Optical methods on semi-automated or automated chemistry analysers

Discipline - Clinical chemistry

Alanine aminotransferase (ALT)

Facility level: 2. Laboratory

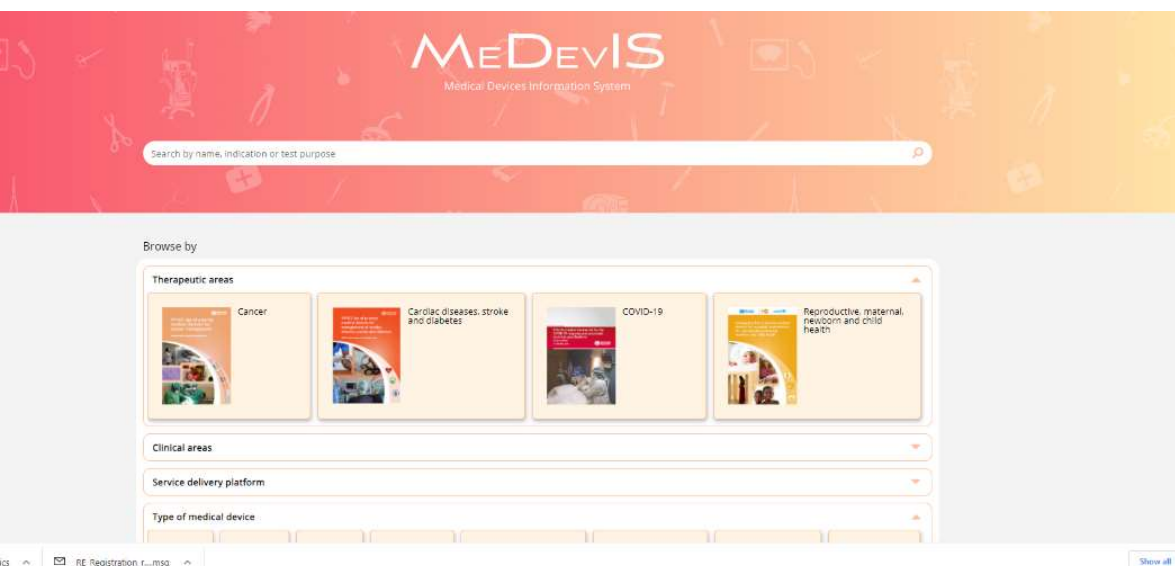
Assay formats	Optical methods on semi-automated or automated chemistry analysers
Status history	First added in 2018 Changed in 2020
Purpose type	Aid to diagnosis
Purpose	To aid in the diagnosis of liver disease as a marker of liver injury.
Specimen types	Serum, Plasma

WHO recommendation	History	References
Summary of SAGE IVD recommendation		
General in vitro diagnostics tests are the general core and routine laboratory tests for clinical chemistry, haematology, blood transfusion, microbiology (virology, bacteriology, parasitology and mycology) and histopathology. These tests were selected on the basis of the scientific validity of an analyte, i.e. the association between an analyte and a clinical condition or physiological state; and clinical utility. Many of these tests are required for effective management of patients and have already been described in WHO publications.		

<https://edl.medevis.test.evidenceprime.com/>

WHO Priority medical devices information system,

MEDEVIS is similar to eEML and eEDL, includes 1500 devices. <https://medevis.test.evidenceprime.com/>



<https://medevis.test.evidenceprime.com/>

< Anesthesia System, MRI safe

Alternative names	Anaesthesia machine: anaesthesia system
WHO list of priority medical devices	Cardiovascular diseases and diabetes
Various conditions or disease specific	Various
Particular indications (ICD-11)	Multiple
Organ or system related according to ICD-11	Many
Interventions (non-exhaustive list)	Magnetic resonance imaging, Magnetic Resonance Imaging (MRI) technique
Life course	Pregnant, Childbirth, Childhood (28 days to 9 years), Adolescent (10-19), Adults (20-64), Later adults
Sex	All
Service delivery platforms	6. Second referral level and above (Regional or National hospital)
Healthcare setting	Medical Imaging (Diagnosis / interventional)
Type of medical device	Imaging
Capital, reusable or single-use	Capital
Requirements	electricity (batteries), electricity (mains), emergency power supply, gases (Carbon Dioxide), gases (compressed air), gases (Nitrogen), gases (Nitrous Oxide), gases (Oxygen)

Discussion on standardization of nomenclature in the WHA74, 29 and 31 May 2021



[Seventy-fourth World Health Assembly \(who.int\)](https://www.who.int)

Requests by Member States

Interventions by 21 Member States.

Importance of nomenclature, coding and classification of medical device to support regulation, procurement, assessment

Should be transparent, harmonized and evidence based, open systems to be accessible for all

Requested WHO not to create a new nomenclature to avoid duplications

Concerns of EMDN not harmonized with GMDN

Request to: Map EMDN to GMDN to minimize impact,

Costing study, Consultations with IMDRF, and industry.

WHO response 31 of May

Set of countries advocate for proprietary system (GMDN)

Set of countries advocate for open existing systems (ie. EMDN)

WHO confirms will not create a new nomenclature.

Information and consultation sessions in 2021 to report to Executive Board 150, February 2022.

WHO requires support by Member States to find agreements of nomenclature systems to map, have a transparent system to assign codes, and make information openly available, with no IP restrictions.

Consultations 2021




- 1. Country data has been received, compiled and posted for review**
- 2. Various stakeholder consultations**

Country consultation of Global Atlas of Medical devices. 1 to 30 September

Global atlas of medical devices 2021

Albania



Country indicators

Population 000s (rank):^a 2,878 (137)
World Bank income group:^a Upper-Middle
Life expectancy at birth (years):^a 78.8

Under-five mortality (per 1000 live births):^a 9.7
Probability of dying aged 30-70 yrs of NCDs (%):^a 17.00%
Human Development Index (inequality adjusted HDI) rank:^a 0.8 (10.7): high
ICT Development Index (rank):^a 51 (80)

UHC - Service coverage index (1-100):^a 59
UHC - Population with household spending >10% (>25%) of corresponding income (%):^a 16.7% (5.0%)
Global innovation index (rank):^a 271 (83)
High-technology exports (% of manufacture exports):^a 0.00%

National policy on health technology
Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: Yes
Website: http://www.who.int/medical_devices/survey_resources/health_technology_national_policy_albania.pdf; <https://shendetesia.gov.al/>
Language(s): English and Albanian
MOH responsible for health technology policy implementation: Unit for the Management of Medical Devices.

National lists of medical devices
National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
List available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —
National list for different types of healthcare facilities (hospitals, laboratories, etc):
List available: No
Website - hospitals: —
Website - IVD: <http://akbpm.gov.al/publicine/>; <http://akbpm.gov.al/wp-content/uploads/2020/12/Registim-Servise-Shpore2020.doc>
Nomenclature systems used for devices and tests: —
National list for specific clinical interventions/emergencies:
List available: No
Website: —

National health technology assessment unit
Designated unit/department for health technology assessment (HTA):^a No
National unit/department that includes HTA for medical devices: —
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

National regulatory authority
Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: National Agency for Drugs and Medical Devices (AKBPM)
Website(s): <http://akbpm.gov.al/>; <https://shendetesia.gov.al/misioni-2/>
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc: Agjencia Kombetare e Sertifikimit dhe Pajisjeve Medike (National Agency for Drugs and Medical Devices).
Other agency's website: <http://akbpm.gov.al/?lang=en>

National regulatory comments (Annex 1):
There is not yet an HTA national unit but it has been acknowledged at a political level by the MoH. There is a centralized system for managing health products pricing and reimbursement via the Ministry of Health, the National Agency for Drugs and Devices, and the Drug Price Commission.

National regulatory comments (Annex 1):
—

WHO European Region

World Health Organization

WHO European Region

World Health Organization

Medical device nomenclature system
Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: For procurement purposes
Website: —

Medical device incorporation
Policy or guideline: Yes Website: —
National level procurement: Yes Website: —
Donations
Policy or guideline: Yes Website: —
Technical specifications
Technical specifications to support procurement or donations: No
Publicly available: —
Website: —

Medical equipment

	Total	Density per 100,000 population
Magnetic Resonance Imaging*	5	1.58
Computerized Tomography Scanner*	17	5.36
Positron Emission Tomography Scanner*	0	0
Gamma camera or nuclear medicine*	0	0
Mammography*	18	54.4
Radiotherapy*	6	2.08

* Density per 1,000,000 females aged from 15-49 y.o.

Healthcare facility*

	Total	Density per 100,000 population
Health posts	415	13.08
Health centres	n/a	n/a
General/district hospitals	23	0.72
Specialized/regional/national hospitals	9	0.28
Estimation % of health facilities with none or very limited oxygen supply:		n/a

Medical equipment management unit
Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Unit for the Management of Medical Devices. Unit website: —
Contact name: Ms. Ledina Picari Contact email: lpicari@shendetesia.gov.al
Website with publicly available technical specifications: —
Number of regional/state offices/units: 4

Inventories and medical equipment management software
Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: Yes Software name: Clingo.

Medical devices workforce
Density of medical doctors (per 10 000 population):^a 16.47
Number of biomedical/clinical engineers professionals in the country:^a 55

Contacts
MOH focal point
Name: —
Department: —
Email: —
Other country focal point
Name: Ms. Ledina Picari
Email: lpicari@shendetesia.gov.al
WHO health products focal point:
Name: —
Email: —
WHO Representative/WHO Liaison Officer:
Name: Dr. Gerald Rockenschaub
Email: rockenschaub@who.int

General comments (Annex 1): Concerning the HT national policy, it was provided the following document: http://www.who.int/medical_devices/survey_resources/health_technology_national_policy_albania.pdf

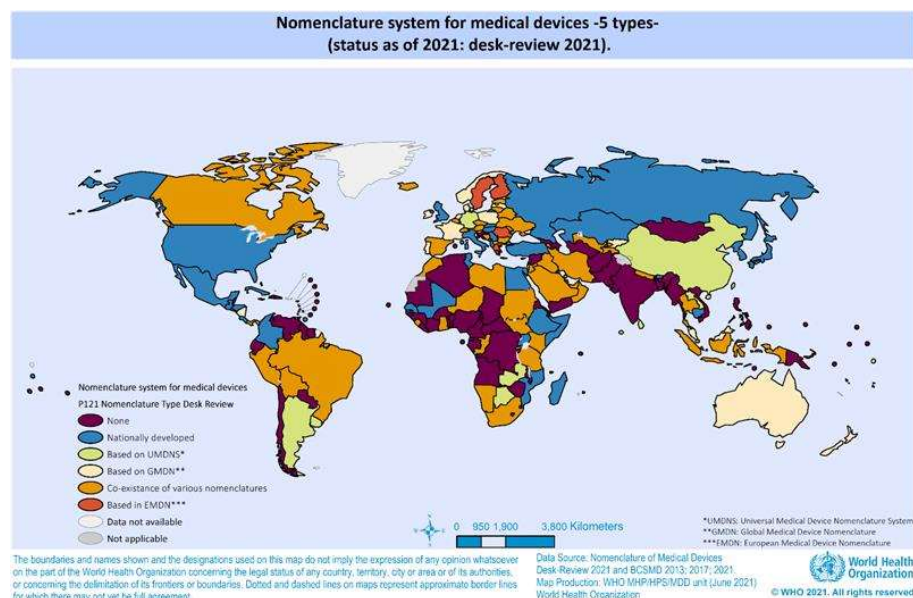
Nomenclature comments (Annex 1):
It is needed the GMDN code for registration of medical devices, as well as the HS code.



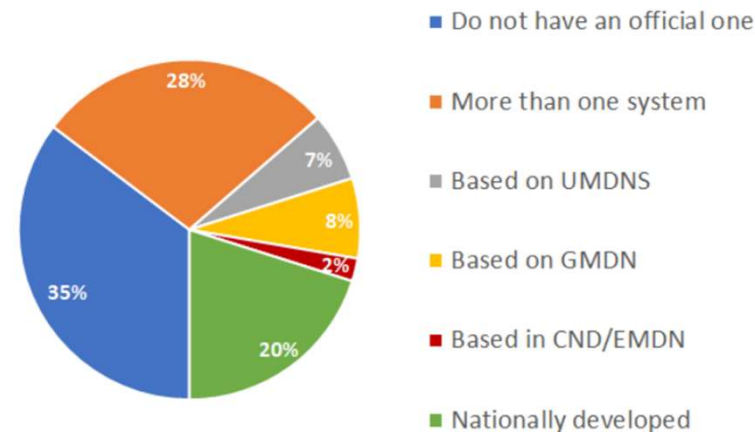
<https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices/global-atlas-of-medical-devices>

Survey and desk review for consultation .

For comments and review by MS DRAFT



Existence and type of an official nomenclature system for medical devices (data from the MD 2021 country consultation verified by desk-review 2021)



Stakeholders consultations July to September 2021



- Several meetings with different stakeholders:
 - WHO Regional Advisors (2 and invited to all nomenclature agencies meetings)
 - Medical devices industry associations (3)
 - Bilateral meetings with Nomenclature Agencies (EMDN, GMDN, UNSPSC, UMDNS) (5)
 - Biomedical & Clinical Engineers association (3)
 - UN Agencies and International NGOs (3)
 - MOH, Regulatory agencies (2 today, 3 next week and will continue)
- Minutes shared with participants
- Surveys were elaborated according to each type of entity, discussed with entity, circulated for feedback and now posted in WHO website
- GOAL: To brainstorm about the way forward and discuss possible solutions.

WHO standardization of medical devices nomenclature

Activities towards the 150 Executive Board in February 2022 and World Health Assembly May 2022



Date	Activity	Expected outcome
May-June	WHA74 and EB149	-----
24 June, 13 and 16 September	<i>IMDRF teleconference</i>	<i>Briefing of WHA and next steps</i>
16, 20 July, 3 September	WHO HQ meetings, ICD-11, MeDeVIS	Status, ongoing activities, nomenclature convergence platform possibilities
19 July, 23 August	WHO Regional Advisors	Status, plan and their input
22 July, 26 August 21 September	Medical devices industry Medical devices industry and Regional WHO Meeting with industry and UN	GMTA, DITTA , Discussion of the outcomes of survey Status, ongoing activities
30 July, 27 August 1 3 September	UN agencies and NGOs UN agencies and NGOs and Regional Advisors UNICEF, Global Fund	Nomenclature and tech specs uses Discussion of the outcomes of the survey Nomenclature used, catalogue and codes used, challenges
1 st round: 29 and 30 of July, 03 August 2 nd round: 24 and 25 August 8 September 3 rd round: 15 September	Nomenclature agencies Nomenclature agencies and Regional WHO All 4 nomenclature agencies together Nomenclature agencies	Single agencies and all agencies. Willingness to map, transparent process, fees and copyright issues. Discussion of the outcomes of the survey Findings on bilateral meetings, willingness to map, brainstorm, Symmetric Willingness to share survey, to nomenclature pilot and to participate in MS session
29 July, 26 August 22 September	Biomedical and Clinical engineers Biomedical and Clinical engineers and Regional Advisors	Use of nomenclature in health care facilities Discussion of the outcomes of the survey
21 September,	Regional regulators and MOH AFRO and EURO	Nomenclature uses and challenges Global Atlas for Medical Devices 2021 review.
23 September	Member States information session	Report on the consultation sessions and defining next steps
TBC (27 Sept - October)	Other country and regional consultations	Nomenclature uses and challenges
1 October	Report for EB150	Report sent for WHO internal clearance
October, November, December	Development of mapping study; Other consultations as needed.	Publish report Consensus and mapping outcomes.
1 February 2022	EB150.	Presentation to the Executive Board

All surveys provided by organizations are uploaded in WHO website on nomenclature MD



Countries ▾

Newsroom ▾

Emergencies ▾

Data ▾

About WHO ▾

procurers and health facility managers, and Member States.

- WHO expects to have a new report in October with the outcomes of surveys and consultations and have it ready to be presented for discussion for the next EB 150.
- WHO requires help from MS, to find agreements between available systems, including between the Global medical devices nomenclature proprietary system, the European Medical Devices Nomenclature, and other major nomenclature systems, to ensure an international classification, coding and nomenclature is available, especially in these times when access to medical devices is indispensable for the outbreak response and to reinforce health systems.

