WHO Comparative analysis of nomenclature systems: CND, GMDN, UMDNS, UNSPSC and SNOMED CT. v. 1 April 2021

(originally December 2019, updated October 2020, for consultation for EB148/13, on standardization of medical devices nomenclature [1] last update April 2021)

In document EB145/3, reference was made to a concept note produced in July 2018 in which the Secretariat had proposed the principles that would underpin an international classification, coding and nomenclature of medical devices, and invited input and collaboration[2]. Since then, WHO has been searching for a solution that complies with those principles, which are summarized below:

(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, the following are required:

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

(c) Access to information

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.

[1] https://apps.who.int/gb/ebwha/pdf_files/EB148/B148_13-en.pdf

[2] Request for input and collaboration towards international classification, coding and nomenclature of medical devices. Concept note (https://www.who.int/medical_devices/priority/ConceptNoteNomenclaturemedicaldevicesv13forconsultation.pdf?ua=1 accessed 13 October 2020).

Organization	Governance	Classification, coding and nomenclature characteristics	Access to information and convergence	Remarks
ECRI Institute[1]	ECRI is a not-for-profit organization. Although the ECRI Institute has dedicated full- and part-time staff for maintenance and development of the UMDNS, it does not have a transparent review and feedback mechanism for defining nomenclature/codes. Some feedback is taken from users who have paid for licenses to use other ECRI products. Regulators are not engaged in nomenclature review in any structured manner.	(i) There is transparency in terms of public disclosure of approved codes; however, access to the mechanisms for establishment of these codes is only open to the ECRI and not to other stakeholders. (ii) The periodicity of updates is dynamic and does not take place in a pre-set manner; however, updates are known to only the users of the UMDNS. (iii) There is a polyhierarchical taxonomy, composed of a main hierarchy and sets of attributes, which is suitable for generating alternative views and hierarchies. The hierarchy is rigid, with tags, flags, attributes and cross-connections between terms. (iv) There is non-discriminatory inclusion of medical devices across all categories available to licensed users. (v) The UMDNS is available in two United Nations languages (English and Spanish) and German, with the cost of further such translation falling on the user community.	(i) Starting from 15th of October 2019, ECRI announced that UMDNS free access will be subject to subscription and not free any more. Many users may also need to purchase other ECRI products to have full utility of codes and access to complete information. (ii) Code research, definitions and code list are available. (iii) UMDNS is not currently required by any jurisdiction to be assigned to the device identifier of UDI (UDI-DI)	Hierarchy, structure and relationships between terms are not freely available. Users need to purchase a subscription in order to be able to fully obtain, update and implement the UMDNS. The nomenclature is a polyhierarchical taxonomy, flexible and suitable for various categorization and classification approaches. "Copyright Notice: UMDNS is owned and copyrighted by ECRI. UMDNS codes and terms may not be disseminated, reproduced, or in any way made available to any third party or be used any commercial purpose whatsoever without the prior written consent of ECRI." UMDNS website accessed 1 April 2021. https://www.ecri.org/solutions/umdns

[1] ECRI Institute comments on the WHO concept note and proposal for collaboration on international nomenclature, coding and classification of medical devices are available at https://www.who.int/medical_devices/priority/ECRI.pdf?ua=1 (accessed 13 October 2020).

Organization	Governance	Classification, coding and nomenclature characteristics	Access of information and convergence	Remarks
GMDN Agency[1]	The GMDN Agency is a not-for-profit organization with its own staff. It does not have a transparent review and feedback mechanism for defining nomenclature/codes. Some feedback is taken from users with licenses. It is free for regulatory agencies and other users for a defined package. Regulators are not engaged in nomenclature review in any structured manner.	(i) mechanisms for defining nomenclature and codes are privy only to GMDN and are not available to other stakeholders. (ii) The periodicity of updates is dynamic and does not take place in a pre-set manner (iii) The taxonomy is polyhierarchical, composed of a main hierarchy and sets of attributes. (iv) medical devices hierarchy across all categories is available to licensed users. (v) Some terms are available in 23 languages, including four official United Nations languages.	(i) Free for various stakeholders, including regulators, for defined packages. (ii) Each package has distinct characteristics in terms of access to information. (iii) Not free for manufacturers and consultants. (iv) Researchers and academics cannot use multiple-user licenses (v) GMDN is currently required by certain jurisdictions to be assigned to the device identifier of UDI (UDI-DI) and is made publicly available through the US Global UDI Database (GUDID).	GMDN nomenclature is not free for all stakeholders. Non-paying users can only search and access individual codes on the GMDN website. The structure, hierarchy and relationships are not freely available for consultation and download, so the public cannot take advantage of the GMDN hierarchy for analysis purposes. Implementation of GMDN nomenclature requires subscription. "Access to the GMDN Database by you (the 'Licensee') is controlled by an electronic permit activated by entering a user ID and password. The user IDs and passwords are supplied by The GMDN Agency on a subscription basis. To be issued with such a user ID and password the Licensee must complete the Registration Form and submit it as directed. https://www.gmdnagency.org/Legal/License (accessed 1 April 2021)

[1] GMDN Agency comments on the WHO concept note and collaboration proposal for international nomenclature, coding and classification of medical devices are available at https://www.who.int/medical_devices/priority/GMDN_Agency.pdf?ua=1 (accessed 13 October 2020).

