Registry
Arthroplasty
Clinique
Registries
Accepted
Review

Introduction

The first nationwide orthopaedic registry was created in Sweden in 1975 to collect data on total knee arthroplasty (TKA). Since then, several countries have established registries, with varying degrees of success. Managing a registry requires time and money. Factors that contribute to successful registry management include the use of a single identifier for each patient to ensure full traceability of all procedures related to a given implant; a long-term funding source; a contemporary, rapid, Internet-based data collection method; and the collection of exhaustive data, at least for innovative implants. The effects of registries on practice patterns should be evaluated. The high cost of registries raises issues of independence and content ownership. Scandinavian countries have been maintaining orthopaedic registries for nearly four decades (since 1975). The first English-language orthopaedic registry was not created until 1998 (in New Zealand), and both the US and many European countries are still struggling to establish orthopaedic registries. To date, there are 11 registered nationwide registries on total knee and total hip replacement. The data they contain are often consistent, although contradictions occur in some cases due to major variations in cultural and market factors. The future of registries will depend on the willingness of health authorities and healthcare professionals to support the creation and maintenance of these tools. Surgeons feel that registries should serve merely to compare implants. Health authorities, in contrast, have a strong interest in practice patterns and healthcare institution performances. Striking a balance between these objectives should allow advances in registry development in the near future.

1. Introduction

The first registry on joint prostheses was created 45 years ago (in 1969) at the Mayo Clinic in Rochester, MN, USA. In 1975, efforts led by Professor Bauer led to the establishment in Sweden of the first nationwide registry, which collected data on total knee arthroplasty (TKA) [1].

The objective of this work is to review the current status of orthopaedics and traumatology registries, to discuss their impact, and to highlight their limitations. Traumatology registries are few in number, largely confined to Scandinavian countries, and designed only for epidemiological purposes. This paper is therefore confined to nationwide registries of TKA and total hip arthroplasty (THA), which are the oldest and most informative.

2. What is a registry?

In France, a decree issued on 6 November 1995 by the National Registry Committee (Comité national des registres, CNR) defines a "qualified registry" as "a continuous and exhaustive collection of nominative data about one or more health-related events in a geographically defined population, by a team having specific expertise, to be used for research and public health studies". Unfortunately, article 2 of this decree prescribes the creation of registries for implantable medical devices and the collection of outcome data on implant recipients [2]. This legislative barrier is among the main reasons France is far behind other countries in the area of orthopaedic implant registries.

3. How is a registry created?

Orthopaedic and traumatology registries collect data from a single or multiple sites, within a specific geographic region or nationwide. Only a limited amount of information is collected, to reflect the limited purpose of the registry. Thus, the minimum dataset established by the International Society of Arthroplasty Registries (ISAR) contains only 14 items [3].
Longitudinal data are collected to assess the outcome of the implant(s) in each patient. In contrast to disease-based registries, which collect the vital status of the patients, implant registries assess the survival of the implants. Thus, the death of a patient whose implant is still in place is classified as a probable or relative success of the implant procedure. Implant revision is the only indisputable endpoint, although it is affected by a number of factors (e.g., patient health status, inadequate implant monitoring, or missed diagnosis of implant failure). The term “revision” must, however, be clearly defined. The Swedish registry uses the following stringent definition: any new surgical procedure during which one or more prosthesis components are replaced, removed, or added. The Norwegian registry, in contrast, defines revision as the removal of all the implant components and therefore classifies patellar resurfacing, for instance, as a simple re-operation.

The key to ensuring the efficacy of an implantable medical device registry is the use for each patient of a single identifier, preferably the statutory health insurance number or national identity number. This identifier ensures that a primary prosthesis implanted at a given institution at a given date can be connected to subsequent revision of the implant at a different institution. Recording the side is informative in patients with bilateral arthroplasty. This automatic cross-referencing function is effective only if data collection is exhaustive.

When comparing implant performance for benchmarking purposes, survival curves are the best tool. To plot survival curves, information must be available on the vital status and, therefore, the identity of the patients. Many countries have laws forbidding the collection of data on patient identity. The Australian registry circumvents this problem by using the revision rate per 100 observed component years, which allows comparative analyses without knowledge of patient death dates. The same method is used in the British registry (patient time incidence rate), European Arthroplasty Register (EAR), and French SoFCOT THA registry ([https://sofcot.memdoc.org/]) [4,5].

