3.5 Medical devices: Nomenclature system

3.5.1. Introduction

The nomenclature of medical devices is a coding system used to generically classify and identify all medical devices and related health products. Having a nomenclature system in place for medical devices facilitates their management and regulation by standardizing terms that enable communication despite linguistic and other barriers. Such standardization is currently used in some regulatory systems but is also a prerequisite for inventory management and databases for maintenance of equipment.

Several naming systems for medical devices exist and each is used by a different group of professionals depending on the needs of that particular group, needs such as maintenance, procurement, accounting, stock keeping, regulatory affairs, adverse medical device event reporting and customs operations. The number of systems in existence can make it difficult to communicate between individuals and organizations. Therefore, WHO is working towards a unified nomenclature system that can be used globally. Currently, several countries have their own nationally used nomenclature systems. However, the two nomenclature systems most widely used for medical devices are the Global Medical Devices Nomenclature System (GMDN)[i] and the Universal Medical Devices Nomenclature System (UMDNS)[ii] that are explained in more detail below.

The GMDN was developed by the European Committee for Standardization (CEN) and medical device experts from around the world (manufacturers, healthcare authorities and regulators) based on the international standard ISO 15225. It is managed and maintained by a not-for-profit company, the GMDN Agency, which reports to a Board of Trustees on which medical device regulators and industry are represented. To ensure continuing permanency of the GMDN, revenues are generated through the licensing and sale of GMDN Agency products, particularly the GMDN codes. The GMDN is a poly-hierarchical system. Product identification is done by unique numerical five-digit numbers that are associated with a term (medical device name), a definition that includes the intended use(s) and the device category (based on device application, technology, or other common characteristics). Identification of all specific medical devices having substantially similar generic features is possible through cross-referencing.

The UMDNS was developed by the Emergency Care Research Institute (ECRI). ECRI is a nongovernmental, not-for-profit organization, governed by an Executive Committee and a Board of Trustees. The UMDNS is poly-hierarchical and is developed as an interrelated vocabulary based on terms naming the medical devices. Terms are assigned a 5 digit code using consecutive numbering with no intrinsic meaning. The code is associated with a definition and a description of the intended use. Associated properties provide additional attributes for classification. Maintenance is done by a core group of ECRI nomenclature specialists, both for the ECRI's internal use and to provide support to external clients and licensees.

Further nomenclature systems of interest for medical device identification include, for example:

- The International Statistical Classification of Diseases and Related Health Problems (ICD)[iii]. ICD-10 is the tenth revision of a WHO developed medical classification list for diseases, disorders, health symptoms, and injuries. It serves to accurately code medical diagnoses and is employed by all member states, in for example, epidemiology, health management and clinical settings.
- The Unique Device Identification (UDI)[iv] system that is being developed by the U.S. Food and Drug Administration (FDA) to label medical devices through their distribution and use. The related Global UDI Database will be publically accessible for download and use.
- The United Nations Standard Products and Services Code (UNSPSC)[v] that is an open, global, multi-sector classification system divided in five hierarchical levels. It was developed by the United Nations Development Programme (UNDP) and Dun & Bradstreet Corporation (D&B) in 1998 and is managed by GS1 US, a not-for-profit organization, since 2003.

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.

