



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 under-used 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.

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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/m² 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 Ankarani (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 ($\geq 95\%$). 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

Table 1
European Arthroplasty Registries: Overview.

Country/ Region	Sweden	Sweden	Finland	Norway	Denmark	Geneva, Switzerland	Denmark	Scotland, UK
Name	Swedish Knee Arthroplasty Register (SKAR)	Swedish Hip Arthroplasty Register (SHAR)	Finnish Arthroplasty Register	Norwegian Arthroplasty Register	Danish Hip Arthroplasty Registry	Geneva Arthroplasty Registry	Danish Knee Arthroplasty Registry	The Scottish Arthroplasty Project
Website/ publication/ annual report	http://www.myknee.se/en/	https://registercentrum.blob.core.windows.net/shpr/r/-rsrapport-2014-rk2f2y6UL.pdf	www.thl.fi/far	http://nrlweb.ihelse.net/eng/	http://danskhoftelalloplastikregister.dk/en/dhr/	http://www.ear.effort.org/downloads/The%20Geneva%20Hip%20Arthroplasty%20Registry.pdf	https://www.sundhed.dk/content/cms/99/4699_dkr-rapport-2016.pdf	http://www.arthro.scot.nhs.uk/docs/2016-08-09-SAP-Report.pdf?1
Type Established	National 1975	National 1979	National 1980	National 1987	National 1995	Hospital 1996	National 1997	Regional 1999
Total primary hip included (until year)		396197 (2014)	173500 (2016)	163690 (2014)	149154 (2015)	7114 (2016)		38089 (2015)
Total hip revision		40549	35781	27272	23430	869		4479 (2015)
Total primary knee included (until year)	228066 (2014)		175814 (2016)	62561 (2014)		4202 (2016)	104476 (2015)	37317 (2015)
Total knee revision	5930 (2013)		14925	5760		355	12372	2365 (2015)
Coverage	97%	98.1%	95%	95%	97.5%	100%	97.1% (2015)	
Country/ Region	Emilia-Romagna, Italy	Romania	Lombardy, Italy	Czech Republic	England, Wales & Northern Ireland	Ankaran, Slovenia	Slovakia	Catalonia, Spain
Name	Register of Orthopaedic Prosthetic Implants – RIPO Emilia Romagna	Romanian Arthroplasty Register (R.N.E.)	Registro Ortopedico Lombardo Protesi – ROLP	National register of joint replacement	National Joint Registry (NJR)	Valdoltra Hospital Arthroplasty Register	Slovak Arthroplasty Register (SAR)	Catalan Arthroplasty Register – (RACat)
Website/ publication/ annual report	https://ripo.cineca.it/	http://www.rne.ro/site	http://tempiattesa.servizirl.it/shared/ccurl/739/453/4420_06_VI_Rapporto.ROLP.pdf	http://www.nrkkn2006publicoutputs2.pdf http://www.achot.cz/dwnld/achot.2011_supplA.01_18.pdf	http://www.njrcentre.org.uk/njrcentre/Reports/PublicationsandMinutes/tabid/85/Default.aspx	http://www.ob-valdoltra.si/sites/www.ob-valdoltra.si/files/upload/images/valdoltrahiparthroplastyregistryreport.2014.pdf	http://sar.mfn.sk/dokumenty.327.html http://sar.mfn.sk/file/subory/SAR_EN_final.pdf http://sar.mfn.sk/file/subory/Annual%20report%20-%202011.pdf	http://www.ncbi.nlm.nih.gov/pubmed/?term=Joint+Registries+as+Continuous+Surveillance+Systems%3A+The+Experience+of+the+Catalan+Arthroplasty
Type Established	Regional 2000	National 2001	Regional 2001?	National 2002	National 2002	Hospital 2002	National 2003	Regional 2005
Total primary hip included (until year)	87993 (2014)	50486 (2011)	56140 (2010)	63073 (2009)	796636 (2015)	11543 (2014)	28446 (2011)	45135 (2014)
Total hip revision	14670	4713	7137	8931	88822	1976	3189	5051
Total primary knee included (until year)	72873 (2014)	10437 (2011)			871472 (2015)		10774 (2011)	58798 (2014)
Total knee revision	6023	315 (2011)			54278		411	6473 (2015)
Coverage	98%	100%			97%			80–85%

