World Health Organization

EXECUTIVE BOARD
145th session
Provisional agenda item 5.1

EB145/3
30 April 2019

Standardization of medical devices nomenclature

International classification, coding and nomenclature of medical devices

Report by the Director-General

1.   At their consultation with the Director-General in October 2018, the Officers of the Executive Board agreed to recommend deferral of the consideration of a proposed item on standardization of medical devices nomenclature to the Board's 145th session as there was insufficient time on the provisional agenda of the 144th session to give the topic the required consideration, and furthermore deferral would allow for consultations.[1] This report responds to the request for consideration of the item at the present session of the Board.

THE NEED FOR MEDICAL DEVICES

2.   Medical devices are health technologies that are essential in health services for prevention, diagnosis, treatment, rehabilitation and palliation;[2] they are not medicines or vaccines. They are required throughout the life course, as well as in emergencies and disease management. Medical devices are essential for the attainment of the three one-billion goals of WHO's Thirteenth General Programme of Work, 2019–2023, because they underpin universal health coverage and are central to responses to emergencies and for maintaining well-being.

3.   Owing to rapid scientific and technological development, more than 20 000 types of medical devices now exist. They range from stethoscopes, condoms, syringes and defibrillators through in vitro diagnostics,[3] surgical equipment and biocompatible implants, such as hip prostheses and pacemakers,

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[1] See document EB144/1 (annotated) and summary records of the Executive Board at its 144th session, first meeting, section 1.

[2] A medical device is an article, instrument, apparatus or machine (including mobile medical applications and software) that is intended by manufacturer to be used alone or in combination in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means. See Global Harmonization Task Force, document GHTF/SG1/N071:2012 (http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n071-2012-definition-of-terms-120516.pdf#search=, accessed 18 April 2019).

[3] A subset of medical devices, defined as devices which, whether used alone or in combination, are intended by the manufacturer for the examination in vitro of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. They include reagents, calibrators, control material and test kits. (See Global Harmonization Task Force. Definition of the terms medical device and in vitro diagnostic (IVD) medical device. Geneva: World Health Organization; 2012, http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n071-2012-definition-of-terms-120516.pdf, accessed 3 May 2018).

to X-rays and complex, expensive medical imaging equipment, such as magnetic resonance imaging and nuclear medicine. At present, there is no common standard name for each type of medical device, an inconsistency that causes confusion between the various types of devices, affects traceability and has an adverse impact on health care delivery.

4.   WHO produces guidance for the regulation, selection and management of medical devices with the goals of increasing access, availability and affordability and of ensuring that these devices are safe and of good quality.

5.   The lack of access to affordable, appropriate, good quality and safe medical devices is a major public health issue. These devices are crucial to timely diagnoses, monitoring disease or well-being and providing the treatment and good-quality, essential health services that are required.

THE NEED FOR STANDARIZED NOMENCLATURE OF MEDICAL DEVICES

6.   A standardized classification and nomenclature of medical devices will serve as a common language for recording and reporting medical devices across the whole health system at all levels of health care for a whole range of uses. Such a classification would support patient safety, allow comparisons and measurement of the availability of medical devices as well as assessment of access to devices in the community using health facility assessments tools. Standardization of nomenclature is also essential for defining and naming innovative technologies, classifying the devices for regulatory approval (registration) and for streamlining procurement of these products. The standardized naming of medical devices is required when describing the devices needed for the benefits packages for universal health coverage and it would also support common referencing in electronic health records and other health information systems.

7.   The lack of a nomenclature system has hampered the development of the evidence- and web-based health technologies database to provide guidance on appropriate medical devices as requested in resolution WHA60.29 (2007) on health technologies. A standardized classification of medical devices could link to WHO's other international classification systems, such as the International Classification of Health Interventions, the International Statistical Classification of Diseases and Related Health Problems, and the International Classification of Functioning, Disability and Health and be part of WHO's family of international classifications, in order to support organized and standardized information for policy-makers and managers.

8.   In resolution WHA67.20 (2014) on regulatory system strengthening for medical products the Health Assembly requested the Director-General to prioritize support for establishing and strengthening regional and subregional networks of regulatory authorities, as appropriate, including strengthening areas of regulation of health products that are the least developed, such as regulation of medical devices, including diagnostics. A classification system for medical devices would facilitate this effort, which would be in line with the Health Assembly's mandate to the Secretariat: to continue to develop appropriate norms, standards and guidelines, including taking into account national, regional and international needs and initiatives, in accordance with WHO's principles.

CHALLENGES AND PRIORITIES

9.   Many naming systems for medical devices exist and are used in different contexts, for instance national priority lists, policies, guidelines, maintenance procedures, procurement specifications, stock-keeping, regulatory affairs, adverse medical device event reporting and customs control. This

multiplicity of systems makes communication difficult between individuals, countries and organizations. Several countries have developed their own national nomenclature system.