Despite these limitations, registries allow epidemiological and demographic studies, as well as comparisons of outcomes across implants and institutions within a country. Registries are designed to collect information from all surgeons, instead of only from the highly specialized groups that contribute most of the studies published in the international medical literature. Thus, registries provide a more accurate view of the real-life healthcare provided to the population.

Management of a registry requires large amounts of time and other resources, most notably when exhaustive data are collected. For many registries (e.g., in Sweden and Finland), the registries were created under the impetus of professional societies. Elsewhere (e.g., in Canada and the UK), the health authorities required that healthcare institutions establish registries and, therefore, contributed to the data recording effort. In many cases, these two situations followed one upon the other.

4. Historical overview

Whereas Scandinavian countries have been maintaining orthopaedic registries since 1975, the first English-language orthopaedic registry was not created until 1998 (in New Zealand) and both the US and many European countries are still struggling to establish similar tools. To date, there are 11 registered nationwide registries of TKA and THA (Table 1).

4.1. The Swedish Knee Arthroplasty Register and the Swedish Hip Arthroplasty Register

The Swedish Knee Arthroplasty Register created in 1979 ([http://www.shpr.se/en/]) remained confidential until 1989, when their results were first reported in an international journal [6]. Since then, they have gained increasing international prominence, as their contents are described in an English-language report every 2 years [7]. Sweden now has 73 nationwide registries, whose total cost of 35.6 million € per year is entirely covered by non-industrial sources [2].

4.2. The Finnish National Arthroplasty Register

The Finnish National Arthroplasty Register ([http://www.knee.se]) was started in 1980 to collect data on both THA and TKA. Data reporting to the register was initially on a voluntary basis but has been mandatory since 1997. The THA revision rate was 19.6% in 1999 when the population of Finland was 5.1 million [8] and remained as high as 15.2% in 2001–2010.

4.3. The Norwegian Arthroplasty Register of THA

The Norwegian Arthroplasty Register of THA ([http://wwwnrweb.ihelse.net/eng/]) was created in 1987. It is ill suited to comparisons of implants and collects outcomes of the few thousand THA procedures performed annually in this small country with a population of 4.5 million. In 2003, the 10-year probability of non-revision for 78,534 primary THA procedures was 88.6% and the revision rate was 14.5% [9].

4.4. The Danish Hip Arthroplasty register

The Danish Hip Arthroplasty register ([http://www.dhr.dk/ENGLISH.htm]) was first envisioned in 1989 but was not initiated until 1995. The first report was for the 1995–1999 period and showed a 15.5% revision rate [10]. This registry now has nearly 100,000 patients and the number of new entries is 9000 per year in this country with a population of 5.3 million. Denmark has 60 to 70 accredited clinical registries, which are entirely funded by regional taxes, their total cost being 6.5 million €[2].

4.5. The New Zealand Joint Registry for THA and TKA

The New Zealand Joint Registry for THA and TKA ([http://www.nzoa.org.nz/nz-joint-registry]) started in 1998 was the first English-language arthroplasty registry. It contains only limited data on arthroplasty outcomes. For the 5579 THA procedures done in 2003, the revision rate was 13.3%, and the revision rate in the latest report was 11.5%.

4.6. The Australian Orthopaedic Association (AOA) National Joint Replacement Registry

The Australian Orthopaedic Association (AOA) National Joint Replacement Registry ([https://aoanjrr.dmac.adelaide.edu.au/]) initiated in 1999 is funded by the Ministry of Health. Data collection was extended to the entire country in 2007 with funding via a fee included in the price of each implant. With over 266,000 primary THA procedures, this registry complements the Swedish registry, as only 18% of all implants are cemented and some implant models are unavailable on the Swedish market.

4.7. The nationwide Canadian Joint Replacement Registry (CJRR)

The nationwide Canadian Joint Replacement Registry (CJRR) established by the Canadian Institute for Health Information (CIHI) ([http://www.cihi.ca/cjrr]) was started in 2001 as an extension of
Table 1
Chronology and recent revision rates in the 11 main registries of total hip and knee arthroplasty.