Name	Total Hip Arthroplasty Register SOFCOT	Dutch Arthroplasty Register (LROI)	Portuguese Arthroplasty Register	Belgian National Arthroplasty register	Lithuanian Arthroplasty Register	Swiss arthroplasty register (SIRIS)	Endoprothesenregister Deutschland (EPRD)	Italian Arthroplasty Registry Project (RIAP)
Website/ publication/ annual report	http://www.sofcot.fr/Pages/Registre-des-protheses-de-hanche	http://www.lroi.nl/en/annual-reports	http://www.rpa.spot.pt/	https://www.ehealth.fgov.be/sites/default/files/assets/fr/pdf/orthopride/3e_analyse_des_donnees.du_registre_orthopride_decembre.2015.pdf	http://ac.els-cdn.com/S1010660x14000214/1-s2.0-S1010660x14000214-main.pdf?_tid=c3d9bbea-f3d7-11e4-a770-00000aab0f6c&acdnat=1430907055_d1514678646639487fa35cc1a9b89085	http://www.siris-implant.ch/fr/Tlchargements	http://www.eprd.de/fileadmin/Dateien/Medien/Publikationen_verschieden/EPRD_Statusbericht_2014_FINAL_Online_Version.pdf	http://www.iss.it/binary/riap2/cont/20140407_Brochure_in_inglese.pdf
Type	National	National	National	National	National	National	National	Federation of regional registries
Established	2006	2007	2009	2009	2010	2012	2012	2001/2014
Total primary hip included (until year)	23909 (2015)	169628 (2014)	20862 (2013)	28165 (2014)	6072 (2012)	57718 (2015)	223151 (2015) Hip AND knee	737406 (2013) 16475 (2014)
Total hip revision	2901	22795	2960	893	149	7998		1413
Total primary knee included (until year)		157661 (2014)	20111 (2013)	28642 (2014)	3823 (2012)	51157 (2015)	See above	618614 (2013) 4726 (2014)
Total knee revision		13164	1324	696	25	5300		39018 (2013) 186 (2014)
Coverage		97%			85%	91%	36.7% (2015)	80% hip, 56% knee

Table 2
Outcomes reported in European Arthroplasty Registries.

Country/ Region	Sweden Knee**	Sweden Hip	Finland	Norway**	Denmark Hip	Geneva, Switzerland	Denmark Knee	Scotland	Emilia-Romagna, Italy	Romania	Lombardy, Italy	Czech Republic	England, Wales & Northern Ireland	Ankaran, Slovenia	Slovakia	Catalonia, Spain	France	Netherlands	Portugal	Belgium	Lithuania	Switzerland	Germany	Italy
Revision rates/Survival	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Surgical complications (including non-revised cases)																								
Infection		X	X		X	X	X	X	X				X											
Dislocation		X	X			X		X																
Peri-prosthetic fracture		X				X			X															
Medical complications																								
Mortality	X	X	X	X	X	X	X	X	X	X			X		X	X		X				X		
Patient-reported outcome measures (PROMs)																								
Pain	X	X			X	X	X						X					X						
Function	X	X			X	X							X				X							
General health*	X	X			X	X							X					X						
Satisfaction	X	X			X	X							X					X						
Drug use postoperative																								
Analgesic use postoperative					X												X							
Antibiotic use postoperative		X																						
Radiographic outcomes																								
Health care utilization																								
Length of stay/																								
Discharge destination																								
Readmission	X	X	X		X	X	X						X											
Reoperation		X	X		X	X	X																	
Health care costs	X										X		X											

^aGeneral health assessment with SF-12 or EQ-5D.

^bPROMs data are collected on a sample only.

^cPreoperative knee score.

Joint Registry for England, Wales, Northern Ireland and the Isle of Man (NJR) and recently the Dutch registry. Pre- and postoperative information on pain, function, general health and satisfaction are continuously collected. Lately, facilitated by data linkage, health care indicators (e.g. readmission and reoperation rates) and surrogate measures of complications such as specific drug prescription have been introduced in joint replacement registries (e.g. Denmark, Sweden, Catalonia), (Table 2).

