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Registries might support updating and improvement of the national MD classification CND: an example for spinal devices

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Introduction

The Italian Implantable Prostheses Registry (RIPI) is organised as a set of registries including the Italian Arthroplasty Registry (RIAP) and the Italian Spinal Implant Registry (RIDIS). Each registry considers also a dedicated MD database (the so-called MD Library) fed by the manufacturers with the information useful to MD identification and characterization. MD Libraries are critical for registries' activity, MD surveillance and vigilance. RIPI MD Libraries are based on the Italian MD classification (CND), a hierarchical classification divided into subgroups with homogeneous properties. In 2019, CND was selected by the EU Commission as a basis for the development of the European MD Nomenclature (EMDN) to be used in the EUDAMED (EU databank for medical devices).
MD are subject to continuous technological innovation and evolution. Consequently, their classification needs to be constantly updated, an activity that might be usefully supported by the registries thanks to the information collected in their component database specifically designed to identify and characterize the registered devices. Since 2016, RIAP has been closely cooperating with the Ministry of Health to continuously update CND for joint prostheses by developing a dedicated methodology. The aim of this study is to present an application of this methodology to update spinal device CND.

Materials and Methods

The design of each MD Library taxonomy is organized in the following four steps:

1. selection of the devices of interest by the experts (including surgeons) of the registry panel;
2. search and analysis of the technical datasheets available online or from BD-RDM. When available, study of nomenclatures already developed at the international level;
3. discussion of the taxonomy with the interested manufacturers;
4. comparison of the taxonomy with CND, highlighting of the new categories and classes and proposal for CND updating.

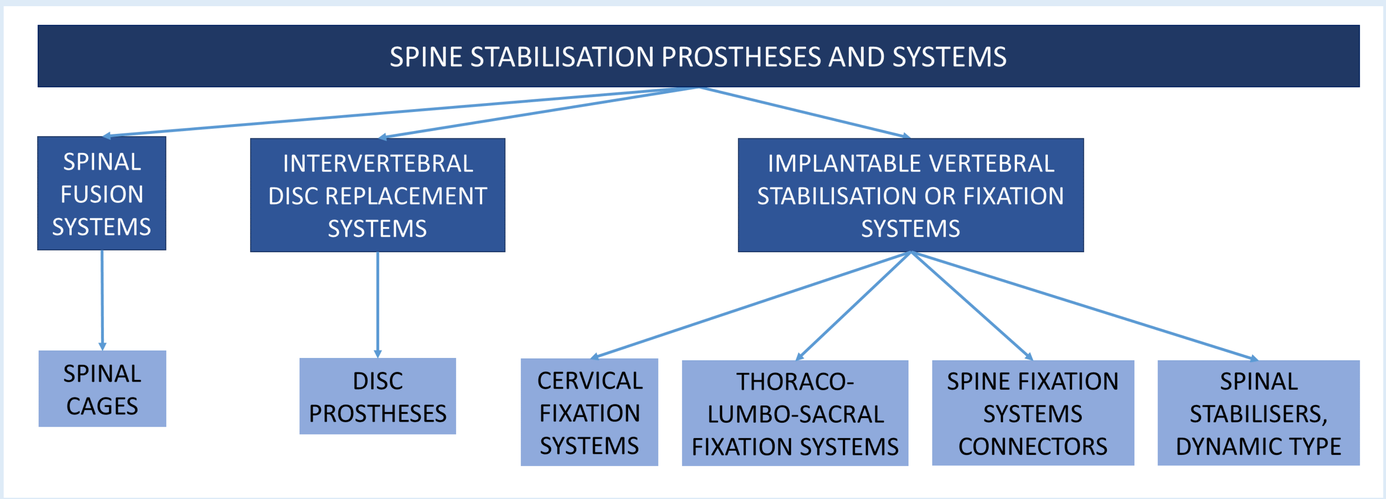

Figure 1: The structure of CND for the spinal categories considered in the analysis, by CND level

Results

Figure 1 shows the original CND classification for spinal devices.
As a result of step 4, the following actions have been highlighted (Figure 2):

a) to split the class "Spinal Cages" into "Intersomatic cages" and "Corpectomy cages";
b) to add the new class "System for sacroiliac or pelvic stabilisation/fixation" to the classes "Prostheses, cervical fixation systems" and "Thoracolumbosacral spine, fixation systems" already existing.

