

**Information Session with Member States
12 April 2021.**



Standardization of medical devices nomenclature

Invitation sent to MS by GBS on 7 April

You are invited to a virtual Information session on Standardization of medical devices nomenclature on Monday, 12 April 2021 from 14:00 to 15:15 CET in response to the request from Members of the Executive Board on 23 January 2021, in the context of the Report by the Director-General on Standardization of medical devices nomenclature (document [EB148/13](#)) and previously document [EB145/3](#).

The agenda is as follows:

14:00 Welcome by Dr Clive Ondari, Director, Health Product Policy and Standards Department, Access to Medicines and Health Products Division.

14:10 Presentation of status quo of nomenclatures, use cases, principles and analysis of existing nomenclatures by Adriana Velazquez.

14:20 Addressing questions and proposals from Member States followed by closing statement.

Interpretation will be available to Arab, English, French, Russian and Spanish. Further information on the nomenclature of medical devices is available at: [medical devices](#) and [nomenclature medical devices](#).

Should you require additional information please do not hesitate to contact Adriana Velazquez, Team Lead Medical devices and in vitro diagnostics at medicaldevices@who.int.

Join Zoom Meeting <https://who.zoom.us/j/93436868945> Meeting ID: 934 3686 8945 Passcode: MS12St@nd

Medical devices are indispensable to prevent, protect, screen, diagnose, monitor, palliate or rehabilitate population in different settings.

From home to specialized care



Agenda

- Status quo of nomenclature systems
- Use cases
- Requests from Member States in the EB sessions
- Analysis of existing nomenclatures
- Next steps

Status quo, 2017 survey, presented in the Global Atlas of medical devices.

3.5.2 Global facts

The Baseline Country Survey collected information about whether countries had nomenclature systems in place and if so, which type of system was used. In total, 174 countries responded. An overview of the results can be seen in Fig. 3.5-1.

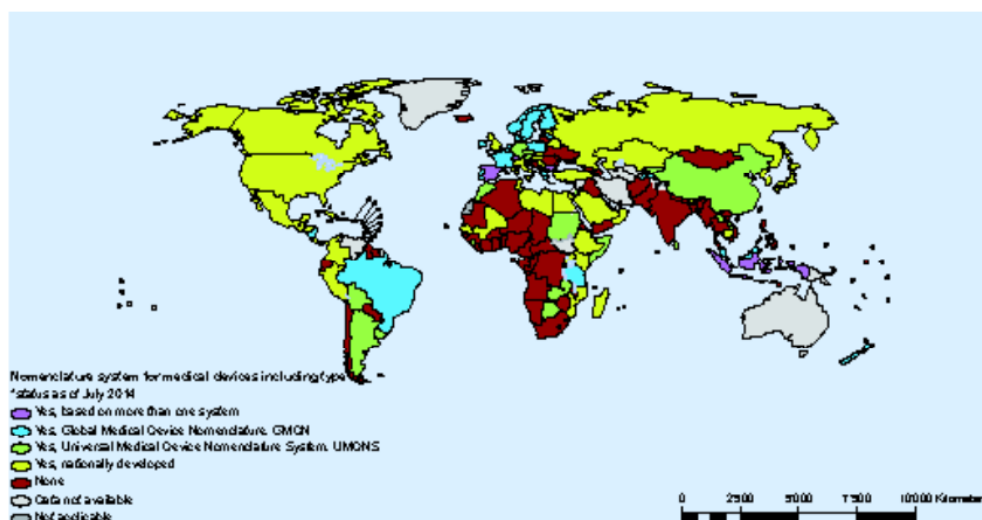


Fig. 3.5-1. Nomenclature systems for medical devices

About half of the responding member states, i.e. 90 countries (52%), use at least one official nomenclature system for medical devices. In contrast, 84 member states do not have any official national nomenclature (49%; see Fig. 3.5-2).

The 90 countries who have an official nomenclature system are using the following types: 26% have developed a system nationally, 12% use Universal Medical Device Nomenclature System (UMDNS) only, 10% use Global Medical Device Nomenclature (GMDN) only, and 3% more than one system.

More than 50% of LMIC did not have an official nomenclature system in 2017.

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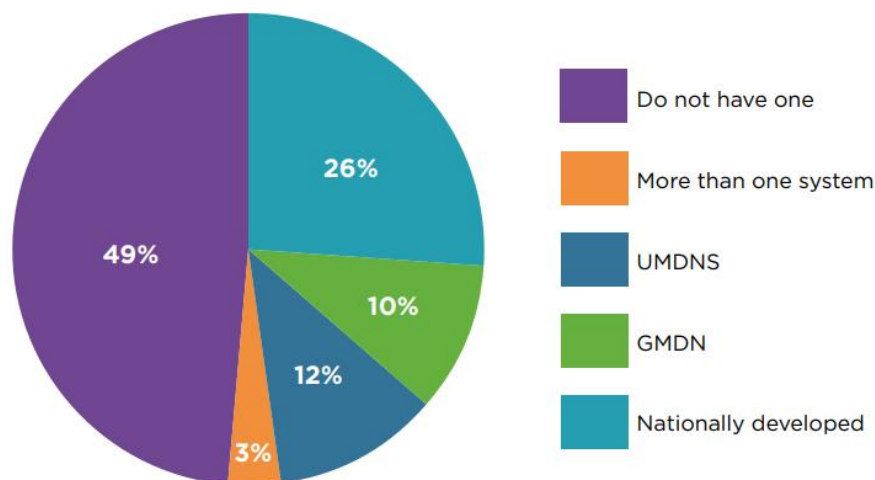


