Towards International Harmonized Nomenclature for Medical Devices

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WHO 4th Global Forum on Medical Devices
**Definitions**

**Health Technology**: “The application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of life.” (WHA 60.29)

**Medical Device (brief)**: “An article, instrument, apparatus or machine that is used 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.” (full definition GHTF/SG1/N071:2012)

*Medical devices are health technologies that include also in-vitro diagnostics, implantables, medical equipment, software and surgical instruments.*
Classification, Nomenclature and Coding Systems

A Nomenclature System, in brief, is composed by the following 3 elements.

Classification (also called Categorisation)
The process of grouping products into categories and of building relationships, by classifying them by properties and criteria and by defining and assigning relations.
With regards to Medical Devices, several criteria can be suitable for classifying them, including, function, applications, operation principles, material and other properties, type of use, etc..

Nomenclature
A system providing common descriptions for terms, which can be classes and/or items, according to the applicable classification and to a set of rules and criteria.
With regards to Medical Devices, the nomenclature system should avoid any possible misunderstanding, by generically identifying Medical Devices and related health products.

Coding
The process of assigning a unique identifier, or code, to each term of the classification and nomenclature systems.
Problem identification: the “Nomenclature Gap”

Consolidated results, by average country income

https://www.who.int/medical_devices/priority/mde_nomenclature/en/

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Problem identification: the “Nomenclature Gap”

WHO Medical Devices Atlas 2017

Consolidated results, by region


https://www.who.int/medical_devices/priority/mde_nomenclature/en/

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Problem identification: the “Nomenclature Gap”

WHO Medical Devices Atlas 2017

Summary of some final considerations for future development on Medical Devices:

• > 10,000 types of medical devices, difficulties in selection, procurement and use
• 55 countries do not have regulatory authority for Medical Devices
• 97 countries do not have a list of medical devices for public procurement
• 88 countries do not have standard technical specifications for Medical Devices
• Need for defining standards, priorities and procedures, based also on reference guidance documents, such as from WHO

Furthermore, most of International Organisations, and UN Agencies as well, have their own classification, nomenclature and coding systems, not harmonised.

Problem identification: the "Nomenclature Gap"

WHO 2018 Survey on Medical Devices Nomenclature

Result of Stakeholder Request for Collaboration in nomenclature of medical devices

<table>
<thead>
<tr>
<th>Description</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>43 total responses</td>
<td></td>
</tr>
<tr>
<td>23 offers to collaborate or provide feedback</td>
<td></td>
</tr>
<tr>
<td>11 different existing systems of nomenclature suggested</td>
<td></td>
</tr>
<tr>
<td>3 respondents are currently developing a system of nomenclature</td>
<td></td>
</tr>
</tbody>
</table>

https://www.who.int/medical_devices/priority/mde_nomenclature/en/index2.html
Analysis of the effects of the “Nomenclature Gap”

Final considerations on the effects of the “Nomenclature Gap”

• Cross-mapping not existing, current Nomenclature Systems are not, or at best barely, inter-operable
• Issues on standard guidalines, listing, assessment, procurement and supply of Medical Devices
• Negative effects for regulatory purposes
• Indirect negative effects on the response time and efficacy of aid, development and emergency interventions in the Health sector, including donations
• Management and maintenance of Medical Devices are more complicated
• Slower and less effective management and tracking of adverse events and recall related to the use and operation of Medical Devices

All the above, which is only a short resume, leads in the opposite direction of “SDG 3 Ensure healthy lives and promote well-being for all at all ages”
Two recent cases of potential application

ICIJ “Implant Files” dossier
https://www.icij.org/investigations/implant-files/

CBS News:
“An analysis of Health Canada data obtained through Access to Information also reveals that in the past 10 years, devices such as replacement hips, insulin pumps and pacemakers are suspected to have played a role in more than 14,000 reported injuries and 1,416 deaths.”