April - October 2021 - WHO Consultation on Nomenclature Systems for Medical Devices

The consultation includes a survey directed to **nomenclature agencies** in **August-September 2021**. Please find below the survey responses from each nomenclature agency:

- [EMDN](#)
- [GMDN](#)
- [UMDNS](#)
- [UNSPSC](#)

The consultation also surveyed other **stakeholders including NGOs**. Please find below the survey responses completed in **August-September 2021** by other stakeholders:

- [CHAI](#)
- [DITTA](#)
- [GMTA](#)
- [ICRC](#)
- [IFMBE CED](#)
- [MSF](#)
- [StopTB](#)

The consultation also includes a survey for **UN agencies** in **August-September 2021**. Please find below the survey responses from various UN agencies:

- [IAEA](#)
- [UNFPA](#)
- [UNHCR](#)
- [UNICEF](#)
- [UNITAID](#)
- [UNOPS](#)
- [WHO](#)

NOTE: All survey responses have been published with the consent of the survey participants.

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

- Nomenclature used by UN Agencies and NGOs

Agency/NGO	EMDN	GMDN	UMDNS	UNSPSC	None of the 4	Developed by their own	Comments: reference to any the 4 is for internal use only.
IAEA		X					GMDN descriptions to the most appropriate-helpful
UNDP		X		X			GMDN at a basic level and UNSPSC for budgeting and reporting
UNFPA				X		X	UNFPA Product Catalogue does not reflect any of the 4
UNHCR					X	X	
UNICEF		X	X	X		X	UNICEF Catalogue does not reflect any of the 4
UNITAID					X		
UNOPS				X			Or May adopt Country specific or Manufacturer's coding/nomenclature systems as per applicable, does not reflect any of the 4
WHO	X	X	X	X		X	EMDN from 2021 and future, UNCCS (will change to full adoption to UNSPSC in new ERP system)- Before 2020: GMDN, UMDNS, UNSPSC WHO Global Supply Catalogue does not reflect any of the 4
CHAI					X		--
ICRC		X					not used in the entire organization
Global Fund		X				X	WAMBO catalogue does not reflect any of the 4 (taken from the meeting with GF on September 3 rd)
MSF		X				X	Nomenclature developed by MSF is based on GMDN terms. Planning to star using EMDN
PATH							Not received yet
StopTB						X	For internal use only

Analysis Nomenclature agencies

Comparison of characteristics of nomenclature systems

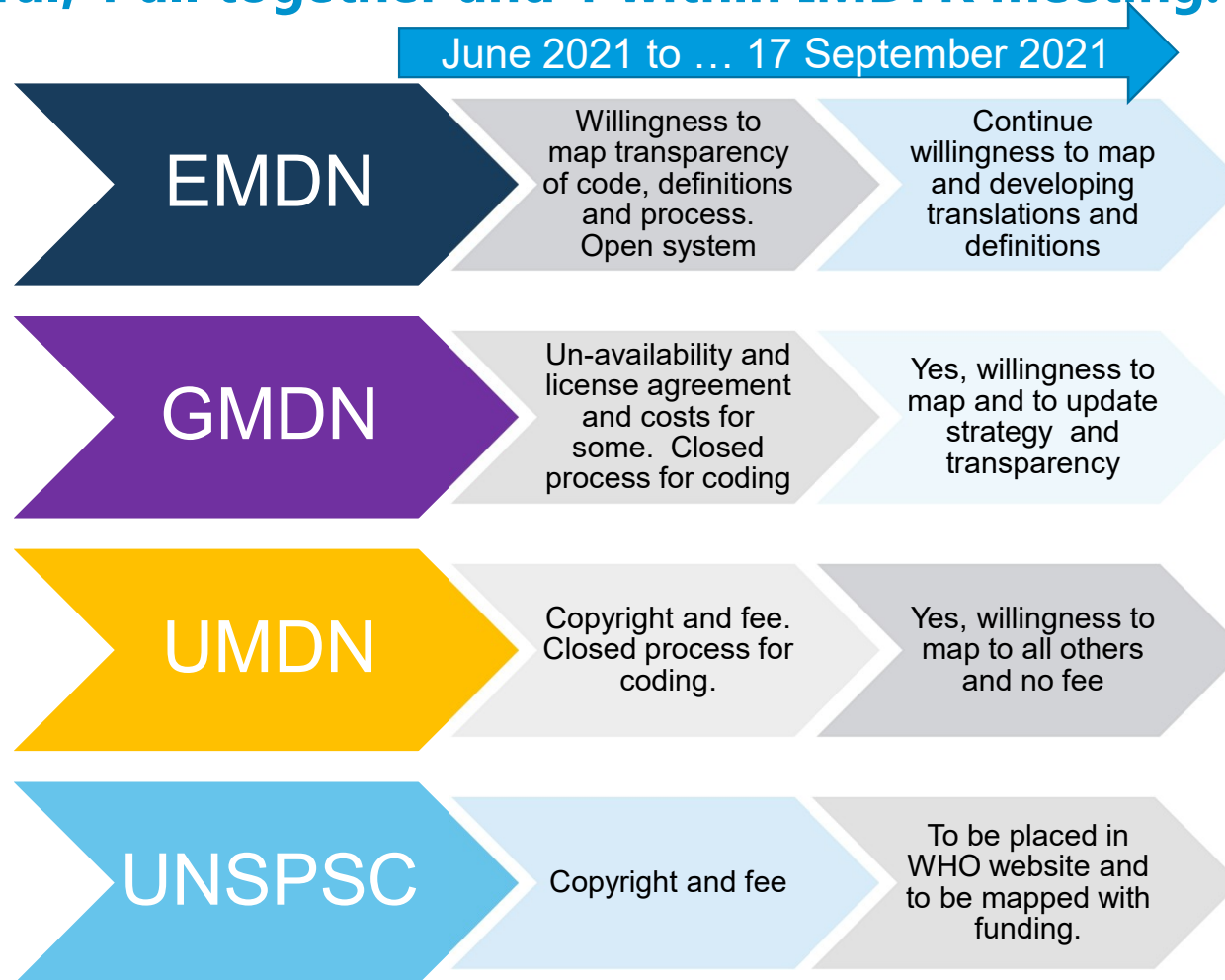


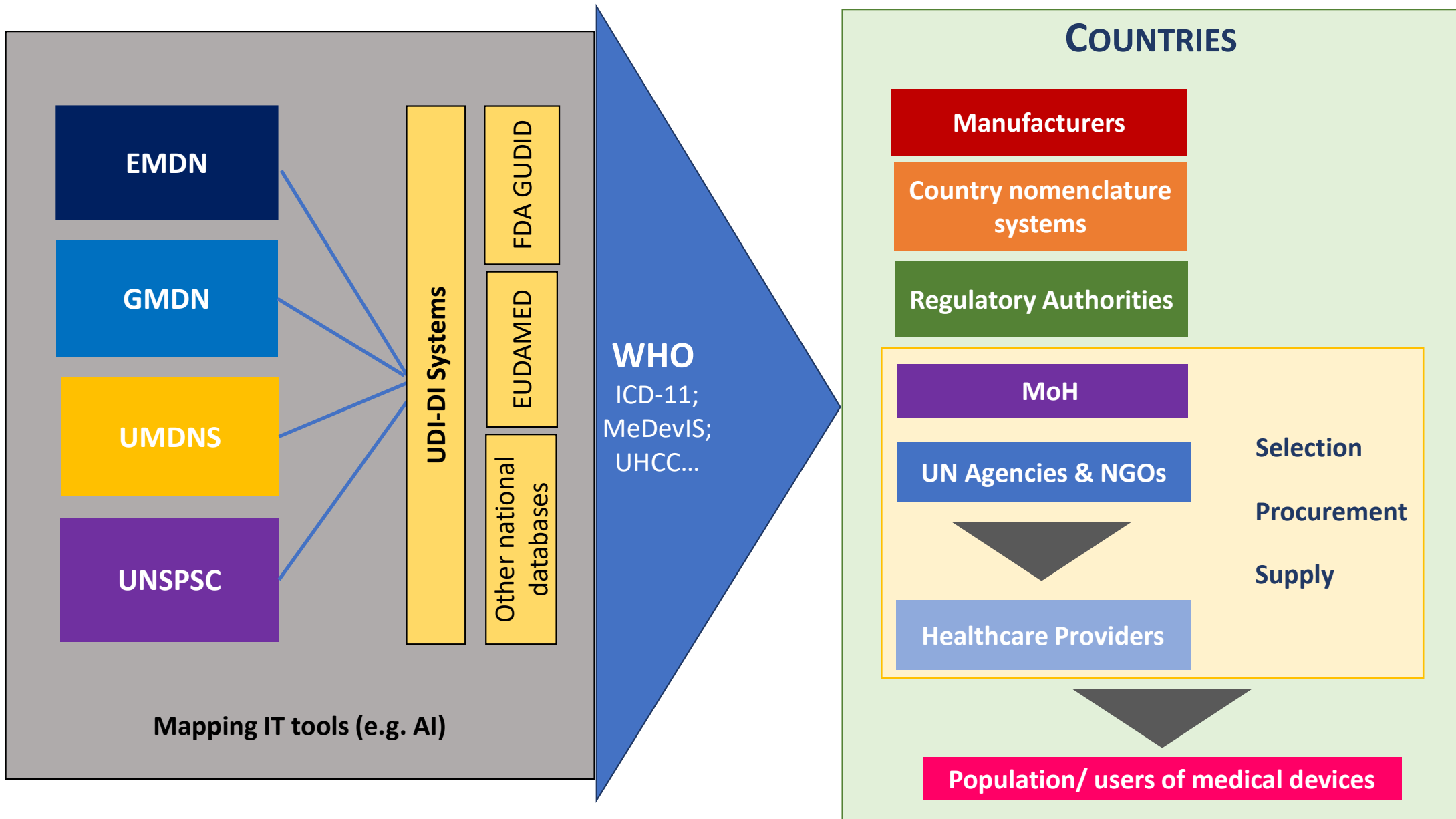
Updated as of **24 June 2021**

	Universal Medical Device Nomenclature System (UMDNS) 1983..	Global Medical Device Nomenclature (GMDN) 1991		United Nations Standard Products and Services Code (UNSPSC)	European Medical Devices nomenclature (EMDN) May 2021
Host Organization	ECRI Institute	GMDN Agency		GS1 US	European Commission
Transparent methodology, processes for the classification, coding and establishment of nomenclature terms.	✗	✗		✗	✓
Hierarchical organization of terms and codes into categories and subcategories, to meet the various needs of its stakeholders including regulatory and supply systems.	✓	✓		✓	✓
Freely available, downloadable, exportable terms, codes and hierarchies	✗	✗		✓	✓
Possibility to have translation	✓	✓		✓	✓
Non proprietary	✗	✗		✓	✓

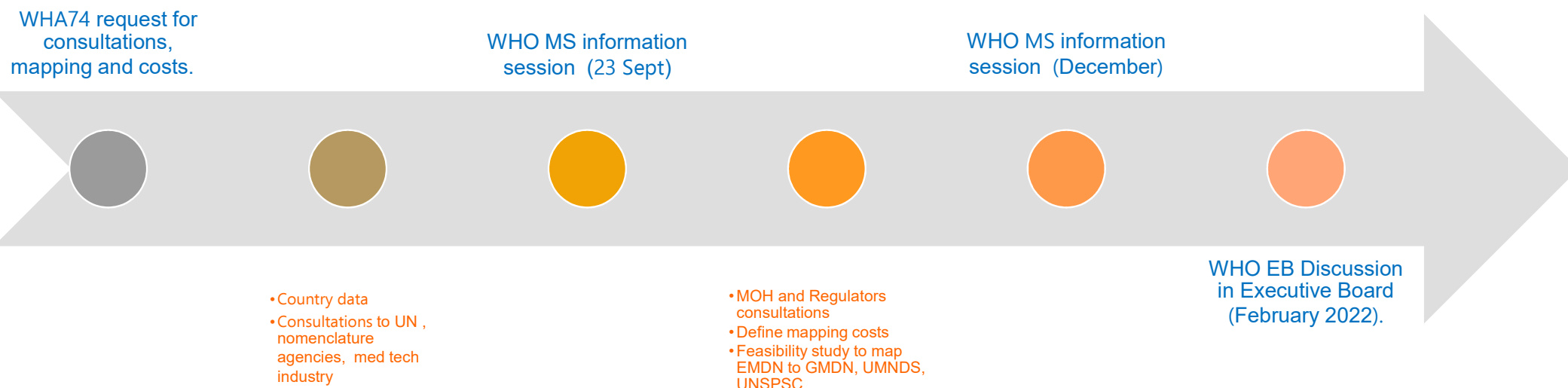
Findings up to 13 sept and presented in IMDRF	EMDN	GMDN	UMDNS	UNSPSC
Information freely available	yes	Yes, for all registered users	Yes, for non-commercial users	Yes, fully downloadable after registration
Processes used for: code development and maintenance,	Managed by the Medical Device Coordination Group (MDCG) subgroup on Nomenclature (NOM WG), (each EU Member State is represented	highly qualified technical authors. Requests by companies are analyzed	The ECRI agency creates the codes and descriptions	Only registered users can request codes
License agreement	No need.	Standard license and costs in website. Special license to 8 public entities.	Revised license is coming.	Standard license, no need to pay for PDF.
Willing to work on mapping to other existing nomenclatures?	Yes, to GMDN	<i>(not responded)</i> <i>(updated on 20th to: Yes)</i>	Yes, to EMDN, GMDN and UNSPSC	Yes, to the other 3 if funded
Willing to provide code, name, definitions and hierarchy to WHO for electronic platforms?	Yes	To be discussed and agreed	Yes for non-commercial	Codes owned by UNDP, so could be shared to UN family

4 rounds of meetings with nomenclature agencies: 3 bilateral, 1 all together and 1 within IMDFR meeting.

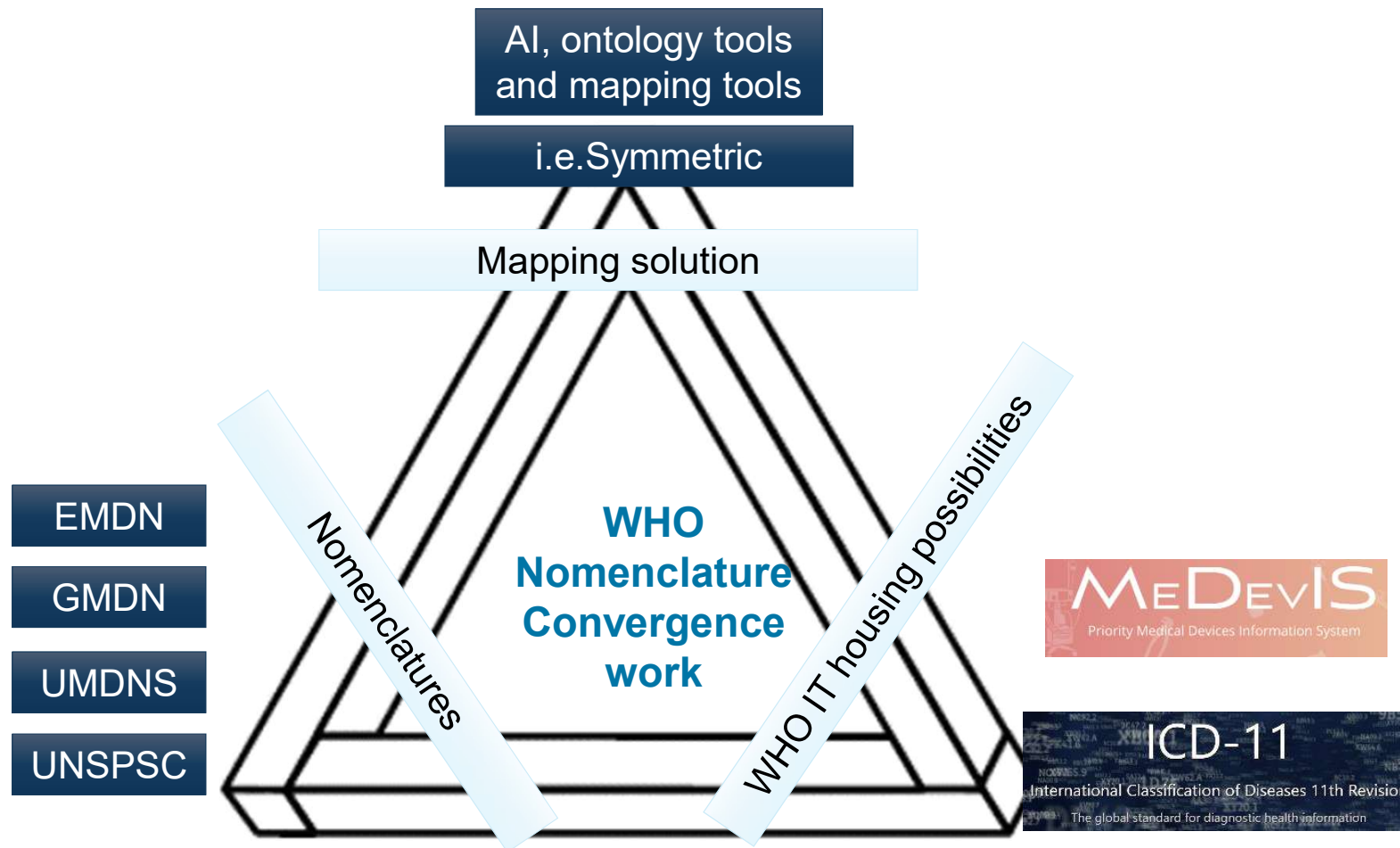




Road map towards the EB Feb 2022.