Interpretation of data on the outcomes of joint replacement need to take account of patient and surgical factors as well as those related to type of implant. In regard to patient-related factors (Table 3) all registries record age, sex and diagnosis. Next most recorded items are previous surgery, BMI, and ASA score. The inclusion of BMI and ASA score is recent in several registries. Other comorbidity measures assessed less often are Charnley disability grade, and the Charlson and Elixhauser comorbidity indexes. Socioeconomic status, lifestyle factors, and concomitant drug use are only available in a small number of registries. Information regarding hospital type/volume is recorded in most registries (Table 4). By contrast to patient data, information on the details of surgery and implant information is more widely available. The most frequently reported items are fixation type, implant brand, bearing surface and surgical approach. The highest granularity of outcomes data and covariates was found in the Geneva Arthroplasty Registry, in the UK registry, and in Sweden.

The available data from these European registers were then analyzed to determine any substantive differences in the patient population they covered (Table 5). In hip replacement the mean age at surgery varied between 64 years in Romania and 71 years in Germany. The proportion of women ranged from 52% in Switzerland to 67% in Norway. There was evidence of differences in other patient factors. Thus among the registries reporting BMI at surgery, the highest value was found in the UK. The proportion of patients with ASA grade 3–4 differed substantially and ranged from

14% in the Netherlands to 37% in Finland. Differences were also seen in diagnosis, illustrated for primary osteoarthritis and acute fracture.

For knee replacement the mean age at surgery varied between 66 years in Slovakia and 72 years in Catalonia. The proportion of women ranged from 57% in the UK and Sweden to 80% in Lithuania. Again, among the registries reporting BMI at surgery the highest value was found in the UK. The proportion of patients with ASA grade 3–4 differed substantially and ranged from 14% in the Netherlands and Portugal to 38% in Finland. Differences were also seen in the proportion of patients with primary osteoarthritis.

There was considerable variation in the types of implants and technique used in hip replacement (Table 5). The use of cementless fixation of cup and stem was reported in just 8% of the implants in Lithuania, but 21% in Sweden, 41% in the UK, 70% in Norway, and in more than 90% of the procedures in Italy. Eleven of the 16 hip national registries with available data reported cementless fixation in more than 50% of the procedures.

The use of a ceramic-polyethylene bearing varied greatly from less than 5% in Denmark and France to more than 50% in Norway, Geneva, Netherlands, Germany, and Italy. There was also considerable variation in surgical approach. The posterior approach only occasionally performed (less than 20%) in Switzerland and the Eastern European countries, was, by contrast, the most frequently used approach (more than 50%) in Sweden, Finland, Denmark, the UK, France, Netherlands, and Italy.

4. Discussion

European countries have an extensive experience with joint replacement registries of more than 40 years. In this review we identified 24 registries, the majority being national registries and described the different information they record. The presented work provides 'a directory' of available data. In addition, the dif-

Table 3

Patient-related factors reported in the European Arthroplasty Registries (directly or obtained via data linkage).

Country/ Region	Sweden Knee	Sweden Hip	Finland	Norway	Denmark Hip	Geneva, Switzerland	Denmark Knee	Scotland	Emilia-Romagna, Italy	Romania	Lombardy, Italy	Czech Republic	England, Wales & Northern Ireland	Ankaran, Slovenia	Slovakia	Catalonia, Spain	France	Netherlands	Portugal	Belgium	Lithuania	Switzerland	Germany	Italy
Demographics																								
Age	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Sex	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Height-weight (BMI)	X	X	X		X	X	X						X	X		X		X	X			X	X	
Marital status ^a		X			X	X							X											
Socioeconomic status																								
Education		X			X	X																		
Deprivation index													X				X							
Occupation						X																		
Joint specific history																								
Diagnosis	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Previous surgery	X		X			X	X				X		X		X		X		X	X	X	X	X	X
Life style factors																								
Smoking		X				X												X						
Level of activity						X													X					
Alcohol abuse						X																		
Co-morbidities																								
ASA class	X	X	X	X	X	X							X						X					
Charlson					X		X						X						X	X			X	
Elixhauser		X															X							
Charney grade	X	X			X	X												X				X		
Medication use					X	X											X							

^aMarital status: In the UK “Living arrangements” are recorded, which include information on marital status.**Table 4**

Hospital-, surgery- and implant-related factors reported in the European Arthroplasty Registries.