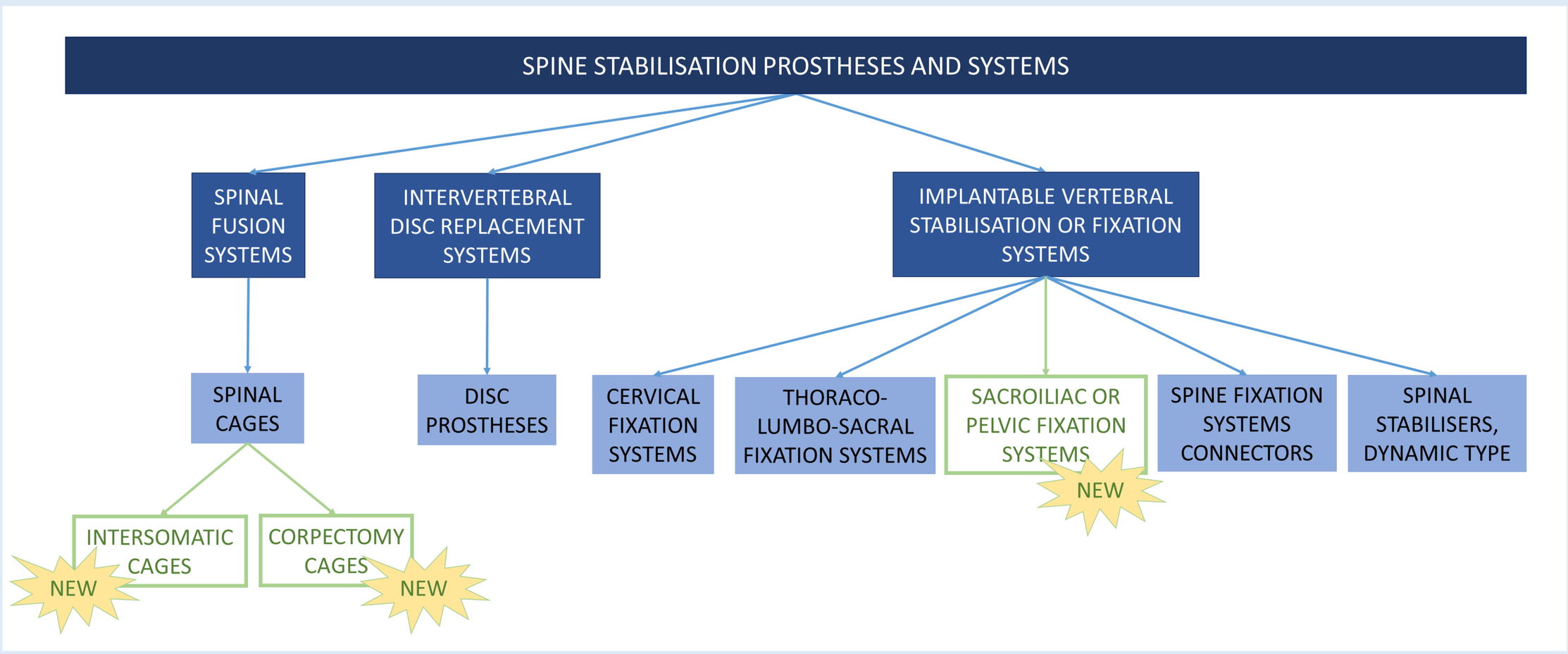

Figure 2: The structure of CND for the new proposal for spinal categories, by CND level

Discussion/Conclusion

The study showed that a general classification system like CND can benefit from the constant and high-specialized work performed by implant registries to design and keep updated their MD Libraries. In particular, it highlighted how to better define the categories related to spinal devices. A close interaction between registries and regulatory bodies should be promoted for a better identification and characterisation of the implanted MD and for supporting the future activity of EUDAMED.

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