Towards a Global Public Good, mapping feasibility study




Medical devices purchased and supplied by UN agencies and NGOs , undergo QA, delivery to LMIC.

Ideally to have harmonized naming and coding to simplify transactions and traceability.

Interested in being part of the pilot?



Medical devices Nomenclature standardization

A photograph of a pier at sunset. The sun is low on the horizon, creating a strong backlight effect through the wooden pilings of the pier. The water is calm, reflecting the golden light. The sky is a mix of orange, yellow, and blue.

It always seems
impossible until it's
done

- Nelson Mandela -

**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

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

Four Nomenclature Agencies presentation

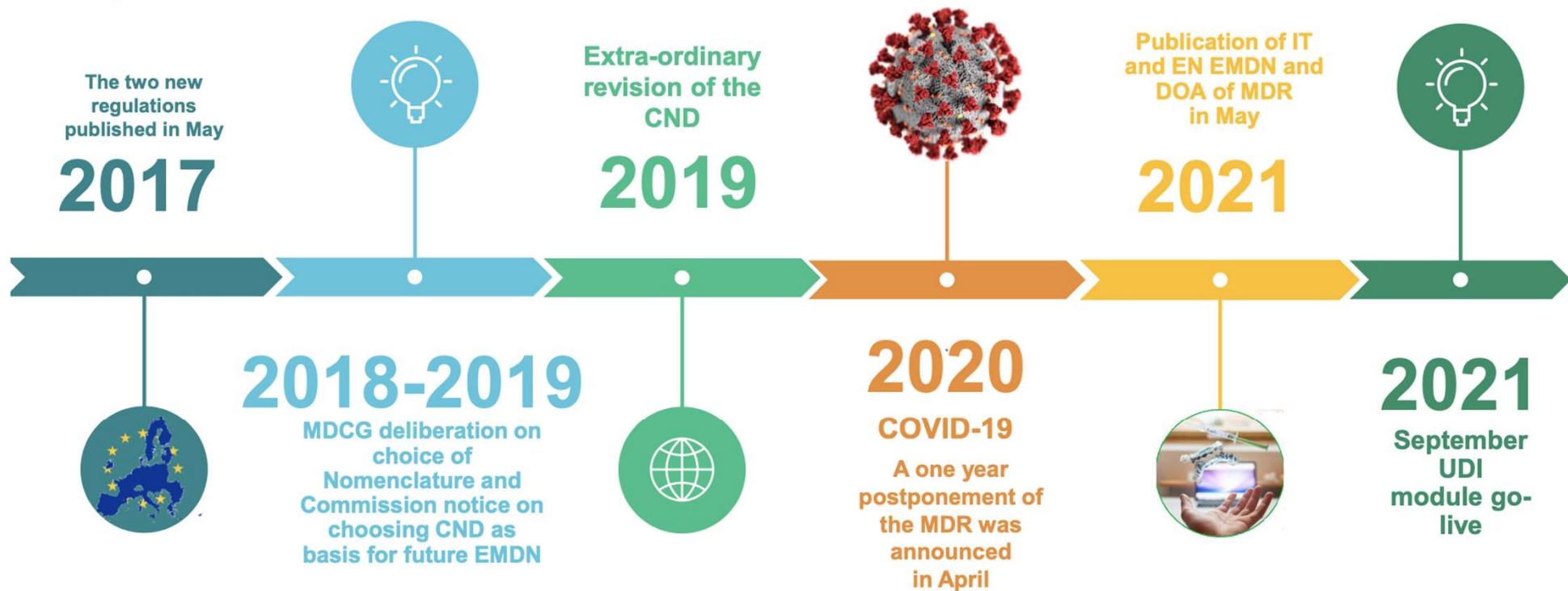


European Medical Device Nomenclature

*SANTE B6 Medical Devices and HTA -
Nada Alkhayat*

Background

The road towards the EMDN



Key EMDN principles

- The EMDN is based on fundamental key principles jointly set out by the European Commission and EU regulators. These principles include but are not limited to:
- **(a) Regulators-led:** regulators play a key role in managing, validating, updating and advising on the nomenclature.
- **(b) Structured:** the nomenclature has transparent hierarchies by which terms and codes could be meaningfully clustered into groups and types.
- **(c) Predictable:** the structure and content remains sufficiently stable to allow various regulatory uses of the nomenclature, in a manner which still allows for the accommodation of technological innovation.

EMDN key principles continued.

- **d) Transparent:** the policies for updates of the nomenclature terms and descriptions are sound and reflect the needs of regulators and the wider healthcare community.
- **(e) Inclusive:** the periodic reviews are open to all, based on real-world use and demonstrable needs.
- **(f) Available:** the terms, descriptions and codes are available, in full, to all users.
- **(g) Accessible:** no manufacturer or natural/legal person should be subject to fee or suffer from any discrimination, compared to other operators, in relation to the use of the nomenclature.
- **(h) International:** internationally recognised at the time of the date of application of the MDR/IVDR.



European Medical Device Nomenclature



- Serves as terms associated to the UDI-DI
- Supports work related to market surveillance and vigilance.
- Used for sampling basis for Class II A & B as well as Class B & C.
- Used in the implant card*
- Used on certificates*
- Used in the clinical investigation application form
- Used in the SAE reporting form



Beyond the medical device regulation (non-exhaustive):

- Can be used by hospitals and clinics internally in their systems
- Empowers the patient in gaining more information regarding their device, and other devices falling within the same code.
- Can play a role in other healthcare related frameworks
- Data analysis and research

Categories

A - DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION

B - HAEMATOLOGY AND HAEMOTRANSFUSION DEVICES

C - CARDIOCIRCULATORY SYSTEM DEVICES

D - DISINFECTANTS, ANTISEPTICS, STERILISING

F - DIALYSIS DEVICES

G - GASTROINTESTINAL DEVICES

H - SUTURE DEVICES

J - ACTIVE-IMPLANTABLE DEVICES

K - ENDOTHERAPY AND ELECTROSURGICAL DEVICES

L - REUSABLE SURGICAL INSTRUMENTS

M - DEVICES FOR GENERAL AND SPECIALIST DRESSINGS



N - NERVOUS AND MEDULLARY SYSTEMS DEVICES

P - IMPLANTABLE PROSTHETIC AND OSTEOSYNTHESIS DEVICES

Q - DENTAL, OPHTHALMOLOGIC AND ENT DEVICES

R - RESPIRATORY AND ANAESTHESIA DEVICES

S - STERILISATION DEVICES (EXCLUDING CAT. D - Z)

T - PATIENT PROTECTIVE EQUIPMENT AND INCONTINENCE AIDS

U - DEVICES FOR UROGENITAL SYSTEM

V - VARIOUS MEDICAL DEVICES

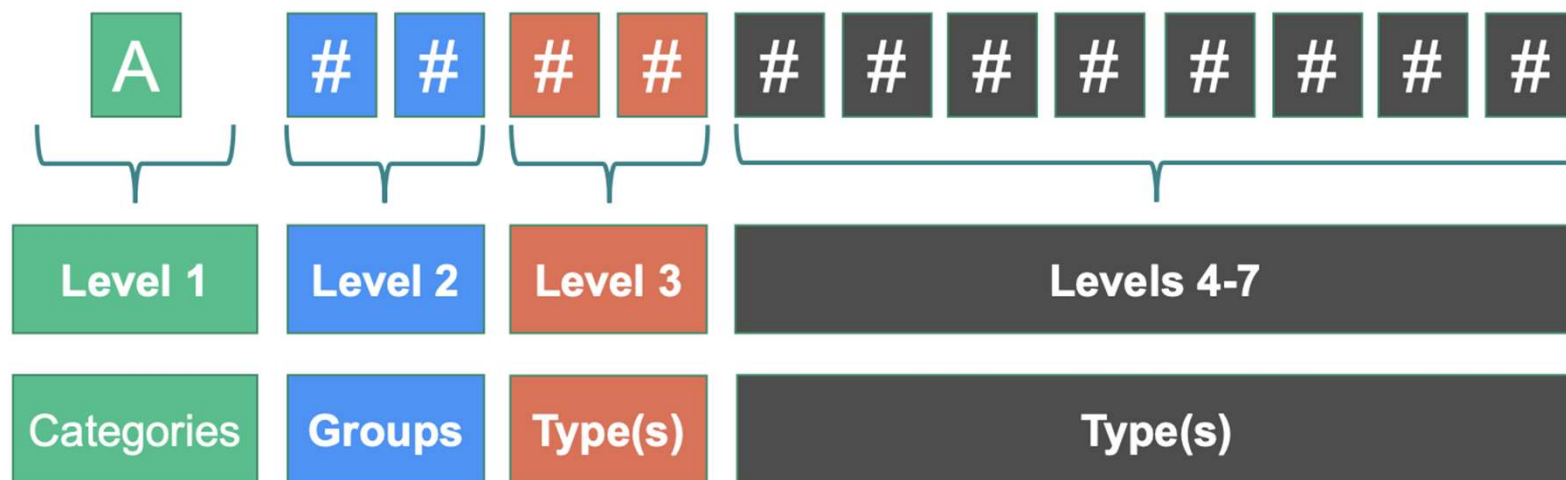
W - IN VITRO DIAGNOSTIC MEDICAL DEVICES

Y - DEVICES FOR PERSONS WITH DISABILITIES NOT INCLUDED IN OTHER CATEGORIES

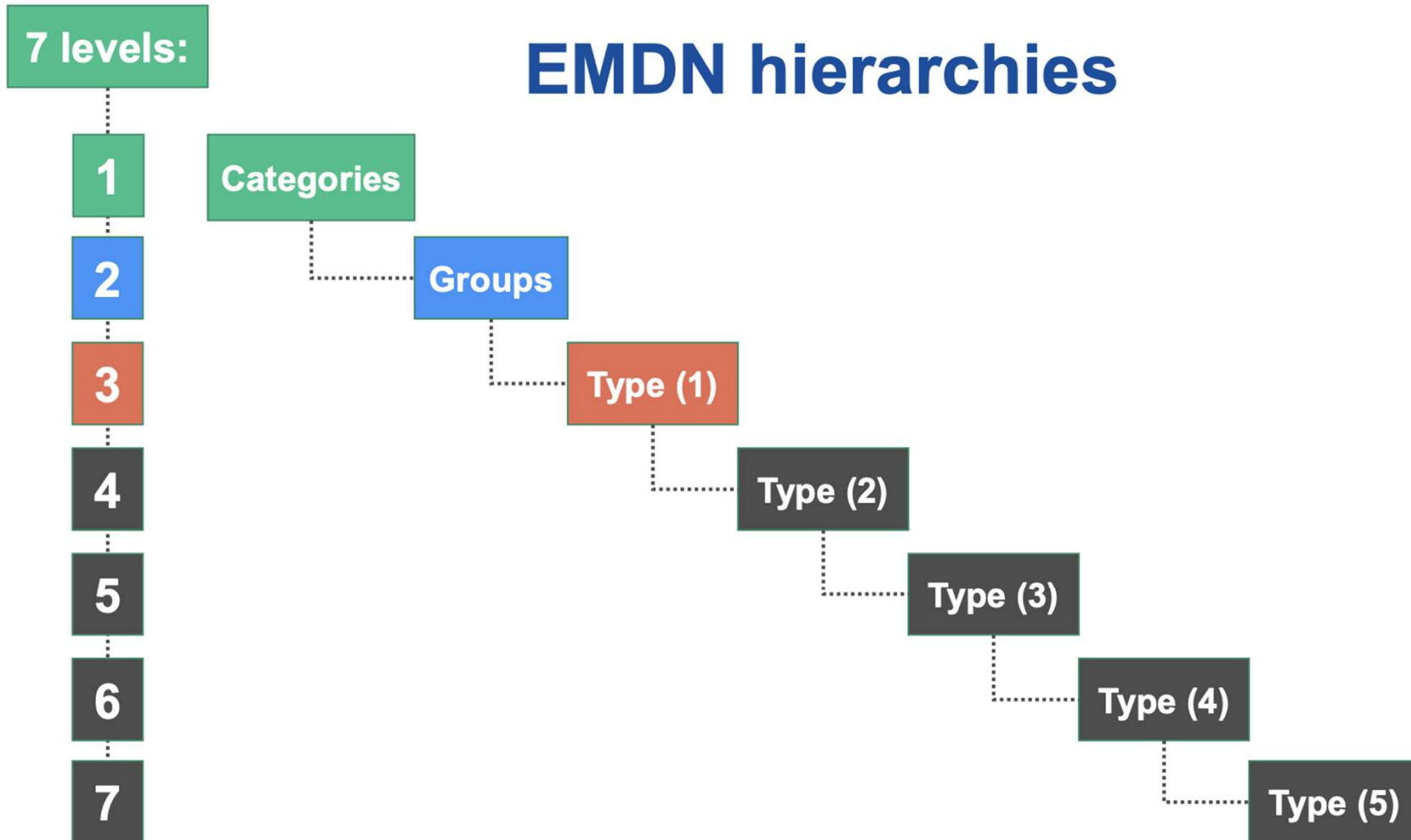
Z - MEDICAL EQUIPMENTS AND RELATED ACCESSORIES, SOFTWARE AND CONSUMABLES



EMDN structure



EMDN hierarchies



EMDN structure in practice

- Alphanumeric structure



Device description

A	0	1	0	1	0	1	0	1	→	HYPODERMIC SYRINGE NEEDLES
C	0	1	0	4	0	1	0	1	→	CARDIAC ANGIOGRAPHY DIAGNOSTIC DEVICES
J	0	1	0	1	0	1	0	1	→	IMPLANTABLE SINGLE CHAMBER PACEMAKERS (SC)
T	0	2	0	6	0	3			→	MEDICAL USE FACE MASKS, TYPE I
Z	1	2	0	3	0	1			→	ANAESTHESIA AND PULMONARY VENTILATION SUPPORT INSTRUMENTS

EMDN public access portal



EN English

Search

[Home](#) > [Health & Food Safety](#) > [European Medical Device Nomenclature \(EMDN\)](#)

European Medical Device Nomenclature (EMDN)

According to 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), and following discussions with the Medical Device Coordination Group, the European Commission announced in 2019 that the European Medical Device Nomenclature (EMDN) would be created and based upon the Italian Ministry's 'Classificazione Nazionale dei Dispositivi medici'.

The EMDN is the nomenclature of use in the European database on medical devices (EUDAMED). Among its various uses, it will be utilised by manufacturers for the registration of medical devices, where it will be associated to each Unique Device Identifier – Device Identifier (UDI-DI).

The EMDN is multi-purposed and plays a key role in device registration, device documentation and technical documentation, notified bodies' sampling of technical documentation, 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.

The entirety of the EMDN is fully accessible to all stakeholders, free of charge. It can hence be utilised by a non-exhaustive list of stakeholders such as manufacturers, research organisations, practitioners, hospitals, pharmacies etc. The EMDN can be accessed and downloaded in excel format below.

Currently, the European Commission is holding a public consultation on the draft EN version of the EMDN with the aim of collecting feedback from users and the wider healthcare community as regards the EN translation of the EMDN. Any errors and or syntax suggestions can be flagged through a submission on this page.