<table>
<thead>
<tr>
<th>Registry</th>
<th>Site</th>
<th>Year created</th>
<th>Study period</th>
<th>n revisions</th>
<th>Revision rate %</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>n primary procedures</td>
<td></td>
<td>(primary + Rev)</td>
</tr>
<tr>
<td></td>
<td>THA</td>
<td>1979</td>
<td>188,093</td>
<td>5146</td>
<td>9.2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>347,129</td>
<td>34,981</td>
<td></td>
</tr>
<tr>
<td>Finland</td>
<td>THA &amp; TKA</td>
<td>1980</td>
<td>2001–2010</td>
<td>12,750</td>
<td>15.2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>H: 71,318</td>
<td>5930</td>
<td>6.6</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>K: 83,575</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>147,401</td>
<td></td>
<td></td>
</tr>
<tr>
<td>New Zealand</td>
<td>THA &amp; TKA</td>
<td>1998</td>
<td>1999–2012</td>
<td>12,731</td>
<td>12.9</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>H: 85,769</td>
<td>5089</td>
<td>7.3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>K: 64,799</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Australia</td>
<td>THA &amp; TKA</td>
<td>1999</td>
<td>1999–2012</td>
<td>44,729</td>
<td>14.4</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>H: 266,465</td>
<td>35,620</td>
<td>7.7</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>GK: 429,228</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Canada</td>
<td>THA &amp; TKA</td>
<td>2001</td>
<td>2010–2011</td>
<td>4303</td>
<td>10.2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>H: 38,513</td>
<td>3652</td>
<td>7.2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>H: 3,757</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Romania</td>
<td>THA</td>
<td>2001</td>
<td>2001–2011</td>
<td>4713</td>
<td>5.8</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>H: 392,109</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>H: 105,455</td>
<td>5982</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>K: 79,272</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

THA: total hip arthroplasty; TKA: total knee arthroplasty; NS: not specified; H: hips; femoral prostheses and/or THA depending on the registry; K: knees; partial prosthesis (unicompartmental patello-femoral or tibio-femoral prosthesis) and/or TKA depending on the registry.

a simple arthroplasty counting system established in 1994. In 2010–2011, this registry still covered only 43.8% of the country.

4.8. The Romanian Arthroplasty Register

The Romanian Arthroplasty Register (http://www.rne.ro/?lang=en) of THA is the first registry created in Eastern Europe. Only THA procedures are recorded. The number of procedures remains limited (8828 primary THAs in 2011).

4.9. The National Joint Registry of England

The National Joint Registry of England and Wales (http://www.njrcentre.org.uk/njrcentre/default.aspx) was set up in 2002 based on experience gained with a preliminary regional registry started in 1990 in the Trent region of England [11]. One must keep in mind here the episode of the Capital Hip™ prosthesis marketed by 3 M and chiefly used in the UK in the 1990s. Over 6 years elapsed before the titanium-alloy femoral stem was recognized to result in a high failure rate and corrective measures were taken for the 4500 patients carrying this implant. This health disaster prompted the British health authorities to create a THA registry for England and Wales in 2001 [12]. Thus, whereas the Trent regional registry was a local experiment, the national registry was controlled in practice by the health authorities, a fact that raised considerable concern in the orthopaedic community [13].

4.10. The Dutch Arthroplasty Register (LROI) of THA and TKA procedures

The Dutch Arthroplasty Register (LROI) of THA and TKA procedures (http://www.lroi.nl/en/home) was initiated in 2007. After a failed attempt in 1992, 15 years elapsed before the Netherlands Orthopaedic Association (NOV) obtain public funding, after implementation of the registry was included among Good Professional Practice criteria.

5. Usefulness of registries

5.1. Post-marketing surveillance of implantable medical devices

Innovations are introduced in countries where freedom of prescription and research still allow their evaluation, via prospective studies that comply with legislation designed to protect volunteer patients. Although registry data are less satisfactory, prospective clinical studies are challenging to perform in the field of prosthetic surgery, and the considerable time needed to obtain and disseminate their results precludes the effective detection of early failure of implantable medical devices [14]. According to Robertson, to obtain 80% power for detecting a significant difference for an implant whose revision rate is 30% above the mean (e.g., 6.5% instead of 5%), 4000 patients must be randomised then followed-up for 10 years [1]. Web-based registries constitute an effective solution to this problem [15]. Recording new implantable medical devices in registries allows comparisons of their early outcomes to those of the reference standard implants, thereby ensuring the detection of suboptimal performance within a few years. A few examples are presented below.

