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A review of national shoulder and elbow joint replacement registries

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Background: The aim was to review the funding, organization, data handling, outcome measurements, and findings from existing national shoulder and elbow joint replacement registries; to consider the possibility of pooling data between registries; and to consider wether a pan european registry might be feasible.
Materials and methods: Web sites, annual reports, and publications from ongoing national registries were searched using Google, PubMed, and links from other registries. Representatives from each registry were contacted.
Results: Between 1994 and 2004, 6 shoulder registries and 5 elbow registries were established, and by the end of 2009, the shoulder registries included between 2498 and 7113 replacements and the elbow registries between 267 and 1457 replacements. The registries were initiated by orthopedic societies and funded by the government or by levies on implant manufacturers. In some countries, data reporting and patient consent are required. Completeness is assessed by comparing data with the national health authority. All registries use implant survival as the primary outcome. Some registries use patient-reported outcomes as a secondary outcome.
Conclusions: A registry offers many advantages; however, adequate long-term funding and completeness remain a challenge. It is unlikely that large-scale international registries can be implemented, but more countries should be encouraged to establish registries and, by adopting compatible processes, data could be pooled between national registries, adding considerably to their power and usefulness.

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New implants are expected to be equivalent or superior to existing implants regarding pain relief, range of motion, health-related quality of life, complications, and survival of the implant. However, new implants and methods of fixation are only required to provide data on material safety not clinical efficacy before they are released onto the market. Some will, despite excellent theoretical design, turn out to be inferior to existing implants or even, in some cases, a clinical disaster.[28] The hip replacement registries in Norway and Sweden were able to detect inferior results before they were reported in conventional studies.[6,13,14,17,19]

Although individual institutions, such as the Mayo Clinic (Rochester, MN, USA), began a joint replacement registry in the late 1960s,[21] the first national registry to be established was the Swedish Knee Arthroplasty Register in 1975, followed by joint replacement registries in Finland in 1980 and in Norway in 1987. Since then, national and regional joint replacement registries of hip and knee implants have been established in many other countries.[27]

Inspired by the experiences with hip and knee registration, shoulder and elbow replacement have been added to existing joint replacement registries or have been established as individual registries within the last decades. The aim of this study was to review the funding, organization, data handling, outcome measurements, and findings from existing national shoulder and elbow joint replacement registries; to consider the possibility of pooling data between registries; and to consider wether a pan european registry might be feasible..

Materials and methods

A search for Web sites and annual reports from ongoing national shoulder and elbow joint replacement registries was conducted by the first author using the Internet (Google) and by using links from each Web site to other registries. In addition, the Internet (Google) and Medline (PubMed) were used to search for publications related to a national shoulder or elbow joint replacement registry.

The eligibility criterion for a registry was an ongoing shoulder or elbow joint replacement registry established on a national basis. Registries from specific hospitals or regional registries were not included in the review.

The following characteristics were collected: name of the registry, Internet site, the year of establishment, initiative, funding, coordination, organization, validation, if the reporting from the surgeon was obligatory, data handling, if patient consent was required, outcome measurements, and publications. Subsequently, a standardized form was sent to representatives from each registry asking them to validate the preliminary information.

Results

We identified 6 shoulder joint replacement registries and 5 elbow joint replacement registries. Furthermore, the National Joint Registry in the United Kingdom (UK) plans to include shoulder and elbow replacements from 2011 (Table I). The oldest registry is the Finnish Arthroplasty Register, which has included shoulder and elbow replacements since it was established in 1980. The Norwegian Arthroplasty Register was established in 1987, initially as a hip replacement registry, but it was extended to include other joint replacements, including shoulder and elbow replacements in 1994. The New Zealand National Joint Register was established in 1999 and has included shoulder and elbow replacements since 2000. The Swedish Shoulder Arthroplasty Registry and the Swedish Elbow Arthroplasty Registry were established in 1999 as individual registries but have now merged into one registry. The Danish Shoulder Arthroplasty Registry was established in 2004. The National Joint Replacement Registry in Australia was established in 1998 and has included shoulder and elbow replacements since 2004.

Funding

All existing registries were created as an initiative of orthopedic societies. The registries in Australia, Denmark, Finland, Norway, and Sweden are financed by their respective governments. The New Zealand registry is financed by orthopedic surgeons through a levy on implants, 2 government agencies, and a private hospital group. The UK registry is funded by a levy on implant manufacturers.

Organization

All registries are coordinated from a university department, an orthopedic department, or by a health department. The steering committee of each registry consists mostly of orthopedic surgeons representing each region in the country. There are also representatives from the implant supply industry and the New Zealand Arthritis Society in New Zealand. The steering committees are responsible of defining the strategies, supervising the annual report, and encouraging hospitals and orthopedic surgeons to participate.

