Executive Summary

Introduction

This is the 1st Report of the Italian arthroplasty registry (RIAP, Registro Italiano ArtroProtesi), and comes out after 10 years of tireless work, presenting a formal and public account of all the activities from its start until now. This period of time was necessary not only to create a collaborative network with all the stakeholders, but also to establish and test protocols that could be used within the existing regional and national health systems. Strictly speaking, it is not yet a national registry (geographic coverage is still partial) but *"alea iacta est" ("the die is cast"*), and sooner or later data collection will reach the whole country: this publication aims to be an incentive in that direction.

Report structure

The volume is structured in 5 Chapters, followed by 15 Appendixes with reference documentation and information for further reading.

Being a primer, a whole chapter (Chapter 1) was dedicated to the description of the background and development, what issues have been encountered and how they have been addressed. It also includes a detailed analysis of the existing national regulations, and then looks to the future of the Registry and its sustainability.

Medical devices are a key element of the RIAP architecture; procedures for identification and characterization of implanted devices are detailed in Chapter 2, as applied within the framework of the "National System for Medical Devices".

Stakeholders' involvement is a cornerstone of RIAP. Chapter 3 presents the contributions of all participating institutions, companies and patients, which are represented within the Scientific Committee.

Chapter 4 and 5 focus on data analysis performed on Hospital Discharge Records (HDR) and on RIAP data, respectively. Out of a substantial amount of data (the entire population for HDR and over 220,000 interventions from the registry), results allowed for some general observations on joint replacement surgery at a national level.

Future development

Some critical issues still remain, partly due to the peculiar structure of a federal registry, partly in common with other experiences of establishing a registry in large countries worldwide.

As to the first point, resolving the issue will depend largely on regional involvement, as RIAP can only suggest technical solutions and guidelines for a quick implementation of data collection protocols. Device traceability belongs to the second type of issues. Specifically, the absence of a recognised standard for bar codes, as requested from many sides, prevents the adoption of automatized methods of product identification.

Mandatory registration might be an unavoidable step towards the ultimate success of the project, whose dissemination cannot do without a constructive collaboration from the orthopaedic surgeons' side. International experiences show that initial scepticism quickly resolves into greater confrontation when data are shared and discussed. Broad diffusion of this report and RIAP activities will hopefully help move in this direction. Information feedback that the Registry con provide to the surgeon will be an invaluable aid evidence-based decision-making, thus improving quality of healthcare.

RIAP in 5 points

1) Structure and organization

A Scientific Committee was established within RIAP, representing all the stakeholders (public health authorities, administrative regions and autonomous provinces, existing regional registries, hospitals, orthopaedic surgeons, manufacturers and patients), to actively participate in the operative choices of the project.

The RIAP architecture is based on three main pillars:

- To be a federation of regional registries coordinated by ISS
- To use the Hospital Discharge Records integrated by an additional Minimum DataSet (MDS) of information describing procedure (operated side, previous operation, diagnose, type of procedure, surgical access, fixation method) and device (CND classification code, manufacturer's name, product code and lot number)
- To identify the implanted device using a "Dictionary" of catalogue numbers (Ref. codes) built by RIAP in close cooperation with manufacturers and to describe the device by a list of attributes provided in cooperation with the International Consortium of Orthopaedic Registries (ICOR, established by U.S. Food and Drug Administration) and selected in the General Repository of Ministry of Health.

2) Data collected and participating institutions

RIAP collects data from hip and knee procedures. From 2015 onwards, shoulder replacements will be registered as well. 9 Italian regions (Lombardia, Toscana, Marche, Lazio, Abruzzo, Puglia, Basilicata, Calabria e Sicilia), 2 autonomous provinces (Trento e Bolzano) and Livio Sciutto Foundation of Pietra Ligure participate actively.

3) Treatment of personal data, informed consent and data confidentiality

The RIAP may collect and process personal data and clinical studies of patients only if they have signed the informed consent. This complies with the provisions of the Law on Protection of Personal Data (Legislative Decree no. 196/2003). To promote the start of the RIAP project, the Ethics Committee of the ISS approved the regulation included in the General Permission by the Privacy Guarantor (n. 9/2012).

4) RIAP sustainability: normative aspects and funding

The RIAP project has been funded by the Italian Ministry of Health, Directorate General of medical devices and pharmaceutical services (previously *Direzione Generale dei dispositivi medici, del servizio farmaceutico e della sicurezza delle cure*) as a tool to support post-marketing surveillance and vigilance activities for medical devices. A decree from the President of the Ministers' council to put into effect the establishment of the implantable devices registries among others, as prescribed by the Law 221/2012 (art. 12, comma 10), is currently under finalization. A more solid legal base for the launch and support of implantable devices Registry will strengthen the undertaken activities, with positive consequences on quantity and quality of data.

5) RIAP in the national and international setting

- It is one of the ISS special projects, under the title *Sperimentazione del flusso informativo per l'istituzione del Registro Italiano delle ArtroProtesi since 2006*;
- Since 2010 it is a project Study of the National Statistical Programme (*Programma Statistico Nazionale*);
- Since 2012 it is member of the International Society of Arthroplasty Registers (ISAR) and takes part in the activities of the International Consortium of Orthopaedics Registries (ICOR).