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Registries need detailed medical device classifications. Moving from arthroplasty to other devices: a lesson learnt at the international level

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Introduction
Medical Device (MD)-Libraries, structured according to detailed taxonomies and allowing MDs characterisation by specific sets of technical attributes, have shown to be useful to effectively monitor MD safety. Cross-registries analyses at international level are possible if common standards describing and classifying MD are adopted. The National Joint Registry (NJR) started this process in cooperation with the Endoprothesen Register Deutschland and a shared taxonomy was achieved on which the common Component Library was built. The aim of this work is to describe the benefits and advantages of this approach.

Materials and Methods
In 2018, to characterise the collected MD, the Italian Arthroplasty Registry (RIAP), instead of implementing its own taxonomy, proposed to NJR to participate in the implementation of a common database to be directly fed by manufacturers.

Results
In 2021, an agreement was signed with NJR aimed to create a single international database for MD implanted in United Kingdom and Italy. The manufacturers of MD implanted in Italy, but not registered yet in the Component Library, agreed to upload to the Component Library all the requested technical attributes according to already established standards.

Discussion
In a global context in which MD safety and traceability are considered a priority to improve patients' health, the implementation of international collaborations among registries for building common and internationally shared MD Libraries is essential to allow data exchange and wider and reliable statistical analyses. The lesson learnt for joint prostheses has paved the way to a broader application of this approach to other implantable devices registries making them able to operationalise much faster. The International Spine Registries working group is already acting in this direction and will be followed by all the registries considered by the Italian National Implantable Registry and by the UK programme announced in the 2020 Cumberlege report.

Notes