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

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***Abstract*— In 2017, the European Medical Device Regulation 2017/745 made official and effective the implementation of a unified European database on medical devices, EUDAMED, and stated the need to adopt a medical device (MD) nomenclature to support its functioning. Registries are a fundamental tool to evaluate MD long-term safety and to contribute to its traceability. To achieve these goals, the MD Library embedded in the Registry framework plays an important role as it contains all information useful to identify the implanted medical devices and to compare their performance. Similarly to EUDAMED, MD Registry Libraries are based on a detailed and defined MD taxonomy that allows a correct MD categorisation on the basis of a selected set of technical features. The aim of this study is to propose a generalised approach to build a MD taxonomy to be implemented in a MD Registry Library starting from the experience gathered in the implementation of the MD Registries included in the Italian Implantable Prostheses Registry (RIPI).**

***Keywords*— medical devices, nomenclatures, registry, RIPI**

I. INTRODUCTION

IN 2017, the European Medical Device Regulation (MDR) 2017/745 made official the implementation of a unified European database on medical devices, EUDAMED, and stated that a medical device (MD) nomenclature should be made available to facilitate the functioning of EUDAMED [1]. In 2021, the Regulation (EU) 2021/2078 was issued providing all the rules for EUDAMED implementation and use [2]. Accordingly, all medical devices marketed in Europe should be collected in the single database EUDAMED and identified by a unique number, the Unique Device Identifier (UDI).

The selection of a MD nomenclature was fundamental to the functioning of EUDAMED in order to classify all medical devices into macroscopic and homogeneous classes. The European Medical Device Nomenclature (EMDN) was adopted by the European Commission (EC) on March 4th, 2019 taking as a reference the Italian national MD classification (Classificazione Nazionale dei Dispositivi medici, CND) [3],[4]. In 2021, WHO analysed different nomenclatures concluding that CND was the one that complies with the WHO principles for international classification, coding and nomenclature of medical devices. [5]. Moreover, WHO and EC have recently been collaborating in view of adopting an international standardised nomenclature [6].

Besides its role in EUDAMED, EMDN is also a useful tool for other purposes, representing a 'classification root' from which other systems can be developed [4]. Among them, MD Registries can benefit from more detailed and specific classifications, or taxonomies, to classify the implanted devices [7]. Indeed, in depth device knowledge allows a more complete, consistent and informative interpretation of the clinical data collected from the Registry, helping to obtain information on device usage and performance and to compare similar devices [8]. A medical device Registry is defined as an "organized system that continuously and consistently collects relevant data in conjunction with routine clinical care, evaluates meaningful outcomes, and comprehensively covers the population defined by exposure to particular device(s) at a reasonably generalizable scale (e.g. international, national, regional, and health system) with a primary aim to improve the quality of patient care" [9]. Since it represents a fundamental tool to contribute to the traceability of the device and to improve patient safety [10], its establishment is encouraged by MDR especially for class III MDs [1]. Certainly, a Registry should rely on a MD Library based on a defined taxonomy, classification or nomenclature to ensure MD traceability and monitoring,[11]-[13].

The aim of this study is to describe the methodology set up by the Italian Implantable Prostheses Registry (RIPI) [14] to design a taxonomy specific for a class of medical devices. The final scope of the taxonomy design is to complement the existing nomenclature, providing more detailed technical features of the device, and to set up the basis for the development of a dedicated MD Registry Library, essential to promptly identify and characterise the implanted device [8], [15], [16].

This work has been conducted for the purposes of the development of the MD Libraries for the Italian National Registries of spinal implants (RIDIS) and of cardiac devices, defibrillators and pacemakers, (RIDEP). Both RIDEP and RIDIS are included into RIPI.

II. STATE-OF-THE ART

A. The Italian Implantable Prostheses Registry (RIPI)

RIPI was established by law at the Italian National Institute of Health in 2017 (Istituto Superiore di Sanità, ISS) (DPCM 03/03/2017). It is organised as a cross coordination structure of individual registries of implantable devices divided by subject: joint prostheses like hip, knee, shoulder, and ankle (Italian Arthroplasty Registry, RIAP); spinal implants (Italian Spinal Implants Registry, RIDIS); implantable cardioverter defibrillator and pacemaker (Italian Implantable Cardioverter-defibrillator and Pacemaker Registry (RIDEP); artificial heart valves (Italian Heart Valves Registry, RIVAC) and implantable hearing devices (Italian Implantable Hearing

Device Registry, RIDIU) (https://ripi.iss.it/ripi/en/). Currently, RIAP is already active and collects data routinely; RIDIS and RIDEP have been completely designed while design of RIVAC and RIDIU is ongoing.