Table I Details of each registry

Variable	Australia	Denmark	Finland	New Zealand	Norway	Sweden		UK*
						Shoulder	Elbow	
Initiative	Society	Society	Society	Society	Society	Society	Society	Society
Established	2004	2004	1980	2000	1994	1999	1999	2011
Funding	G	G	G	G†	G	G	G	G†
Coordination	U	U	H	D	D	D	D	G
Organization	Committee	Committee	Health institute	Committee	Committee	Committee	Committee	Committee
Obligatory	No	Yes	Yes	Yes	No	No	No	Yes
Collecting data	Paper	Internet	Paper/Internet	Paper	Paper	Paper/Internet	Paper	Paper
Patient consent	No	No	No	Yes	Yes	No	No	Yes
Outcome‡	S	S, W	S	S, O	S, O, E	S, W, E	S, D	S, O
Validation	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

D, orthopedic department; *E,* EuroQol-5D quality of life score; *G,* government; *H,* health department; *O,* Oxford Shoulder Score or Oxford Elbow Score; *Q,* short version of the Disabilities of Arm, Shoulder and Hand (Quick DASH); *U,* university; *UK,* United Kingdom; *W,* Western Ontario Osteoarthritis of the Shoulder (WOOS) score.

* Expected to be established in 2011.

† Funded through levies placed on the sale of the implant.

‡ Survival of the implant.

Procedures for collecting data

In all countries, the surgeon or another health professional completes a form, which is sent to the registry in paper format as mail or electronically with a direct linkage to the register. The reporting is voluntary, except in Finland and Denmark, where it has been mandatory since 1997 and 2006, respectively. The patient's consent is required in the UK, New Zealand, and Norway. The collected data differ between registries, but personal data (civil registration number, sex, age, diagnosis) and surgical data (date of surgery, duration of surgery, surgical approach, type of implant, fixation, and operative complications) are reported in most registries (Table II). The follow-up results are connected to the existing data using a unique identification number for each patient. To assess completeness of reporting, the number of joint replacements reported to the registries is compared with the data from the national health authorities.

Outcome measurements

All registries use implant survival as the primary outcome. In addition, the New Zealand National Joint Register uses the Oxford Shoulder Score (OSS) and the Oxford Elbow Score (OES), respectively, at 6 months and subsequently every 5 years,[4,5] and the Danish Shoulder Arthroplasty Registry uses the Western Ontario Osteoarthritis of the Shoulder (WOOS) index at 12 months.[18] In the Swedish Shoulder Arthroplasty Registry, the WOOS score is used at 1, 5, and 10 years, together with EuroQol (EQ)-5D quality of life score.[16] Ten high-volume centers are also measuring WOOS and EQ-5D at baseline (preoperatively). The Swedish Elbow Registry uses the short version of the Disabilities of the Arm, Shoulder, and Hand (Quick DASH) at 1, 5, and 10 years.[1] In Norway, the EQ-5D quality of life score and OSS were collected during 2010. The UK registry will use the OSS and the OES preoperatively and postoperatively at 1, 3, and 5 years for shoulder and elbow replacements, respectively. There is no additional outcome measurement in Australia or Finland.

Publications

The registries have published annual reports that can be downloaded without charge from the registry Web site. We found the following annual reports:

- The Australia National Joint Replacement Registry, Supplementary Reports 2010, Outcome of Shoulder Arthroplasty;
- The Danish Shoulder Arthroplasty Registry, Annual Report 2009 (only available in Danish);
- The Finish Arthroplasty Register, The 2002-2003 Implant Yearbook on Orthopedic Endoprostheses;
- The New Zealand Joint Registry, An Eleven Year Report 2010;
- The Norwegian Arthroplasty Register, Annual Report 2010 (available in Norwegian and English); and
- The Swedish Shoulder Arthroplasty Registry, Annual Report 2008. The Swedish Elbow Arthroplasty Registry has no published annual report but some data are available from the registry Web site.