Propose a new translation for an EMDN term description

Select the EMDN term description ([download full list](#))

Search



The EMDN browser

Propose a new translation for an EMDN term description

Select the EMDN term description ([download full list](#))

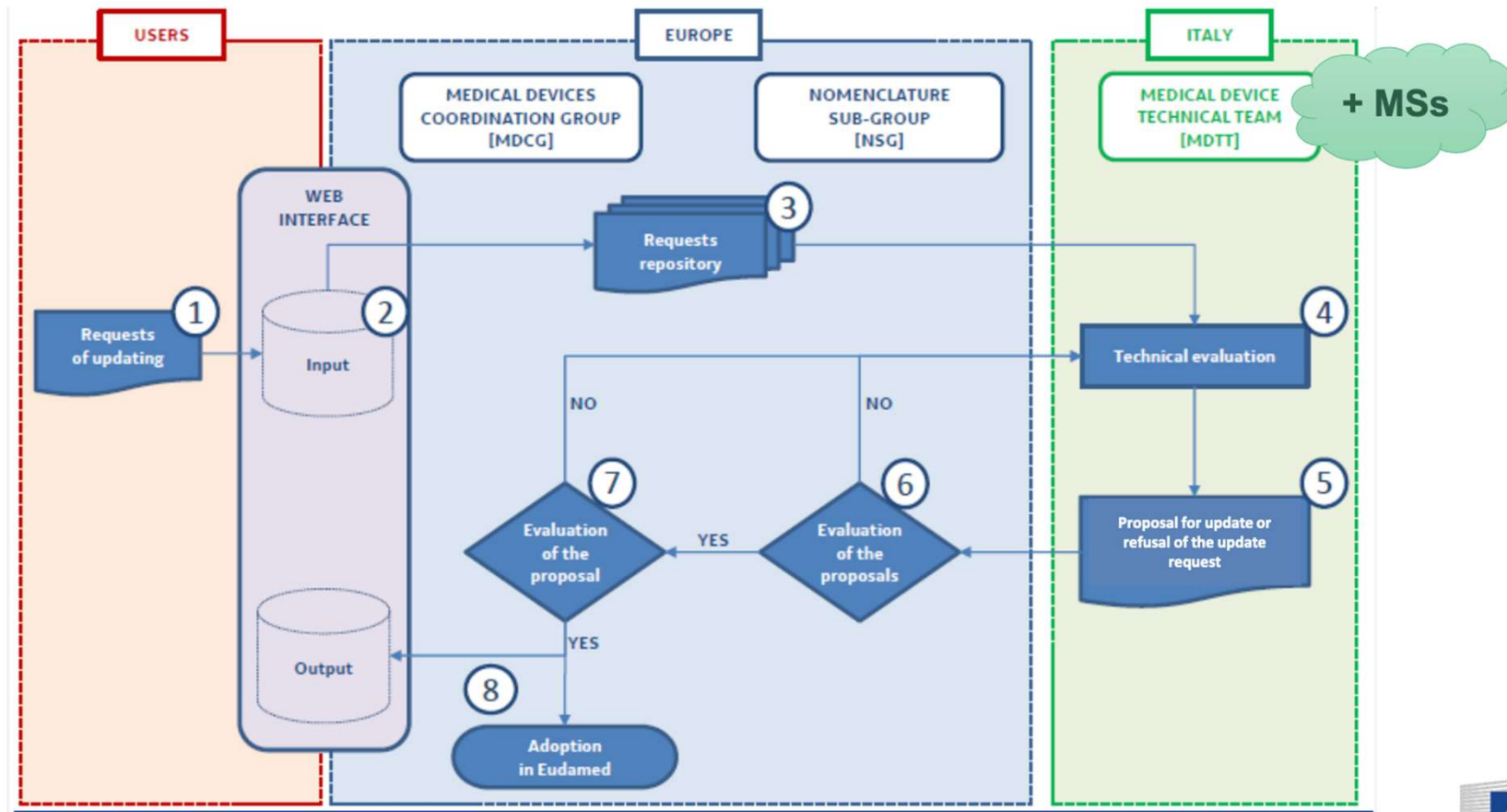
Search

- ☒ A - DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION
- ☐ B - HAEMATOLOGY AND HAEMOTRANSFUSION DEVICES
- ☐ C - CARDIOCIRCULATORY SYSTEM DEVICES
- ☐ D - DISINFECTANTS, ANTISEPTICS, STERILISING AGENTS AND DETERGENTS FOR MEDICAL DEVICES
- ☐ F - DIALYSIS DEVICES
- ☐ G - GASTROINTESTINAL DEVICES
- ☐ H - SUTURE DEVICES
- ☐ J - ACTIVE-IMPLANTABLE DEVICES
- ☐ K - ENDOTHERAPY AND ELECTROSURGICAL DEVICES
- ☐ L - REUSABLE SURGICAL INSTRUMENTS
- ☐ M - DEVICES FOR GENERAL AND SPECIALIST DRESSINGS
- ☐ N - NERVOUS AND MEDULLARY SYSTEMS DEVICES
- ☐ P - IMPLANTABLE PROSTHETIC AND OSTEOSYNTHESIS DEVICES
- ☐ Q - DENTAL, OPHTHALMOLOGIC AND ENT DEVICES
- ☐ R - RESPIRATORY AND ANAESTHESIA DEVICES
- ☐ S - STERILISATION DEVICES (EXCLUDING CAT. D - Z)
- ☐ T - PATIENT PROTECTIVE EQUIPMENT AND INCONTINENCE AIDS (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT - PPE)

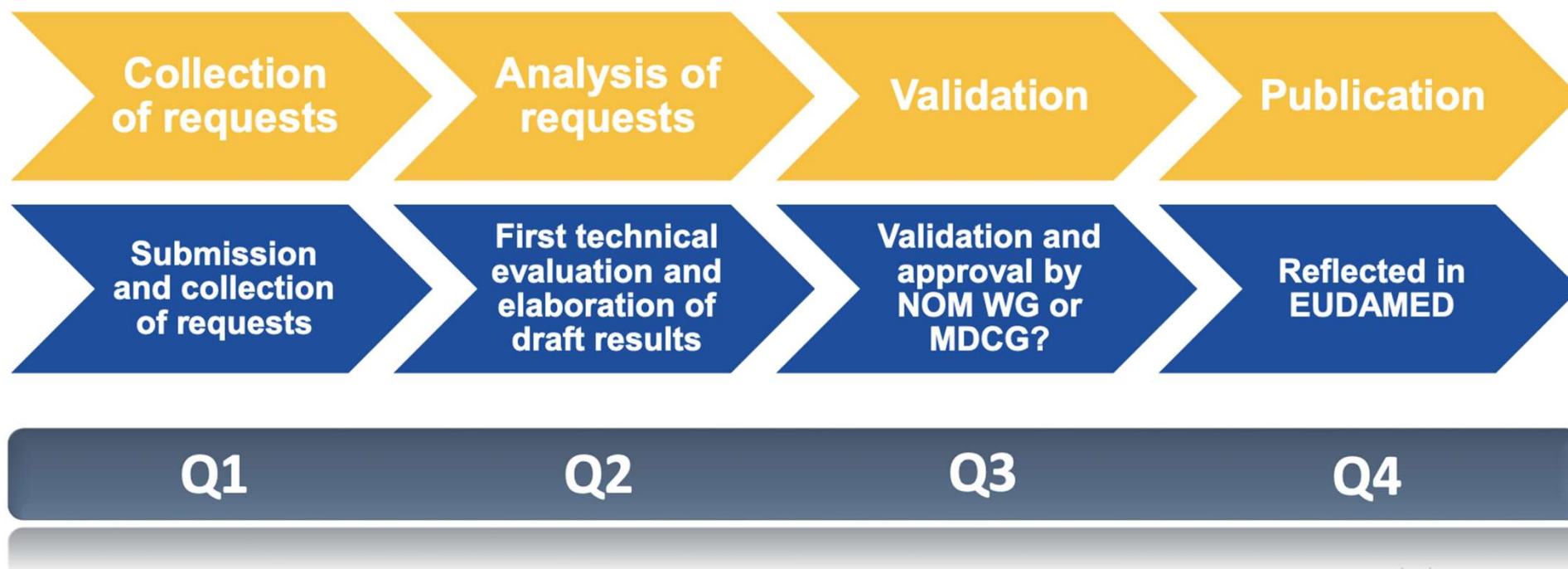
- ☒ A - DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION
 - ☐ A01 - NEEDLES
 - ☒ A02 - SYRINGES
 - ☐ A03 - TUBULAR DEVICES
 - ☐ A04 - SOLUTION FILTERS
 - ☐ A05 - MECHANICAL INFUSION SYSTEMS, SINGLE-USE
 - ☐ A06 - DRAINAGE AND FLUID COLLECTION DEVICES
 - ☐ A07 - ADAPTERS, CONNECTORS, RAMPS, STOPCOCKS, CAPS
 - ☐ A08 - NUTRITION AND INFUSION BAGS AND CONTAINERS, SINGLE-USE
 - ☐ A09 - ORGAN CONTAINERS
 - ☐ A10 - ABDOMINAL OSTOMY DEVICES
 - ☐ A11 - SAMPLE COLLECTION SWABS
 - ☐ A12 - SAMPLE COLLECTION SPATULAS
 - ☐ A99 - DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION - OTHER

- ☒ A - DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION
 - ☐ A01 - NEEDLES
 - ☒ A02 - SYRINGES
 - ☐ A0201 - SINGLE-USE SYRINGES
 - ☐ A0202 - REUSABLE SYRINGES
 - ☐ A020201 - REUSABLE INFUSION SYRINGES
 - ☐ A020202 - REUSABLE IRRIGATION SYRINGES
 - ☐ A020203 - CARTRIDGE SYRINGES
 - ☐ A020299 - REUSABLE SYRINGES - OTHER

Open update procedures for EMDN accessible to all



Annual EMDN updates procedures



Ad-hoc EMDN updates procedures

1

2

2021

Procedures for the updates of
the European Medical Device
Nomenclature

Thank you



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Slide xx: **element concerned**, source: **e.g. Fotolia.com**; Slide xx: **element concerned**, source: **e.g. iStock.com**





Meeting the needs of WHO Member States

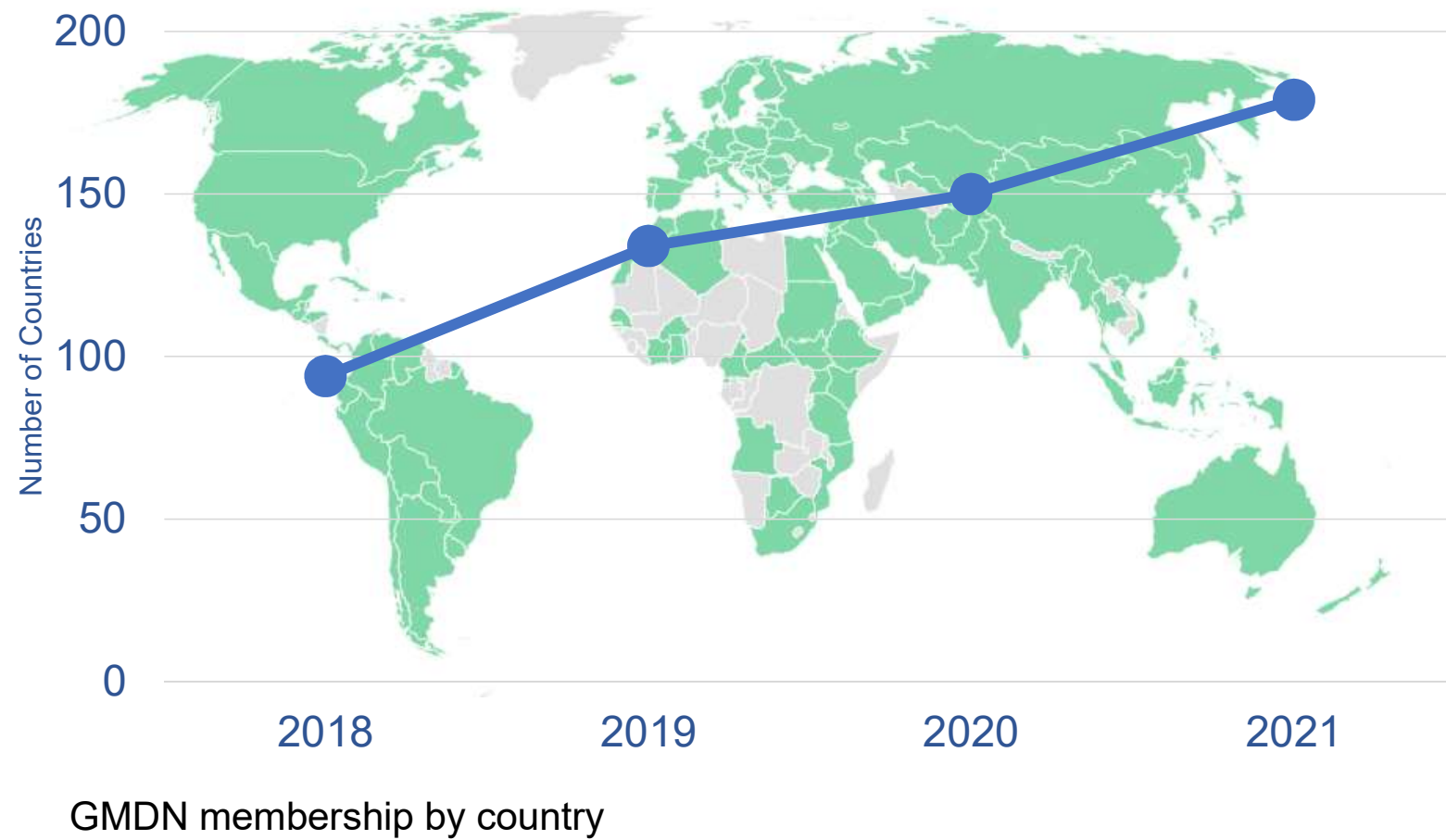
Mark Wasmuth – CEO, GMDN Agency



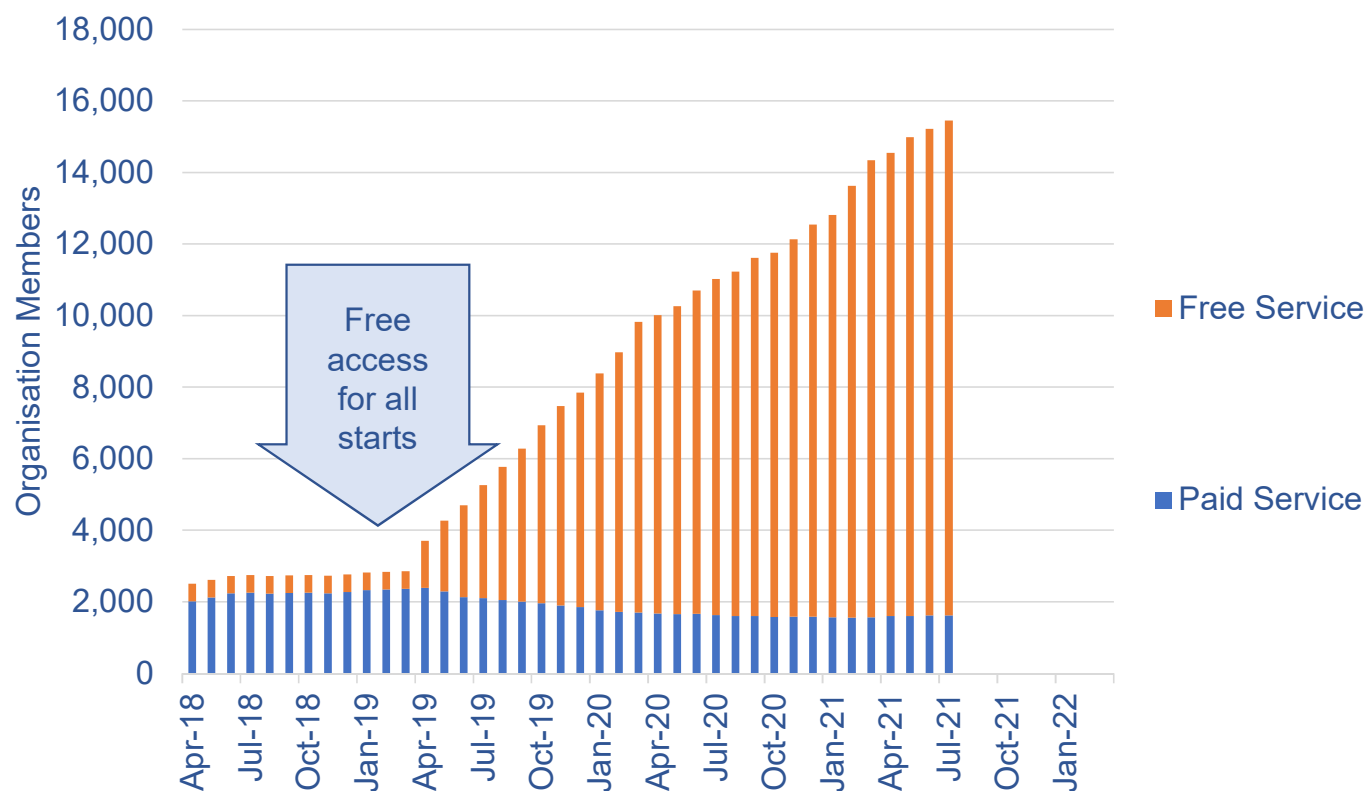
GMDN has grown consistently over the last year:

- **No barriers to access**
- **Global demand for GMDN**
- **Free membership continues to drive growth**

Global use of GMDN



Free GMDN access for all



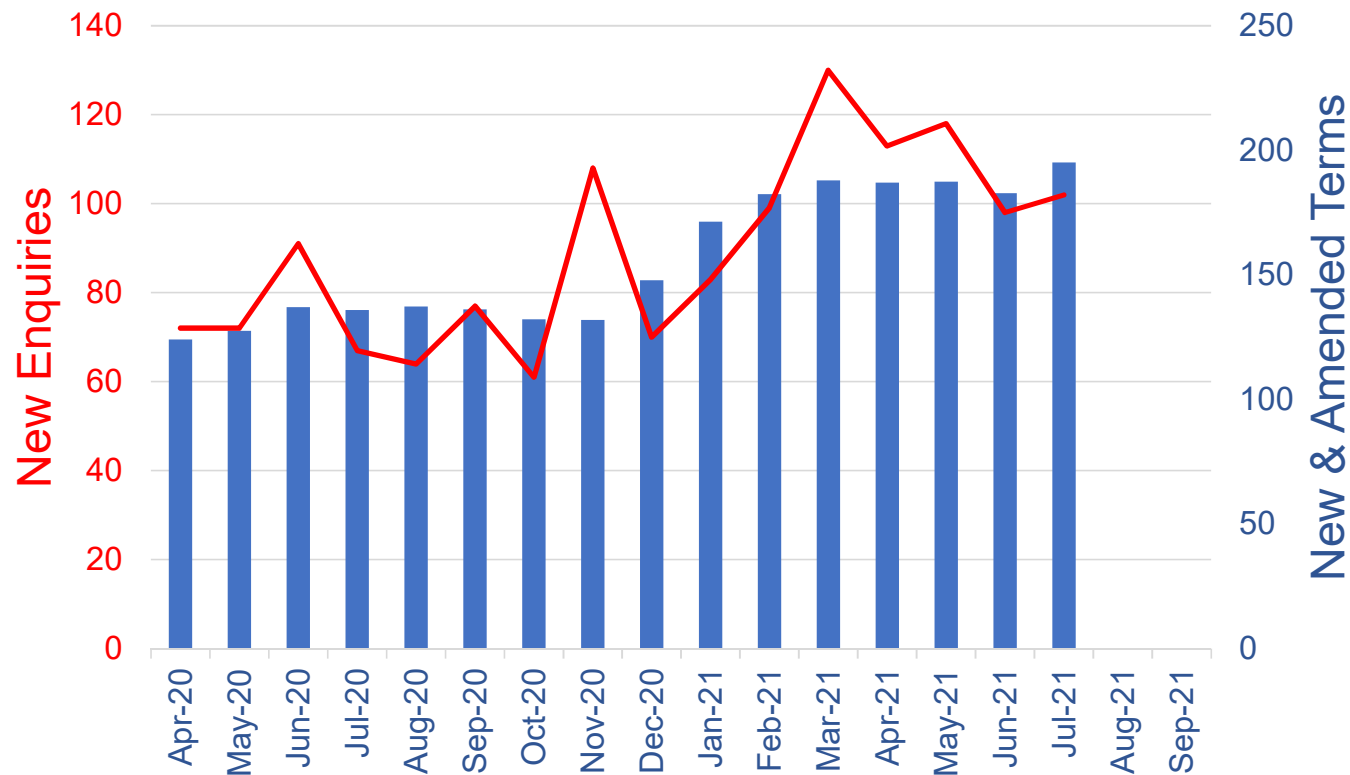
GMDN membership grown since 'free access for all' introduced

A microscopic image showing numerous red, spherical virus particles, likely representing the COVID-19 virus, against a light background. The particles are clustered together, with some in sharp focus and others blurred in the background.

Effective, agile response to added demands caused by COVID-19:

- Streamlined our processes
- Responsive to users needs, helped authorities across globe
- Improved quantification and data analysis

Active through the Covid-19 pandemic



“Our sector files one new European patent every 50 minutes” – MedTech Europe

Most active areas

Most active
in the last
year:



Covid-19 IVDs



**Respirators,
Masks and PPE**



**Ventilators,
Oxygenators**

New
issues:



**Personalised MDs -
Custom / Patient-
matched / Adaptive**



AI, SAMD, etc

Launching our 2021-2025 Strategy

To be launched later this year, the strategy will outline how we intend to:

**Be more
transparent
(operational and
strategic)**

**Increase dialogue
and engagement
with stakeholders**

**Be ambitious for
future 'how can
we enhance our
value to
stakeholders'**

**Promote greater
global
harmonisation**



mark.wasmuth@gmdnagency.org

www.gmdnagency.org

Better data, better decisions



ECRI

The Most Trusted
Voice in Healthcare

UMDNS



Universal Medical Device Nomenclature
System



51 Years of Safe and Effective Healthcare

SERVING TENS OF THOUSANDS OF MEMBERS GLOBALLY

Hospitals, Health Systems,
Government Agencies,
Payers, Insurers

INDEPENDENT TESTING & EVALUATION LAB

The only independent
medical device testing
and evaluation lab in
North America and
Asia Pacific

PATIENT SAFETY ORGANIZATION

Listed by the U.S.
Department of Health
& Human Services
and now one of the
largest in the U.S

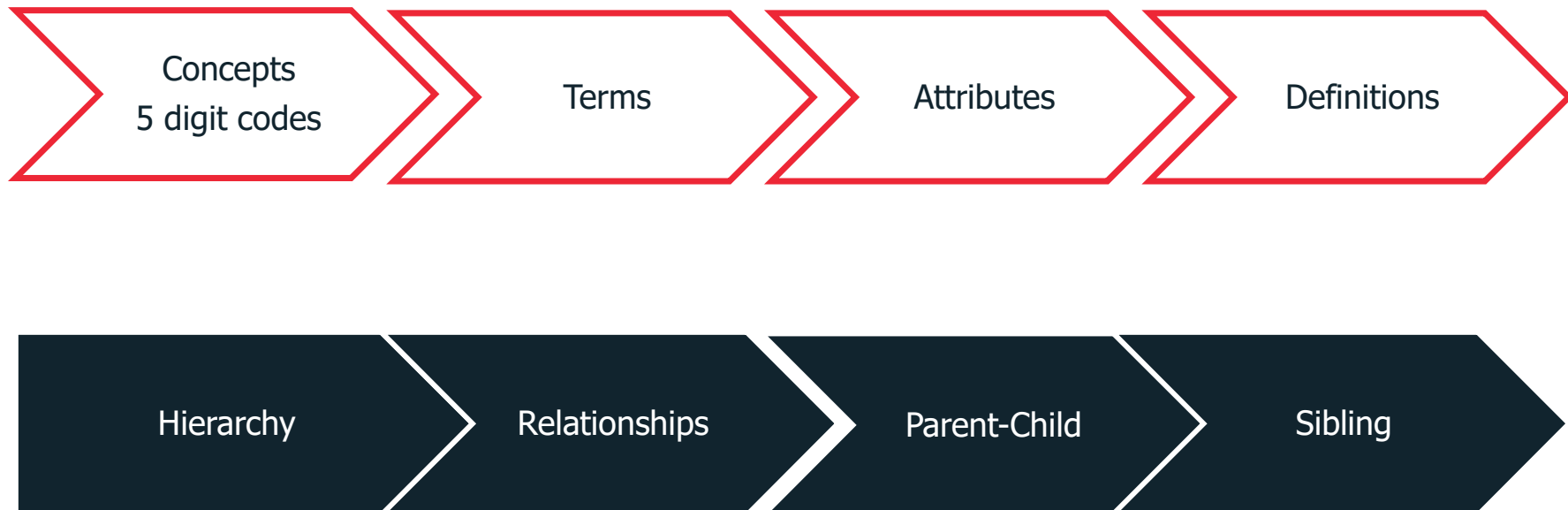
EVIDENCE-BASED PRACTICE CENTER

Designated as an
Evidence-Based Practice
Center by the U.S. Agency
for Healthcare Research
& Quality

“The country’s most respected independent laboratory for testing medical products”

The New York Times

UMDNS Components



UMDNS Licensing

Free license for non-commercial
use
1971 – 2019

Paid license required for both commercial and non-
commercial use
2019 - 2021

Resuming free license for non-commercial use
2022 -

UMDNS LOOKUP TOOL

— Currently for internal ECRI use only: <https://umdns.ecri.org>

UMDNS

Tree

Search

▼ Software

Software, 3D printing

Software, Anesthetic Gas Monitoring

Software, Anesthetic Gas Recording

▶ Software, Automation System

Software, Body Pressure Mapping

▶ Software, Chromatography System

Software, Computed Tomography

▼ Software, Computed Tomography Study

▶ Software, Computed Tomography Study, Blood-Flow

Software, Computed Tomography Study, Bone Mineral

Software, Computed Tomography Study, Cardiac

Software, Computed Tomography Study, Dental

Software, Computed Tomography Study, Pulmonary

Software, Computed Tomography/Positron Emission Tomography

Software, Computed Tomography/Single Photon Emission Tomography

▶ Software, Computer-Aided Design/Manufacturing System

▶ Software, Computer-Aided Detection System

Software, Computerized Speech Therapy

Software, Data Interface Unit/System

▶ Software, Device Programming/Testing

Detailed view ☒

Software, Computed Tomography Study [26875]

Code :

26875

Status :

Status Reason :

APPROVED

Kind :

UMDNS_KIND

Last Updated On :

12-21-2010

Created On :

12-21-2010

Properties

Device Type :

Device has SEE ALSO references.

Definition :

Software designed to acquire, process, and archive data and images obtained during computed tomography (CT) studies. This software usually works with CT systems and may also interact with devices used in the procedures, such as monitors, printers, contrast media injectors, and recorders. CT study software is intended to work only with one or a few models of CT scanning systems and related devices, usually supplied by the same manufacturer. This also facilitates the processing and sending of data to and from hospital information systems. The software may or may not be available separate from the CT equipment and may be updated and/or upgraded (i.e., through the release of modified versions) during the life of the equipment. Dedicated software is available for a variety of CT studies, such as bone mineral and cerebral blood flow analysis and also for cardiac, dental, and pulmonary image studies.

Definition Status :

Releasable

SPECIALITY_NAME :

Healthcare Information Technology

SPECIALITY_NAME :

Radiology

Synonyms(1)

Types of Relationships Between Terms

- Entry terms point to preferred terms
 - One-to-many (Use More Specific Term, SEE)
 - Example: Breast cancer gene

Breast Cancer Gene Mutation Detection Reagents

Use More Specific Term See:

IVD Test Reagent/Kits, Molecular Assay, Gene Anomaly, Mutation, BRCA1 [24-319]

IVD Test Reagent/Kits, Molecular Assay, Gene Anomaly, Mutation, BRCA2 [24-321]

Early-onset Breast Cancer Gene Mutation Detection Reagents

Use More Specific Term See:

IVD Test Reagent/Kits, Molecular Assay, Gene Anomaly, Mutation, BRCA1 [24-319]

IVD Test Reagent/Kits, Molecular Assay, Gene Anomaly, Mutation, BRCA2 [24-321]

Familial Breast Cancer Gene Mutation Detection Reagents

Use More Specific Term See:

IVD Test Reagent/Kits, Molecular Assay, Gene Anomaly, Mutation, BRCA1 [24-319]

IVD Test Reagent/Kits, Molecular Assay, Gene Anomaly, Mutation, BRCA2 [24-321]

Attributes

- Way of assigning general properties to UMDNS concepts
 - Implantable
 - Reusable/disposable
 - Capital equipment
 - Clinical specialty
 - Trackable device
- These provide another method of classifying and sorting concepts
- Properties apply to multiple concepts
- Concepts can have multiple properties applied to them

Recent strategic initiatives

- Expansion of in vitro diagnostics category to include genetic tests (including multigene panels for cancer genomics, proteomic, epigenetic, mitochondrial, whole exome, whole genome, whole transcriptome tests)
- Expansion of UMDNS scope to meet stakeholder needs:
 - Devices used in laboratory and animal research
 - Devices used in telehealth (e.g. mobile medical apps, wearables, home monitoring devices)
 - Expansion of non-traditional device coverage to accommodate equipment planning in healthcare facilities

What makes UMDNS unique?

- Used world-wide
- UMDNS has been continuously maintained for more than 40 years
- UMDNS is a constituent of the Unified Medical Language System. This provides linkages with more than 100 other medical controlled vocabularies (SNOMED CT, ICD-9, ICD-10, LOINC, MeSH, HCPCS, etc.)
- Continuous quality improvement and R&D
- Emerging technologies – barometer of technology evolution world-wide



Introduction and Overview UNSPSC®

United Nations Standard Products and
Services Code®

Hussam El-Leithy, Global Standards Director, GS1 US
23. September 2021





Agenda

- What is UNSPSC?
- UNSPSC Design
- Access to the UNSPSC Codeset



What is the UNSPSC?

- United Nations Standard Products and Services Code[®] (UNSPSC[®])
 - A free open standard
 - A taxonomy of materials, products, and services
 - A practical business tool
- Owned by **The United Nations Development Program (UNDP)**



UNSPSC: Timeline & Provenance

- Started by Dun & Bradstreet as the Standard Product and Services Code (SPSC)
 - First generation spend analytics derived from DUNS numbers as a (“from whom”) entity identifier.
- 1998: Merged with UNCCS
 - Owned and operated by The United Nations Development Program (UNDP)
 - Became the United Nations Standards and Products Code (UNSPSC)
- 2003: UNDP contracted GS1 US to operate UNSPSC. The codeset development and maintenance must be self funded.
- 2019: Addition of over 65,000 ICD-10 diagnostic codes to the codeset
- 2021: UNSPSC Codeset covers all materials, goods, and services
 - About 160,000 Codeset entries
 - Over 11,000 downloads per year from every continent



UNSPSC Design

- Hierarchical 4-level tree structure:
 - Segment, Family, Class and Commodity
 - Note: “Commodity” is not defined as bulk materials, e.g. futures contracts on soybeans, but in the broader sense as any article of commerce including capital equipment, high-value products, and professional services.
- Category titles are unambiguous and mutually exclusive
- Products appear in only one category; categories each have only one parent
- Products are grouped according to dominate usage in world market

Example of UNSPSC

“root” = All Products and Services (implied)

- └ **Segment 44** Office equipment and accessories and supplies
 - └ **Family 10** Office machines and their supplies and accessories
 - └ **Class 15** Duplicating machines
 - └ **Commodity 01** Photocopiers
 - └ **Class 31** Printer and facsimile and photocopier supplies
 - └ **Commodity 03** Printer or facsimile toner



44101501 **Photocopiers**



44103103 **Toner**





UNSPSC Components

- UNSPSC Code: 8 digits, e.g. 44103103
- Title: natural language text up to 400 characters long, e.g. “Toner”
- Definition: free form text gives concise explanation
- Key/Unique ID: sequential, arbitrary code used to semi-automate version updates (optional to use)
- Synonyms: where applicable, these will provide other terms for the Commodity



How to access to UNSPSC

- The UNSPSC codes can be used royalty free.
- UNSPSC codeset can be searched free of charge on the UNSPSC web page.
- A PDF version with all information can be downloaded free of charge.
- A tabular version can be obtained for a fee.
- Changes to the codeset can only be requested by subscribers. Subscribers need to pay a fee.
- The codeset can be used free of charge in software product and online services.

