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# Mapping existing hip and knee replacement registries in Europe

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ABSTRACT

The general shortage of evidence regarding benefits and harms of medical devices has been highlighted following the serious safety concerns with metal-on-metal hip replacements and silicone breast implants and was again pointed out in a recent survey of European Health Technology Assessment institutions. In this context the new European medical device regulation will enforce post-marketing surveillance of existing and new implants. The usefulness of registry data as a source of information for medical device real-world clinical performance and safety has been demonstrated. However, these data might be underused by researchers and policy makers. One reason for this is the insufficient awareness of their existence. The aim of this review is to provide information to relevant stakeholders on the extent and breadth of the data currently collected in European joint replacement registries. We identified 24 registries, most of them of national coverage. Total numbers of primary total hip and knee replacements included were over 3.1 and 2.5 million records, respectively. The current focus of these registries is on whole-lifespan implant surveillance via revision rate monitoring, quality assessment of surgical and perioperative care, and hospital performance assessment. More recently, national and international comparison and benchmarking have increasingly become part of their endeavors.



## 1. Introduction

A general shortage of clinical evidence supporting the use of many medical devices has been highlighted following the serious safety concerns with metal-on-metal hip replacements and silicone breast implants [1,2]. This has emphasized the necessity for improvement in regulation, science and public health policy [3–5]. Improvement will depend on greater availability of high quality data for patients, clinicians, regulators, researchers and policy makers.

The latest revision of the EU device regulation, adopted in April 2017 intends to [1] enhance legal clarity and coordination in the field of post-marketing vigilance and safety, [2] increase transparency regarding medical devices on the EU market, including their traceability, and [3] enhance the involvement of external scientific and clinical expertise, among other changes [6]. With respect to post-marketing surveillance the new regulation aims at enforcing regular benefit-risk assessment of existing and new implants [6]. In this process registry data will be important data sources for describing real-world clinical performance and safety [3,7,8].

The lack of clinical evidence regarding the benefits and harms of medical devices is greater for new implants in Europe than in the United States [9]. Kynaston-Pearson et al. reported that 24% of all primary hip replacement prostheses implanted in 2011 in the United Kingdom (UK) had no published evidence for their clinical effectiveness [10]. Another study found that there were only a limited number of comparative studies in joint replacement: the few that have been published were often of insufficient quality. Further comparison of data from registries was hampered by lack of harmonization of data definitions and analytical methods [11]. Lack of evidence for new medical devices and low quality of available evidence was also highlighted in a recent survey of 16 European Health Technology Assessment (HTA) institutions [12].

In Europe joint replacement registries have since 1975 monitored real-world treatment on a national (and sometimes regional) level with a focus on long-term surveillance of implant and surgical performance [13]. This is traditionally measured as revision rate or as implant survival. Recognizing the existence of failures that were not treated or not treatable with revision surgery, patient-reported outcome measures (PROMs) [14,15] were more recently added in association with a registry for the first time about 15 years ago. In contrast to revision, which is both an indicator and

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a treatment of the failure, PROMs provide only the former as well as a more patient-centered measure. Lately the registries' data collection has further expanded to include indicators of health care quality, such as complications, readmission, reoperation or early revision rates [16,17]. These indicators are intended to measure hospital performance and surgical quality and to allow for benchmarking. Although the usefulness of registry data including those from joint replacement registries was clearly demonstrated [18], they were found to be under-used by researchers and policy makers [19,20]. Reasons for this include legal restrictions to data access, lack of push by data custodians, lack of methodologically trained research staff, and, significantly, insufficient awareness of the existence of registry data [19]. There is a need to provide information to relevant stakeholders on the extent and breadth of the data currently collected in these registries.

There are previous publications on international joint replacement registries, however all with a focus different from our work. They have either reviewed coordinating institutions, funding, data collection and validation methods, and dissemination strategies [21]; measured the scientific production of national joint replacement registries and their impact [20]; described the status of medical device registries (including those on joint replacement) in Europe and classified their structure [22]; provided an historical overview and discussed strengths and limitations as well as the future role of registries in orthopaedic surgery [23]; or have assessed the comparability of recorded outcomes [24]. This review has intentionally focused on European registries. Information on joint replacement registries from North America, Australia, and New Zealand are published elsewhere [25–28].