10.   The number and variety of medical devices are increasing as new software and hardware applications, new materials and new combination products are developed; these include combination products with medicines and/or vaccines and some with clinical sensors and data, which are also classified under eHealth or digital health applications.[1] It is a complex task to classify these according to the intended purpose and the different options. The Secretariat would need support from international experts to elaborate the terms, definitions and links to disease conditions, as appropriate.

11.   The benefits of an international classification, coding and nomenclature system would be: to facilitate functional inventories, to allow monitoring and evaluation of the use of medical devices, to provide elements for unique device identification, to track usage of implantable medical devices, to follow donated and/or refurbished equipment, to facilitate market authorization and streamline trade, to compare prices and technical characteristics, and to assign customs coding and manage taxation of these products.

INTERNATIONAL CONTEXT AND THE SECRETARIAT'S ACTIVITIES

12.   WHO's Global atlas on medical devices, issued in 2017,[2] presents the reports of 174 countries responding to the baseline country survey. The survey showed that 84 Member States (49%) do not have any official national nomenclature and that 90 Member States report that they use an official nomenclature system. In total, 26% have developed a national nomenclature system, 22% use a proprietary system and 3% use more than one system.

13.   Since 2010, WHO has conducted several consultations on issues related to medical devices, including discussions during WHO's four global forums on medical devices (in 2010, 2013, 2017 and December 2018),[3] and country surveys to determine country needs; in all, the topic of lack of standardized nomenclature was noted. In response to the gaps, WHO has developed guidance documents on: how to formulate policies on medical devices; how to select, assess, manage and procure relevant devices; and effective donation of medical devices, but the nomenclature had been pending.[4]

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[1] See, for example, resolution WHA66.24 (2013) on eHealth standardization and interoperability (http://apps.who.int/gb/ebwha/pdf_files/WHA66/A66_R24-en.pdf?ua=1, accessed 16 April 2019).

[2] WHO. Global atlas of medical devices (WHO medical devices technical series). Geneva: World Health Organization; 2017 (http://www.who.int/iris/handle/10665/255181, accessed 15 March 2019).

[3] See First WHO global forum on medical devices: context, outcomes, and future actions. Geneva: World Health Organization; 2011 (https://apps.who.int/iris/bitstream/handle/10665/70668/WHO_HSS_EHT_DIM_11.11_eng.pdf;jsessionid=3D5D851A23A5 A699A88AB8631FDD2684?sequence=1); Second WHO global forum on medical devices: priority medical devices for universal health coverage. Geneva: World Health Organization; 2014 (https://www.who.int/medical_devices/global_forum/2ndgfmd_report.pdf?ua=1); Third WHO global forum on medical devices: report. Geneva: World Health Organization; 2018 (https://apps.who.int/iris/bitstream/handle/10665/273192/WHO-EMP-2018.02-eng.pdf?ua=1); and Fourth WHO global forum on medical devices: improving access to safe, effective and innovative quality medical devices. Geneva: World Health Organization; 2019 (https://www.who.int/medical_devices/global_forum/Final_Draft_4GFMD_Report.pdf?ua=1) – all URLs accessed 29 March 2019).

[4] WHO. Publications on medical devices, (https://www.who.int/medical_devices/publications/en/, accessed 29 March 2019).

14.   WHO has developed model lists of medical devices so as to support their access at country level. Specifically, it has published the WHO Model List of Essential In Vitro Diagnostics (first edition, 2018)[1] and lists of priority medical devices for Ebola virus disease, cancer,[2] and reproductive maternal and child health,[3] the interagency emergency health kits,[4] and disease commodity packages[5] for emergencies and outbreaks. The Secretariat is elaborating a list of health products for primary health care. Although some of these lists have been developed as interagency guidance, they lack a common standard name, coding and classification.

15.   Currently, entities in the United Nations system, such as UNFPA, UNICEF, the United Nations Office for Project Services and WHO, and three other organizations, namely the International Committee of the Red Cross, Médecins Sans Frontières and the Global Fund to Fight Aids, Tuberculosis and Malaria, all of which select and procure medical devices to support Member States, have their own nomenclature systems for classification and coding of medical devices. Therefore, interagency documents do not have a harmonized coding; this incoherence complicates procurement, listing and supply, and price comparisons and, as a consequence, access to medical devices at country level, for routine supply as well as for emergency preparedness and response.

16.   WHO produces evidence-based selections of priority and essential lists of devices for prevention, screening, diagnosis, treatment, rehabilitation and palliative care at primary care centres and use in referral systems[6] but this process is hampered by the fact that these products lack common names. In order to support universal health coverage, these names should be standardized so as to facilitate linkage to all other international classifications.