WHO IT data platforms: classification system and clearinghouse



International Classification of Diseases 11th Revision

Medical devices perspective

Dr Robert Jakob, WHO

Unit Lead

Classifications and Terminologies

International Classification of Diseases (ICD)

- Legally mandated health data standard* – in effect from January 2022 (mortality and morbidity)
- Conceptual framework independent of language and culture
- Integration of terminology and classification
- End-to-end digital solution (API, tools, online and offline)
- Up-to-date scientific knowledge
- Comparable statistics – semantic interoperability - for 150 years
- Free: **Creative Commons Attribution-NoDerivs 3.0 IGO license (CC BY-ND 3.0 IGO)**



*WHO Nomenclature Regulations 1967, WHO constitution, World Health Assembly (WHA 72 2019)

WHO core classifications



ICD

**International Statistical Classification of Diseases
and related health problems – diagnoses, injuries, findings, primary care**



ICF

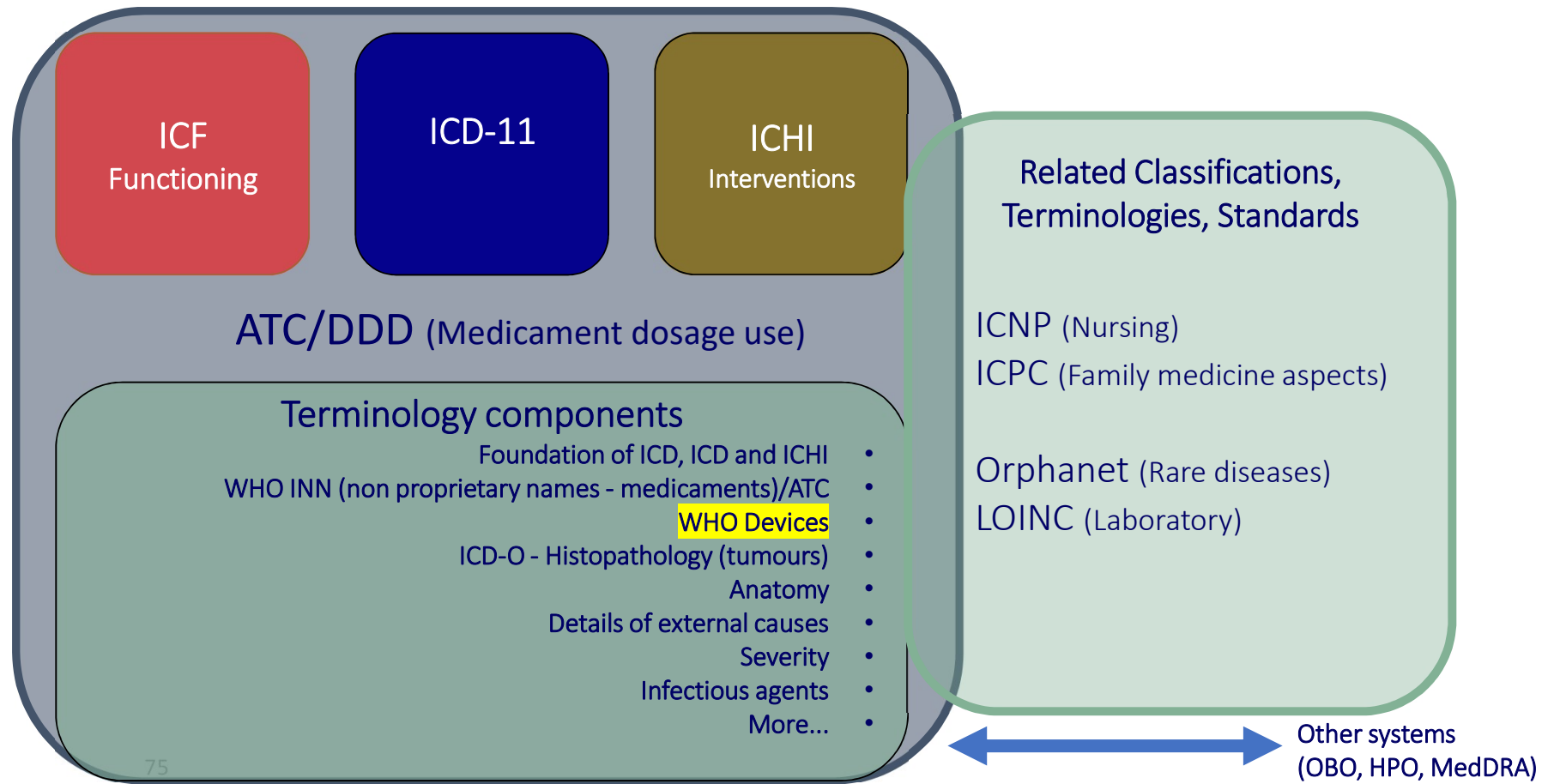
**International Classification of Functioning, Disability and Health:
Describes functional health status and social impact (bio-psycho-social model).**



ICHI

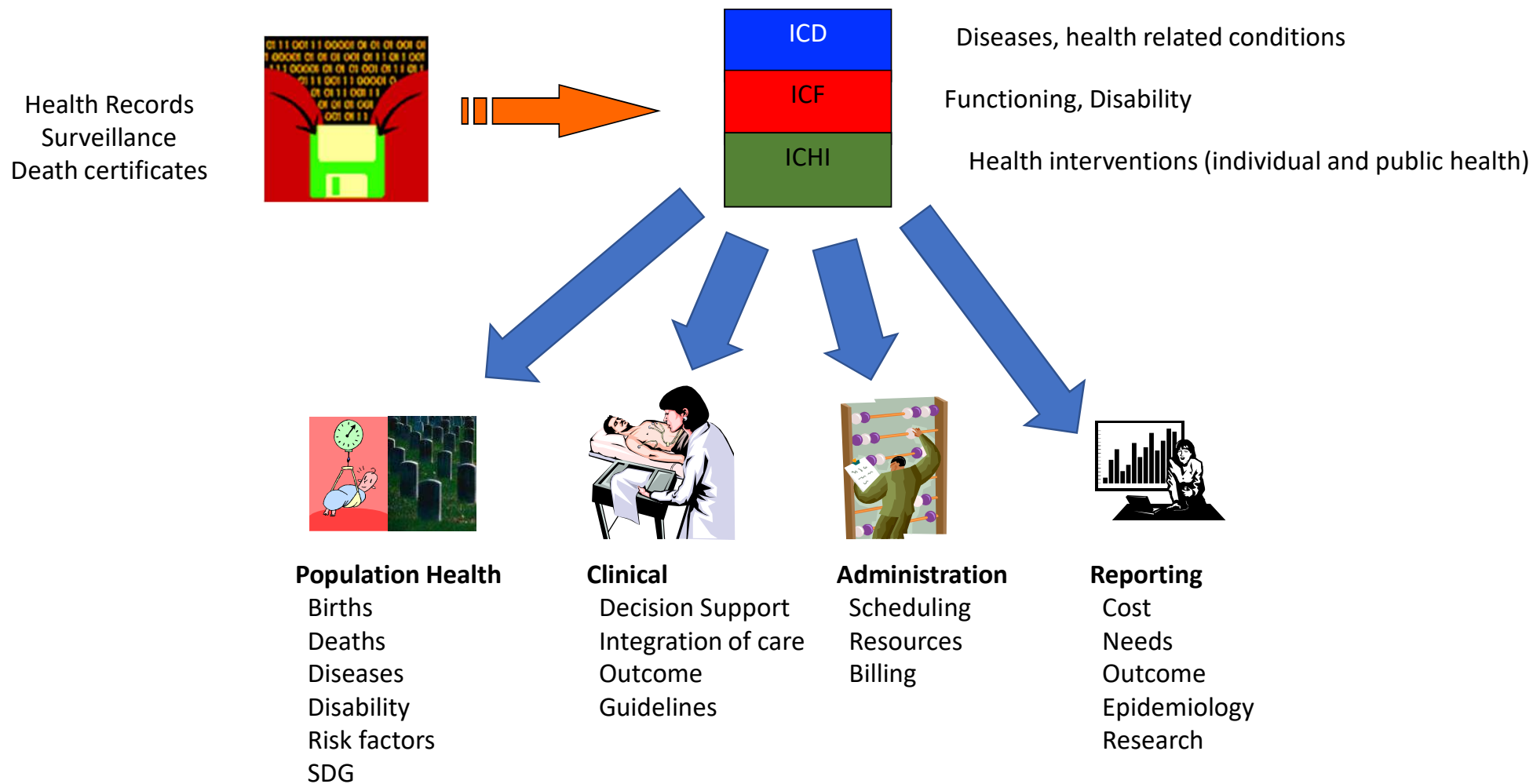
**Interventions for treatment, prevention and diagnostics:
Medical, nursing, rehabilitation, laboratory, imaging, ultrasound, public health...**

The WHO Family of International Classifications and Terminologies (WHO-FIC)

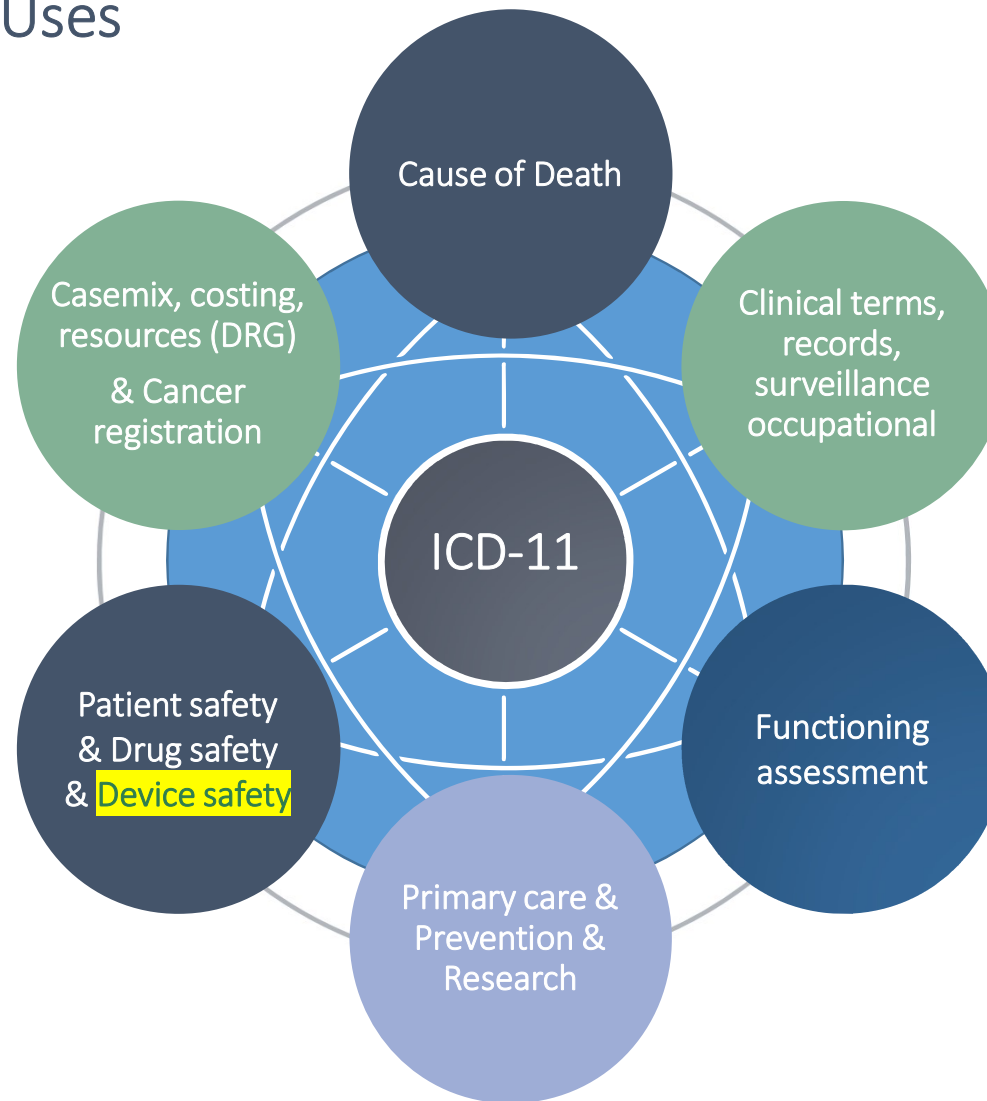


WHO-FIC

Information and Interoperability



Designed for Multiple Uses



ICD-11 – more than diagnoses

Traditional Classes and Terminology

Diagnoses

Injuries

Signs

Symptoms

Findings

Reasons for encounter or health status

External causes of illness & death

Traditional medicine conditions

Functioning assessment – WHO-DAS2

Extension codes - Terminology

Anatomy

Laterality

Infectious agents and AMR

Histopathology (ICD-O)

Chemicals and Medicaments (INN)

Devices

Mechanisms of harm (Safety)

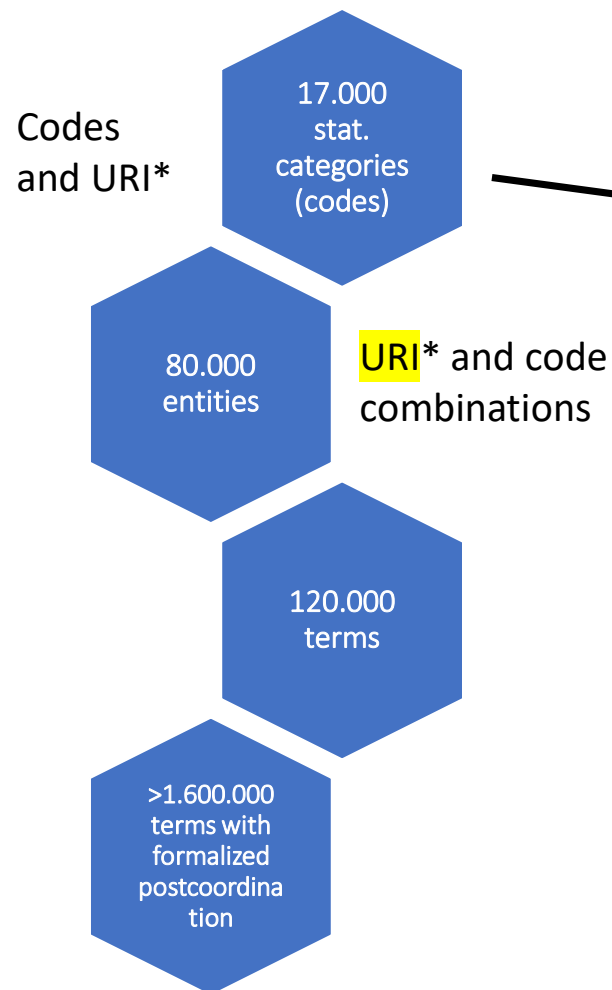
Activities

Places

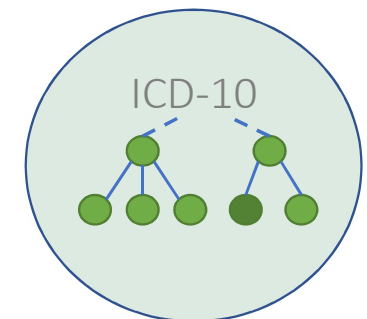
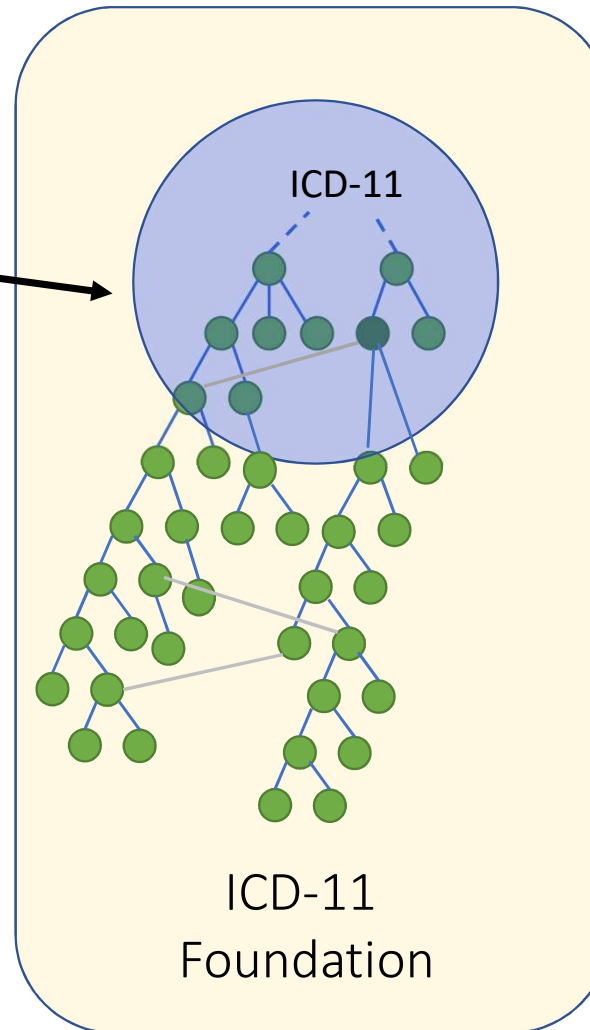
Objects

e.g. devices: EMDN classification embedded

ICD-11 – Clinical system

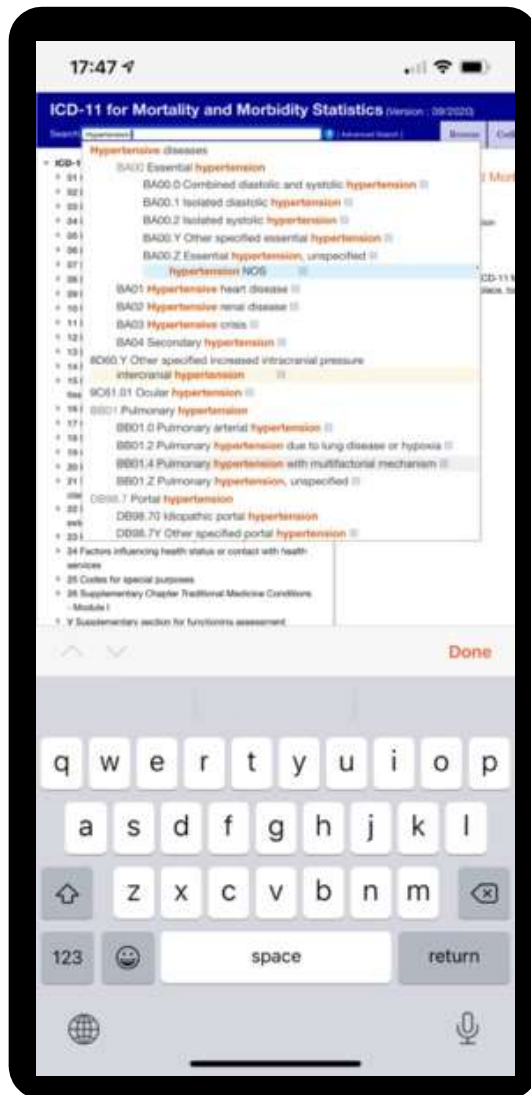


*URI: Uniform Resource Identifier - IT



14000 categories
Separate text index
Separate rule base
Need terminology link
Outdated content
Statistical system
used in
clinical setting