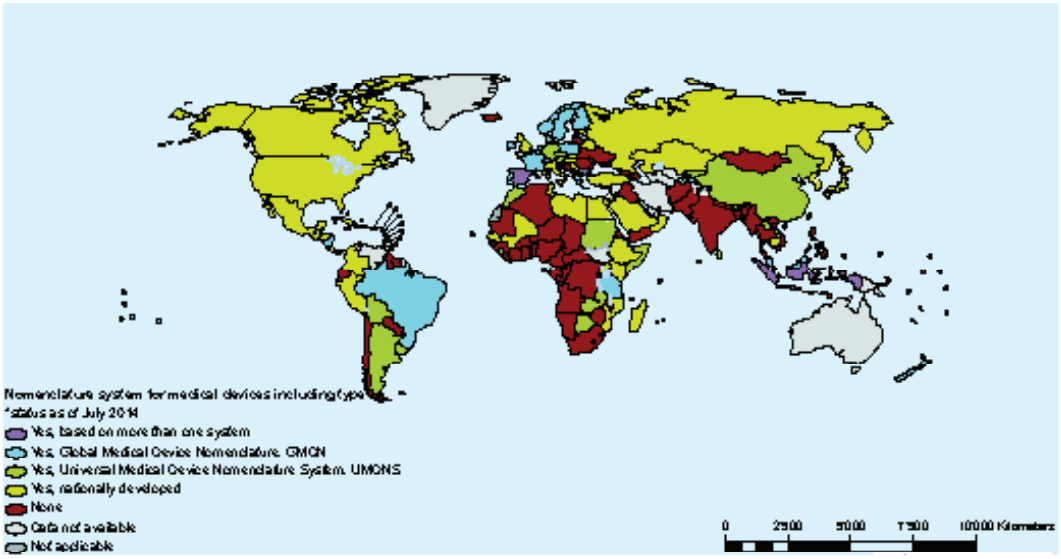

Fig. 3.5-1. Nomenclature systems for medical devices

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.

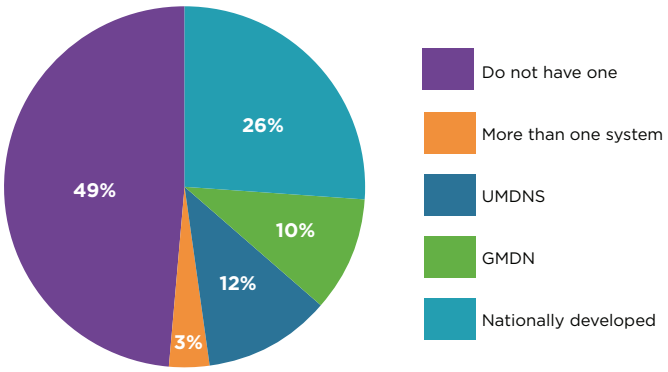

Fig. 3.5-2. Existence and type of the countries' official nomenclature system for medical devices.

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).

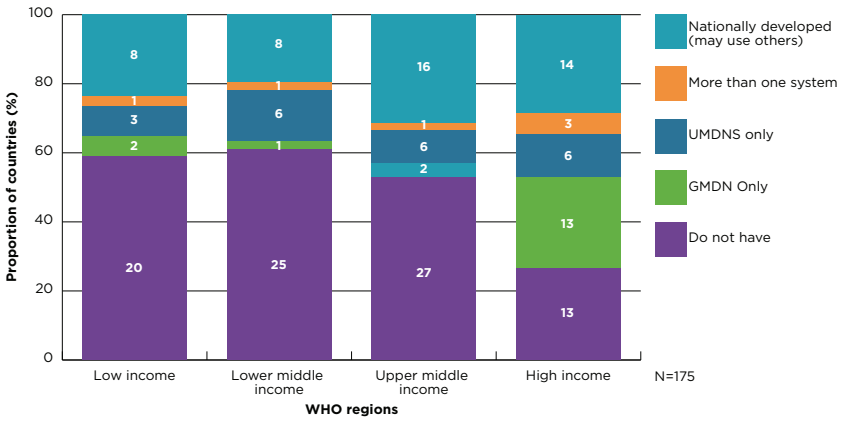

Fig. 3.5-3. Presence and type of the countries' official nomenclature system for medical devices by World Bank income group

More than 50% of the countries of WPR, SEAR, and AFR regions do not have an official nomenclature system. In contrast, more than 65% of the countries of EMR and EUR have an official nomenclature system (see Fig. 3.5-4).

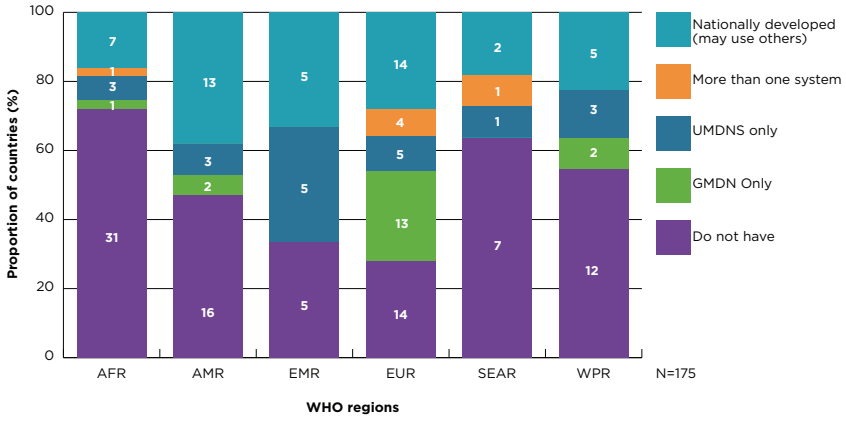

Fig. 3.5-4. Presence and type of the respondent countries' official nomenclature system for medical devices by WHO regions