17.   WHO, through its observer status to the International Medical Device Regulators Forum, has contributed to the development and maintenance of terminology for reporting of adverse events related to medical devices. This terminology is critical for ensuring patient and user safety as it allows for vigilance practices to be streamlined and reduces the potential for miscommunication about the seriousness of an event. It is necessary that a harmonized system of classification and nomenclature of medical devices is used globally for surveillance.

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[1] WHO. First WHO model list of essential in vitro diagnostics. (WHO Technical Report Series No. 1017). Geneva: World Health Organization; 2019 (https://apps.who.int/iris/bitstream/handle/10665/311567/9789241210263-eng.pdf?ua=1 accessed 29 March 2019).

[2] WHO. WHO list of priority medical devices for cancer management. (WHO Medical device technical series). Geneva: World Health Organization; 2017 (https://apps.who.int/iris/bitstream/handle/10665/255262/9789241565462-eng.pdf;jsessionid=E549267137B337D169F15E3372BDCF42?sequence=1, accessed 26 March 2019).

[3] WHO, UNFPA, UNICEF. Interagency list of priority medical devices for essential interventions for reproductive, maternal, newborn and child health. Geneva: World Health Organization; 2016 (http://www.who.int/iris/handle/10665/205490 , accessed 26 March 2019).

[4] WHO. Interagency emergency health kit 2017. Geneva: World Health Organization; 2017 (https://www.who.int/emergencies/kits/iehk/en/, accessed 15 March 2019).

[5] WHO. Disease commodity packages. Geneva: World Health Organization (https://www.who.int/emergencies/what-we-do/prevention-readiness/disease-commodity-packages/en/, accessed 15 March 2019).

[6] WHO. Priority medical devices: WHO lists of priority and medical devices. Geneva: World Health Organization (https://www.who.int/medical_devices/priority/en/, accessed 15 March 2019).

18.   The Secretariat issued in response to Member States' requests, for instance during the global forums, a concept note on the principles of a classification, coding and nomenclature system.[1] Following the comments received,[2] it has initiated the development of a standardized nomenclature, to be a global public health good, using the platform of the International Statistical Classification of Disease and Related Health Problems.[3] The first draft version of the system was presented at the Fourth WHO Global Forum on Medical Devices (Visakhapatnam, India, 13-15 December 2018).[4] The proposal was also presented in March 2019 to the members of the International Medical Device Regulators Forum.

THE WAY FORWARD

19.   WHO is seeking contributions to and proposals for the development of the International classification and nomenclature of medical devices.[5] Expertise will need to be strengthened for this complex task on medical devices, particularly in the areas of biomedical engineering, health information systems and in laboratory and in vitro diagnostics.

20.   In March 2019, in the light of new European Union Regulations on medical devices,[6] the European Commission selected a nomenclature system for medical devices. It will make the nomenclature available for the European Databank on Medical Devices and is exploring ways to support WHO's work in the field.

21.   It is envisaged that effective governance of the international classification, coding and nomenclature of medical devices would be needed through a reference group of editorial experts defined by the Secretariat. The nomenclature system would have transparent methods for developing the terms, classification, definitions and hierarchies and should be freely available and exportable to other health care information systems. It could be referenced and used by all stakeholders and could be used for tracking as an element of a unique device identifier.

22.   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).

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[1] Request for input and collaboration towards international classification, coding and nomenclature of medical devices (https://www.who.int/medical_devices/priority/ConceptNoteNomenclaturemedicaldevicesv13forconsultation.pdf?ua=1, accessed 15 April 2019).

[2] WHO. Responses to collaboration proposal for international nomenclature (2018). WHO concept note and collaboration proposal for international nomenclature, coding and classification of medical devices. Geneva: World Health Organization (https://www.who.int/medical_devices/priority/mde_nomenclature/en/index2.html, accessed 3 April 2019).

[3] WHO. Classifications (https://www.who.int/classifications/en/, accessed 15 March 2019); see also documents A72/29 and A72/29 Add.1 submitted to the Seventy-second World Health Assembly.

[4] Presentations on nomenclature and classification of medical devices (https://www.who.int/medical_devices/global_forum/4th_gfmd_plenary_presentations/en/index2.html, accessed 29 March 2019).

[5] WHO Request for contribution and proposals towards the first development version of the ICMD (International Classification and Nomenclature of Medical Devices) (https://www.who.int/medical_devices/priority/mde_nomenclature/en/index4.html, accessed 29 March 2019).

[6] Medical devices nomenclature (https://ec.europa.eu/docsroom/documents/34264/attachments/1/translations/en/renditions/native, accessed 15 April 2019).

23.   The Secretariat requires Member States' continuing support to develop this system of international classification, nomenclature and coding as a global good.

ACTION BY THE EXECUTIVE BOARD

24.   The Board is invited to note the report and to provide further guidance.

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