In Search of a Harmonized Nomenclature for Medical Devices

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**Objectives**

- Analysis of the findings of WHO Survey on the “Nomenclature Gap”
- Overview of the benefits and impact of an international, harmonised, freely available nomenclature system of Medical Devices
- Presentation of the ICD-11 ontological database as a platform for a nomenclature of Medical Devices
- Considerations from WHO – Operations, Supply and Logistics dept. experiences with priority medical device lists and impact of the nomenclature gap.
- Collect feedback and engage in group discussion for path forward in designing and implementing the nomenclature system

**Problem Identification and Analysis: the “Nomenclature Gap”**

WHO 2018 Survey assessed that > 50% of Low and Middle Income countries do not have a nomenclature system, and amongst other countries the nomenclature is neither standardised nor harmonised.

The so called “Nomenclature Gap” is the global and local lack of a standard system, and of a comprehensive matching and connection between different systems in use.

This “gap” represents a global limitation to the access to quality-standardised healthcare services, and at local level the impact on the access and quality of care can be serious, in particular for low and medium income countries, lacking of internal capacity and of a efficient regulatory and management system.

**Benefits of one standardised and harmonised international Nomenclature System for Medical Devices**

**Guiding Principles**

- Safety and Risk
  - 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.

- Support Universal Health Coverage
  - By having lists of Medical Devices and Kits with standard codes.
  - By supporting efficient and reliable exchange of information.

- Financial and Access
  - Facilitate HTM, Procurement and Supply Chain.
  - Facilitate Planning and Budgeting.
  - Facilitate logistics and customs and tax clearance.

- Enhance Assets Management
  - Enhance HTA, availability, inventory, maintenance, monitoring and evaluation of Medical Devices.

- Improve aid/emergency/donations
  - Facilitate standardisation of delivery for development aid initiatives, emergency interventions and donations.

**3rd Sustainable Development Goal addressed, by supporting Access to Universal Health Coverage**

**Concept strategy and methodology**

**Pilot implementation 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, ICH) 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.

**Next steps**

- 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 the nomenclature system