14. Standardisation of medical devices nomenclature

Contents

In focus

WHO has been discussing the standardisation of medical devices nomenclature since EB145 in May 2019. The goal is to have an open standardized international classification, coding and nomenclature for medical devices that would support: patient safety; access to medical devices for universal health coverage; emergency preparedness and response; efforts to increase quality of health care.

WHO is not working towards a new nomenclature system, but working towards harmonisation of the four most widely used nomenclature systems in accordance with WHO principles of governance, transparency and access.

Raw results from the 2021 survey of countries' medical device nomenclature systems is presented in the Draft 2 Overview and will be published in EB150/14 Add.1 (not yet published).

EB150/14 report provides details of the Secretariat's continuing work towards convergence and harmonisation in this area. The proposed first step would be a feasibility study on the challenges and benefits of using innovative mapping techniques to allow information from four of the most widely used nomenclatures to be publicly available on WHO platforms for use by Member States as a way towards standardization.

The Secretariat seeks a decision from the EB which would endorse continued mapping and collaboration with various stakeholders and a progress report for WHA76 in 2023.

Background

The four nomenclature systems, used by more than one Member State, are:

- the (open, EU sponsored) European Medical Device Nomenclature (EMDN),
- the (not-for-profit but pay-walled consortium) Global Medical Devices Nomenclature (GMDN),
- the (privately owned, pay-walled, US based) Universal Medical Devices Nomenclature System (UMDNS), and

- the United Nations Standard Products and Services Code (UNSPSC).

EB145/3 explained the need for a standardised nomenclature thus:

> *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.*

These 'needs' have not been critically analysed in any of the documents so far produced by the Secretariat, nor has there been any exploration of the role device nomenclature plays in these functions, or why a standardised nomenclature will better facilitate these functions.

The reference to **patient safety and quality of health care** appears to refer to the role of standardised nomenclature for regulatory approval (implying mandatory registration) and in the assessment of levels of access to devices across facilities. International standardisation would support regional device regulation and regulation by reference to an international system of qualification.

A standardised nomenclature **will facilitate procurement** both for the supply officials ordering devices and for international corporations seeking to avoid having to adapt their catalogues to national differences.

The reference to **universal health coverage** appears to envisage the use of a standardised nomenclature in specifying 'essential benefit packages'. Clearly the global UHC donors would prefer to have an internationally standardised nomenclature to facilitate the operations of benefit packages imposed on LDCs. Presumably the approved devices will be listed in WHO's UHC Compendium of services and programs.

See Tracker links to previous discussions of medical devices and health technologies

PHM Comment

Standardised nomenclatures are useful. There are potential benefits to be gained from an internationally standardised nomenclature.

However, PHM has some concerns about the purposes of the current exercise and possible uses of an international standardisation:

- UHC as a minimal safety net under a privatised and marketised mainstream;
- imposition of restrictive standards which advantage transnational suppliers over local suppliers.

The purposes and uses of international standardisation have been assumed rather than analysed in the discussion so far.

See PHM comment on Item 11 at EB148

Notes of discussion