The Norwegian Arthroplasty Register detected poor performance of Boneloc® bone cement by showing a downward slope in the survival curves of well-known implants that had been consistently providing satisfactory outcomes [16]. The problem was identified within 3 years and Boneloc® was permanently removed from the market.

The Inter-op™ (Sulzer, Austin, TX, USA) used in the USA is another illustrative example. The Swedish registry identified the failure of this device as early as 1998 by showing a 16.7% revision rate within the first 6 months, although the device was recalled only 14 months later. This lost time and lack of reactivity of the
orthopaedic community related to the absence of a rapid and effective information system generated strong criticism [17].

In the Finnish registry, of 10 TKA implants recently introduced on the market, 4 had abnormally high early revision rates, indicating the existence of a learning curve [18].

In 2005, the NJRR showed abnormally high 2-year revision rates (ranging from 27.7% to 49.3%) for four TKA devices introduced in 2003 and having a femoral component made of Oxinium®. These devices were removed from the market.

In 2007, the NJRR reported an abnormally high revision rate after use of the ASRM™ resurfacing system (DePuy Orthopaedics, Warsaw, IN, USA). Despite the implementation of a training programme, this device was removed from the Australian market in 2009 then from the worldwide market.

The most striking finding from the NJRR is that all THA and TKA innovations introduced in 2003–2007 failed, although they had obtained marketing licenses via procedures similar to those used in Europe, proving that these procedures are inadequate [19].

5.2. Use of registries to generate scientific evidence

Over more than two decades, registries have allowed many technical advances. For instance, data from the Swedish THA registry documented advances in second-generation cement fixation and the adverse impact of older age at primary THA, with an overall 30% decrease in 20-year survival among patients younger than 50 years compared to those older than 75 years.

In 2009, the team responsible for the European Arthroplasty Register (EAR) initiated the Quality of Literature in Arthroplasty (QuoLA) project that compares registry data to the data in the international literature. After THA, the mean revision rate was 1.29 per 100 observed component years [20]. This approach also confirmed the high quality and integrity of French articles on THA [21].

Information on a number of public health issues can be obtained only by very long-term epidemiological monitoring. More than 15 years of data collection in the Finnish registry were required to eliminate a relationship between metal-on-metal bearings and the development of certain cancers [22].

The Swedish TKA registry recently showed a correlation between younger age at arthroplasty and higher mortality from cardiovascular, gastrointestinal, and genitourinary diseases. This result indicates a need for close monitoring of patients who undergo arthroplasty at a young age [23].

5.3. Cost-saving effects

In Sweden, in 2002, the cost of THA revision was estimated at 11,700 US$. Therefore, a 1% decrease in the number of revisions would save 1,368,900 US$ [24]. The Australian NJRR showed revision rate decreases from 14.8% to 11.1% for THA and from 10.4% to 7.9% for TKA over a 4-year period, corresponding to a cost decrease of 44.6 million Australian $ [2]. In the US, a 5% decrease in revision rates would save about 30 million US$ per year [14].

6. Limitations of registries

Even the exemplary Swedish THA registry has a number of limitations, which are found in variable degrees in other national registries. Comparative analyses long focused solely on primary hip osteoarthritis and used a single endpoint, namely, revision for aseptic loosening, creating major obstacles to comparisons with the international literature. The registry contains little or no cases for many implant models, as implants associated with inadequate outcomes were removed from the Swedish market. Thus, in 2011, three implants accounted for 97.6% of all cemented THAs in the registry: Lubinus-SP® (Link), 55.1%; MS30® (Zimmer), 11.9% and Exeter® (Stryker), 11.6%. Many reliable implants recognized as valid by the international community are completely absent from the Swedish registry: examples include AML™ (DePuy), Zweymüller-Alloclassic® (Zimmer), Charnley-KerboullTM (Stryker), and Taperloc® (Biomet). These implants cannot be evaluated based on the registry.

The ability of the Swedish THA registry to improve professional practice has fluctuated over time. Thus, the revision rate in Sweden increased from 8.3% in 2002 to 9.2 in 2011. However, an unexpected trend in practices has been noted in Sweden, with 3% of cementless THA procedures in 2002 and 17% in 2011, in contradiction with the strong historical recommendation from the Swedish registry to consistently use cement fixation.