It can be observed that in the European (34 of 50 respondent countries), Eastern Mediterranean (7 of 14 respondent countries), and American (17 of 34 respondent countries) regions at least 50% of the respondent countries have an official nomenclature system and a regulatory authority. In the case of African, South-East Asia, and Western Pacific regions more than half of the participant countries do not have any nomenclature system independent of the existence of a national regulatory authority for medical devices (Fig. 3.5-5).

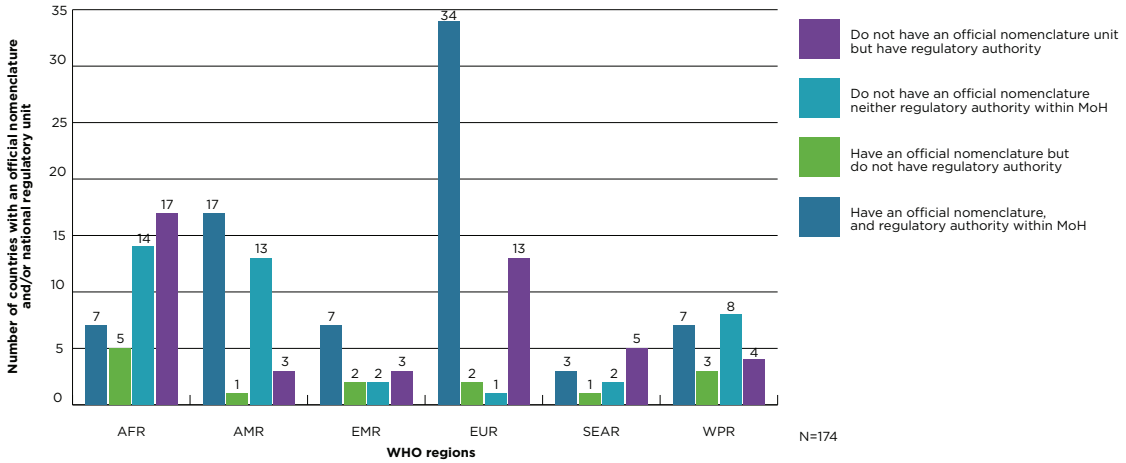

Fig. 3.5-5. Presence of an official nomenclature system and/or national regulatory authority for medical devices by WHO region

Fig. 3.5-6 shows that in none of the regions do more than 30% of countries have an official nomenclature system as well as lists recommending health technology within the ministry of health. However, in the European region 32 (71%) of 45 respondent countries, in the Eastern Mediterranean region 9 (64%) of 14 respondent countries and in the American region 18 (55%) of 33 countries have at least an official nomenclature system. Furthermore, for African, South-East Asia, and Western Pacific regions, more than half of the participant countries do not have any nomenclature system independent of the existence of any list recommending health technology within the ministry of health.

