# Harmonisation of medical devices classification systems: development of a generalised approach starting from hip prostheses. A first example of an international and standardised nomenclature to be integrated within the European Medical Device Nomenclature

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***Abstract*— Medical device (MD) nomenclatures are essential for market surveillance and vigilance activities. Currently, more than 25 arthroplasty Registries are established in Europe, each of them based on a different MD nomenclature. A common and shared nomenclature of orthopaedic implants is important to analyse implant performance across different national databases referring to a unique definition of its characteristics. Aim of this study is to describe an approach to compare and harmonise two different nomenclatures: a first step towards the organization of an international nomenclature of medical devices.**

***Keywords*— medical devices, nomenclature, EMDN, CND**

## I. Introduction

MEDICAL device (MD) nomenclatures are essential for market surveillance and vigilance activities. They allow to organize medical devices in homogeneous categories of products intended to perform a similar diagnostic or therapeutic intervention [1]. Currently, more than 25 arthroplasty Registries are established in Europe [2], each of them based on a different MD nomenclature.

The National Joint Registry for England, Wales, Northern Ireland and the Isle of Man (NJR) [3] introduced a new component nomenclature for hip and knee in 2018/19 [4]. Recently, NJR has upgraded its component database and classification, in cooperation with the EndoProthesen Register Deutschland (EPRD). This classification (NJR-EPRD nomenclature) is currently used in both countries. The Italian Arthroplasty Registry (RIAP) [5] uses the National Classification of Medical Devices (CND) established in 2007 by the Italian Ministry of Health (MoH) [6]. On 4th March 2019, the EU Commission adopted the CND nomenclature as a base to support the activity of the future European database of medical devices Eudamed [7]. As for joint prostheses, RIAP is supporting the project to extend CND to the EU level and develop the EU nomenclature EMDN (European Medical Device Nomenclature). The adoption of an internationally recognised medical devices nomenclature available free of charge to facilitate the functioning of Eudamed was recommended by the EU Regulation 2017/745 [8].

Moreover, a common and shared nomenclature is needed to support patient safety, define and name innovative technologies, classify the devices for regulatory approval [9].

The aim of this study is to describe the results of the comparison and harmonisation of two different MD nomenclatures for hip prostheses: a first example of a standardised and international nomenclature to be proposed as integration within the EMDN. Moreover, starting from this result, a generalised approach is proposed.

This work was performed within the framework of the cooperation recently set up between RIAP and NJR, in order to organise a single international database of the orthopaedic prostheses implanted in both countries. Thanks to this cooperation, the NJR-EPRD nomenclature was available for this study.

## II. Material And Method

### A. Tools and sources of data

The following tools and databases were used:

1. CND
2. NJR-EPRD nomenclature
3. RIAP MD Dictionary
4. RIAP Database
5. MD National Database of the Italian MoH

1. CND

CND is structured as a hierarchical classification. It is organized in 22 anatomical/functional categories, each one identified by a letter and organised in groups and sub-groups structured in several levels (up to 7). Implantable prosthetic devices are described in Category P and subdivided in groups and sub-groups according to specific technical characteristics (anatomic component, type, fixation method, material) [10].

2. NJR-EPRD nomenclature

NJR-EPRD nomenclature has a flat/non-hierarchical structure. It provides each component of the joint with groups of specific technical characteristics (type, material, fixation method, design, size), each one including several attributes. Therefore, a device can be described by a set of attributes taken from different groups. This architecture is dynamic, comprehensive and flexible. It supports validation through incorporation of business rules, easy upload of data by manufacturers and, finally, ease and speed of computational analysis of the underlying database.

3. RIAP MD Dictionary

The RIAP MD Dictionary is a database of the implanted MD built by RIAP in close cooperation with manufacturers. Currently, it includes more than 66.000 implants (hip, knee and shoulder) described by catalogue code (Ref. code), manufacturer, MD description, CND code [11].

4. RIAP Database

The RIAP Database includes about 430.000 surgical procedures recorded since 2006 for hip, knee and shoulder. The collected data describe procedure and implanted devices, including joint, type of procedure, diagnosis for primary intervention and revision, fixation method, manufacturer and catalogue code. About 1.67 million of implanted devices are recorded [11].

5. MD National Database of the Italian MoH

The MD National Database of the Italian MoH is a database of all the devices marketed in Italy. It is available on an online platform. MD information on manufacturer, CND code and device description is public available, while devices' technical datasheets can be consulted only through private access [12].

### *B. Method*

Comparison between CND and NJR-EPRD nomenclatures was performed considering NJR-EPRD nomenclature as the "reference nomenclature" and CND as the "compared nomenclature", with the aim of updating CND and, consequently, EMDN. The comparison was made for hip prostheses.