As the results obtained in each region and institution are available to the public, patients can make informed choices. However, this system can limit the willingness of surgeons to innovate, as they may prefer to perform well-established procedures and implants to comply with the precautionary principle. The American media shine a strong spotlight on problems with implants. In the US, the THA revision rate was as high as 18% and 52% of procedures were done by surgeons who performed fewer than 10 THAs per year, with higher complication rates [25]. In the UK, the public release of registry data is generating active controversy in the orthopaedic community [26].

Registries may fail to provide effective warning signals in the first few years after their creation. A case in point is the England/Wales NJR registry created in 2003, the year the ASRM™ resurfacing system (DePuy) was introduced [4]. Despite a first alert in 2005 followed by confirmation in 2008, the device was not removed from the market until 2010, after two lost years, creating a massive media blitz.

7. Divergences and convergences across registries

Registry data must be subjected to close scrutiny, and each definition and table of results must be analysed with care. In addition, under the combined influence of demographics and adherence variations, the number of implants included per year varies 20-fold. Finally, the international usefulness of some registries is limited by the lack of availability of an English-language version (Danish and Dutch registries).

7.1. THA registries

A 2009 comparison of data from nine THA registries showed that the mean annual number of primary THA procedures was 133/100,000 population, with major variations across patient age groups, of up to 3.4-fold for the 55–64 year group between New Zealand and Portugal [27]. Fixation methods varied widely, with cementless implants contributing 17% of THAs in Sweden, 40% in Finland, and 89% in Emilia-Romagna (Italy).

For a given type of implant, survival varied across registries from culturally similar countries. For instance, 10-year survival of the Exeter® (Stryker) implant was 96% in Sweden compared to only 92% in Finland, due to differences in the redefinition of revision between these two registries (http://www.snhr.se/en/ and http://www.fimea.fi/frontpage, respectively).

Table 2 compares the frequencies of the five main reasons for THA revision in four major national registries and a French prospective study [28]. Aseptic loosening remains the main reason for primary THA revision, with variations from 29.9% of cases in Australia to 58.4% in the UK.
Since the late 1990s, all registries have consistently documented a marked improvement in the performance of last-generation cementless implants.

7.2. TKA registries

Comparisons of 2006 reports from the most representative registries indicate shared epidemiological and demographic trends. Women predominated in all registries. Mean age was about 70 years but showed a steady decline related to an increase in the number of TKAs performed between 45 and 54 years of age. Knee osteoarthritis was the main reason for TKA; the proportion of patients with inflammatory disease ranged from 4% in Canada to 13% in Finland. Fully cemented fixation was used in the vast majority of cases, the only exception being the Australian registry, with 23.8% of cementless TKAs. Uncompartmental knee arthroplasty usually contributed fewer than 10% of cases (11.8% in Australia and 12% in Norway). Finally, aseptic loosening was the main reason for revision, with 20% (UK) to 44% (Sweden) of cases. Absence of patellar resurfacing was consistently associated with a higher risk of revision. The latest revision rates were remarkably similar across countries (6.6% in Finland and 7.7% in Australia) (Table 1).

National preferences for specific TKA devices depend heavily on the local orthopaedic culture and market share distribution among implant manufacturers. These factors are at least as powerful as implant performance. Table 3 reports the three most commonly used implants in each registry in 2006. The data from the four Scandinavian registries indicate a high level of practice uniformity, with each implant trio having about two-thirds of the relevant national market. The Norwegian registry, however, had a different trio (Profix®, LCS®, and Genesis®) that was very similar to that used in Australia.

7.3. Collaboration between THA and TKA registries

As early as 2006, the number of TKAs increased faster than the number of THAs. A larger number of TKAs than THAs was performed each year in Finland, Australia, Canada, and England/Wales. In all registries, revision rates were about 50% lower for TKA than for THA (Table 1). The largest difference was reported in 2004 in the Medicare population in the US, with revisions in 7.3% of TKA patients and 18% of THA patients [29].

The Nordic Arthroplasty Register Association (NARA) created in 2007 is a collaboration among the TKA and THA registries of Sweden, Denmark, and Norway [30]. Of the 280,201 primary THAs, 89% were cemented in Sweden and 46% in Denmark. Overall implant survival was longer in Sweden (Table 4). The three registries showed concordant results for three points. The two most widely used THA devices were the cemented Luminus® (Link) and Exeter® (Stryker) implants. The three leading reasons for revision were aseptic loosening (63% to 75% across countries), dislocation (5.8% to 12%), and infection (6.7% to 11%).