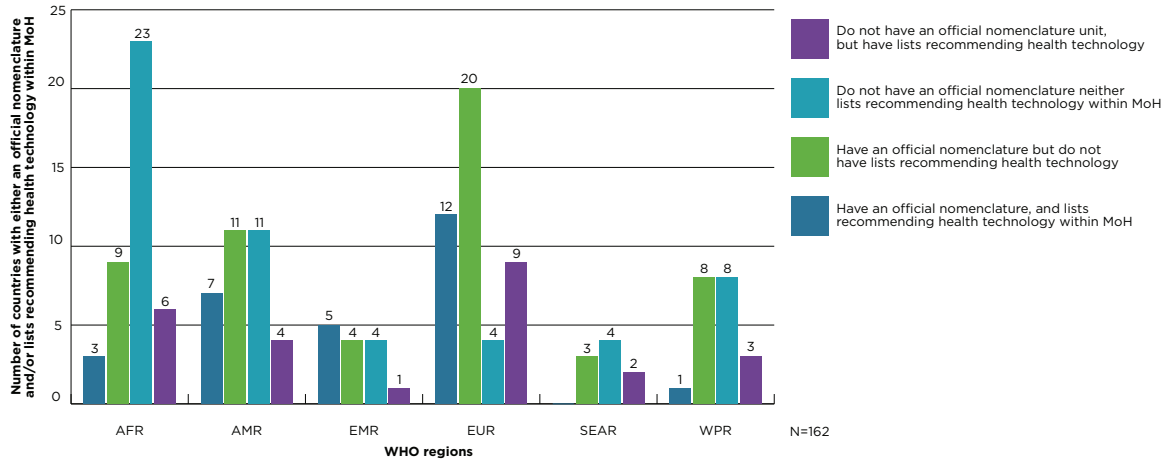

Fig. 3.5-6. Presence of an official nomenclature system and/or lists recommending health technology for medical devices by WHO regions

The nomenclature systems are used for different purposes such as for as regulatory purposes, for procurement and/or inventory. An overview of the types of usages in the respondent countries can be seen in Figs. 3.5-7 and 3.5-8.

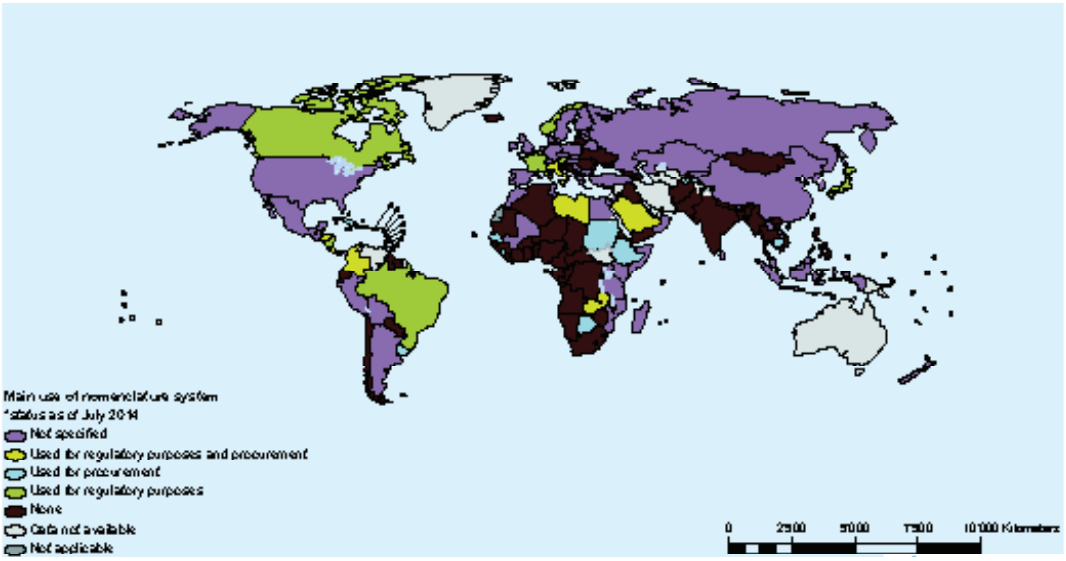

Fig. 3.5-7. Nomenclature system usage types for medical devices

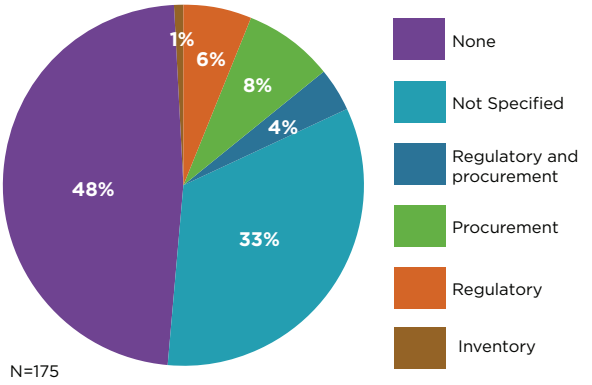

Fig. 3.5-8. Distribution of nomenclature system usage types: regulatory purposes, procurement, and inventory

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).