Source:
Health Canada and ICIJ

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Objective: ICMD

“To identify an international classification, coding and nomenclature system of Medical Devices (ICMD) to support the access to medical devices for better health care delivery in line with the Sustainable Development Goal #3 and the WHO Thirteenth General Programme of Work (2019–2023), including universal health coverage, response to health emergencies and better health and wellbeing.”

http://apps.who.int/gb/ebwha/pdf_files/WHA71/A71_4-en.pdf?ua=1

Sustainable Development Goals SDG 3
Ensure healthy lives and promote well-being for all at all ages
Objective: ICMD
### Benefits of ICMD

Before and after global public terminology for medical devices

<table>
<thead>
<tr>
<th>Before</th>
<th>After</th>
</tr>
</thead>
<tbody>
<tr>
<td>Donations may go to a facility that doesn’t have the infrastructure to support the donated medical devices</td>
<td>Facilitated registration for market approval in regulatory authorities.</td>
</tr>
<tr>
<td>Gaps in priority medical equipment and access to medical devices go unidentified</td>
<td>Patient safety supported by tracking devices from manufacturer to user through life cycle</td>
</tr>
<tr>
<td>Donated equipment may not include necessary accessories, spare parts and consumables</td>
<td>Support Universal Health coverage by having a basic/priority list of medical devices with code selected for health interventions</td>
</tr>
<tr>
<td>No link between regulation, management and maintenance</td>
<td>Enhance assets management in health care facilities</td>
</tr>
<tr>
<td>Confusion of what equipment is where because equipment inventory may not be tracked and maintain</td>
<td>Facilitate functional inventories, availability, monitoring and evaluation of medical devices</td>
</tr>
<tr>
<td>Difficult to track and maintain devices which would help in identification of safety problems</td>
<td>Facilitate follow up of donated/refurbished equipment</td>
</tr>
<tr>
<td></td>
<td>Track usage of medical devices/implantables in patients</td>
</tr>
</tbody>
</table>
## Challenges VS Benefits of ICMD

### Challenges

<table>
<thead>
<tr>
<th>Category</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory</td>
<td>Lack of interest by stakeholders, Complexity related with the development</td>
</tr>
<tr>
<td>Implementation</td>
<td>Availability of resources, Difficulties of mapping or linking existing systems, Complexity related with the adoption of a nomenclature system for countries without any system and/or resources</td>
</tr>
<tr>
<td>Market</td>
<td>Competition with owners and developers of current systems</td>
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</table>

### Benefits, grouped by sector

<table>
<thead>
<tr>
<th>Sector</th>
<th>Details</th>
</tr>
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<tbody>
<tr>
<td>Safety and Risk</td>
<td>Facilitate registration for market approval by regulatory authorities. Support patient and operator safety by tracking devices from manufacturer to user through lifecycle. Support improvement of adverse event and recall.</td>
</tr>
<tr>
<td>Support Universal Health Coverage</td>
<td>By having lists of Medical Devices and Kits with standard codes. By supporting efficient and reliable exchange of information.</td>
</tr>
<tr>
<td>Financial and Access</td>
<td>Facilitate HTM, Procurement and Supply Chain. Facilitate Planning and Budgeting. Facilitate logistics and customs and tax clearance.</td>
</tr>
<tr>
<td>Enhance Assets Management</td>
<td>Enhance HTA, availability, inventory, maintenance, monitoring and evaluation of Medical Devices</td>
</tr>
<tr>
<td>Improve aid/emergency/donations</td>
<td>Facilitate standardisation of delivery for emergency and development programs and for donations</td>
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</tbody>
</table>
ICMD as a link along the life-cycle of the Medical Devices

From R&D, to Manufacturing, Procurement, Management, Use, Safety and post-market Surveillance, to Decommissioning

For manufacturers
- To comply with UDI requirements
- For innovators
- To track manufacturers

For regulators
- To do regulatory approval
- Classification of medical devices for risk
- To follow post market surveillance

