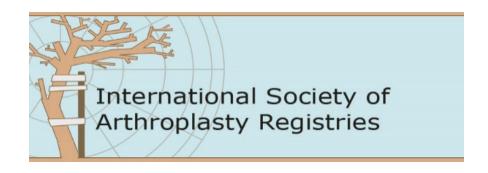


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Italian Arthroplasty Registry: A probabilistic approach for the medical device identification using the barcode

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Introduction

In case of recall, correct identifying the implanted medical devices is crucial for their traceability. The Italian Arthroplasty Registry (RIAP) pilot phase showed that inputting manually catalogue and lot codes resulted in a high probability of error, identifying in the Ministry of Health Medical Devices Databank only 30% of collected codes. A dedicated library, the RIAP-Medical-Device-Library currently consisting of 55,000 records, provided by 60 Manufacturers and including catalogue code, manufacturer's name and description but not barcode, was built and integrated in the Registry flow. Lacking in Europe a unique standardized coding for device identification, like the Unique Device Identifier (UDI) implemented by FDA, a probabilistic approach was investigated to offer the surgeons the opportunity of identifying the device by using a barcode scanner.

Methods

An algorithm able to identify in a barcode all the possible strings compatible with all the catalogue codes available in the RIAP-Medical-Device-Library was developed.

Results

The algorithm is not affected by false negatives, therefore if the code available in the Library is also included in the barcode, it will be always recognized. False positives, i.e. codes random identified in a string but not semantically connected with the device, have to be discarded by the operator. The identified codes are uploaded into the RIAP-Medical-Device-Library.

Conclusion

As soon as the UDI is adopted also for implants marketed in the European Union, their traceability will be warranted. Meanwhile, the introduction of the barcode-scanner might provide data of higher quality and reduce burden for surgeons.