Organization	Governance	Classification, coding and nomenclature characteristics	Access of information and convergence	Remarks
GS1[1]	International, not-for-profit organization that develops and maintains standards for business communication. GS1 is a business process developer which uses an identification method common to all goods/products	(i) Nomenclature is developed for the trading sector and includes all possible goods and services – not specific to medical devices. (ii) Rigid codes are additive and include the full hierarchy path. (iii) The creation of codes is only in the purview of GS1 and the process is not known or shared with stakeholders.	(i) Free to a limited extent. (ii) Does not include many categories of medical devices and the list it covers is restrictive depending upon the trade needs. (iii) Unique product identification is possible but not specific to medical devices. (iv) Access is subscription based (v) GPC is not currently required by any jurisdiction to be assigned to the device identifier of UDI (UDI-DI)	GPC nomenclature is managed by GS1 with no fully open and transparent review process and criteria. GPC is a general nomenclature for trading, not specifically developed for the health sector. The structure and hierarchy are rigid, and this structure does not meet the need for flexibility required by the health sector. Website https://www.gs1.org/industries/healthcare (accessed 31 March 2021)

[1] GS1 comments on the WHO concept note and collaboration proposal for international nomenclature, coding and classification of medical devices are available at https://www.who.int/medical_devices/priority/GS1.pdf?ua=1 (accessed 13 October 2020).

Organization	**Governance**	**Classification, coding and nomenclature characteristics**	**Access of information and convergence**	**Remarks**
SNOMED International[1]	A not-for-profit entity founded by the governments of Australia, Canada, Denmark, Lithuania, Sweden, the Netherlands, New Zealand, the United Kingdom and the United States. Members of SNOMED International can be an agency of a national government, or another body (such as a corporation or regional government agency) endorsed by an appropriate national government authority within the territory it represents. Members play a critical governance role through the approval of the organization's budget and strategy.	(i) Development and update criteria are not fully published. (ii) Ontology and terms are unique, and hierarchy is generated by a set of relationships. (iii) Intended for use in electronic health records/clinical records and focuses primarily on health care interventions with the purpose of capturing information in clinical records. As part of this process, terminologies for health products are also captured. (iv) Available in five languages	(i) Free access only allows for downloading of the current code set, not the framework. (ii) Free for institutions from territories that have become paid members of the consortium. (iii) The list of codes is available, but the methodology for code generation/modification is not available. (iv) Requires members to develop extension pathways for nomenclatures, as per their needs. (v) Participation is limited by	SNOMED CT was developed for health records and is not the optimal solution for regulatory, management and procurement purposes related to medical devices. Website: https://www.snomed.org "A license is required to download and use SNOMED CT. Information and resources pertaining to the January 2021 SNOMED CT International Edition Release

[1] SNOMED International comments on the WHO concept note and collaboration proposal for international nomenclature, coding and classification of medical devices are available at https://www.who.int/medical_devices/priority/SNOMED.pdf?ua=1 (accessed 13 October 2020).

			subscription/membership. (vi) SNOMED is mapped to a subset of GMDN terms and through that connection is currently mapped in certain jurisdictions to the device identifier of UDI (UDI-DI)	is located on our releases page." https://www.snomed.org/news-and-events/articles/Jan-31-2021-SNOMED-Intl-Edition (accessed 31 march 2021) "
Organization	**Governance**	**Classification, coding and nomenclature characteristics**	**Access of information and convergence**	**Remarks**

CND[1] **(Responsible organization:** **Italian Ministry of Health)**	Developed by the Italian Ministry of Health, and adopted by the European Commission to help fulfil the regulatory requirement in the new European Union regulations	(i) Nomenclature developed and managed specifically for medical devices by Italian Ministry of Health. (ii) methodology of coding, classification and updating is done through a structured process which involves stakeholders. (iii) transparent methodology, processes for the classification, coding and establishment of nomenclature terms. (iv) Codes are additive and include the full hierarchy path.	(i) Freely available on the website in Italian and in English. (ii) Although it is not based on an interactive platform, it is downloadable. (iii) other countries which adopted CND (Greece and Portugal) carried out the translations (iv) Non-subscription/ license based. (v) CND will be used as the basis for developing the EMDN. EMDN is required by the European Commission to be assigned to the device identifier of UDI (UDI-DI) as will be available as part of the publicly available European Union UDI Database (Eudamed)	(i) The European Commission has informed WHO that it will be adopting the CND as the Basis for the European Medical Devices Nomenclature. EMDN is not yet available. (31 March 2021) http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=328&area=dispositivi-medici&menu=classificazione&tab=1 "Founded on pre-established criteria and requirements and based on orientations provided by the Medical Device Coordination Group (MDCG), the European Commission decided in favour of the use of the 'Classificazione Nazionale Dispositivi medici (CND)' as the basis For the EMDN." https://ec.europa.eu/health/sites/health/files/md_topics-interest/docs/md_emdn_eudamed_nomenclature_en.pdf

[1] More information on the CND from the Italian Ministry of Health (in Italian) is available at http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=328&area=dispositivi-medici&menu=classificazione (accessed 13 October 2020).