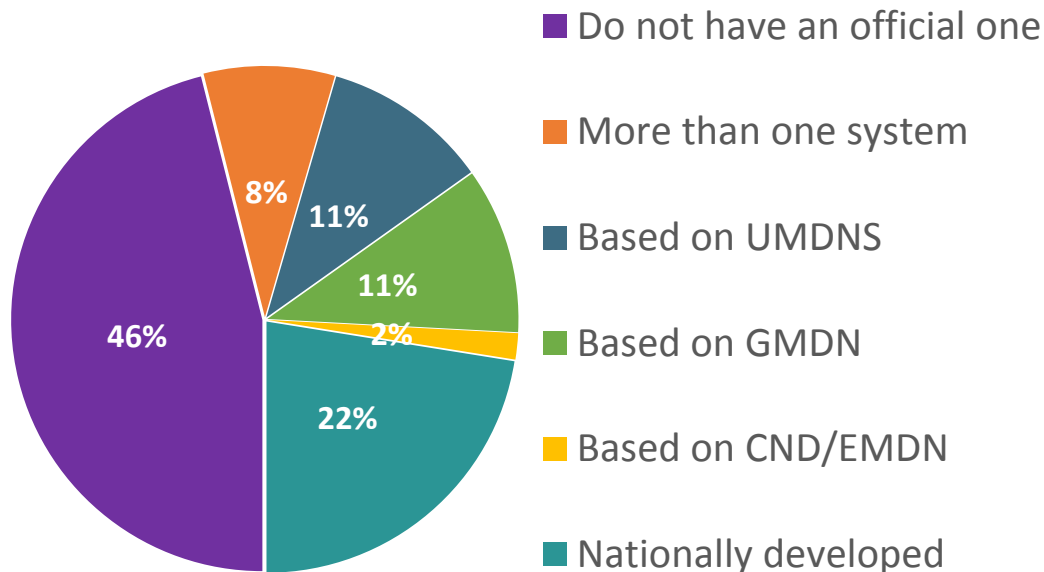
Fig. 3.5-2. Existence and type of the countries' official nomenclature system for medical devices.

More than 50% of the low- to middle-income countries do not have an official nomenclature system (71 countries from 126 responding low- and middle-income countries). In contrast, 74% of high-income countries have an official nomenclature system (36 from 49 responding high-income countries; see Fig. 3.5-3).

2021 Survey data of nomenclature systems by Member State (work in progress)

Comparison Type of Nomenclature Pie Charts 2013-2017 versus 2021 data

Existence and type of an official nomenclature system for medical devices (preliminary data from the 2021 consultation: n =178 countries)

