World Health Organization

Survey – Questions for Biomedical / Clinical Engineers

As mandated by WHA74 and for input towards EB 150.
August 2021

Institution / Organization	IFMBE Clinical Engineering Division (CED)
Public or private?	Global Professional Organization includes both
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Website (if any)	https://ced.ifmbe.org/
Country	Global (400+ Health technology leaders, 165 countries)
Date	17 September 2021

Response to questions below are an aggregate of the global CE experience.

WHO thanks you very much for your participation in the meeting to discuss the standardization of medical devices nomenclature, as mandated by WHA74.

Please find below the survey for Biomedical / Clinical Engineers, as mentioned during our meeting. Please provide all the evidence required for every statement provided (for example, website screenshots, links to your website or attach the documents required).

1. Have you used an existing nomenclature? (please check one or more if required)	
a. Which one(s) do you use?	
EMDN	Too new, just begun use across Europe, & fully by 2022 (based on Italian CND used since early 2000s)
GMDN	x
UMDNS	x
UNSPSC	x
Other, specify: many other countries/institutions developed their own	
Developed by your own: Yes: x , No:	

b. In which languages is your nomenclature available?	
English	x
Spanish	x
French	x
Russian	X
Chinese	X
Arabic	X
Other(s)	German, Portuguese, …etc.

c. Please provide as appropriate: c.1 statement if it is open access, or d. c.2 link to your license agreement and limitations e. c.3. any subscription needed f. c.4 any costs associated with the use of your nomenclature g. c.5 can you disseminate, publish, the information with the codes in any document or electronic platform? h. c.6. do you need to request authorization or copyright?
c.1 (a) EMDN is open access - https://webgate.ec.europa.eu/dyna2/emdn/.* (b) Nationally developed are typically open access. (c) GMDN, UMDNS not open access. c.2 (a) No cost for EMDN use. (b) ECRI provides UMDNS licenses still copyrighted - https://www.ecri.org/solutions/umdns/. GMDN license - https://www.gmdnagency.org/ c3. GMDN costs for certain organizations - https://www.gmdnagency.org/Services/Plans c4. For EMDN, there are no costs for use. For example, for all regulatory needs – database registration or incident reporting - there no charge for using the codes. c5. EMDN available for download into Excel table that can be manipulated however as needed. C6. See information for EMDN below, no authorization apparently needed.

*https://webgate.ec.europa.eu/dyna2/emdn/

"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:

- *Regulators-led: regulators play a key role in managing, validating, updating and advising on the nomenclature.*
- *Structured: the nomenclature has transparent hierarchies by which terms and codes could be meaningfully clustered into groups and types.*
- *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.*
- *Transparent: the policies for updates of the nomenclature terms and descriptions are sound and reflect the needs of regulators and the wider healthcare community.*
- *Inclusive: the periodic reviews are open to all, based on real-world use and demonstrable needs.*
- *Available: the terms, descriptions and codes are available, in full, to all users.*
- *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.*
- *International: internationally recognised at the time of the date of application of the MDR/IVDR."*

i. Is the subscription free? For each level and under what conditions?

For EMDN it's free, see above. For GMDN - https://www.gmdnagency.org/Services/Plans
For ECRI/UMDNS, see https://www.ecri.org/solutions/umdns/.

j. What are the limitation(s) of the nomenclature(s) used?

Limitations / Nomenclature	GMDN	EMDN	UNSPSC	UMDNS	Other
Language					
Definitions					
Terms					
Hierarchy	x			x	
Codes					
Structure					
Marketing					
Implementation					
Regulation					
Continuous updating					
Key search					
Accessibility (open-source database)	x				
Economical resources					

- Other (specify): For GMDN and UMDNS, there is unclear hierarchy of codes.
- Instead, EMDN can go from the general to the more specific - categories to groups to types at several levels that are very helpful and necessary for Clinical Engineering and Health Technology Management activities.
- This is not possible with GMDN & UMDNS.
- Unclear how UNSPSC can be used by Clinical Engineering - https://www.unspsc.org/.
- Missing good classification of emerging wide range of Digital Health products.

