## 1st Congress of International Society of Arthroplasty Registries



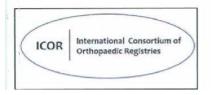
## **ISAR 2012**



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## The Italian Arthroplasty Registry

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**Background:** The Italian Arthroplasty Registry is the result of an agreement between the Italian Ministry of Health and the Istituto Superiore di Sanità (ISS). The project is developed in collaboration with the Italian Society of Orthopaedics and Traumatology, regions, manufacturers' and patients' associations. The draft Health Pact between State and Regions for 2013-2015 includes governance activities to monitor the safety of patients who have medical devices implanted. Given that more than 160,000 joint replacements are performed each year in 850 hospitals in Italy, the implementation of a registry was motivated by the high impact of arthroplasties on the Italian public health system.

Aim of the Registry are to provide surgeons with the best evidences about the implants used in Italy by assessing the effectiveness of the implanted device, to enhance early failures and to track patients in case of adverse events.

Materials and methods: The Registry is organised as a federation of regional registries coordinated by ISS. Data collection uses Hospital Discharge Records (HDRs) integrated by a Minimum Data Set (MDS) of additional information. MDS includes the keys to perform the linkage with the HDRs as well as clinical (side, surgical procedure, diagnosis, previous intervention, approach) and implant information (manufacturer, ID code, lot number). The linkage with the National Medical devices database at the Ministry of Health allows the identification of the implanted devices. This activity is carried out in close cooperation with the manufacturer representatives.

**Results:** A close cooperation with all the involved stakeholders (public health institutions, surgeons, manufacturers and patients) has been established. Data collection has been tested for hip replacement in 13 of the 21 regions, 3 new regions will be enrolled in 2012. The enrolled regions represent about 80% of the annual national volume. At present data collection includes more than 200 hospitals and considers about 60.000 procedures. Data collection sheet for knee arthroplasties has been defined.

**Discussion and conclusion:** The results obtained until now demonstrate that it is possible to create an arthroplasty registry in Italy; the model will be progressively extended to other regions, evaluating the possibility of measuring the quality of life in subsets of patients. Taking into account the high variability of health regional organisation, the federative structure has demonstrated to be the best solution. The official establishment of the national arthroplasty registry by law, making the participation mandatory, will ensure a high degree of coverage and definitely solve the problems related to the personal data protection requirements.

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