

Title

Principles leading the design of the RIPI Information System: an example of a multi-level registry structure for different medical devices.

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Introduction

The Italian Implantable Protheses Registry (RIPI) is a multi-level registry system assessing various implantable medical devices in terms of effectiveness and safety and tracing them for post-market safety-related activities. This study aims at presenting the concepts in designing the RIPI Information System (RIPI-IS).

Materials and methods

RIPI-IS design was based on the following pillars:

1 - reflecting the fragmented structure of the Italian health care system where each region is autonomous in managing its own regional health care system, therefore each national registry in RIPI (specific for a medical device) is organized as a federation of regional registries.

2 – defining common principles to be implemented by each region, to guarantee operational interoperability.

3 – satisfying both GDPR and traceability requirements: the patient is pseudonymized with a unique code throughout the country and in the various registries included in RIPI.

Results

The modular structure adopted for RIPI-IS allows to consolidate established registries, such as RIAP (arthroplasty), and to easily integrate any additional one.

To collect data, each region can decide either to use the national platform, provided at central level, or to implement its own system by following the shared common principles.

Throughout the country, the unique patient code allows to trace patients and implanted devices in order to overcome issues related to inter-regional mobility.

Discussion

The modularity of the structure and the scalability of the system allow to optimize data collection and the information available to surgeons, regions and policymakers.

The definition of common principles led to the standardization of registry procedures, thus ensuring patient safety in a health context lacking homogeneous features, such as the Italian one.

The methodology designed to manage national and regional registries in Italy might be considered useful experience to be exported to broader and international contexts.