For list of medical devices and procurements
- For list of medical devices
- For technical specifications
- For procurement and donations
- For pricing and reimbursement

For final users in hospitals or patients
- For inventories
- For CMMS
- To follow up implants and track users
- Track refurbished and donated equipment

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ICMD facilitate Management of Medical Devices

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## WHO Agenda for ICMD

<table>
<thead>
<tr>
<th>Month</th>
<th>Activities</th>
</tr>
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<tbody>
<tr>
<td>January 2018</td>
<td>• Discuss with UN agencies. Develop specifications. Survey stakeholders.</td>
</tr>
<tr>
<td>February – March 2018</td>
<td>• Collect survey results. Present needs, use cases and specifications.</td>
</tr>
<tr>
<td>July 2018</td>
<td>• Publication of principles for classification and nomenclature.</td>
</tr>
<tr>
<td>September – November 2018</td>
<td>• Review proposals. Develop a pilot project with collaboration of existing systems, as possible.</td>
</tr>
<tr>
<td>December 2018</td>
<td>• Present results of pilot test at the 4th WHO Global Forum of Medical Devices.</td>
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</table>
WHO Strategy for ICMD

Guiding Principles

Governance
• Member States, selected Stakeholders
• Formal review structure
• Defined mechanism for stakeholders’ feedback

Characteristics
• Transparent methodology
• Defined mechanism for update
• Non-discriminatory or biased, fair
• Mutually exclusive
• Supports translations

Access of Information
• Free and entirely available (codes, criteria, structure, hierarchy)
• Mappable to other available local/global nomenclature systems
• Compatible with UDI
• Suitable for implementation in health, logistics, management and procurement software and systems
Question time
WHO proposal on the ICD-11 platform

Concept strategy and methodology
Pilot implementation of ICMD database on the ICD-11 platform

The set of terms used for populating the first pilot of nomenclature represents the majority of terms from the last available WHO Medical Device Technical Series publications, analysed and standardised.

ICD-11 provided the platform to implement the pilot nomenclature system.

The backbone is the same ICD-11 ontological database, which:
• provides for the most advanced classification, attributes, tagging and relation system;
• suitable for linking with UDI systems at any level;
• will support natively the integration of diseases (active, ICD-11), devices (pilot, ICMD) and procedures (in development, already published, ICHI) nomenclatures and coding systems;
• is transparent and fully free (codes, structure and relations), suitable for network (online) and local (offline) access, an API is available for linking and implementing ICD-11 database to/in any other system;
• sample ICMD database
  https://icd.who.int/dev11/l-m/en
  X Extension Codes / Health Devices, Equipment and Supplies
• ICD-11 video presentation https://www.who.int/health-topics/international-classification-of-diseases (6 min.)
WHO proposal on the ICD-11 platform

Characteristics of ICD-11 database

- **Ontological database**, provides for the most advanced classification, attributes, tagging and relation system

- Suitable for coding of any desired hierarchy and relation system, any “term” can be freely linked

- Non-speaking coding system, hierarchy-independent, suitable for maximum flexibility: the structure of the database is based on a set of terms and a list of relationships, which define the classification criteria

- Suitable for classifying the terms according to any criteria, which generates its own structure and view

- Suitable for mapping and linking ICMD with other databases, such as ICHI (in development), ICD-11, any available nomenclature system (provided that mapping criteria are defined), and any UDI system

- **Fully free** (codes, structure and relations), suitable for network (online) and local (offline) access, an API is available for linking and implementing the database to/in any other system
Sources for first ICMD database

Sources for the Classification and the Nomenclature implemented are the last WHO Medical Devices Technical Series publications, in particular:

• WHO list of priority medical devices for cancer management
• Interagency list of medical devices for essential interventions for reproductive, maternal, newborn and child health
• Essential list of medical devices for emergency interventions (in development)
• WHO list of assistive devices