Given the differences between CND and NJR classification systems, the translation of the English terminology was made before comparing them. Cultural adaptation of the devices' features was accomplished by studying the devices' descriptions available in the RIAP Dictionary, the technical datasheets available in the MD National Database and, finally, the commercial catalogues and scientific publications.

Each final level of CND was compared with all the attributes considered by the NJR-EPRD nomenclature, looking for a possible correspondence of each CND final level with one or more attributes of the NJR-EPRD nomenclature with the aim to build an association table.

Since the NJR-EPRD nomenclature considers more attributes than the CND final levels, in some cases a unique association of the two nomenclatures could not be established. In these cases, the following further analyses were performed for each "non-associated" attribute:

a. for each type of device, the "non-associated" attribute was searched in the MD description field of the RIAP MD Dictionary and a list of devices of interest was built (including their Ref. code and CND code);
b. using the Ref. code, frequency of implantation of the listed devices was measured in the RIAP Database;
c. the most frequently implanted devices having "non-associated" attributes were more deeply investigated both for the design and characteristics, by studying the technical datasheets available from the MD National Database of the Italian MoH and the commercial catalogues available online, and for their performance, by analysing scientific publications and Registries reports.

New sub-groups relevant to "non-associated" attributes were included in CND and EMDN nomenclatures for devices having: high frequency of implantation; high recurrence in the RIAP MD Dictionary; innovative design; technical characteristics potentially influencing their performance.

One or more "non-associated" attributes were considered to define each new sub-group according to the essential principles of the CND and EMDN classification system. When needed, additional levels were considered.

Finally, a generalised approach was developed from the steps followed to define the hip prostheses sub-groups integrated in EMDN.

## III. RESULTS

### *A. New sub-groups included in EMDN*

Table I reports the new sub-groups selected for inclusion in EMDN with the corresponding combination of attributes identified in the NJR-EPRD nomenclature. They consider the following devices: polyethylene acetabular inserts, fixed-neck femoral stems for primary surgery, modular neck femoral stems for primary surgery, femoral stems for revision surgery, biarticular cups.

For polyethylene acetabular inserts, standard, eccentric, lipped and constrained attributes were selected because they were highly recurrent in the description of the devices collected in the RIAP Dictionary.

For the femoral stems, the cultural adaptation resulted in the change of the terms "non-modular" and "modular", previously used by CND, in "fixed-neck" and "modular neck".

For the "straight" "modular neck femoral stems – primary surgery", the attributes i) one-piece, ii) proximal component (two-pieces) and iii) distal component (two-pieces) were selected, due to both their high recurrence in the RIAP MD Dictionary and their potential influence on device performance.

For the biarticular cups, the "preassembled" and "modular" attributes were selected to find the association between CND and NJR-EPRD nomenclature s.

TABLE I
HIP PROSTHESIS: NEW SUB-GROUPS INTRODUCED IN EMDN

| *EMDN sub-group* | | | *NJR-EPRD* |
|---|---|---|---|
| *level$_i$* | *level$_{i+1}$* | *level$_{i+2}$* | *COMPONENT: attributes* |
| *polyethylene acetabular inserts* | *standard* | | ACETABULAR INSERT: standard, polyethylene |
| | *eccentric* | | ACETABULAR INSERT: Angulated, polyethylene |
| | *lipped* | | ACETABULAR INSERT: lipped, polyethylene |
| | *constrained* | | ACETABULAR INSERT: constrained, polyethylene |
| *fixed-neck femoral stems - primary surgery* | *straight* | | FEMORAL COMPONENT: modular head stem, straight |
| | *anatomical* | | FEMORAL COMPONENT: modular head stem, anatomical |
| | *conservative* | | FEMORAL COMPONENT: metaphyseal prosthesis |
| *modular neck femoral stems -primary surgery* | *straight* | one-piece | FEMORAL COMPONENT: femoral stem with modular neck, straight |
| | | two-pieces proximal | FEMORAL COMPONENT: femoral stem proximal section, straight |
| | | two-pieces distal | FEMORAL ACCESSORY: stem central section, straight |
| | *anatomical* | | FEMORAL COMPONENT: femoral stem with modular neck, anatomical |
| | *conservative* | | FEMORAL COMPONENT: metaphyseal prosthesis with modular neck |
| *femoral stems - revision surgery* | *fixed-neck* | | FEMORAL COMPONENT: modular head stem, revision specific |
| | *modular* | | FEMORAL COMPONENT: femoral stem with modular neck and femoral stem proximal section, revision specific |
| *biarticular cups* | *preassembled* | | MODULAR HEAD: bipolar monobloc |
| | *modular* | | MODULAR HEAD: bipolar modular head and bipolar modular insert |

### *B. The generalised approach*

Aim of the generalised approach is to compare two different nomenclatures of medical devices and update or check the "compared nomenclature", using the other one as "reference nomenclature". It is structured in 3 steps (Table II).