The first peer-review article was published in 1991 and was related to the Finnish Arthroplasty Register, describing the establishment.[22] Similar articles from New Zealand and Norway were published in 1999,[12,26] from Sweden in 2001,[24] and from Australia in 2004.[11] The registries in Finland and Norway have also published articles about the risk of revision after total elbow replacement[8,29] and after

Table II Items reported to the registry

Item	Australia	Denmark	Finland	New Zealand	Norway	Sweden		UK
						Shoulder	Elbow	
Identification number	X	X	X	X	X	X	X	X
Name	X	X	–	X	X	X	X	X
Date of birth	X	X	X	X	X	X	X	X
Gender	X	X	X	X	X	X	X	X
Hospital	X	X	X	X	X	X	X	X
Date of surgery	X	X	X	X	X	X	X	X
Side operated on	X	X	X	X	X	X	X	X
Indication	X	X	X	X	X	X	X	X
ASA class	–	–	–	X	X	–	–	X
Operating theater	–	–	–	X	–	–	–	X
Operation time	–	–	–	X	X	–	–	X
Anesthetic type	–	–	–	–	–	–	–	X
Antibiotics	–	–	X	X	X	–	–	X
Anticoagulants	–	–	–	–	X	–	–	X
Grade surgeon	–	–	–	X	–	–	–	X
Surgical approach	–	–	–	X	–	X	X	X
Prior surgery	X	X	–	X	X	X	X	X
Arthroplasty brand	X	X	X	X	X	X	X	X
Arthroplasty design	X	X	–	X	X	X	X	X
Stem	X	X	–	X	X	X	X	X
Fixation (cement)	X	X	–	X	X	–	–	X
Caput	X	X	X	X	X	X	X	X
Glenoid component	X	X	-	X	X	X	X	X
Bone graft	X	–	X	X	X	X	X	X
Condition of cuff	X	–	–	–	–	X	-	X
Additional surgery	X	X	–	–	–	X	X	X
Peri-op complications	X	–	–	–	X	–	–	X
Type of revision	X	X	X	X	X	X	X	X
Cause of revision	X	X	X	X	X	X	X	X

ASA, American Society of Anesthesiologists; *UK,* United Kingdom.
X signifies item reported to the registry.

shoulder replacement.[9] No articles have been published related to the registry in Denmark (Table III).

Discussion

Funding and organization

This review shows that a registry can be successfully maintained disregarding funding and organization; however, the government and the orthopedic societies can have different intentions with a registry. The government is likely to use a registry to eliminate inferior implants and methods, with the intention to assess efficacy and lower cost. Orthopedic societies and their members are interested discovering and predicting which of the implants and techniques are underperforming and the reasons for this. The precise objectives of the registry can affect what data are collected and how the data are analyzed and published.

Nevertheless, the obvious advantage of federal funding is guaranteed financial support. Contributions from the members of the orthopedic societies and grants can be an unreliable funding source, with the risk of the registry failing, as shown by the German Arthroplasty Register.[23]

Data collection and validation

In most countries with a well-established and structured health care system, each person has a unique identification number that makes it possible for the registry to validate the data by comparing their number of joint replacements in the record with the number of joint replacements reported to the health authorities.[7] All of the ongoing shoulder and elbow joint replacement registries have reported a completeness of at least 90%, but the completeness can be compromised in several ways. In the Danish and Finnish registries, voluntary reporting has reduced the completeness in the past, and in both countries, mandatory reporting is now necessary to achieve an acceptable level; nevertheless, all other registries have voluntary reporting without any difficulties. Completeness can also be compromised by the need for patient consent, as shown in the Canadian Joint Replacement

Table III Internet site for each registry and all published articles related to a national shoulder or elbow registry

Location	Internet site	Publications
Australia	http://www.dmac.adelaide.edu.au/aoanjrr/	Graves et al, 2004[11]
Denmark	http://www.skulderalbue.dk	Not applicable
Finland	http://www.thl.fi/implanttirekisteri	Paavolainen et al, 1991[22]
		Skytta et al, 2009[29]
New Zealand	http://www.cdhb.govt.nz/NJR/	Rothwell, 1999[26]
Norway	http://nrlweb.ihelse.net/default.htm	Havelin et al, 1999[12]
		Fevang et al, 2009a[8]
		Fevang et al, 2009b[9]
Sweden		
Elbow	http://www.ssas.se/saar/pages/	Rahme et al, 2001[24]
Shoulder	http://www.ssas.se/axel/index.php	Rahme et al, 2001[24]
UK*	http://www.bess.org.uk/	Not applicable
	http://www.njrcentre.org.uk/	

* Expected to be established in 2011.

Registry[2]; however, this has not influenced the completeness of the existing shoulder and elbow registries.

Another major problem for registries is uncompleted reports that can diminish the accuracy and reliability of the data. Unfortunately, the method for handling missing data and what effort is made to increase the compliance is rarely described in the annual reports. It is desirable that uncompleted reports are sent back for revision by the appropriate person, and this is currently being done in Norway, Australia, and New Zealand.