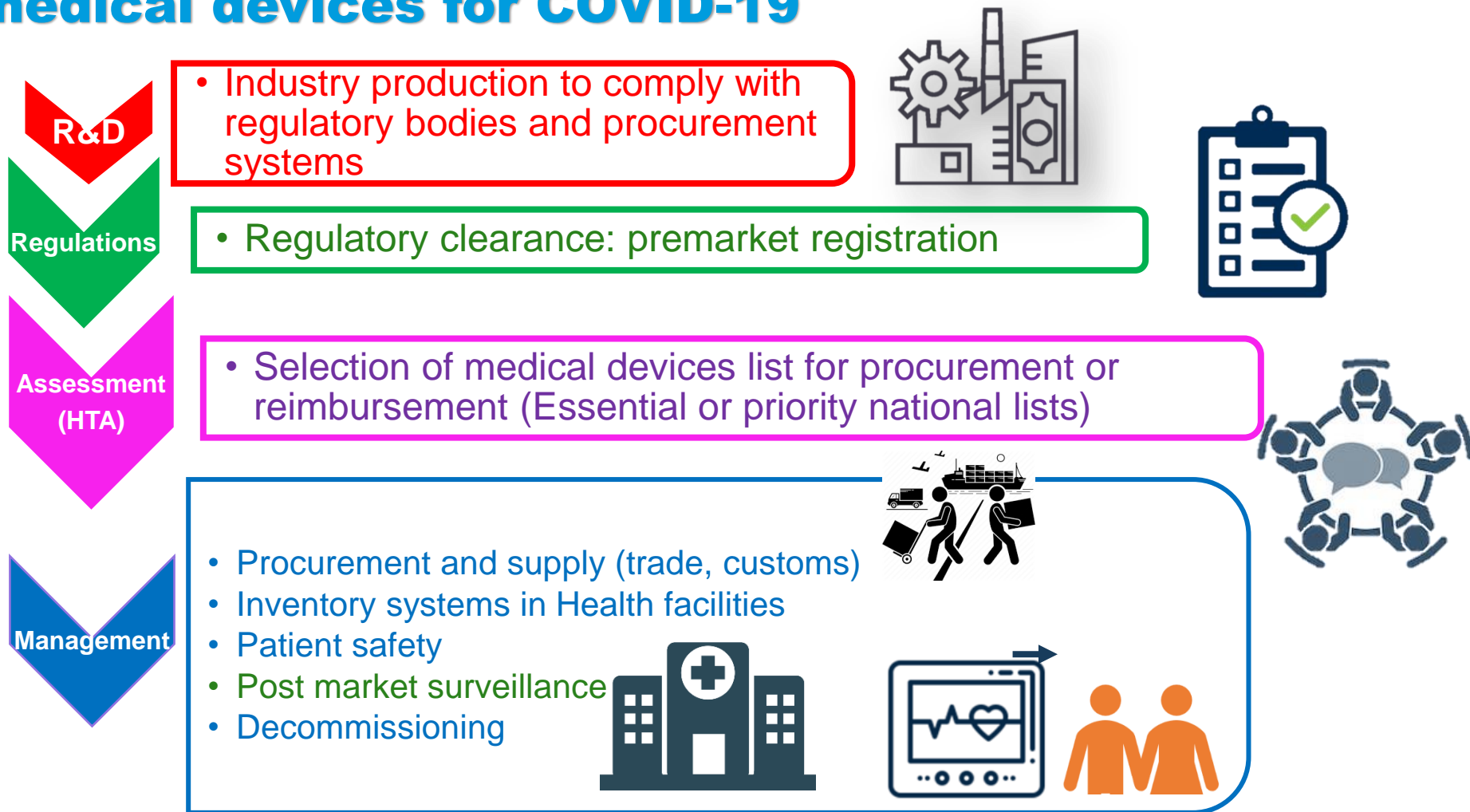


- Decrease of the countries that do not have an official one.
- Increase in the % of countries that based their nomenclature in one of the two systems either UMDNS or GMDN
- Increase in the % of countries that use more than one system (either nationally developed; UMDNS, GMDN, or other)
- Appearance of the CND/EMDN nomenclature that is still not finished but EU (27 countries: https://europa.eu/european-union/about-eu/countries_en) have agreed to use it:

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Nomenclature is used in all stages to ensure improved access of safe, quality medical devices for COVID-19



Uses of nomenclature referred in 2017

In most regions, the nomenclature of medical devices is used for procurement and regulatory processes. However, in the African region, where regulatory processes of medical devices are very limited, the nomenclature systems – when available – are mainly used for procurement. The countries of the South-East Asia region did not specify any specific uses for the nomenclature systems (Fig. 3.5-9).