B. The MD Library

The Library is the database of all implantable devices collected by a specific Registry included in RIPI. Each device contained in the Library is described by a set of technical features. The Library is designed to be directly fed by manufacturers, according to the rules stated by a high-specific taxonomy.

C. The agreement with NJR to adopt the NJR-EPRD classification and share the MD Library

Most of the existing implant registries collect only the device ID or its barcode, which provide only market data for traceability but not specific device information [17]-[19]. However, the Dutch registry LROI [8], the English National Joint Registry (NJR) (https://www.njrcentre.org.uk/njr-annual-report-2022/) and the Endoprothesen Register Deutschland (EPRD) (https://www.eprd.de/de/downloads-1/berichte) have defined their detailed taxonomies to classify the registered devices. Remarkably, in 2018, NJR and EPRD, in the absence of a universally recognised and shared nomenclature for joint prostheses, agreed in developing and continuously updating over the years an internationally shared taxonomy [13],[16],[20]. This collaboration is the first example of an inter-registry international cooperation for classifying medical devices. For joint prostheses, ISS has recently signed an agreement with NJR in order to adopt the already defined NJR-EPRD classification and set up a shared international MD database linking both RIAP and NJR Libraries.

III. Materials and Methods

1) 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 RIDIS and RIDEP taxonomies, 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 [21];
- Medical Devices Database of the Italian Ministry of Health (BDRDM): a database that contains all medical devices marketed in Italy, together with their technical datasheets (the registration is mandatory) [22];
- Medical Devices datasheets: technical documents available on the manufacturers websites;
- 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.

In particular, the following CND classes (version 2022, January 26) were considered:

- RIDIS:
  i. “P0907. Prostheses and Stabilisation Systems of the Vertebral Column”, i.e., systems for interbody fusion, cages or cages and disc prostheses;
  ii. “K0103. Devices for Minimally Invasive Spinal Surgery”, i.e., devices used for kyphoplasty, vertebroplasty and products for cementation;
  iii. “J020202 Totally implantable spinal neurostimulators”;
- RIDEP:
  i. “J01. Cardiac Function Devices”, i.e., pacemakers, implantable defibrillators and leads;
  ii. “C02Devices for Arrhythmology”, i.e., leads and cardioversion devices.

2) Methods

A technical expert panel composed by clinicians nominated by the involved scientific societies and by researchers of ISS was established to define a first draft of the taxonomy structure, organised in groups and sub-groups. Both engineering and clinical aspects were considered to define the taxonomy: the first ones due to the fact that they are more closely related to the technical features of the devices, the last ones as they are associated to the device intended purpose.

The items included in the first structure were then weighed by associating the number of devices registered in BDRDM in order to have an overview of all specific devices actually marketed in Italy, selected on the basis of the proper CND code.

A set of technical features was then selected from the technical sheets, the manufacturers' manuals and catalogues, and associated to each item included in the first version of the taxonomy. To ensure device identification and traceability, the following information were selected and included in the taxonomy for each device: CND, manufacturer, product catalogue code, lot, barcode, UDI, ID registration in BDRDM.

The taxonomy was then shared and discussed with the clinical experts: only the technical features deemed as most useful to characterise the device and to carry out future analyses were retained. Subsequently, the taxonomy was shared with the manufacturers covering the highest portion of the spinal device market in Italy and was then finalised in a consensus meeting aimed at refining and making the taxonomy feasible and functional.

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, useful for the subsequent implementation of the MD Library in the RIPI platform. To perform this step, the names of the identified variables were translated into English, according to the specifications provided by RIPI-IT group. Moreover, specific business rules were introduced, namely syntactical and semantic rules providing a set of variable combinations which help avoid mistakes in compilation and ensure data coherency.

IV. Results

The designed methodology is structured in the following six steps (reported in Table I):

1. The CND (EMDN) codes of medical devices matching the registry area of interest are identified;
2. The first minimum core set of technical and functional features essential to assess the MD performance is defined on the basis of the information available from different sources (technical datasheets, institutional MD Database, EUDAMED, commercial catalogues, scientific publications);
3. The draft of the core set is discussed with the clinicians in order to check completeness of the list of variables useful to assess the performance of the devices from the clinical perspective;
4. The taxonomy is shared with the representatives of the industries to verify its feasibility and functionality at industrial level. To quantify the characteristics that they could easily routinely upload in the Library, manufacturers are required to classify the information requested on the taxonomy as "available", "not available" and "searchable". To ensure the consideration of all crucial technical features of the selected devices, it is advisable to include the highest number of manufacturers, if possible all, in this process;
5. Specific business rules are introduced to enter only valid combinations of values into the web-based platform in order to reduce compilation errors. The rules are defined using both manufacturers' datasheets and surgeons' opinions;
6. The taxonomy is converted into XML and XSD schemas to allow its implementation in the Registry Library. When feeding the MD Library, manufacturers are required to structure their data by using the XML format in accordance with the XSD schemas.