Country/ Region	Sweden Knee	Sweden Hip	Finland	Norway	Denmark Hip	Geneva, Switzerland	Denmark Knee	Scotland	Emilia-Romagna, Italy	Romania	Lombardy, Italy	Czech Republic	England, Wales & Northern Ireland	Ankaran, Slovenia	Slovakia	Catalonia, Spain	France	Netherlands	Portugal	Belgium	Lithuania	Switzerland	Germany	Italy
Hospital-related																								
Type of hospital	X	X		X	X	X	X				X		X	X	X				X					X
Hospital volume	X	X		X	X	X	X						X	X	X	X		X				X		
Surgery-related																								
Surgical approach	X	X	X	X	X	X	X			X	X	X	X	X	X		X	X	X	X	X	X		X
Operation time	X		X	X		X	X						X											
Surgeon experience		X				X		X					X											
Anesthesia type	X					X	X						X							X				
Antibiotics	X		X	X	X	X				X			X		X		X			X				
Anticoagulants	X		X	X	X	X							X											
Implant-related																								
Implant details	X	X	X	X	X	X	X		X	X			X		X	X	X	X	X	X	X	X	X	X
Fixation	X	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Bearing surface (hip)		X	(X)	X	X	X			X				X	X		X	X	X		X		(X)	X	X

(X) will be implemented in the future.

ferent registries with their different populations and approaches to surgery provide a basis for the comparison of outcomes between these approaches. “League tables” comparing health outcomes between countries are a powerful tool to raise standards and change practice. Observational data such as these have their limitations but their ready availability on a continuing basis provide a tool for use in promoting better use of resources in an area of health care which is a major expense for all developed countries. The registries, to varying extents, however, record factors potentially influencing the outcomes, which include patient-, implant- and surgery-related variables. Patient-related factors such as age, sex and diagnosis are collected universally. Information on BMI, socioeconomic status, co-morbidities, life style factors and peri-

operative medication use is increasingly recorded. The observed differences in patient characteristics between the registries may reflect the demographic structure of the population covered and the variation in incidence of the underlying disorder. There is also substantial variation with regard to the implants and surgical techniques that are used in hip replacement. The variation for the latter is greater than that in their patient characteristics. The increased ‘richness’ in available data more likely depends on resources and especially linkage to other routinely collected data than on registry size. They offer the scope however for adjusted analyses to address comparative performance.

Prosthesis revision has remained the main outcome collected almost universally. It is a hard endpoint – indicator and treatment

Table 5
European Arthroplasty Registries: Patient- and surgery-related characteristics.