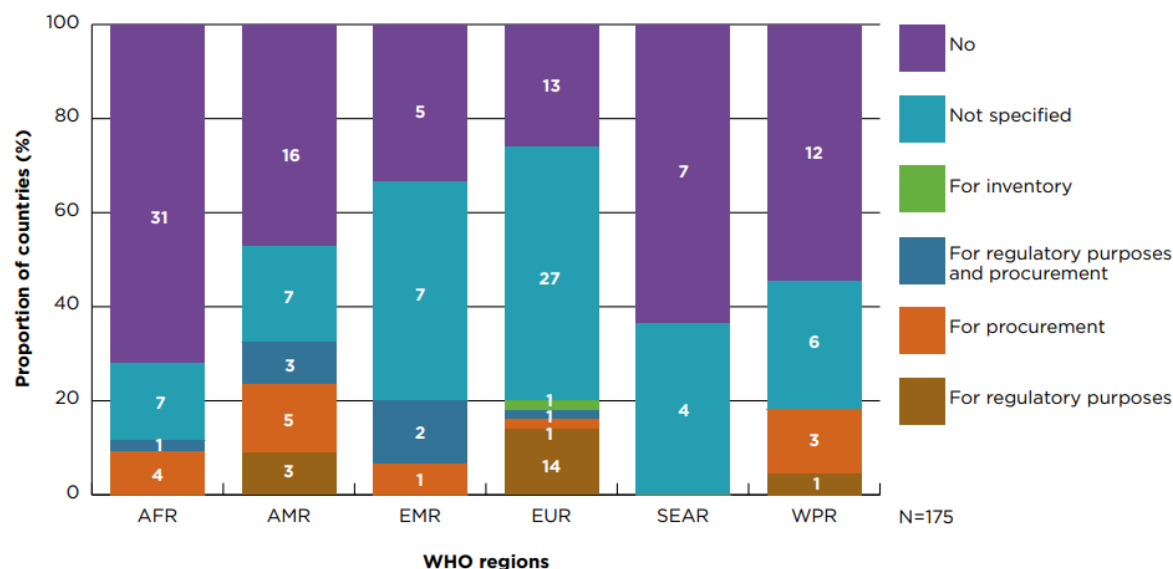
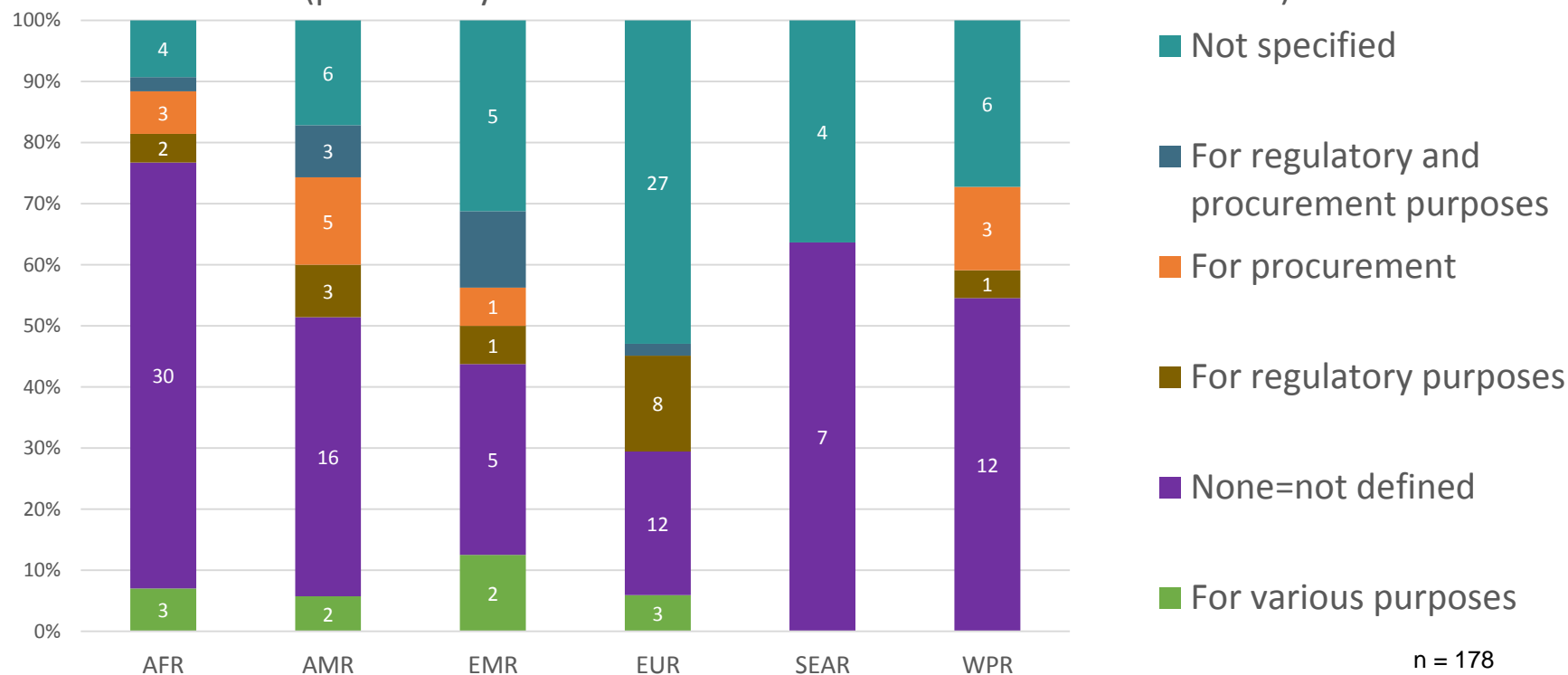


Fig. 3.5-9. Nomenclature system usage types for medical devices by WHO regions

Use cases informed in 2021 survey

Important to note regional initiatives: MercoSur, EURO, Eurasia, GHWP, IMDRF, AMDF

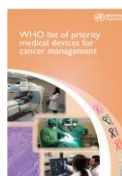
Nomenclature system usage by WHO regions
(preliminary data from the 2021 consultation: n=178 countries)



WHO global guidance that would benefit from international nomenclature system



Innovative health technologies
(2011, 2014, 2017, 2021)



Priority medical devices for:
reproductive, maternal, newborn
and child, Cancer cardiac diseases,
stroke, diabetes (@3000 devices)
(2015, 2017, 2021*)



Essential in vitro diagnostic List
(EDL) @200 tests. (2021)



Model Regulatory Framework for
medical devices including IVDs.
(2017)



guidance for Post market
surveillance (2020)



e-EDL and Priority Medical
Devices Information System
(clearinghouse) (2021*)



Procurement, donations,
maintenance, decommissioning
guidance (several publications
2011 to 2020)



Priority medical devices for COVID-
19 and associated technical
specifications for procurement
(2020)



Technical specifications for
personal protective equipment
(2020)

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Executive Board EB145/3, 2019

Standardization of medical devices nomenclature



Statements by Member States

Regional: EMRO, AFRO, European Union: support initiative, to serve as a common language to report and record medical devices.

20 Member States:

- supported to continue the work for a globally accessible, transparent and harmonized nomenclature to increase access to medical devices,
- impact on patient safety and to track substandard and falsified medical devices;
- will enable faster response to natural disasters and emergencies.

4 Member States:

- that encouraged WHO to participate in the IMDRF to develop a harmonized approach, (in process)
- do not support the development of other new nomenclature system which will cause complexities and confusion. Proposed that WHO uses existing systems. (in process)

<https://www.who.int/about/governance/executive-board/executive-board-145>

Executive Board discussion EB148/13

23rd January 2021.



