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LEGAL AND ETHICAL REQUIREMENTS FOR THE ITALIAN ARTHROPLASTY REGISTRY IMPLEMENTATION AND GOVERNANCE

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Introduction: Data collection of the Italian Arthroplasty Registry (RIAP) is based on Hospital Discharge Records integrated by an additional minimum dataset essential for epidemiological and statistical analyses. RIAP is a federation of regional registries, whose participation is voluntary, coordinated by the Italian National Institute of Health (ISS). In this framework, legal requirements, mainly provided by the Italian legislation on personal data treatment, and ethical recommendations have an important impact on the RIAP activities. Legal tools construction and ethical procedures for the implementation of the Registry are presented.

Methods: A thorough analysis of the regulations provided by the Italian legislation on personal data treatment (2003-2012) was carried out in order to evaluate and select the tools to be designed. Moreover, ethical guidelines at national and international level were taken into account to compare and integrate, if necessary, legal requirements.

Results: An information note and a consent form were designed to collect patients' data (starting from 2013 hospitalizations) prospectively. For all the patients previously recorded in the regional registries a request, referring to a recent national legal authorization to use archived health data, was presented for approval to the ISS ethics committee.

Discussion: RIAP is not yet regulated by law and acts as an epidemiological project. Therefore, a great effort from the legal and ethical perspectives was required to allow the health data to flow from the regional registries to ISS and vice versa. In this framework, the crucial task was to find an operational balance between the public health collective needs and the patients individual rights.