ICD-11 Digital



Tooling for use by humans

Modern ontology

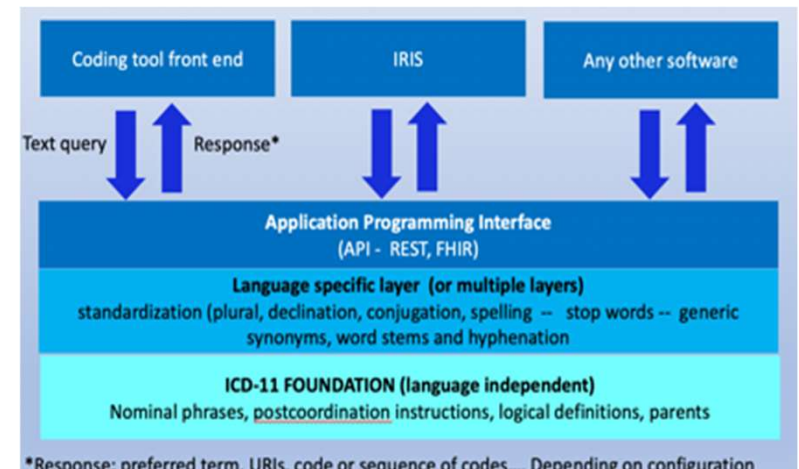
Fully digital

Portable: offline & online

Tools for use by software

Application Programming Interface (API)

Software applications on all devices and OS



Easy to use

Type a diagnostic statement into the Coding Tool

e.g. *cancer of stomach*

The screenshot shows a web-based coding tool interface. At the top, there is a search bar containing the text "cancer of stomach". Below the search bar, the interface is divided into two main sections: "Word list" and "Destination Entities".

Word list: This section contains a list of related words: "digestive", "organs", "nodes", "veins", "metastasis", and "esophagoastric". It also includes a "sort" dropdown menu set to "Relatedness/repetition".

Destination Entities: This section displays a list of medical entities with their corresponding codes and descriptions. The entities are sorted by "Matching score". The top result is "2B72.Z Malignant neoplasms of stomach, unspecified *". Other results include "2B71.Z Malignant neoplasms of oesophagogastric junction, unspecified", "2B72.Y Other specified malignant neoplasms of stomach", "2B72.1 Malignant neuroendocrine neoplasm of stomach", and "2D8Y Malignant neoplasm metastasis in other specified digestive system organ". Each result has a "+" icon and a "[Details]" link.

Two red arrows point from the text "Easy to use" to the search bar and the "Destination Entities" list, highlighting the ease of use of the tool.

The Coding Tool will find the best match

Training 30 minutes = 88% correct coding

In ICD-11 diseases, interventions and medical devices
i.e. “infusion”

The screenshot displays the ICD-11 for Mortality and Morbidity Statistics website. The search bar at the top left contains the word "infusion". A dropdown menu shows a list of search results, including:

- XE7NV **Infusion** or flow problem
- XE6YH Excess flow or over-**infusion**
- XE1H4 Improper flow or **infusion**
- XE2DM Intermittent **infusion**
- XE1S7 Insufficient flow or under **infusion**
- XE1JK Failure to **infuse**
- XD8QY1 **Infusion** Pumps
 - XD4CT3 **Infusion** Pumps, Volumetric
 - XD52M6 **Infusion** Pumps, Volumetric, Nuclear Magnetic Resonance
 - XD8DH3 **Infusion** Pumps, Enteral nutrition
 - XD36Q1 **Infusion** Pumps, Syringe
 - XD1N14 **Infusion** Pumps, Syringe, Nuclear Magnetic Resonance
- QB30.1 Adjustment or management of **infusion** pump
- XD5ED6 **Reinfusion** dialysis lines
- XD25C5 Dialysate tanks, collection and **reinfusion**
 - XD1ZR7 Dialysate tanks, **reinfusion**
- PK91.2Y Other specified cardiovascular devices associated with injury or harm, prosthetic or other implants, materials or accessory devices
 - Mechanical complication of **infusion** catheter
- NE80 Injury or harm arising following **infusion**, transfusion or therapeutic injection, not elsewhere classified
 - NE80.0 Air embolism following **infusion**, transfusion or therapeutic injection
 - NE80.1 ABO incompatibility reaction
 - infusion** reaction to incompatible blood group
 - NE80.2 Rh incompatibility reaction
 - Reaction due to Rh factor in **infusion** or transfusion
 - NE80.Y Other specified injury or harm arising following **infusion**, transfusion or therapeutic injection, not elsewhere classified
 - NE80.Z Injury or harm arising following **infusion**, transfusion or therapeutic injection, not elsewhere classified.
- 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 relative accessories
- XD4U38 General purpose electrocardiographs
- XD6UU3 Oxygen Concentrators
- Extension codes of particular relevance to skin diseases

The right side of the screen shows a section titled "units (CPAP)" with a "Show all ancestors" link and a "Hide index terms" link. At the bottom right, there is a "Caveats" warning icon.

Sample of medical devices for COVID-19 that include the EMDN

ICD-11 for Mortality and Morbidity Statistics

Search

[Advanced Search]

Foundation

Linearizations

Proposals

Info

XD4E8U Surgical gowns, standard

XD9LJ2 Standard surgical face mask

Medical devices, urogenital apparatus

Medical devices - various

XD2AJ4 Electronic thermometers and end caps

XD97L1 Clinical trays and bowls

In vitro diagnostic devices (D. Lgs. 332/2000)

XD5GV0 C-REACTIVE PROTEIN

XD9YL7 Transport media

XD9S44 Coronavirus-NA Reagents

XD9N16 Coronavirus (diagnostic)

XD7M68 Other Virology - RT & POC

XD1C76 Reagents for DNA and/or RNA extraction and preparation : bacteria and/or virus

XD6EG0 Blood gas portable analysers

XD80L4 Samples transport containers- others

Supports or technical aids for disabled persons

Medical equipment and related accessories and materials

Foundation URI : <http://id.who.int/icd/entity/812018134>

XD3SM4 Intensive care ventilators

Parent

Medical equipment and related accessories and materials

All Index Terms

- Intensive care ventilators

External References

EMDN: Z12030105

A blue arrow pointing from the text 'EMDN' to the 'EMDN: Z12030105' entry in the 'External References' section of the ICD-11 interface.

27/09/2021

| Title of the presentation

83

WHO willing to describe the different nomenclatures, codes and terms if agreement from the nomenclature organizations.

- Haemodialysis, hemofiltration, haemodiafiltration filters
 - Dialyzers - UHF < 18 ml/h/mmHg
 - Dialyzers - UHF < 18 ml/h/mmHg, cellulose membranes
 - Dialyzers - UHF < 18 ml/h/mmHg, substituted cellulose membranes
 - Dialyzers - UHF < 18 ml/h/mmHg, synthetic membranes
 - Dialyzers - UHF < 18 ml/h/mmHg - others
 - Dialyzers - UHF = 18 - 35 ml/h/mmHg
 - Dialyzers - UHF > 35 ml/h/mmHg
 - Dialyzers for special hemodiafiltration and other therapies
- Hemoperfusion filters

External
References ?

+ Add new value

Source	Term ID
other...	...
EMDN	abc
GMDN	xyz

ICD-11 ontological platform has created a page specific for devices having URI, using EMDN structure open to add other systems for mapping

The screenshot shows a web browser window with the address bar displaying <https://icd11files.blob.core.windows.net/healthdevicesbrowser/index.html>. The page title is "Health Devices, Equipment and Supplies (2021-05)". Below the title is a search bar with the placeholder text "Type for starting the search". The main content area is divided into two columns. The left column contains a hierarchical list of categories and subcategories, including "Health Devices, Equipment and Supplies", "Devices for administration, collecting and picking", "Hematology and hemotransfusion devices", "Cardiocirculatory devices", "Disinfectants, antiseptics and proteolytics for medical devices (D. Lgs. 46/97)", "Dialysis devices", "Gastrointestinal devices", "Suture devices", "Active-implantable devices", "Endotherapy and electrosurgical devices", "Reusable surgical instruments", "Devices for generic and specialistic medication", "Devices for nervous and medullary systems", "Implantable prosthetic devices and osteosynthesis devices", "Dental, ophthalmologic and ear, nose and throat devices", "Respiratory and anaesthesia devices", "XD9246 Nasopharyngeal tubes", "XD2M69 Airway guedel tubes", "XD78N3 Laryngeal masks", "XD0T92 Endotracheal tubes, without cuff", "XD37X2 Endotracheal tubes, with cuff", "XD3UM6 Endotracheal tubes - accessories", "XD2MG6 Tracheolaringostomy cannulas and kits, with cuff", "XD7EB1 Bipap/CPAP circuits", "XD5GF6 Respiratory masks and balloons, single-use and reusable", "XD3W67 Air/oxygen masks and nasal cannulas", "XD0VQ3 Air/oxygen masks", "XD5RM4 Venturi masks", and "XD6175 Air/oxvnen nasal cannulas". The right column is titled "Health Devices, Equipment and Supplies" and is currently empty.

Multilingual (23 more languages in translation)

Select languages

ICD-11 for Mortality and Morbidity Statistics (Version : 05/2021)

Search hypertension [Advanced Search]

Browse

Coding Tool

Special Views

Info

EN

English

Arabic

Spanish

Chinese

> Arabic

> Spanish

> Chinese

ICD-11 - ICD-11 for Mortality and Morbidity Statistics

01 Certain infectious or parasitic diseases

02 Neoplasms

03 Diseases of the blood or blood-forming organs

04 Diseases of the immune system

05 Endocrine, nutritional or metabolic diseases

06 Mental, behavioural or neurodevelopmental disorders

07 Sleep-wake disorders

08 Diseases of the nervous system

09 Diseases of the visual system

10 Diseases of the ear or mastoid process

11 Diseases of the circulatory system

Hypertensive diseases

BA00 Essential hypertension

BA01 Hypertensive heart disease

BA02 Hypertensive renal disease

BA03 Hypertensive crisis

BA04 Secondary hypertension

KB45 Neonatal hypertension

Hypotension

Ischaemic heart diseases

Diseases of coronary artery

Pulmonary heart disease or diseases of pulmonary circulation

Pericarditis

Acute or subacute endocarditis

Heart valve diseases

BC20 Chronic rheumatic heart diseases, not elsewhere classified

Diseases of the myocardium or cardiac chambers

Cardiac arrhythmia

Heart failure

Foundation URI : <http://id.who.int/icd/entity/761947693>

BA00 Essential hypertension

Parent

Hypertensive diseases

Show all ancestors

Description

Essential (primary) hypertension, accounting for 95% of all cases of hypertension, is defined as high blood pressure for which a secondary cause cannot be found.

Inclusions

• high blood pressure

Exclusions

• Cerebrovascular diseases (8B00-8B2Z)

• Background retinopathy and retinal vascular changes (9B78.1)

Coded Elsewhere

• Pre-existing essential hypertension complicating pregnancy, childbirth or the puerperium (JA20.0)

Postcoordination

Add detail to Essential hypertension

Has manifestation (use additional code, if desired.)

BA03 Hypertensive crisis

Associated with (use additional code, if desired.)

XT9T Ageing-related

Release Notes

Foundation URI : <http://id.who.int/icd/entity/761947693>

فَرْطَ ضَغْطِ الدَّمِ الْأَسَاسِي

فَرْطَ ضَغْطِ الدَّمِ

إظهار جميع العناصر الأصلية الأعلى

وصف

فَرْطَ ضَغْطِ الدَّمِ الْأَسَاسِي (أولوي) هو المسؤول عن 95% من جميع حالات فَرْطِ الضَّغْطِ، وتعرِّفه أنه ارتفاع ضغط الدم لم يمكن معرفة سبب ثانوي له.

المُشْتَمَلَات

• ضغط دم مرتفع

المُستَبعَدَات

• أمراض دماغية وعائية (8B00-8B2Z)

• اعتلال الشبكية الخلقية وتغيرات وعائية في الشبكية (9B78.1)

تم ترميزه في مكان آخر

• فَرْطَ ضَغْطِ الدَّمِ الْأَسَاسِي السابق للحمل والذي يسبب مضاعفات للحمل أو الولادة أو النفاس (JA20.0)

الرابط اللاحق

أضف تفاصيل ارتفاع ضغط الدم الأساسي

له مظاهر (يستخدم رمزًا إضافيًا، عند الرغبة في ذلك.)

BA03 هجمة ارتفاع ضغط الدم

مرتبط مع (يستخدم رمزًا إضافيًا، عند الرغبة في ذلك.)

XT9T مرتبط بالتشيخ

ملاحظات حول الإصدار

Tools for Users

Coding

API- Integration
with IT

Training
(WHO-FIT)

Guides for
implementation
and use

Mappings to ICD-
10

Causes of death

Casemix
(development
started)

ANACOD 3 –
quality assessment
of cause of death
statistics

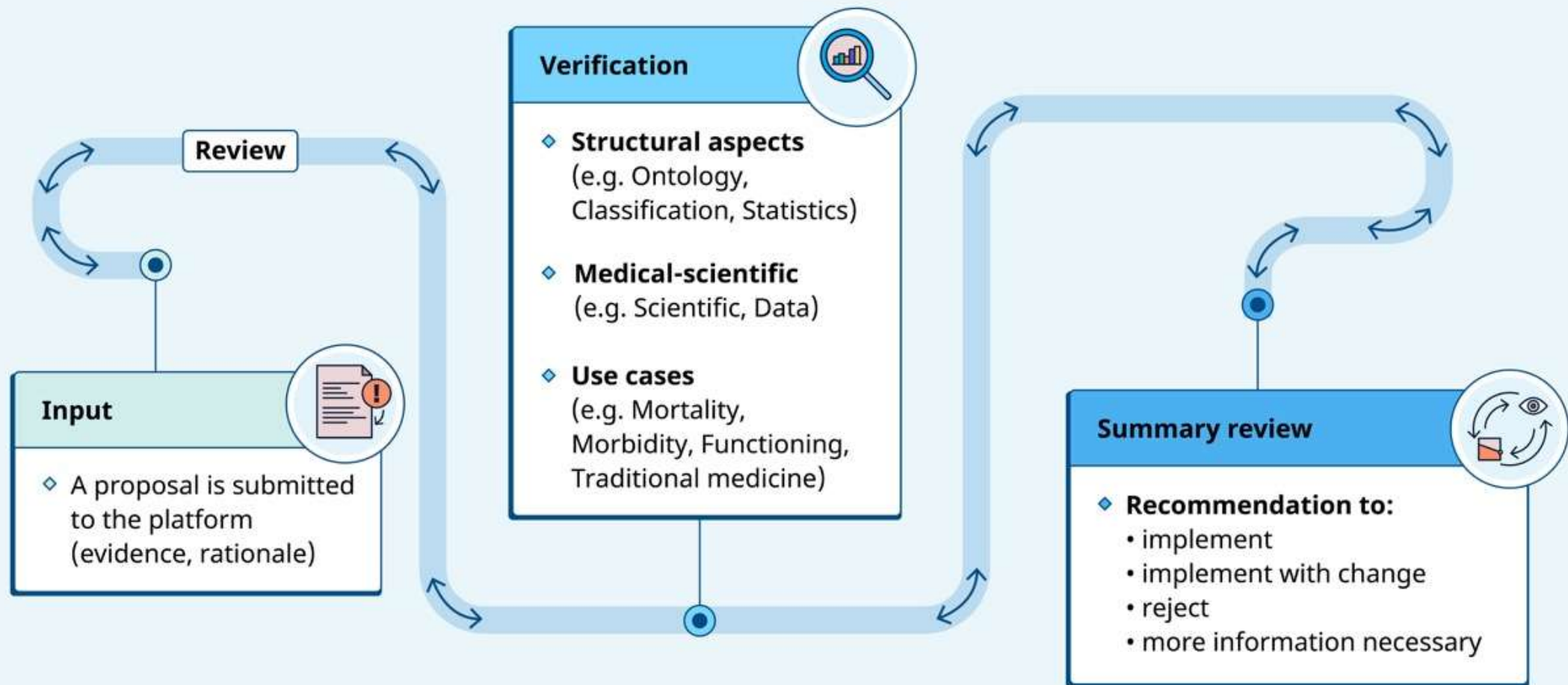
Software assisted
selection cause of
death (testing
prototype)