> 2000 terms generated, covering almost entirely the capital medical devices

...... to be continued, starting by harmonising and standardising other WHO documents!
Current ICMD implementation

Categories provided by WHO publications

ICD-11 (Mortality and Morbidity Statistics)

- 11 Diseases of the circulatory system
- 10 Diseases of the ear or mastoid process
- 12 Diseases of the respiratory system
- 13 Diseases of the digestive system
- 14 Diseases of the skin
- 15 Diseases of the musculoskeletal system or connective tissue
- 16 Diseases of the genitourinary system
- 17 Conditions related to sexual health
- 18 Pregnancy, childbirth or the puerperium
- 19 Certain conditions originating in the perinatal period
- 20 Developmental anomalies
- 21 Symptoms, signs or clinical findings, not elsewhere classified
- 22 Injury, poisoning or certain other consequences of external causes
- 23 External causes of morbidity or mortality
- 24 Factors influencing health status or contact with health services
- 25 Codes for special purposes
- 26 Traditional Medicine conditions - Module I

ICD-11 Maintenance Platform

Welcome to the ICD-11 Maintenance Platform

IMPORTANT! The content made available here is not a released version of the ICD-11. It is a work in progress in between released versions.

For the latest release of the classification please see ICD-11 Browser.

You need to create an account for yourself if you wish to contribute to the classification by writing proposals or comments by following the link below.

Register

Please note that the accounts you’ve created before the release of the classification are still valid.

Caveats

- The audience for this site is the maintainers, contributors and translators of the classification
- The classification seen on this is not the released version of the classification.
- The content in this platform may change on an ongoing basis
- For the latest release of the classification please see ICD-11 Browser (blue)

Related Information

ICD-11 Home Page

For more information about how to use this site, please see the User Guide.

For more questions, please contact icd@who.int
Current ICMD implementation

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Current ICMD implementation

Managing the granularity

Pre-Coordination: pre-assigned hierarchy

- Health Devices, Equipment and Supplies
  - Assistive Devices
  - Medical Devices
    - XD7QL5 Medical Equipment
      - XD4Y1 Imaging, Diagnostic – Interventional
        - XD6IG5 Computed Tomography Imaging
        - XD6E1 Nuclear Magnetic Resonance Imaging
        - XD7BH0 Nuclear Medicine Imaging
        - XDHN7 Positron Emission Tomography
          - Single Photon Emission Computed Tomography Imaging
      - XD5XJ1 Hybrid Radiology Systems
      - XD93L8 Ultrasound Imaging
      - XD2BA1 Video Imaging
    - XD6DR5 X-Ray Imaging
      - XD6UT1 Radiography Systems
        - XD57H8 Radiography Systems, Fixed
          - XD9784 Radiography Systems, Fixed, Digital
      - XD81P9 Radiography Systems, Fixed, Analog
      - XD77J5 Radiography Systems, Mobile
      - XD6CNB Mammography Systems
      - XD13P1 Radiography – Fluoroscopy Systems

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Current ICMD implementation

Managing the granularity

Post-Coordination: term with optional configurations

- JA00 Abortion
- JA01 Ectopic pregnancy
  - JA01.0 Abdominal pregnancy
  - JA01.1 Tubal pregnancy
  - JA01.2 Ovarian pregnancy
  - JA01.4 Other specified ectopic pregnancy
- JA01.Z Ectopic pregnancy, unspecified
- JA02 Molar pregnancy
- JA03 Missed abortion
- JA04 Blighted ovum or nonhydatidiform mole
- JA05 Complications following abortion, ectopic or molar pregnancy
- JA07 Abortion outcome of pregnancy, unspecified
- Obstetric, perinatal, or hypertensive disorders in pregnancy, childbirth, or the puerperium
  - Obstetric haemorrhage
- Certain specified maternal disorders predominantly related to pregnancy
- Maternal care related to the foetus, amniotic cavity or possible delivery problems
- Complications of labour or delivery
- JB00 Preterm labour or delivery
  - JB00.0 Preterm labour without delivery
  - JB00.1 Preterm spontaneous labour with preterm delivery
  - JB00.2 Preterm labour with term delivery
  - JB00.3 Preterm delivery following iatrogenic induction of labour or caesarean section
  - JB00.4 Other specified preterm labour or delivery
  - JB00.Z Preterm labour or delivery, unspecified

JB00.0 Preterm labour without delivery

Parent
JB00 Preterm labour or delivery

Description
A condition characterized by the onset of labour before 37 completed weeks, without delivery.