WHO Executive Board 148, Session 12 (14.15-17:00). Item 11 Standardization of medical devices nomenclature

10 interventions of Members of the Executive Board:

- a. Requested conversation with Member States (12 April 2021)
- b. Propose the GMDN to be used at international level and the harmonization of EMDN with GMDN. Requested more information on why GMDN does not comply with WHO principles. (12 April)
- d. 47 AFRO member's Region to convene regulators. (September 2021?)
- e. Requested information on the transition period and managing the nomenclature.
(after and agreement is defined with existing nomenclatures)
- f. Highlighted that a global system is a normative function of WHO not to be managed by private entity

5 Non-Members of the Executive Board

- a. To engage with IMDRF and discussions with Member States (25th March, others as needed)
- b. EU Member States, encourage WHO to continue working on the planned nomenclature
- c. Supports WHO leading role

(<https://www.who.int/about/governance/executive-board/executive-board-148th-session>)

5 key points

1. “As requested by Member States during the 145th session of the Executive Board, WHO will not be creating a new nomenclature to be added to the existing ones, but will select from the available ones which one can be hosted, made available to all Member States and after a transition period, managed by WHO”
EB148/13
2. WHO to consider the existing nomenclature systems analyze options to ensure the selected nomenclature becomes a Global Good with governance system based in WHO, transparent process and availability of data to all stakeholders in all MS, sustainable.
- 3 The international Nomenclature (INMD) system, classification and coding should be used for manufacturers, regulators, policy makers, procurement systems, supply systems, in health care facilities and by final users.
4. Support MS that have no nomenclature system across their health systems
5. Support patient safety, quality of care, trade, tracking systems, monitoring availability.

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As stated in EB148/13

Characteristics of an international nomenclature, classification and coding for medical devices.

a. Governance

- i) Organizational and review structures should be in place to ensure that all stakeholders from different regions are able to provide feedback according to global needs.

b. Classification, coding and nomenclature characteristics, required:

- (i) a transparent methodology and processes;
- (ii) a transparent mechanism for regular updates;
- (iii) hierarchies grouped into categories and subcategories to meet stakeholder needs;
- (iv) Include medical devices used outside highly regulated countries;
- (v) mutually exclusive terms; (vi) availability of terms in other languages

c. Access to Information should:

- (i) be capable of being referenced and used by regulators, procurers, managers and all users of medical devices (hospitals/health care workers and patients);
- (ii) be freely available and considered a global public good;
- (iii) support unique device identifier system;
- (iv) be accessible through simple and intuitive search ;
- (v) be available for use in all health-related data base systems.

Analysis of characteristics of nomenclature systems that are used in multiple MS



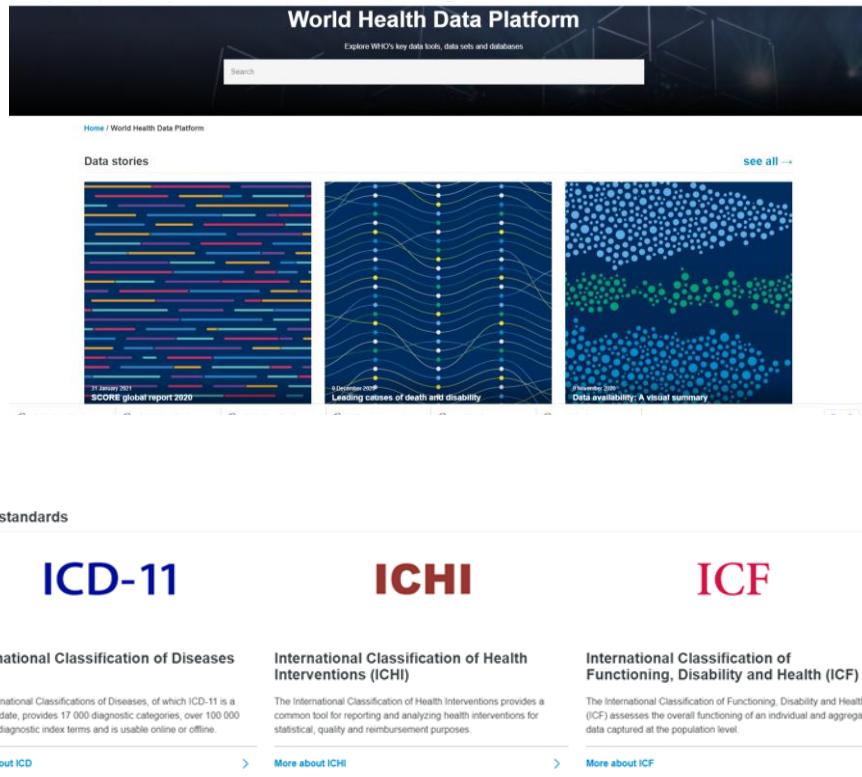
Updated as of 31 March 2021

	Universal Medical Device Nomenclature System (UMDNS) 1983..	Global Medical Device Nomenclature (GMDN) 1991		United Nations Standard Products and Services Code (UNSPSC)	CND (EMDN in May 2021)
Host Organization	ECRI Institute	GMDN Agency		GS1 US	European Commission
A. Governance: Transparent governance. B. Classification and coding: Transparent public processes for the classification, coding and establishment of nomenclature terms, with input from stakeholders.	x	x		x	✓
B.(iii, iv, v) Hierarchical organization of terms and codes into categories and subcategories, to meet the various needs of its stakeholders and availability of terms in other languages	✓	✓		✓	✓
C. Access to information All terms, codes and hierarchy: Freely available, global public good, exportable to other health related databases.	x	x		✓	✓
Comment: Non proprietary	x	x		✓	✓