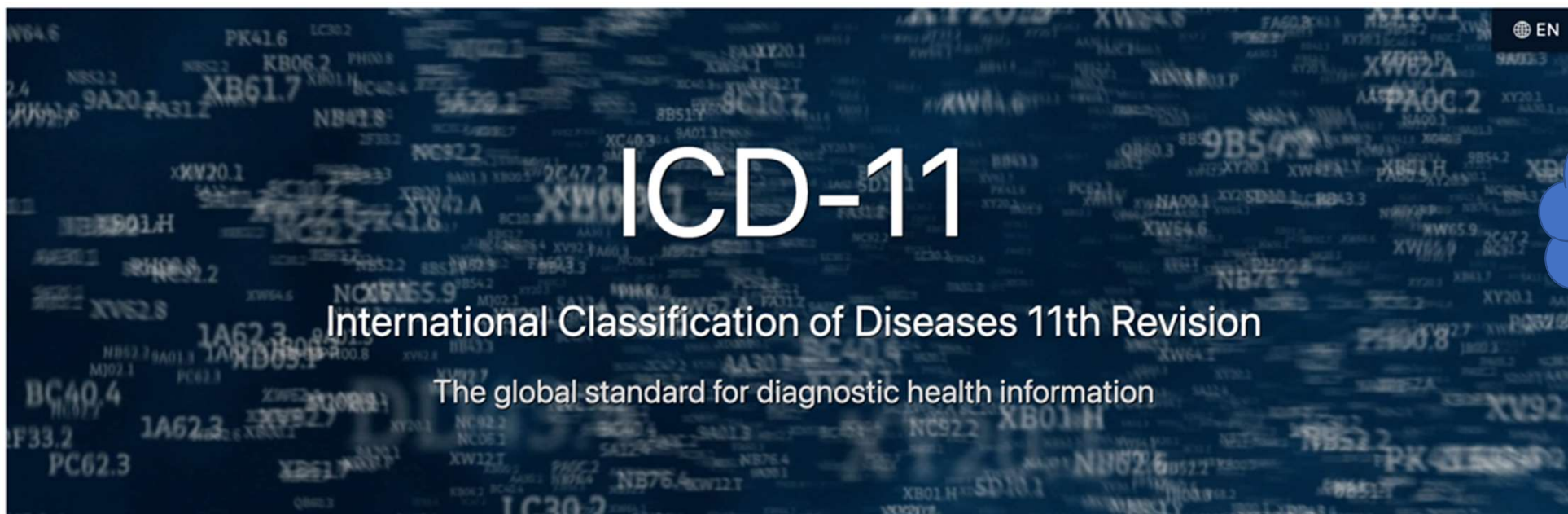
Proposals

Translation

...

ICD-11 maintenance is a transparent public process





Select language

Use ICD-11

ICD-11 Browser

for seeing the content

ICD-11 Coding Tool

for coding with ICD-11

ICD-API

web services to get

programmatic access to ICD-11

ICD-11 Implementation or
Transition Guide

Learn More

ICD Home Page

ICD-11 Reference Guide

ICD-11 Fact Sheet

ICD Video

Older versions

ICD-10 Browser

Be Involved

Our maintenance platform

provides various ways to

contribute

Comments

Proposals

Translations

Register,
submit
proposal

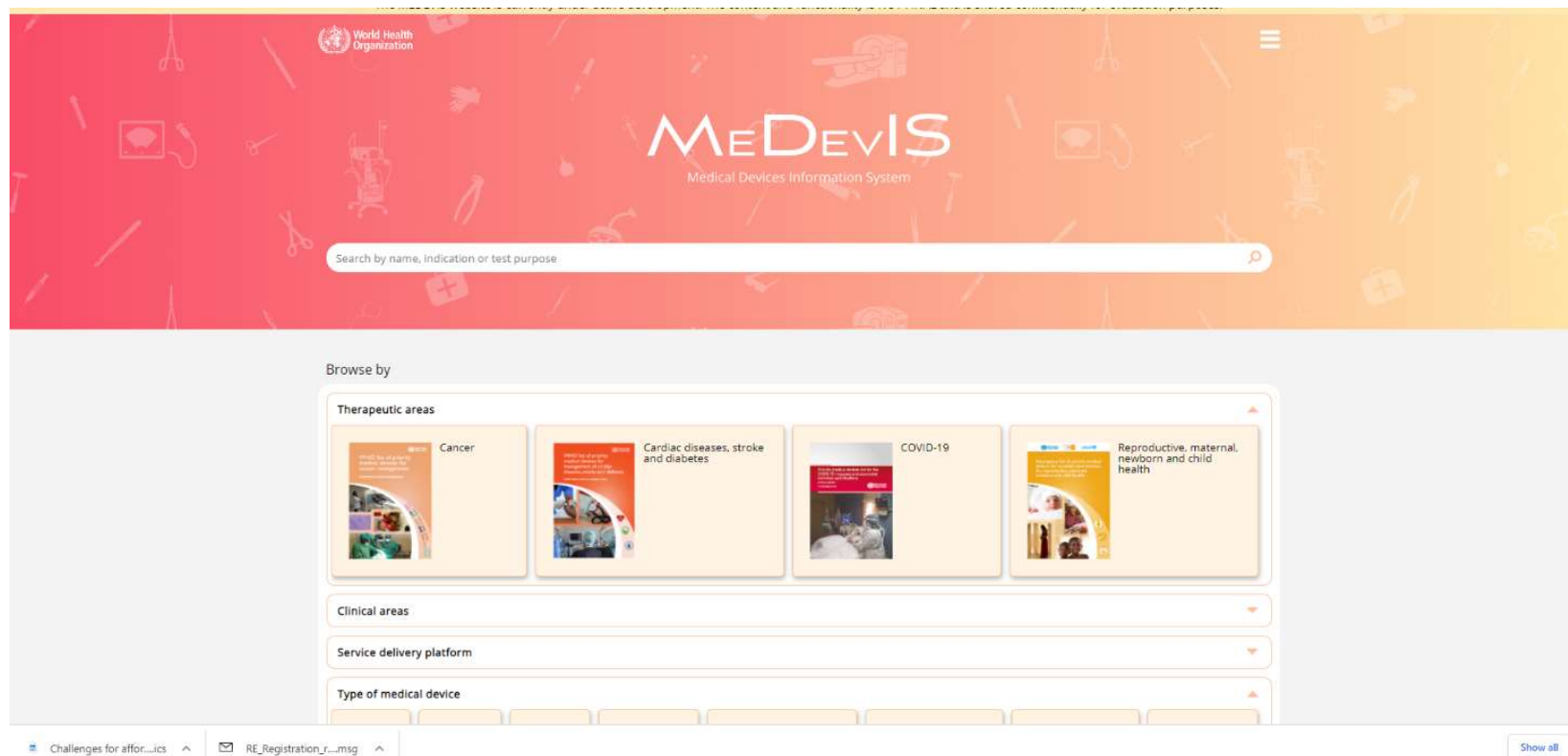


Information and files online : <http://icd.who.int>



- Global Goods
- Mandated by International Regulations
 - Improved and refined by
- Global support, contributions and feedback
- For comparable data, reliable easy use and interoperability
 - Webinars for introduction
- **icd@who.int**

WHO Priority medical devices information system “MEDEVIS” clearing house of WHO documents to support decision making



<https://medevis.test.evidenceprime.com/>

MEDEVIS includes EMDN in pilot project and can add GMDN, UMNDS, UNSPSC codes and terms.



The screenshot displays the MEDEVIS web application interface. At the top, the header features the MEDEVIS logo and the text 'Priority Medical Devices Information System'. Below the header, a search bar contains the query 'Bi-Level Positive Airway Pressure Unit (BiPAP), adult and paediatric'. The search results show one result: 'Bi-Level Positive Airway Pressure Unit (BiPAP), adult and paediatric'. The result details include the EMDN Code: Z1203010504 and the EMDN Nomenclature: ADULT AND PAEDIATRIC/NEONATAL PULMONARY VENTILATORS. On the left side, there are filters for 'WHO list of priority medical devices', 'Various conditions or disease specific', 'Organ or system related according to ICD-11', 'Life course', and 'Sex'. At the bottom, there is a navigation bar with the WHO logo and the MEDEVIS logo.

MEDEVIS
Priority Medical Devices Information System

a01

Device

- A0102—Biopsy needle
- A0102—Biopsy gun
- A01020202—Aspiration set, bone marrow
- A019012—Excisional breast biopsy set
- A010101—Hypodermic needles
- A018002—Non-implantable needle guide
- A01—Needles, sterile, single use
- A019099—Paediatric spinal needles
- A019007—Sclerotherapy endoscopic needles
- A01030101—Spinal anaesthesia needle, single-use
- A019012—Wire localization needle

Type of medical device

Capital, reusable or single use

← → ↻ 🏠 🔍 ⚙️ ⭐ 📄 👤

https://medeis-preview.test.evidenceprime.com/search?query=Bi-Level%20Positive%20Airway%20Pressure%20Unit%20(BiPAP)%2C%20adult%20and%20paediatric

The MEDEVIS platform is currently under active development. It only includes medical devices listed in the WHO publications, limited to specific diseases, health conditions and health care settings. This is a Beta version.

World Health Organization MEDEVIS

Bi-Level Positive Airway Pressure Unit (BiPAP), adult and paediatric

Found 1 result

Export results

Bi-Level Positive Airway Pressure Unit (BiPAP), adult and paediatric

EMDN Code: Z1203010504 EMDN Nomenclature: ADULT AND PAEDIATRIC/NEONATAL PULMONARY VENTILATORS

WHO list of priority medical devices

Various conditions or disease specific

Organ or system related according to ICD-11

Life course

Sex

Feasibility study

Nomenclature Mapping Proposal

Terrie L. Reed
WHO Nomenclature Consultant
Symmetric Health Solutions LLC

Nomenclature Mapping Project

By 1 October 2021

- Understand mapping requirements
- Educate nomenclature stakeholders on innovative tools for using UDI-DI to map nomenclatures
- Offer technical options for integration of UDI-DI with multiple nomenclatures in existing WHO and UN platforms (UHCC, MEDEVIS, ICD-11)
- Provide estimate of costs of feasibility study including technical options

Communicating Product Information: Unique Device Identification



1974 - UPC



1976 - NDC



2013 - UDI

Scan UDI to unlock device information

01: Device Identifier (UDI-DI) = 00606959026605

21 – Serial Number = J18062750CED



UDI-DI

EMDN

Nomenclature
Assignment



UNSPSC



UDI-DI

Model/Version



GMDN

- Improves code assignment
- Avoids disrupting users of global nomenclatures



UMDNS

- Avoids disruption to nomenclature agency processes



UDI-DI

00606959026605



Mapping across Nomenclatures

EMDN	GMDN	UMDNS	UNSPSC
Z12030102	60711	11001	42272202
Continuous positive pressure equipment	Home CPAP Unit	Positive Airway Pressure Units, Continuous	Non-invasive continuous positive air pressure machines

Mapping across Nomenclatures

Device Type – COVID-19

UDI-DI	Manufacturer Description	EMDN Code	EMDN Name	GMDN Code	GMDN Preferred Term	UMDNS Code	UMDNS Term	UNSPSC	UNSPSC Title
10711234160015	Avoximeter Whole Blood Oximeter Optical QC Filters	W0201069002	BLOOD GAS PORTABLE ANALYSERS	56673	Co-oximetry analyser IVD, point-of-care	18635	Oximeters, In Vitro, Point-of-Care	41116203	Monitor or meter accessories
00849686073782	WristOx2 Wearable Pulse Oximeter with Bluetooth	Z1203020408	PULSE OXIMETERS	36118	Pulse oximetry telemetric monitoring system	22855	Monitors, Physiologic, Pulse Oximetry, Personal	42181801	Pulse oximeter units
00874750005703	E1 MASK & HG LARGE HRI LABEL	R03010201	AIR/OXYGEN MASKS	35171	Rebreathing oxygen face mask	39680	Masks, Air-Oxygen, Positive Airway Pressure Unit, Oronasal	42272213	Continuous positive airway pressure CPAP masks or straps
00606959032590	EverFlo w/Oxygen Percentage Indicator, 230V Italy Chile	Z12159004	OXYGEN CONCENTRATORS	12873	Stationary oxygen concentrator	12873	Oxygen Concentrators	42271702	Oxygen concentrators

Mapping across Nomenclatures

Device Type – Cardiovascular Devices

UDI-DI	Manufacturer Description	EMDN Code	EMDN Name	GMDN Code	GMDN Preferred Term	UMDNS Code	UMDNS Term	UNSPSC	UNSPSC Title
10846835007978	CATHETER ELECTROPHYSIOLOGY BLACK 115CM 6FR 5MM SPACE F CURVE FIX QUADRAPOLAR AUTO ID 1MM	C020103	ARRHYTHMOLOGY TETRAPOLAR ELECTROCATETERS	46355	Cardiac mapping catheter, percutaneous, single-use	41923	Catheters, Cardiac, Electrophysiology, Mapping	42203430	Electrophysiology catheters
00811806010717	Guidewire	C0499	CARDIOVASCULAR GUIDEWIRES - OTHER	35094	Cardiac/peripheral vascular guidewire, single-use	36599	Guide Wires, Cardiovascular	42203404	Vascular imaging guidewires

Mapping across Nomenclatures

Device Type – Orthopedic Devices

EMDN Code	EMDN Name	GMDN Code	GMDN Preferred Term	UMDNS Code	UMDNS Term	UNSPSC	UNSPSC Title
P09120699	BONE FIXATION SCREWS, TENDON AND LIGAMENT SYNTHESIS SCREWS - OTHER	45062	Tendon/ligament bone anchor, non-bioabsorbable	32734	Screws, Bone/Graft	42322201	Interference screws
P09088099	HIP PROSTHESES - OTHER ACCESSORIES	43167	Acetabulum prosthesis hole plug	16126	Restrictors, Orthopedic Cement	42322601	Orthopedic hole eliminators or plugs
P09120501	OSTEOSYNTHESIS COMPRESSION PLATES	46642	Craniofacial fixation plate, non-bioabsorbable	15749	Cover Implants, Bur Hole	42296104	Cranial plate or bur hole covers

Nomenclature Convergence Roadmap

- Conduct landscape analysis of Global Nomenclature issues
- Propose a technical solution to address nomenclature mapping
- Obtain agreement from WHO member states and key stakeholders on feasibility study proposal
- Conduct feasibility study and report results and recommendations to Member States and key stakeholder groups

Nomenclature Feasibility Study

Purpose:

To demonstrate and evaluate the technical and cost challenges and benefits of using item level data to map/establish a crosswalk across multiple globally used nomenclatures and integrate the study results into WHO platforms.

Nomenclature Feasibility Study

Draft Proposal

- **Timeline:** October to December 2021
- **Participants:** Regulators, Nomenclature Agencies, Industry, Hospitals, UN agencies, WHO, IT Consultants
- **Scope:** Subset of EDL and Priority medical devices (e.g. COVID, CVD, and Infectious Diseases)
- **Methodology:**
 - Using UDI-DI and other IT tools to retrieve, compare and analyze nomenclature codes and terms
 - Periodic engagement of participants
 - Monthly update to all stakeholders
- **Estimated Cost**
 - \$150,000-\$200,000 (or in-kind)
 - Resources: WHO Subject Matter and IT Consultants , Nomenclature Agencies

Stakeholders statements:

- UN Agencies and NGOs**
- MD Industry**
- Biomedical and Clinical Engineers**

Open discussion from Members States

Conclusions