TABLE I
SUMMARY OF THE METHODOLOGY TO SET UP A MD TAXONOMY

step	*description*
1	*Identification of CND classes of Medical Devices that match Registry area*
2	*Definition of a first core-set of technical features*
3	*Proactive discussion of taxonomy draft within the multidisciplinary team of the Registry technical panel*
4	*Sharing of the taxonomy draft with the leading industries to verify its feasibility*
5	*Definition of business rules*
6	*Adaptation of taxonomy in XML and XSD schemas for subsequent implementation of the Registry MD Library*

Table II shows the macro categories of the taxonomies developed for the RIDIS and RIDEP registries.

V. Discussion

The methodology to design a taxonomy for a specific MD registry was abstracted from the processes developed in the implementation of two Italian implantable prostheses registries: RIDIS and RIDEP.

TABLE II
MACRO CATEGORIES OF MD TAXONOMIES DEVELOPED FOR RIDIS AND RIDEP REGISTRIES

categories	*RIDEP*	*RIDIS*
MD Identification	*Manufacturer, product code, CND/EMDN, UDI, lot number*	
Type of device	*Defibrillator, Pacemaker, catheters and loop recorder*	*Spinal fixation system, cages, disc prostheses, cements*
Technical and functional features	*Chambers connector, remote control, MRI conditional, sensors*	*Geometry, type, materials, spine level, mechanics or physics properties*

Implantable prostheses registries have become increasingly widespread in recent decades [10],[23] because of the highest economic impact on healthcare and invasiveness for the patient (risk class III) of the devices they monitor [24],[25].

This study highlighted some essential features that should be accomplished when designing a specific MD taxonomy: 1) to select only properties actually bringing information and knowledge when comparing devices' performance and their effects on patients, avoiding excessive details unnecessary to reach registry's aims; 2) to involve all actors (clinicians and manufacturers) dealing with the device within the Registry to collect their opinion and retain only the essential characteristics. Indeed, it is crucial to consider all the stakeholder perspectives in the decision-making process of inclusion and exclusion criteria; 3) to share the design of the taxonomy with the largest number of manufacturers to verify that they are able to provide all the selected information because are either available or collectable and not confidential, thus making the feeding of the Library feasible.

The availability of BDRDM was very helpful to draft a first list of medical devices marketed in Italy. However, the integration with other sources, such as literature and catalogues, was necessary to have a global perspective by including also the devices not marketed in Italy.

Hopefully in the near future, EUDAMED could fulfil at least at European level the same role BDRDM has at the Italian level; indeed, it includes information relating both to the economic operator and to the device (Annex VI, Part A) [1].

However, Registries need more specific information regarding the implanted medical devices to perform statistical analyses on their performance. Therefore, MD Libraries represent an important source of long-term data when the Registry goes live [11]. By following the methodology presented in this study, it is possible to implement a MD Registry Library and support health operators in data collection, without asking them to manually input MD codes, thus dramatically reducing identification errors. Moreover, each device is described by a set of technical features useful to conduct analyses on its use and performance over time according to the diseases or conditions of the patients [26]. Accordingly, manufacturers can also receive valuable information on how their devices are performing and they might possibly correct the focus for a safer device design.

A limit of the proposed methodology is related to the possible biased exclusion of selected MD properties in the taxonomy.

Indeed, some technical information characterising the device, that might be important to be studied, may be confidential as protected by patents and therefore not sharable by the manufacturers, thus preventing the Registry to perform subsequent complete statistical analyses.

VI. Conclusion

In this paper, starting from the experience gathered in Italy in the framework of RIPI, a methodology to implement a MD Library functional to achieve the MD Registry goals is presented. In a worldwide context, where safety and traceability of medical devices are considered a priority and data exchange and statistical results are crucial for social and scientific growth, the implementation of MD Libraries and MD taxonomies might be an essential step. Due to its generalisation and its easy use, the presented methodology might represent a first useful reference to set up taxonomies not only for other implantable prostheses, but also for other categories of devices.

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