#2122 - Systematic Review / Free Papers

Harmonisation Of Medical Devices Classification Systems: A First Step Towards An International And Standardized Joint Prostheses Classification To Be Implemented Within The European Medical Device Nomenclature

General Topics / Implants, Biomaterials & Registry Study

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Background

Medical device (MD) classification systems are essential for market surveillance and vigilance activities. They allow to organise MD in homogeneous categories of products intended to perform a similar diagnostic or therapeutic intervention. Currently, more than 25 arthroplasty registries are established in Europe, each of them referring to a different MD classification system. The Italian Arthroplasty Registry (RIAP) uses the "National Classification of Medical Devices" (CND) established in 2007 by the Italian Ministry of Health. On 4th March 2019, the EU Commission adopted CND as a base to support the activity of the future European database of medical devices EUDAMED. Concerning joint prostheses, RIAP is supporting the work in progress to extend CND to the EU level (European Medical Device Nomenclature, EMDN). Recently, the NJR has upgraded its component database and classification, in cooperation with the German Registry (EPRD) with a view to it shortly being utilised by RIAP. A common and shared classification system of orthopaedic implants is essential for the analysis of implant performance across different national databases. The granularity of the attributes in the shared databases allows this to be comprehensively achieved.

Objectives

The aim of this study is to describe the harmonisation between CND and NJR-EPRD implants classifications, to show how a single international database of the orthopaedic prostheses implanted in United Kingdom, Germany and Italy would help towards the harmonisation of an international MD classification.

Study Design & Methods

Both CND and NJR taxonomies were matched and compared for hip joint components by: 1. Analysing both classification systems; 2. Associating each CND terminal level with an appropriate combination of attributes in the NJR/EPRD taxonomy; 3. Selecting a core-set of characteristics essential to characterise

each class that could be used for implant outcome assessment.

Results

The CND is organised in 21 anatomical/functional categories, each one identified by a letter. Category P includes Implantable prosthetic devices and is organised in homogeneous groups and sub-groups. Joint prostheses are organised in sub levels according to the following specific features: anatomic component, type, fixation method, material. The NJR-EPRD classification system is a flat/non-hierarchical structure. Its taxonomy is dynamic and provides each anatomical joint with several attributes. These include anatomic component, type, material, fixation method, design and size. This architecture allows evolution and flexibility. Every CND terminal level finds its equivalent when attributes of NJR-EPRD taxonomy like type, fixation methods and material are appropriately combined. Following the comparison, the following important CND sub-groups were proposed to be included in EMDN: polyethylene acetabular insert, (standard, eccentric and lipped), modular stems including descriptions of every element (distal component, proximal component and modular neck), bi-articular cups detailed either as preassembled or modular.

Conclusions

Data from registries are essential for patient safety and for health systems management. More powerful analyses are possible when data from different registries are combined. 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 implementation of the European nomenclature represents an excellent opportunity for this to be achieved.