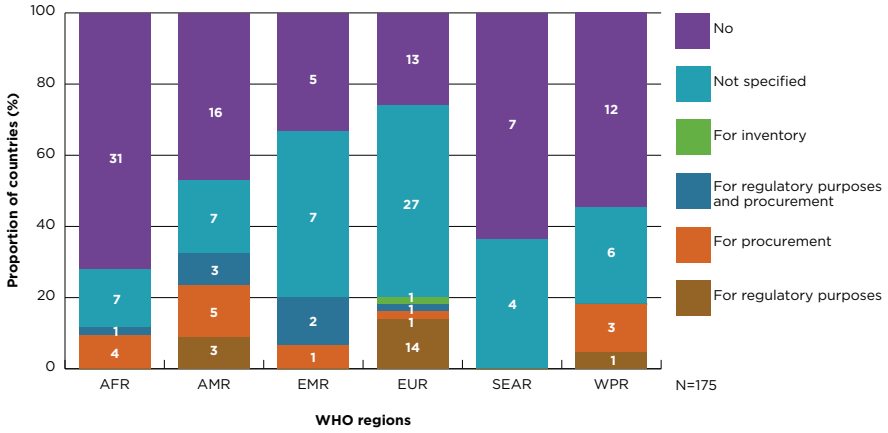

Fig. 3.5-9. Nomenclature system usage types for medical devices by WHO regions

Concurrently, analyzing the results by World Bank income groups shows that in high-income countries, the nomenclature is used to a greater extent for regulatory purposes than in the other countries. In contrary, the low- and lower-middle-income countries use the nomenclature more for procurement purposes, as regulatory processes are limited (Fig. 3.5-10).

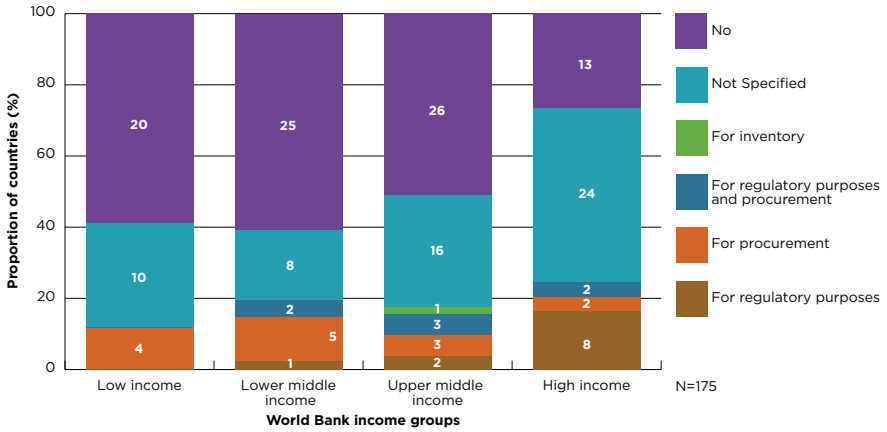

Fig. 3.5-10. Nomenclature system usage types for medical devices by World Bank income groups

3.5.3 Further reading

For more information about medical devices nomenclature systems, please refer to the following documents and websites:

Documents:

- International Medical Device Regulators Forum (IMDRF) Guidance document on the UDI

Websites:

- Global Medical Devices Nomenclature System (GMDN) Agency home page[i] https://www.gmdnagency.org/
- Universal Medical Devices Nomenclature System (UMDNS)[ii] by the Emergency Care Research Institute (ECRI) http://www.ecri.org.uk/umdns/index.htm
- Unique Device Identification (UDI) [iv] by the U.S. Food and Drug Administration (FDA) page http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/
- United Nations Standard Products and Services Code (UNSPSC)[v] page http://www.unspsc.org/

Endnotes

i. https://www.gmdnagency.org/
ii. http://www.ecri.org.uk/umdns/index.htm
iii. http://www.who.int/classifications/icd
iv. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/
v. http://www.unspsc.org/
vi. IMDRF Guidance document on the UDI of medical devices, IMDRF UDI Working Group, release 9 December 2013 (http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-udi-guidance-140901.pdf)