The NARA collected data on 151,814 primary TKAs. Denmark had a 76% rate of patellar resurfacing, compared to only 11% in Norway; and a 22% rate of cementless, compared to only 2% in Sweden.

8. The future of registries

8.1. On the international scene

The creation of registries for implantable medical devices is a major recommendation issued by EUCOMED, which represents the medical technology industry in Europe. The goal is to shorten the response time to alerts generated by post-marketing medical device surveillance, thereby minimising adverse events by ensuring prompt elimination of defective devices from the market.

The European Federation of National Associations of Orthopaedics and Traumatology (EFORT) contributes to promote national registries, while respecting the distinctive characteristics, culture, and options of each country. Since 2005, EFORT has pooled data on specific implants collected in various countries. Finally, ensuring uniformity of data collection in national registries would allow worldwide comparisons and is an objective of the International Society of Arthroplasty Registries (ISAR).

The explosive growth of prosthetic surgery predicted to occur over the next few decades lends urgency to the achievement of these objectives [31]. The creation of an implant registry in the US is still in its preparatory stages, although the Food and Drug Administration created the International Consortium of Orthopaedic Registries (ICOR) in 2011 [32]. The objective of the ICOR is to pool data from existing national registries and to improve data collection uniformity in order to facilitate exchanges, most notably by creating a universal bar code [33].

8.2. In France

In 2006, the SoFCOT created a TKA registry similar to the Swedish and Australian registries, with voluntary reporting (CNIL approval #04-1277). The main requirements were as follows: mandatory information of patients scheduled for arthroplasty; rapid web-based data collection [15]; use of patient-specific identifiers (NIR or INSEE number) to ensure automatic identification of revisions and, above all, identification of patients carrying implants for which alerts are generated; statistical data analysis by a steering committee working with a stable group of experienced hospital professionals; efforts to achieve exhaustive data collection in the long-term, of which a prerequisite is a strong incentive from health authorities; and prevention of data misuse via the maintenance of a certain degree of independence.

Over 250,000 THA and TKA procedures are performed each year in France. This large number of procedures translates into a cost of several hundred thousand Euros per year to maintain a registry. No professional society can obtain funding on such a large scale. The only option to minimise costs is to rely on existing statistical data management agencies. The SoFCOT therefore established a contract with the Institute for Evaluative Research in Orthopaedic Surgery of
Table 3
Registry data on techniques and implants used for primary unicompartamental or total knee arthroplasty in 2006.

<table>
<thead>
<tr>
<th>Registry</th>
<th>% Uni</th>
<th>% patellar replacement</th>
<th>Fully cemented</th>
<th>Hybrid</th>
<th>Cementless</th>
<th>Three most often used implants (study period)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Swedish</td>
<td>9.4%</td>
<td>&lt;10%</td>
<td>98%</td>
<td>2%</td>
<td>0</td>
<td>AGC®, PFC Sigma® &amp; Free-Sam MB®: 6% (1995–2004)</td>
</tr>
<tr>
<td>Finnish</td>
<td>&lt;10%</td>
<td>NS</td>
<td>98%</td>
<td>NS</td>
<td>NS</td>
<td>Duracon®, AGC V2® &amp; PFC Sigma®: 58% (1990–2004)</td>
</tr>
<tr>
<td>Norwegian</td>
<td>12%</td>
<td>15%</td>
<td>±87%</td>
<td>±11%</td>
<td>±2%</td>
<td>Profila®, LCS® &amp; Genesis I®: 64% (1994–2005)</td>
</tr>
<tr>
<td>Danish</td>
<td>5.5%</td>
<td>67.3%</td>
<td>74.4%</td>
<td>14.5%</td>
<td>10.3%</td>
<td>AGC V2®, PFC® &amp; NexGen®: 64.3% (1997–2005)</td>
</tr>
<tr>
<td>Australian</td>
<td>13.3%</td>
<td>41.5%</td>
<td>48.7%</td>
<td>27.5%</td>
<td>23.8%</td>
<td>LCS®, Duracon® &amp; Genesis II®: 31% (1999–2004)</td>
</tr>
<tr>
<td>Canadian England and Wales</td>
<td>8%</td>
<td>73%</td>
<td>84% (83%)</td>
<td>12% (1%)</td>
<td>4% (7%)</td>
<td>NS PFC Sigma®, AGC®, NexGen®, 23% (2003–2007)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NS: not specified.