Country/ Region	Sweden	Sweden	Finland	Norway	Denmark	Geneva, Switzerland	Denmark	Scotland, UK
Name	Swedish Knee Arthroplasty Register (SKAR)	Swedish Hip Arthroplasty Register (SHAR)	Finnish Arthroplasty Register	Norwegian Arthroplasty Register	Danish Hip Arthroplasty Registry	Geneva Arthroplasty Registry	Danish Knee Arthroplasty Registry	The Scottish Arthroplasty Project
HIP								
Women (%)		58%	59%	67.4%	60%	55.8%		
Mean/median age		W 70 yrs., M 67 yrs.	>= 65yrs: 61.5%	69 yrs.	W 70 yrs., M 67 yrs.	W 70 yrs., M 65 yrs.		67 yrs.
Mean BMI		27	28			26.8		
ASA 3–4 (%)		19–20%	36.9%	19%		23%		
Primary OA (%)		78%	>80%	72.7%	78.6%	70.4%		88.4%
Acute fracture (%)		14%	About 5%	8.7%	4.6%	9.3%		
All uncemented fixation (%)		20.9%	62.5%	70–75%	68.5%	58.9%		
Ceramic-polyethylene bearing (%)		15.2%		53.9%	3.8%	98.7%		
Posterior approach (%)		51%	74.2%	37%	91.5%	19.7%		
KNEE								
Women (%)	57.1% (2014)		68.9%	64.8%		68%	60.8%	
Mean/median age	68.8 yrs.		>=65yrs: 68.2%	68.7 yrs.		Women 72 yrs., Men 70 yrs.	67.8 yrs. (2015)	68 yrs.
Mean BMI	29		30			29.6	29.2 (2012–15)	
ASA 3–4 (%)	17.3%		37.8%	18.3%		27.2%		
Primary OA (%)	96.2%		>88%	80.5%		83%	84.4%	96.9% (2015)
Country/ Region	Emilia-Romagna, Italy	Romania	Lombardy, Italy	Czech Republic	England, Wales & Northern Ireland	Ankaran, Slovenia	Slovakia	Catalonia, Spain
Name	Register of Orthopaedic Prosthetic Implants – RIPO Emilia Romagna	Romanian Arthroplasty Register (R.N.E.)	Registro Ortopedico Lombardo Protesi – ROLP	National register of joint replacement	National Joint Registry (NJR)	Valdoltra Hospital Arthroplasty Register	Slovak Arthroplasty Register (SAR)	Catalan Arthroplasty Register – (RACat)
HIP								
Women (%)	60.0%	About 57%	59%	59.9%	59.8%	53%	58.8	52.9%
Mean/median age	66.7 yrs.	64–65 yrs.			W 70 yrs., M 67 yrs.	W 66 yrs., M 63 yrs.	64.7 yrs. (prim.OA)	68.8 yrs.
Mean BMI					28.7			
ASA 3–4 (%)					18%			
Primary OA (%)	67.8%	60–65%	72.3%	68.6%	92%	80%	69%	77.9%
Acute fracture (%)	9.0%	9.4%	8.1%		2.5%			13.4%
All uncemented fixation (%)	85.5%	43.1%	90.4%	35%	41%	98%	51.2%	62.3%

Ceramic-polyethylene bearing (%)	9.7%				26.6%	15%		12.5%
Posterior approach (%)		11.3%	53.4%	1%	67%	<6%	16.5%	
KNEE Women (%)	71.2%	About 70%			57%		68.1%	72%
Mean/median age	70.6 yrs.				Women 70 yrs., Men 69 yrs.		66.4 yrs.	72 yrs.
Mean BMI					30.9			
ASA 3–4 (%)					17%			
Primary OA (%)	85.5%				96.1%		93.8%	98.2%
Country/Region	France	Netherlands	Portugal	Belgium	Lithuania	Switzerland	Germany	Italy
Name	Total Hip Arthroplasty Register SOFCOT	Dutch Arthroplasty Register (LROI)	Portuguese Arthroplasty Register	Belgian National Arthroplasty register	Lithuanian Arthroplasty Register	Swiss arthroplasty register (SIRIS)	Endoprothesenregister Deutschland (EPRD)	Italian Arthroplasty Registry Project (RIAP)
HIP Women (%)	56.9%	66%	55.4%	58.8%	64.2%	52.2%	60.2%	57.2%
Mean/median age	70.2 yrs.	68.9 yrs.	71 yrs.	68.5 yrs.	66–68 yrs.	68 yrs.	F 73 yrs., M 69 yrs.	68.7 yrs
Mean BMI		23% obese	20.9% obese			27		
ASA 3–4 (%)		14%	24.9%			23.3%		
Primary OA (%)	75.2%	87%	60.3%	78.1%	69%	85.2%		87.6%
Acute fracture (%)	6.8%	4%	24.1%	12.7%	18.8%	5.9%		10.6%
All uncemented fixation (%)	64.8%	61%	71%	82.4%	8.2%	83.4%	76.3%	about 90%
Ceramic-polyethylene bearing (%)	<1%	54%	9%	31.3%			74.6%	52.9%
Posterior approach (%)	53.8%	62%	40%	37.4%		15%		51%
KNEE Women (%)		64%	71.6%	66.4%	79.9%	60.9%	62.8%	70.5%
Mean/median age		67.5 yrs.	68 yrs.	68 yrs.	68 yrs.	69 yrs.	Women 71 yrs., Men 69 yrs.	71.2 yrs
Mean BMI		39% obese	40% obese			29		
ASA 3–4 (%)		14%	14.1%			23.8%		
Primary OA (%)		96%	96%	95.5%	90.4%	87%		90.1%

