Riap is funded by
the Italian Ministry of Health, DG for medical devices and pharmaceutical services (Dgdmf)

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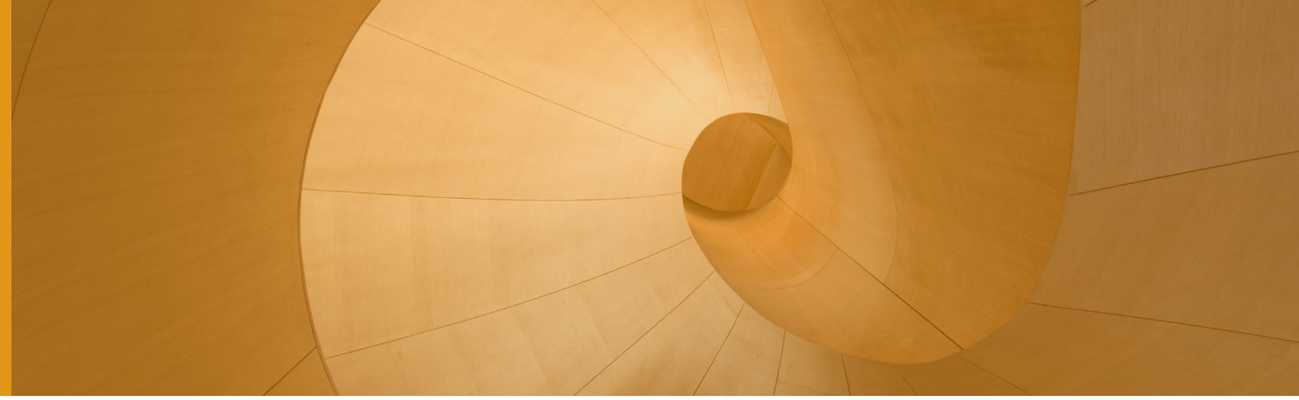
Italian arthroplasty registry. December 2018



riap
registro italiano artroprotesi
italian arthroplasty registry

RIAP: THE PROJECT

What is Riap?
The Italian Arthroplasty Registry, RIAP, was started in 2006 within the framework of a collaboration between the Italian Ministry of Health, GD for medical devices and pharmaceutical services (Dgdmf) and the Italian National Institute of Health (Istituto superiore di sanità, Iss), to set up a data flow to monitor the joint prostheses performance.

What are the goals?
Its main aims are to: monitor the long-term effectiveness of hip, knee, shoulder and ankle prostheses (measured as implant survival); recall patients if there are any reported problems with specific implants.

What information is collected?
The information collected includes Hospital discharge record information (Hdr) and an additional minimum data set (Mds) about the performed procedure and the implanted device identification data. These are specific details such as type of implant, surgical technique used, and operated body side. In 2017, more than 67,366 operations (about 34% of the national volume) were collected from 277 hospitals, representing the 35% of all the structures performing joint arthroplasties in Italy.

How is Riap organized?
Riap is a federation of regional registries coordinated by ISS. Through a web interface, the surgeons collect the Mds, which is successively linked to the Hdr by the regional coordinating centre. The latter is responsible for the transmission of the linked data to ISS. Currently, participation in Riap is on a voluntary basis.

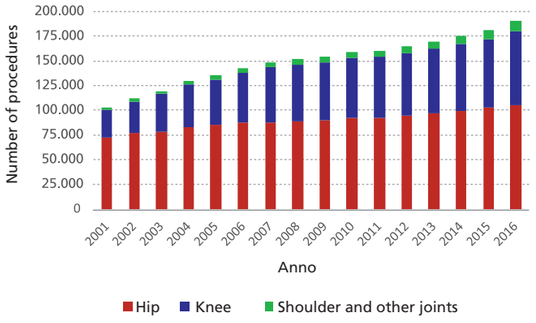
Why a registry, and why a national registry?
Prosthesis implantation can be the solution for disabling joints diseases for the elderly, but also for younger people. In Italy, like in other countries, arthroplasties are constantly growing. A national registry allows assessing the outcomes of primary and revision procedures, based on patient' specificity, and intervention and implanted device characteristics. If needed, there must be the possibility to recall all the implanted patients, even if they were previously operated in a different region from the one they live in. This is the reason why the registry must have national coverage.

How is the implanted device identified?
To identify each implanted device, Riap made the Riap-DM Dictionary available to operators, which is a database containing data supplied by manufacturers, including data single-device specific. The information contained in the Riap-DM Dictionary is checked and matched against the information from the National Database/ Directory of medical devices of the Ministry of Health.

Privacy
Personal data are treated by RIAP in compliance with the current European legislation (EU Regulation 2016/679). Clinical, health and demographic data are treated applying criteria ensuring the highest confidentiality, in compliance with the security regulations for digital and paper-based archives.

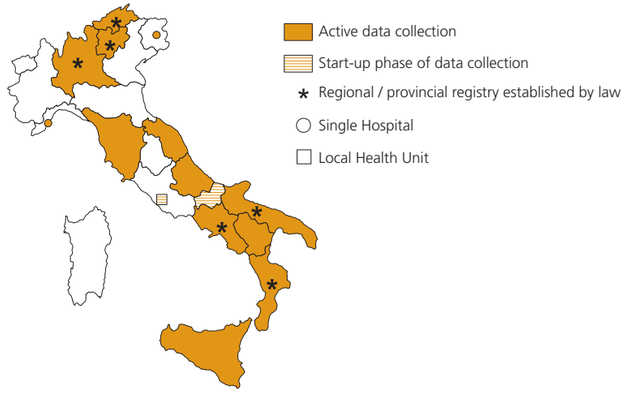
RIAP: CONTEXT, PARTICIPATION, ACTIVITIES

Italian joint arthroplasty procedures (Hdr Data 2001-2016)



In Italy, the procedures performed in 2001 were 103,041, and 190,797 in 2016, with an average annual increase of 4.2% over the period considered.
(Source: Ministry of Health, Sdo Database 2001-2016: acute hospitalization in ordinary or day hospital)

RIAP Participants (December 2018)



Joint	N. interventions	Completeness (%)
Hip	38.460	65,9
Knee	28.023	64,5
Shoulder	883	92,7
Total	**67.366**	**65,6**

Active data collection (2017)

In 2017, Riap received data of 67,366 hip, knee and shoulder procedures (average coverage in the participating regions: about 65%). Out of the total, 277 hospitals collected data, that is to say about 59% of those that carried out interventions of interest for RIAP in the participating regions.