All Index Terms
- Preterm labour without delivery
- Induced preterm labour without delivery
- Spontaneous preterm labour without delivery
- Premature or preterm labour without delivery
- Induced premature or preterm labour without delivery

Add detail to Preterm labour without delivery

Associated with (use additional code, if desired):
- XT3X Duration of pregnancy less than 5 completed weeks of pregnancy
- XT09 Duration of pregnancy 5-13 completed weeks of pregnancy
- XT65 Duration of pregnancy 14-19 completed weeks of pregnancy
- XT0T Duration of pregnancy 20-25 completed weeks of pregnancy
- XT4J Duration of pregnancy 26-33 completed weeks of pregnancy
- XT64 Duration of pregnancy 34-36 completed weeks of pregnancy
- XT6K Unspecified duration of pregnancy
Current ICMD implementation

ICD-11 platform ready for open collaborative development

Foundation Id : http://id.who.int/icd/entity/2009008947

Malignant neoplasms, except of lymphoid, haematopoietic, central nervous system or related tissues

Parent(s)
- Neoplasms

Description
This entity does not have a definition at the moment. You may suggest a definition using our Proposal System available under the Contributions menu.

Exclusions
- Neoplasms of brain or central nervous system
- Neoplasms of haematopoietic or lymphoid tissues
WHO Family of Classifications and Systems of Nomenclature

**ICD** – International Classification of Diseases

**ICHI** – International Classification of Health Interventions

**ICF** – International Classification of Functioning, Disability and Health

**INN** – International Nonproprietary Names for pharmaceutical substances

And potentially **ICMD** – International Classification of Medical Devices

**ICPC** – International Classification of Primary Care

**ICECI** – International Classification of External Causes of Injury

**ATC** – Anatomical Therapeutic Chemicals classification system with defined daily doses

**ISO9999** – Technical aids for persons with disabilities

**ICNP** – International Classification of Nursing Practice
ICMD plan for 4\textsuperscript{th} GFMD and for the future

Current development

- Present the strategy, the methodology, the current pilot and the implementation on the ICD-11 platform
- Collect feedback by stakeholders, in particular countries, national and international users, organisations and institutes, regulators, experts and developers, manufacturers

Establishing a technical panel for the further development of ICMD

Goals for consideration

- In the mid-term, standardise and code the current WHO publications and the UN and international procurement for LMICs, in particular standard kit for emergencies, outbreaks and major diseases / health interventions
- The biggest challenge is not developing just another nomenclature system, even if global and free, but a useful alternative, which shall be suitable for mapping/linking 1 to 1, or as closest as possible, with other systems in place, at international and national level
WHO vision

Sustainable Development Goals SDG 3
Ensure healthy lives and promote well-being for all at all ages

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WHO Vision 2020

Sustainable Development Goals SDG 3
Ensure healthy lives and promote well-being for all at all ages

WHO has available ICMD, free for use and entirely available.

All Member States, UN agencies and any other Country ad Organisation and the Private Sector can use and refer to the same classification, nomenclature and codes for medical devices.

Industry to support development of nomenclature for each new product.

Open source, ICD-11 and/or equivalent platform, to continue and maintain it.

Funding agencies and partners to support ICMD, to facilitate access to health technologies and health services.

Technical review commitee in place, collaborative update and development development methodology and process defined and in place.
Question time
Thank you!

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