WHO supports open access to publications for public benefit



Examples:



WHO supports open access to the published output of its activities as a fundamental part of its mission and a public benefit to be encouraged wherever possible.

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<https://www.who.int/about/who-we-are/publishing-policies/copyright>

Other WHO examples: International Nonproprietary Names (INN)



International Nonproprietary Names (INN) facilitate the identification of pharmaceutical substances or active pharmaceutical ingredients.

Each INN is a unique name that is globally recognized and is public property.

As a result of ongoing collaboration, national names such as British Approved Names (BAN), Dénominations Communes Françaises (DCF), Japanese Adopted Names (JAN) and United States Adopted Names (USAN) are nowadays, with rare exceptions, identical to the INN.

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Next steps, as requested by MS:

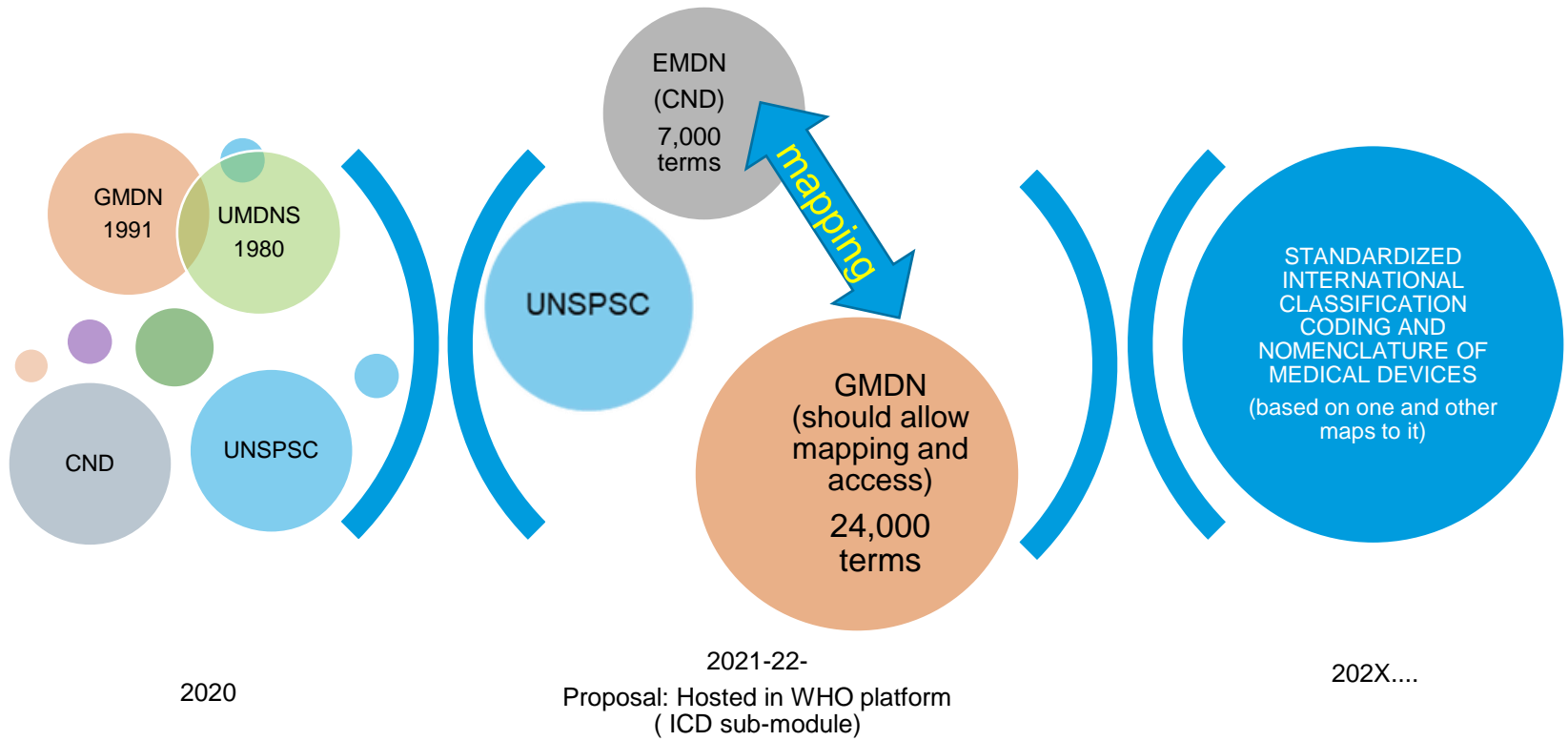
Consultations and information sessions after Executive Board 148/13 (January 2021) as many as needed