Outcome measurements

The main outcome measurement in all the ongoing shoulder and elbow joint replacement registries is revision as an indicator of survival of the implant. This has the great advantage of being simple and reliable, but it has also several limitations. The definition of what constitutes a revision procedure may vary. Most registries define a revision as a new operation in which 1 or more of the components are exchanged, removed, manipulated, or added. Furthermore, the aim of most primary shoulder and elbow joint replacement operations is pain relief and improvement of range of motion. By defining failure as revision surgery alone we do not know if the objectives of pain relief and restoration of function have been achieved. A decision to revise depends on several factors, including patient factors (age, comorbidity, activities of daily living, and patient consent), implant factors (modularity and ease of revision), surgeon factors (skill set and experiences), and institutional factors (the length of any waiting list and resources). In this perspective, it is highly unlikely that there is international or even national consensus on when to revise. Finally and perhaps most important, survival of an implant as an outcome measurement gives no information about most of the arthroplasties that are never revised. The limitations of survival of the implant as a primary outcome measurement has been described in several studies related to hip replacement surgery.[3,10,30,31]

Recognizing the potential limitations of survival of the implant as an outcome measurement, some registries use an additional outcome measurement such as the OES, OSS, or WOOS score. These self-administrated questionnaires have become popular and are increasingly used. For large-scale long-term follow-up, a questionnaire is much easier to integrate than data collected in radiologic or clinical examinations. The most important advantages are that questionnaires do not require the time of an orthopedic surgeon and that they can be completed by the patient and returned by mail, without attending the hospital. Thus, a questionnaire is likely to have a high compliance compared with radiologic and clinical examinations. Furthermore, any influence of interobserver reliability is eliminated when questionnaires are used.

The most appropriate self-administrated questionnaire to use when the functional outcome is reported to a shoulder or elbow replacement registry is disputed. There is no evidence that some questionnaires should be preferred, but the use of different questionnaires and different follow-up times in the registries makes it difficult to pool data and to compare the results.

It is important that a great effort is made to collect missing questionnaires because low completeness can constitute a major problem, especially if the reasons for loss to follow-up are unclear. Unfortunately, this is not reported and discussed in the annual reports. Furthermore, a preoperative measurement (baseline setting) is important and recommended because it increases the level of evidence when the functional outcome is reported. This is currently being done in the Swedish shoulder registry and it will be done in the UK registry.

Publications

The outcome of modern shoulder replacement is considered to be good and continuing to improve. The Norwegian Arthroplasty Register, because of its long history, has been able to track improvement, especially of total shoulder replacement (Fig. 1). The only peer reviewed article from a shoulder registry (Norway) reported a 5- and 10-year failure rate of hemiarthroplasties of 6% and 8%.[9] Results from the New Zealand Joint Registry showed that failure of an implant (need for revision) was most likely to occur within 2 years after the operation, although numbers