Table 4
Comparison of data from the three Scandinavian registries in the Nordic Arthroplasty Register Association (NARA) [31].

<table>
<thead>
<tr>
<th>THA</th>
<th>Number of procedures</th>
<th>% in the NARA dataset</th>
<th>% postero-lateral approach</th>
<th>% cemented</th>
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<table>
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<th>TKA</th>
<th>Number of procedures</th>
<th>% in the NARA dataset</th>
<th>% patellar button</th>
<th>Relative risk of revision (TKA only)</th>
</tr>
</thead>
<tbody>
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<td>22.3</td>
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<td>Danish</td>
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<td>17.4</td>
<td>11</td>
<td>1.4</td>
</tr>
</tbody>
</table>

NS: not specified; TKA: total knee arthroplasty; THA: total hip arthroplasty.

the Bern University, Switzerland, which has acquired considerable expertise in the field since 1967.

Both professional societies and physicians must be actively involved in maintaining registries. The Medical Specialties Federation (Fédération des spécialités médicales, FSM) is in charge of achieving this objective. In addition to ankle prostheses, which have been under close surveillance for 3 years via an observational registry of limited duration, THA (most notably with metal-on-metal bearings) and TKA are the two priorities for orthopaedic registries required by the French health authorities.

In application of chapter IX of the French law of 6 January 1978, projects involving the collection of personal data to be used for healthcare research must be submitted to an advisory committee on healthcare research data management (Comité consultatif sur le traitement de l’information en matière de recherche en santé, CCTIRS), which assesses the scientific method to be used. Then, the project must be approved by the French Data Protection Authority (Commission nationale de l’informatique et des libertés, CNIL). Finally, approval from the National Registry Committee (Comité national des registres, CNR), which relies on resources from the National Institute for Health and Medical Research (Institut national de la santé et de la recherche médicale, Inserm) and French Health Watch Institute (Institut de veille sanitaire, InVS) is required to obtain accreditation as a “qualified registry”.

One more major obstacle to the creation of effective registries is the set of severe restrictions placed on the use of the NIR to identify patients. A decree from the State Council must be obtained to authorise the use of the NIR. One means of circumventing this obstacle may consist in using the national health identifier (INS), which is derived from the NIR using anonymisation techniques. However, the application decree for the INS has not yet been issued [2]. These administrative obstacles have contributed to the delay in establishing effective registries in France.

Finally, strictly voluntary reporting of data to registries has demonstrated limitations. The health authorities can choose among several options to encourage physicians and healthcare institutions to contribute data to registries. One option may consist in including participation in a registry among the criteria used by the French National Health Authority (Haute Autorité de santé, HAS) to certify healthcare institutions. Participation in registries could be included in contracts established with the regional health agencies (Agence régionale de santé, ARS). Healthcare institutions that fail to report data to registries would lose their accreditation for the implantation of the relevant devices [2]. Finally, making reimbursement of the implant and surgical procedure conditional on data reporting to registries would be a powerful tool.

9. Conclusion

The creation of registries of implantable medical devices ensures effective post-marketing surveillance and allows the detection of defects before they translate into public health disasters magnified by the media. Although registries are not the only effective tool for monitoring medical devices, well-designed registries that receive
proper input from healthcare professionals are among the most powerful post-marketing surveillance methods available to date. Registries are a manifestation of the evaluation culture. Thus, their widespread development in some countries (such as Scandinavian, Australia, UK) and their virtual absence in others (such as southern European countries) highlights the impact of cultural differences on healthcare evaluation. France is far behind many other countries, most notably in the field of orthopaedics.

Registries have provided a wealth of information to the surgical community via the development of electronic communication methods and the widespread use of English to report healthcare data. At the individual level, registries allow each surgeon to compare his or her practice to that of the overall community of surgeons in the same specialty. At the national level, registries provide unique information on the performance of implants and healthcare institutions, which policy-makers will soon consider indispensable. This maturity of the actors involved is a key factor for the development of registries aimed at achieving overall improvements in professional practice and thereby at improving the quality of care delivered to patients scheduled for surgery.

Disclosure of interest

C. Delaunay is the unpaid coordinator of the SoFCOT total hip arthroplasty registry and an educational consultant for the Zimmer Institute.

References