VIII Congress of the National Group of Bioengineering (GNB)
Padova, Italy, June 21st-23rd, 2023

Key points to design the MDs Library of a National implant Registry: lesson learned from the Italian experience

Simona Pascucci[1,2], Michela Franzò[2], Veronica Mari[1], Alessia Biondi[1], Stefania Ceccarelli[1], Fabiano Bini[2], Franco Marinozzi[2], Enrico Ciminello[1], Paola Ciccarelli[1], Paola Laricchiuta[1], Eugenio Carrani[1], Marina Torre[1]

[1] Scientific Secretariat of the President, Italian National Institute of Health, Rome, Italy

[2] Department of Mechanical and Aerospace Engineering, La Sapienza University of Rome, Italy

Introduction

The **European Medical Device Regulation (MDR) 2017/745** made official the implementation of a unified European database on medical devices (MD), **EUDAMED**, and stated that the **European Medical Device Nomenclature (EMDN)** should be made available to facilitate its functioning. EMDN has taken as reference the **Italian national MD classification** (Classificazione Nazionale dei Dispositivi medici, CND).
Its aim is to classify all MDs into macroscopic and homogeneous classes.

MD Registries can benefit from detailed and specific classifications to obtain information on device performance and to compare similar devices. To do this, such Registries should rely on a **MD Library**, a database built on a detailed taxonomy that identify and characterise MDs according to a set of established rules. MD Libraries are designed to be directly fed by manufacturers.

The **Dutch registry LROI**, the **English National Joint Registry** (NJR) and the **Endoprothesen Register Deutschland** (EPRD) went further by defining a detailed taxonomy to classify their registered MDs. NJR and EPRD, given the absence of a universally recognised and shared nomenclature for joint prostheses, agreed in developing and continuously updating an internationally shared taxonomy. This agreement is the first example of an inter-registry international cooperation for classifying MDs. Within joint prostheses Registry (RIAP), the **Istituto Superiore di Sanità** (ISS) in 2021 signed an agreement with NJR to adopt the already defined NJR-EPRD classification and set up a shared international MD database linking both RIAP and NJR Libraries.

The aim of this study is to describe the methodology adopted by the **Italian Implantable Prostheses Registry (RIPI)** to design the taxonomies for the MD Library of every specific Registry included in RIPI (Figure 1), with particular reference to the **Italian Spine Registry (RIDIS)** and the **Italian Implantable Cardioverter-defibrillator and Pacemaker Registry (RIDEP).**

Methods

After the selection of MDs categories and relative CND classes, the following steps were followed to design the final version of the taxonomy:

1. Establishment of a **technical expert panel** composed by clinicians, scientific societies and researchers of ISS, to define a first draft of the taxonomy structure considering both engineering and clinical aspects;
2. Evaluation of the items included in the first structure by considering the number of devices registered in the **BDRDM** in order to have an overview of all specific devices marketed in Italy;
3. Selection of a **set of technical features** from technical datasheets, manuals and catalogues associated to each item included in the first version of the taxonomy. To ensure device identification and traceability, CND, manufacturer, product catalogue code, lot, barcode, UDI, and ID registration in BDRDM were selected and included in the taxonomy for each device.
4. Identification of technical features most useful to characterise the device and to carry out future analyses according to clinical experts' opinion;
5. Refinement of the taxonomy according to the **opinion of the manufacturers** covering the highest portion of the spinal device market in Italy.

The final version of the taxonomy was then made suitable to fit into formal **XML** (eXtensible Markup Language, lit. "extensible markup language") and **XSD** ("XML Schema Definition") schemas, and specific business rules were introduced to facilitate the subsequent implementation of the **MD Library in the RIPI platform**.

Results:

The designed methodology is structured in six steps summarised in figure 2. Figure 3 shows the macro categories of the taxonomies developed for the RIDIS and RIDEP registries.