The aim of this study is to map the existing resources on hip and knee replacement in Europe. We first characterize the currently established total hip and knee replacement registries in Europe with respect to size, type, year when they were established, and coverage. Secondly, we assess which outcomes data and which patient-, surgery- and implant-related data they are collecting. Third, we describe each registry with respect to its target population and type of implants and techniques used in hip replacement.

## 2. Methods

We used the member list of the International Society of Arthroplasty Registries (ISAR [29]) and the European Federation of National Associations of

Orthopaedics and Traumatology (EFORT) website [30] to identify national, regional and hospital-based European hip and knee replacement registries. We further searched the Internet (Google) for the remaining European countries. To review available data collected in the registries we obtained the most current annual reports and publications from the Internet (Google), PubMed and/or conference proceedings published until December 2016. Moreover, we searched PubMed for publications with the key words "European arthroplasty registry" or "European hip/knee replacement registry" or "European hip/knee prosthesis registry". Additional information on the use of PROMs was obtained from the ISAR PROMs working group publications [31,32].

From these sources information was extracted regarding the structure of the registry including the geography, catchment area (hospital, regional or national), overall number of primary and revision total hip and knee replacement procedures recorded in the registry, year of establishment, and completeness of coverage. Coverage was extracted from the latest available year when indicated. When indicated separately for primary and revision hip and knee surgery, the highest coverage proportion was chosen. Moreover, we assessed from the latest available reports which of the following were measured and recorded:

- Surgical and patient outcomes and/or surrogates;
- Patient-related factors reported to the registry either directly or via linkage with other databases;
- Hospital-, surgical- and implant-related factors.

To describe each registry with respect to patient population and type of implants and technique used, we recorded – when available – preoperative patient characteristics including age at surgery (mean, median or proportion ≥65 years whatever was presented), sex distribution (proportion of women), diagnosis (percentage with primary osteoarthritis (OA) and acute fracture), body mass index (BMI; mean, median or proportion ≥30 kg/m$^2$ whatever was presented), and comorbidity as assessed with the American Society of Anesthesiology (ASA) score (proportion with ASA 3–4). Regarding type of implants and technique used we assessed – for primary hip replacement only – the percentage with (a) posterior approach, (b) all uncemented component fixation, and (c) ceramic-on-polyethylene bearing (all types) in each registry. The information on preoperative patient characteristics and on surgery-related factors was extracted for the latest year of the report in question when available. Otherwise the overall value was given.

## 3. Results

We identified 17 national registries in 15 countries, a federation of regional registries in Italy, and four regional and two hospital-based registries in Europe (Table 1). The registries of France, Czech Republic, Lombardy (Italy), Italy, and Ankaran (Slovenia) only collect data on hip replacement. Sweden and Denmark have separate registries for hip and knee. All other registers cover both hips and knees. Total numbers of primary total hip and knee replacements recorded in these registries were more than 3.1 million for the hip and 2.5 million for the knee, respectively, according to the latest available annual reports. The first national registries were both established in Sweden: the knee registry founded in 1975 and the hip registry founded in 1979. Other Scandinavian countries followed during the 1980's and 90's. Registry implementation became more widespread in all regions of Europe after 2000. In some countries such as Switzerland, Italy and the UK, hospital-based [33,34] and regional registries [35,36] preceded the creation of the national registry. In other countries such as Spain and Slovenia currently only a regional or hospital-based registry exists. In the majority of countries the registries were initiated by national orthopaedic societies. With the exception of the UK and Germany, national registries are restricted to countries with smaller population size (≤20 million). Coverage in well-established national registries was very high (≥95%). There is however variation in the publicly available data from these registries. Many of the registries provide extensive publicly available annual reports (see website links in Table 1).

In the past the main focus of the registries' recording efforts has been to monitor implant longevity by identifying those undergoing a revision. Surgical techniques and other materials used in joint replacement surgery (e.g. cement, bone grafts) potentially influencing implant survival were monitored simultaneously. Currently almost all European registries still report revision as main outcome (Table 2). Date or year of death is also available in many registries through linkage to the national or regional official mortality statistics. In all other areas of interest there is wide variation in the data collected. Thus, only few registries systematically record medical complications or surgical complications other than those that require an exchange or removal of a part or all implants or an addition of a component, because of complications such as infection or dislocation. PROMs data enhancing the outcomes' evaluation spectrum were introduced in 2001/2002 in the Swedish registries and in the Geneva Arthroplasty Registry, followed by the National

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