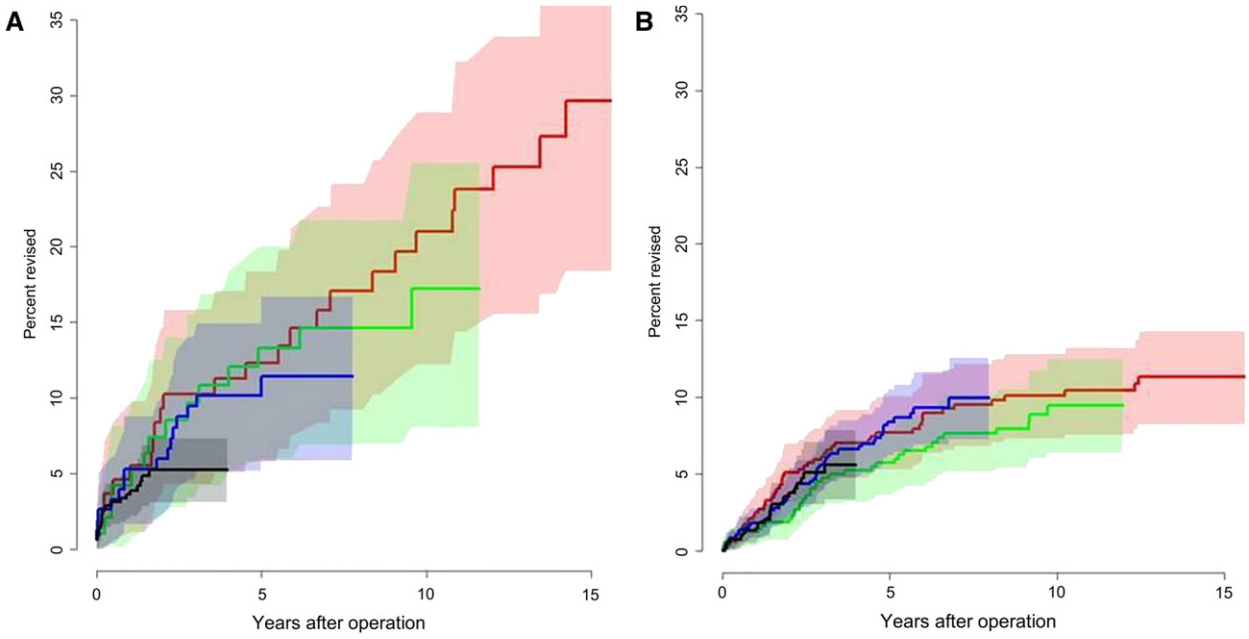

Figure 1 The cumulative revision rate after (**A**) total shoulder replacement and (**B**) hemiarthroplasty shown by data from the Norwegian Arthroplasty Register performed during different time periods marked by color (*red,* 1994-1997; *green*, 1998-2001; *blue*, 2002-2005; and *black,* 2006-2009) with *shaded areas* signifying the 95% confidence intervals.

beyond 5 years were insufficient at present to make any conclusions. The article from the Norwegian registry showed an increased risk of revision for patients operated on due to sequela after a displaced proximal humeral fracture compared with patients operated on due to an acute displaced proximal humeral fracture (relative risk, 3.3).[9]

The Norwegian registry has reported 5- and 10-year failure rates of 8% and 15% for elbow replacements. A peer reviewed article from the Finnish registry reported that operations performed at unspecialized hospitals are associated with an increased risk of revision, and an article from the Norwegian registry reported that the risk of revision was influenced by the diagnosis and by the fixation method of the ulnar component.[8,29]

Shoulder or elbow replacement are rarely performed compared with hip and knee replacement, and it is difficult to find any significant differences regarding arthroplasty design and brands; however, as the data increase, the registries will become a valuable tool for obtaining knowledge on risk factors, functional outcome, and implant survival. The registry data will complement clinical randomized trials and longitudinal studies for the continuing improvement of shoulder and elbow replacement.

Limitation and advantages of registry studies

A registry study has some limitations. There is no predefined objective and control over who is included and what implant is used, and because the patients are not randomly allocated, there is a possibility of different distributions of covariables that influence outcome. This can make it difficult to compare groups (selection bias). Furthermore, low completeness and erroneous reporting can make the results from a registry unreliable. Finally, as previous described, implant survival as the primary outcome has several limitations; the most important is that there is no information about most of the implants that are never revised.

Nevertheless, there are also several limitations in randomized clinical trials and longitudinal studies compared with registry studies. Randomized clinical trials are laborious, expensive, and unsuitable for long-term monitoring. In addition, considering the low rate of revision, it is very difficult to find any significant differences regarding revision in these often-small studies. Furthermore, randomized clinical trials and longitudinal studies restrict the patients studied by use of inclusion and exclusion criteria in an attempt to make the patients as homogeneous as possible. However, among the disadvantages of this is that the results may not be valid for all age groups, for example.

Finally, the surgeons in clinical randomized trials and longitudinal studies are often more experienced and interested in the specific type of operation rather than in general orthopedics. Therefore, these studies do not always reflect the learning curve, which can influence the early results and the results from small centers with few operations. It is likely that randomized clinical trials and longitudinal studies provide information that cannot always be generalized to the average hospital and surgeon.[20]

Among the greatest advantages of registry studies are their ability to undertake comprehensive long-term monitoring.

Because of the large numbers studied, it is possible to find significant differences in the revision rate between different arthroplasty designs. Furthermore, a national registry has the ability to monitor new implants and to identify potential problems and inferior results before they are reported in conventional studies, as shown by the Norwegian and Swedish Hip Arthroplasty Registries.[6,13,14,17,19]

Conclusion

There are few replacements of the shoulder and the elbow compared with the hip and knee, and even in national registries, the number of reported replacements is often limited. It would be desirable to pool data from the separate registries into a larger international registry; however, this does seem very ambitious. First, as shown in this review, there are essential differences between the registries, especially regarding the outcome measurement. Furthermore, it is highly likely that there are differences between countries regarding process and structure of their respective national health care systems, involvement of medical insurance companies, diagnostic criteria, traditions such as the surgical approach, rehabilitation program, and use of antibiotics, among others, It is more likely that a small number of countries with established registries can collaborate and pool their data. This has been shown by the Nordic Arthroplasty Registry Association (NARA), which has published articles about hip and knee replacements in Denmark, Norway, and Sweden.[15,25]

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