Date	Activity	Expected outcome
18- 25 March	IMDRF MEETINGS	WHO to provide an update on the outcomes of the WHO Board meeting
April 12	Information Session with MS	WHO to present the updated analysis and listen to MS requests and proposals for harmonization.
May (TBC)	Information sessions with other stakeholders	Identify requirements and proposals
24 May- 2 June	WHA74 and EB149 World Health Assembly and Executive Board	https://apps.who.int/gb/e/e_wha74.html
September, (TBC)	Member States information session	Open discussion on needs and proposals.
September (TBC)	Information sessions with other stakeholders	Open discussion on needs and proposals.
October (TBC)	Consultation and report for EB150	Discussion of the report
1 February 2022	EB150.	Executive Board discussion

Proposal of co-existence: WHO to be a converging platform with global governance and mapping,

EXAMPLE

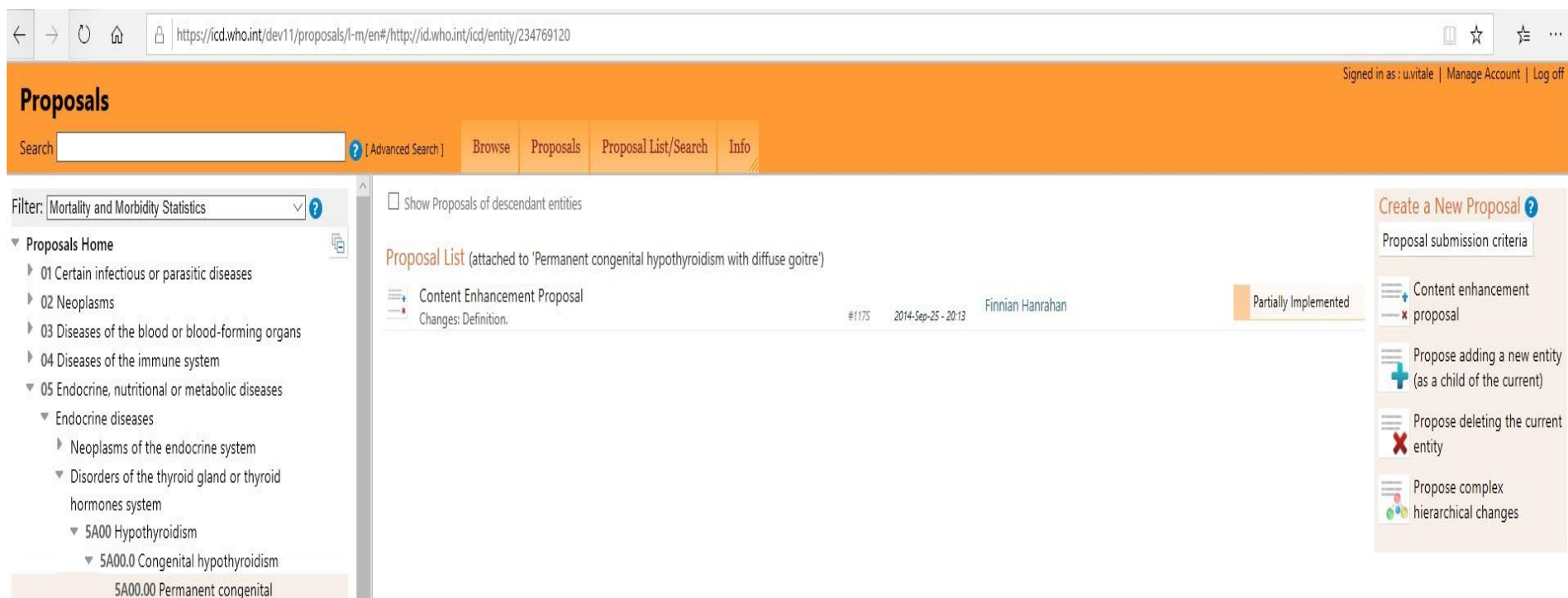
Note: Mapping will only be possible if non-restrictive access and collaboration



On Governance and transparency

Example of ICD platform that allows public proposals to: add, modify or request deletion.

Are online, and available to all stakeholders, request and response are also public, expert group reviews and decide.



The screenshot displays the ICD platform interface. At the top, the browser address bar shows the URL: <https://icd.who.int/dev11/proposals/l-m/en#/http://id.who.int/icd/entity/234769120>. The page title is "Proposals". Below the title, there is a search bar and navigation tabs: "Browse", "Proposals", "Proposal List/Search", and "Info". The "Proposals" tab is active. On the left, a filter dropdown is set to "Mortality and Morbidity Statistics". Below the filter, a sidebar lists categories: "Proposals Home", "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", and "Endocrine diseases". Under "Endocrine diseases", there are sub-categories: "Neoplasms of the endocrine system", "Disorders of the thyroid gland or thyroid hormones system", and "5A00 Hypothyroidism". Under "5A00 Hypothyroidism", there are sub-categories: "5A00.0 Congenital hypothyroidism" and "5A00.00 Permanent congenital". The main content area shows a "Proposal List" (attached to 'Permanent congenital hypothyroidism with diffuse goitre'). The list contains one proposal: "Content Enhancement Proposal" (Changes: Definition), with ID #1175, dated 2014-Sep-25 - 20:13, by Finnian Hanrahan, and status "Partially Implemented". On the right, there is a "Create a New Proposal" section with a "Proposal submission criteria" dropdown and four options: "Content enhancement proposal", "Propose adding a new entity (as a child of the current)", "Propose deleting the current entity", and "Propose complex hierarchical changes".