Categories	RIDEP	RIDIS
Medical Device Identification	Manufacturer, product code, CND/EMDN, UDI, lot number	
Type of devices	Defibrillator, Pacemaker, catheters and loop recorder	Spinal fixation system, cages, disc prosthesis, cements
Technical and functional features	Chambers connectors, remote control, MRI conditional, sensors	Geometry, type, materials, spine level, mechanics/physics properties

Figure 3: Overview on categories implemented for RIDIS and RIDEP registries

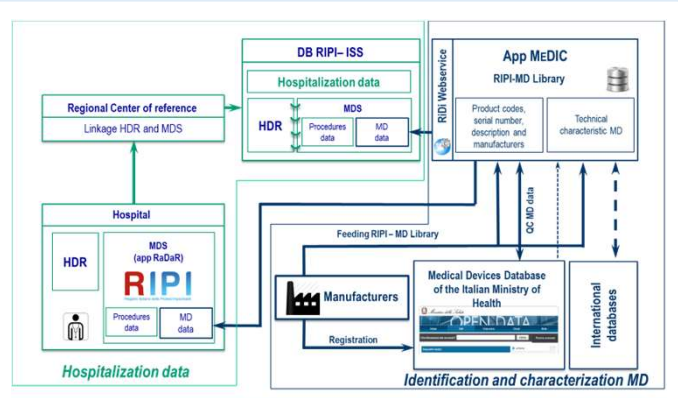

Figure 1: flow diagram of RIPI combined data collection of hospitalisation and medical devices

Materials

The **taxonomy** is a structured list including device-specific variables, properly grouped and described by a minimum core set of technical and identification features. To set up the taxonomy, the following sources of information were considered:

- **CND nomenclature**: a hierarchical classification organised in 22 anatomical/functional categories that characterise devices by homogeneous properties. Each category is organised in groups and sub-groups structured in different levels (up to 7) and identified by a correspondent alphanumeric code;
- **Medical Devices Database of the Italian Ministry of Health (BDRDM):** a database that contains all MDs marketed in Italy, together with their technical datasheets;
- **Medical Devices datasheets:** technical documents available on the manufacturer's website;
- **Literature review:** analysis of studies concerning survival and/or failure of the specific implantable devices;
- **Opinions of experts:** clinicians and specialists, members of the registry technical panel.

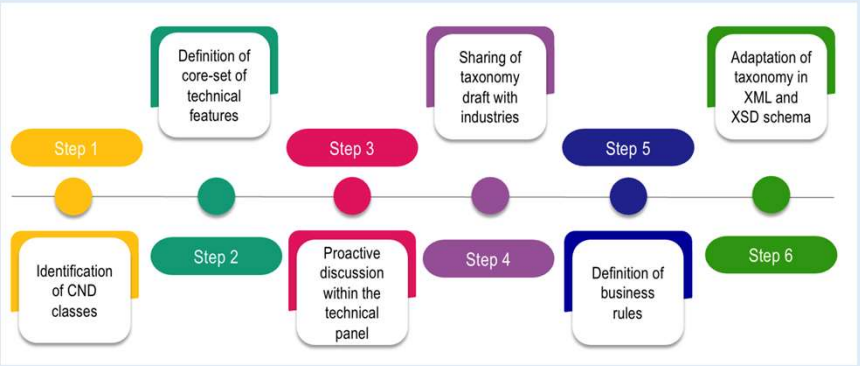

Figure 2: Flow chart of Taxonomy implementation

Discussion/Conclusion

Implantable prostheses registries have become increasingly widespread in recent decades thanks to their reliability in improving MD traceability, patients' safety and health care. MD Libraries represent an important source of standardised data to allow Registries to carry out statistical analyses on MDs performance.
This study highlighted the following essential features to be accomplished when designing a specific MD taxonomy:

- To **avoid** excessive details in describing MDs and to **select** only those properties useful to compare devices performance;
- To **keep** only the essential MDs characteristics defined by involving of all the interested actors (**clinicians** and **manufacturers**);
- To **share** the draft of the taxonomy with the **largest number of manufacturers** before its releasing. This step is essential to verify that the feeding of the MDs Library is feasible for them.

The availability of BDRDM facilitated the review of MDs marketed in Italy. However, the integration with other sources, such as literature and catalogues, was necessary to have a complete overview of MDs to be considered in the taxonomy.
The methodology presented in this study allows to implement a MD Registry Library to:

- **Support** health operators in data collection and limit compilation mistakes;
- **Describe** MDs by a set of technical features useful to conduct analyses on use and performance over time;
- **Provide** manufacturers with valuable information on performances of their devices.

Limit of the proposed methodology: possible biased exclusion of selected MD properties due to confidentiality issues, thus preventing the Registry to perform subsequent complete statistical analyses.

We hope that the experience gathered in Italy in the framework of RIPI might be a useful reference for the implementation of MD Libraries and MD Taxonomies within other Registries worldwide.

This study was coordinated by the Italian National Institute of Health and supported by the General Directorate of Medical Devices and the Pharmaceutical Service of the Italian Ministry of Health