Notes: BMI = Body Mass Index, ASA = American Society of Anesthesiologists Score, OA = OsteoArthritis, yrs = years.

for either an implant or a surgical failure or both, influenced by the patient's characteristics. Given the latter revision rate is not always easy to interpret and there is a need for additional outcomes. Thus the increased adoption by some registries of outcomes such as PROMs, reoperations and indicators of health care utilization can add to revision in providing a full spectrum of outcomes.

Biologically more meaningful surrogate outcomes for revision based on imaging, especially radiostereometric analysis (RSA) for specific clinical studies and serial radiographic evaluation in routine follow-up and clinical studies [37] is attractive. However, imaging data collection at a national level is very difficult and has thus so far been done by large orthopaedic hospitals/centers.

The critical appraisal of each individual registry's quality is of great importance. Factors to take into account in this process are coverage, existence of validation processes, data quality and source, capture rates of revisions, questionnaire response rates, length of follow-up (time since registry started), stability of funding, among others. Data on many of these aspects are not readily available currently and could therefore not be included in this report. Finally, there can be substantial variation in the demographic (e.g. prevalence of obesity, life expectancy), health care and economic context of the country/region covered by a registry, which in turn can influence procedures (e.g. surgical indication, implant selection) and outcomes. As a consequence, it is crucial to provide this type of information (e.g. Romanian report, see Table 1).

There are a number of limitations to consider, first those related to this work and second those related to the registries themselves. Regarding the first, we used different sources, such as annual reports, scientific publications (e.g. Catalonia, Czech Republic) and web sites (e.g. Finland). Since the objective of our work was to map all data collected and reported by the registries we relied on published information such as annual registry reports, which are their main data dissemination tool. We did not contact registry staff members and may thus have overseen information that is actually collected but not reported by the registries. Nonetheless, the effort to collect data longitudinally on a large number of patients is huge and it is unlikely that important data are collected and not reported.

Regarding the second, information from recent years was not available for all registries (e.g. latest information Czech Republic 2009), and the Geneva Arthroplasty Registry report is currently only available upon request. The reports/publications from Denmark, Germany, France and Catalonia were not or only partly available in English. Data were of variable detail and length. Information on age and BMI was inconsistently reported (mean, median or proportion). Moreover, the definition of coverage was inconsistent and sometimes missing. For the purpose of our analysis we have assumed the 'gold standard' target being the number of joint replacements recorded in the relevant administrative databases of the hospitals in the geographical area covered by the joint registry. When indicated coverage most often referred to the number of registrations in a particular registry divided by the number of joint replacements registered in these administrative databases during a particular time period. The determination of the "true" number of joint replacements may be challenging. Occasionally, coverage referred to the proportion of units (hospitals, surgeons) reporting to the registry. However, the former is a more accurate and informative measure of coverage.

5. Conclusion

The European registry landscape has evolved substantially over the last 15 years: by expanding from the northern countries to all other parts of Europe; by broadening their objectives; by harmonizing and extending outcome and covariate data collection; by linking

their information with other data sources; and by engaging in supranational initiatives [38–40]. The national registries currently mainly focus on whole-lifespan implant surveillance via revision rate monitoring, quality assessment of surgical and perioperative care, and hospital performance monitoring. National and international comparison and benchmarking have increasingly become part of their endeavors. Moreover, underperforming implants (outliers) are so far actively identified in the UK [41,42] and, outside of Europe, in Australia [43].

National and regional joint registries have evolved to meet the increasing demands from key stakeholders to understand the outcomes from joint replacement. With that demand the need for comprehensive, accurate and up to date information is growing. This work, which is a detailed and up-to-date assessment of the resources available in European hip and knee replacement registries, will hopefully serve to provide a knowledge basis and encourage future improvements in data gathering, registry quality and international registry harmonization.

Conflicts of interest

None.

IRB approval

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