The first step consists in the analysis of both nomenclatures and in the study of their classifications systems to highlight their differences.

If the two nomenclatures are written in different languages, the translation and cultural adaptation of the terms (steps 2 and 2a) are needed. To do this, implant information could be essential.

The step 3 consists in the comparison of each class of the two nomenclatures. Aim of this step is to find for every class of the reference nomenclature a correspondent class of the compared nomenclature. Studies of both devices' biomechanical features and material properties could provide useful information to find a correct association.

If the comparison of the two nomenclatures results in a unique association between classes, the process ends with step 3, being both nomenclatures harmonised.

If a unique association between the classes cannot be established, the introduction of new classes or new classification branches is made following step 3a and 3b.

In step 3a, the core set of features characterising the new classes or the new classification branches is defined. This selection mainly analyses features of devices having high frequency of implantation, innovative design, and technical characteristics potentially influencing the performance. This information can be collected by consulting Registries databases, MD datasheets, scientific publications and Registries reports.

In the last step (step 3b), the classes and sub-classes defined in the previous step are included in the comparative nomenclature according to the structure of its classification system.

TABLE II
GENERALISED APPROACH

| *step* | *description* |
|---|---|
| *1* | *Collection of nomenclatures and analysis of their classification systems* |
| *2* | *Translation of terms (if needed, go to step 2a, otherwise skip to step 3)* |
| *2a* | *Cultural adaptation of devices' features* |
| *3* | *Comparison between each class of the reference nomenclature (1) and each class of the compared nomenclature (2) and association of the classes. If the comparison does not result in a unique association, go to step 3a.* |
| *3a* | *Selection of a core set of features relevant to the non-associated classes to define new classes and sub-classes* |
| *3b* | *Inclusion of the new classes and sub-classes in the nomenclature (2) to ensure consistency between the two nomenclatures* |

## IV. DISCUSSION

The comparison of CND and NJR-EPRD nomenclature s showed that they are harmonised in the individuation of the technical characteristics of the hip joint prostheses [13]. Every CND sub-group finds its equivalent class in NJR-EPRD nomenclature when type, fixation methods and material are considered. Since the NJR-EPRD nomenclature considers more attributes than the CND final levels, a unique association between all the elements of the two nomenclatures cannot be established.

Information collected by consulting MD Databases, RIAP Database and scientific literature was essential both to compare the CND final level with the NJR-EPRD nomenclature attributes and to define the evidence of the need to classify devices having some particular attributes otherwise included in a more general class. To integrate the new proposed sub-groups it was essential to include additional levels in CND and EMDN. This integration was made respecting the basic principle of CND and EMDN i.e. to consider in the nomenclature only final levels that are described by an essential core set of features.

Exchange of information about MD among different registries and databases is a recognised need [9], [14]. Therefore, several studies compared the structure of the classification systems or the characteristics of different MD nomenclatures adopted either in Europe or in the rest of the world [15]-[18].

This study implemented a comparison of two nomenclatures with the aim of defining a harmonised nomenclature. For hip prostheses, this process allowed to include in the EMDN some new sub-groups that allow a more detailed description of devices otherwise misclassified or assigned to a more general group. It has to be highlighted that the criteria defined for the selection of the subgroups were based on the results provided by the MD registries (for example frequency of use and outcomes of specific devices). Moreover, starting from the specific case of hip prostheses, a generalised approach was presented. This approach can be applied to two different nomenclatures in order to develop a unified harmonised one.

The limit of this study is that the generalised approach was developed by extrapolating only the results obtained for hip prostheses and by comparing only two nomenclatures.

## V. Conclusion

Data from Registries are essential for patient safety and for health systems management. More profound analysis is possible when data from different Registries are combined.

A Medical Devices Nomenclature is a pillar of a Registry. Therefore, harmonising different MD nomenclatures is a first step towards a common language for recording and reporting comparable medical devices outcomes from Registries of different countries.

The proposed approach allowed to compare two different nomenclatures and to harmonise them as far as possible.

Given that the results of the comparison performed in this study turned out as a first propose of updating the EMDN, it may be possible to obtain a unique and harmonized nomenclature in Europe, by applying this approach to other nomenclatures. To reach this goal, further studies need to be performed to validate the approach against other devices, other nomenclatures and other classification systems.

## Acknowledgement

The work was carried out as a part of the Italian Arthroplasty Registry (RIAP) project coordinated by the Italian National Institute of Health with the financial support of the General Directorate of Medical Devices and the Pharmaceutical Service of the Italian Ministry of Health. We acknowledge the RIAP team (Stefania Ceccarelli, Mascia Masciocchi, Alessia Biondi, Emanuela Saquella and Attanasio Cornacchia) for the administrative management of the RIAP project and for the preparation of the database, and Iuliia Urakcheeva for the linguistic revision of the manuscript.

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