k. Please select the applicable options for your Institution Nomenclature

Many nomenclatures available within the country	Typically no harmonization at country level specially in LMIC. Each hospital/institution have their own system and in the case of public sector, might be the same of the MOH and for other insurance entities might have a different one, as well as the regulatory agencies.
Nomenclature focused on manufacturers	Possible other local versions
Not mandatory to use	Typically one nation-wide mandatory by Ministry of Health for regulatory purposes; when nation-wide initiatives, MoH-driven, nomenclature mandatory so standard information available.
Other (please elaborate):	

2. If you have adopted an existing nomenclature, identify which aspect of the nomenclature you use (please check one or more if required)

Depending on the country and situation, e.g for LMIC have developed their own nomenclature based mainly on terms but limited to those they have access to.

Nomenclature	Codes	Terms	Definitions	Hierarchy	Full Nomenclature
EMDN					

GMDN		X			
UMDNS		X			
UNSPSC		x			

3. If you have developed your own nomenclature

a. Describe the methodology to assign codes, definitions, terms, hierarchies, and definitions (please provide an example).

Depends on the hospital / institutions local needs and available resources.

b. Did you use an existing nomenclature to develop your own nomenclature, please specify which part?

Acknowledge that: EMDN based on Italian CND and that GMDN was based on UMDNS.
Other institutions developed their own based on other existing nomenclatures and adapted to their own needs.

c. Do you map to an existing nomenclature? If yes, how do you map?

Usually not mandatory to have mapping between institutions, because each is using their own.

d. Describe the challenges you face when mapping (please elaborate).

Not typically applicable. The main challenge is mapping a "many-to-many" relationship. Another challenge is following changes to one existing Nomenclature.

e. Has your Entity / Institution calculated the costs of mapping to other existing nomenclatures? Please present your estimates.

Nomenclature to be mapped against your nomenclature	**Estimate cost of mapping (in dollars)**
EMDN	Unknown
GMDN	Unknown
UMDNS	Unknown
UNSPSC	Unknown

4. For your Entity / Institution, what do you use the nomenclature for (please select all the applicable uses)?	
a. Planning and evaluation	x
b. Budget, prices, expenditures and financing	x
c. Procurement and supply	X
d. Inventory at health facility level	X
e. Maintenance (CMMS)	X
f. Medical Technologies quality assurance and surveillance (eg, Incident reporting)	X
g. Medical Technologies Assessment	X
h. Documenting implants	Not typically, but specific countries & projects
i. Trade, customs	x
j. Technovigilance	x

Other (specify): UDI will be helpful for inventories, supply and traceability.

5. What is the cost, per year, of development, maintenance and updating the nomenclature you have adopted / you have developed? (please select with the adequate statement).

Less than 100.000 dollars	See note below.**
Between 100.000 and 250.000 dollars	
Between 250.000 and 500.000 dollars	
Between 500.000 and 1.000.000 dollars	
Between 1.000.000 and 2.000.000 dollars	
More than 2.000.000 dollars	

**Best estimate: MoH sets working group typically and healthcare system implements. Typically bi-annual updates thereafter.

6. Has your Entity / Institution developed initiatives with regulatory agencies to promote public health/patient safety/device evaluation?

In many countries, MoH is involved with many hospitals in patient safety initiatives and Clinical Engineers can be asked to contribute about health technologies / medical devices. An example in one country, was MoH developing a patient safety recommendation regarding medical equipment maintenance, and a group of CEs was involved in the project.

7. Have you had any experience working with Unique Device Identifiers? If so, please describe any nomenclature-related work in this area (please elaborate)
Starting now in Europe with the MDR, UDI is being introduced based on risk classification of medical devices. UDI is still not widely used or even some countries are developing their own system
8. Please describe any situation in which nomenclature, naming and coding of medical devices has caused major problems to health care services or bad consequences to patients. (If this has been documented, please share PDF or copy of that report)
(a) Difficult to do inventories to compare with other institutions (b) Difficult to keep track of procurement by type of devices. (c) Difficult for planning and budgeting (d) Difficult to do health facility assessments (e) Clinical Engineers need medical device inventory systems for effective Techno vigilance (post-market surveillance monitoring of adverse events) (f) Required also for Cybersecurity purposes to manage and identify specific models of devices.