Proposals

Search [Advanced Search] Browse Proposals Proposal List/Search Info

Filter: Mortality and Morbidity Statistics

▼ Proposals Home

- ▶ 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
 - ▼ Endocrine diseases
 - ▶ Neoplasms of the endocrine system
 - ▼ Disorders of the thyroid gland or thyroid hormones system
 - ▼ 5A00 Hypothyroidism
 - ▼ 5A00.0 Congenital hypothyroidism
 - 5A00.00 Permanent congenital

☐ Show Proposals of descendant entities

Proposal List (attached to 'Permanent congenital hypothyroidism with diffuse goitre')

	Content Enhancement Proposal	#1175	2014-Sep-25 - 20:13	Finnian Hanrahan	Partially Implemented
	Changes: Definition.				

Create a New Proposal ?

Proposal submission criteria

- Content enhancement proposal
- Propose adding a new entity (as a child of the current)
- Propose deleting the current entity
- Propose complex hierarchical changes

WHO ICD-11 ontology platform has been offered to host the various nomenclature/ definitions /codes...



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

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

The screenshot displays the WHO ICD-11 ontology platform interface. The top navigation bar includes a search bar, a search button, and links for Foundation, Linearizations, Contributions, and Info. The main content area is divided into a left sidebar showing the hierarchy of diseases and a right pane showing the details for the selected entity, Cerebrovascular diseases.

ICD-11 (Mortality and Morbidity Statistics)

Search: [Advanced Search] Foundation Linearizations Contributions Info

Left Sidebar Hierarchy:

- 05 Endocrine, nutritional or metabolic diseases
- 06 Mental, behavioural or neurodevelopmental disorders
- 07 Sleep-wake disorders
- 08 Diseases of the nervous system
 - 0800 Movement disorders
 - 8A00 Parkinsonism
 - 8A01 Choreiform disorders
 - 8A02 Dystonic disorders
 - 8A03 Ataxic disorders
 - 8A04 Disorders associated with tremor
 - 8A05 Tic disorders
 - 8A06 Myoclonic disorders
 - 8A07 Certain specified movement disorder
 - 7A80 Restless legs syndrome
 - 7A81 Periodic limb movement disorder
 - 8A0Y Other specified movement disorders
 - 8A0Z Movement disorders, unspecified
 - Disorders with neurocognitive impairment as a major feature
 - Multiple sclerosis or other white matter disorders
 - Epilepsy or seizures
 - Headache disorders
 - Cerebrovascular diseases
 - Spinal cord disorders excluding trauma
 - Motor neuron diseases or related disorders
 - Disorders of nerve root, plexus or peripheral nerves
 - Diseases of neuromuscular junction or muscle
 - Cerebral palsy
 - Nutritional or toxic disorders of the nervous system
 - Disorders of cerebrospinal fluid pressure or flow
 - Disorders of autonomic nervous system
 - Human prion diseases
 - Disorders of consciousness
 - Other disorders of the nervous system
 - Postprocedural disorders of the nervous system
 - Injuries of the nervous system
 - Neoplasms of the nervous system

Right Pane Details for Cerebrovascular diseases:

Foundation Id: <http://id.who.int/icd/entity/843843448>

Cerebrovascular diseases

Parent

08 Diseases of the nervous system

Description

This is a group of brain dysfunctions related to disease of the blood vessels supplying the brain. This includes "stroke", which includes the following entities - . Intracerebral haemorrhage: Subarachnoid haemorrhage; cerebral ischemic stroke, and Stroke not known if ischaemic or haemorrhagic.

Inclusions

- Cerebrovascular disease with mention of hypertension

Exclusions

- Intracranial injury (NA07)

Coded Elsewhere

- Asymptomatic stenosis of intracranial or extracranial artery (BD55)
- Asymptomatic occlusion of intracranial or extracranial artery (BD56)

All Index Terms

There are no index terms associated with this entity

ICD-10: I60-I69

Caveats

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



Example.

- 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

Consider the nomenclature as an element to:



- Increase Patient Safety
- Monitor availability, track devices linked to the unique device identifier,
- Ensure better access
- Inform Regulatory status
- Map between translated terms using public code,

Overall:

Support emergency response, Universal health coverage, and well being of population.

Countries need to ensure medical devices are available, appropriate, safe and of good quality. Harmonized names and information, enables this.



**Gracias
Thank you
Merci
Shokran
Xie xie
Spasiva**



**World Health
Organization**

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