WHO concept note and collaboration proposal for International Nomenclature, coding and classification of medical devices (ICMD)

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Interest in ICMD: | I participated to the "Single Nomenclature for Medical Devices" Working Group. I found too often in LMIC, hospitals without an inventory because existing nomenclatures are too difficult to use at any level of health centers. In these conditions it is impossible to manage medical devices either at hospital or national level ! This could be solved by the nomenclature chosen by WHO.

General comment on the concept note, especially on the principles :

The survey on the nomenclatures in use, carried out at the beginning of the year, clearly showed that none of the existing ones is suitable for all users. Even nomenclatures dedicated to medical devices like UMDNS, GMDN are far from being adopted by all stakeholders and used in reality. And there is not even a mapping between them. Nomenclatures like UDI, UNSPSC meet very specific needs, those of buyers. What will make the nomenclature sought by WHO better meet its needs than all those currently developed for medical devices ???

The nomenclatures mentioned above are "high level" nomenclatures, complex to use, for the use of regulators, manufacturers, international organizations, in a word more used in high income countries than low income countries. WHO is concerned with all countries, and especially with LMICs, where the training levels of the general population are lower. The nomenclature sought should therefore be a nomenclature easier to use. Simple to use for classification and coding. Simple to use because expressed in the current professional language of the area in which the medical devices are used. In harmony with high level nomenclatures.

The principles developed in the concept note should therefore give priority to "low level stakeholders" (users, managers) and not to "high level stakeholders" (experts, regulators, manufacturers, administrations, etc.). Current experience has shown that it is impossible to meet the specific needs of all the stakeholders at the same time.

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| 34 | Increase trade and better asset management in health facilities are 2 things very different. They should be dissociated. "Better asset management" is the most important answer to point 6 of WHA60.29 | Lines 31 to 35 should be:  
- better asset and priority lists management in health facilities  
- improve procurement and supply management  
- increase post surveillance and trade  
- facilitate product selection  
- faster regulatory process. | H |
| 36 | The mentioned benefits of the desired ICMD are truly needed. In these conditions "could be" must be replaced by "must be at minimum" | Line 36 should be changed to: "To be universally adopted, benefits of an international classification, coding and nomenclature system must be at minimum: " | H |
| 42 | "collaboration" is a weak term to indicate the relations which must be existing between health facilities and national authorities. | I would write line 42 to 44 as: It would help to improve the asset management of MD at the national level with national authorities; to facilitate the collaboration with industry and international organisations dealing with medical devices to…." | M |
| 53 | ECRI has recently completed a bidirectional mapping between UMDNS and UNSPSC | I would write "Just two of these nomenclature systems have been mapped (UMDNS and UNSPSC)" | M |
| 103 to 105 | This principle specifically mentions the regulatory and supply systems. This is not enough. To be universally adopted, a nomenclature system must meet the needs of all stakeholders including the MD users and especially those working in LMICs | This principle should be written: "iii Nomenclature …… to meet the various needs of all its stakeholders" | H |
| After 105 | It is not mentioned that the nomenclature system must be simple to use in order to avoid coding mistakes | A new principle could be inserted after line 105: "Nomenclature must be simple to use by all stakeholders in order to avoid coding errors" | H |
| 110 to 111 | As mentioned before, the MD users and managers are the most important nomenclature users. If they adopt it, other stakeholders, such as regulators, will use it. | "Can be referenced and used by all users of medical devices (hospitals/health workers or patients), managers, procurers, regulators " | H |
| 116 to 118 | Idem line 110 | That the codes could be used with software systems for inventories, adverse event reporting, procurement, refurbishment, regulation, registration, decommissioning or others as necessary. | H |

Please add rows as necessary


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If you would like to propose your nomenclature/coding or classification system from your institution/country, in order to support the development of an international system for medical devices, ICMD, please provide your information below:

| Name of the system: | CNEH Nomenclature |
| Website | No longer on a web site (Since France has adopted GMDN as its official nomenclature system, the CNEH Nomenclature use and development is no longer funded). Documents are joined to the email |
| Owner | Centre National d'Expertise hospitalière (CNEH) |
| Country | France |
| Language | French |

Please feel free to explain your proposal Reasons why your system can be used to support the development of an international system that could be used by all medical devices stakeholders. (You would be contacted in September, once the responses are analysed)

First of all, the presentation made during a "A single nomenclature for MD" working group and the discussion that followed, showed that the ICD11 nomenclature system, very powerful and easy to use, could be transposed to medical devices. The transposed nomenclature would then meet the principles set out in the concept note, if it had a classification and easy-to-use hierarchical coding such as that of ICD11. The use of "dictionaries" of medical terms such as the Unified Medical Language System (UMLS) Metathesaurus, SNOMED, etc ..., is a gateway to the use of exact terms to qualify medical devices, to translate the nomenclature in many languages.

An example of a very simple classification and coding to use at the level of the users, which minimizes the errors, is that given by the CNEH nomenclature. Its main interest remains intact even if it is no longer supported by the French Government and even if it only concerns medical equipment. France has adopted the GMDN nomenclature. Didier VALLENS, a former expert at WHO, is one of the founders of this CNEH nomenclature for medical equipment.

This nomenclature uses a 4 levels classification:

- at level 1, the family (imaging, operating theater, etc.) with an alphanumeric code
- at level 2, the function (cutting imagery, projection imaging, etc.)
- at level 3, the type of equipment (MRI, CT Scanner, ...)
- at level 4, the components (MRI magnet) or accessories (MRI antennas)

The codification is progressive as the equipment is defined:

- 4 characters for the family at level . Ex for imaging equipment: IMAG
- 3 additional digits for the function at level 2. Ex for a projection imaging device: IMAG504
- 2 additional digits to reach the equipment at level 3. Ex for an angiography system: IMAG50411
- 3 additional digits to reach the level 4 component. Ex for an angiography generator: IMAG50411005

This codification is perfectly adapted to CMMS and digital applications by allowing research to be done at any level. Example: a search with "*32401000" allows...
to find all syringe pumps; a search with "*32401*" lists all the syringe pumps and their components. A search with "324" gives the list of all infusion equipment. Etc ... The words, the terms used are those well known to biomedical professionals.

The CNEH coding is perfectly adapted to biomeds who can assign a code gradually according to their personal knowledge of the equipment, by coding equipment only up to the levels they are sure. This avoids coding errors that can be very damaging for equipment management or patient safety.

This codification, which is very significant and easy to use, identifies the equipment with sufficient precision so that correspondence with the GMDN and UMDNS nomenclatures may be established. Regulators, buyers, and other professionals involved ... can therefore use this codification

Associated with the name of the equipment model, that of its manufacturer, this coding may lead easily to the UDI nomenclature. Etc.

The CNEH nomenclature is just one example of a nomenclature that can be easily adopted by users and managers who may have to code MD.

*Kindly send this form to medicaldevices@who.int before 24 August - thank you.*