Comparison of the information in arthroplasty registers from different countries

This article considers some of the problems of the interpretation of information from other national arthroplasty registers when setting up a new register. In order for the most useful information to be available from registers much international co-operation is required between all those responsible for the design of registers as well as those who gather, assess and publish the data.

The national arthroplasty registers in Scandinavia have proved to be important in the assessment of quality of outcome, and have made an essential contribution to advances in arthroplasty. They have demonstrated that it is possible to collect data of sufficient quality on a national scale, allowing assessments to be made that are applicable to the overall activity in a country, which is an essential difference from sample-based studies or surveys. The publications from these registers are recognised worldwide and are appreciated for their high validity.

In the last few years, several countries have initiated projects for their own national registers. The Scandinavian model of a nationwide register run by a central organisation involving the national orthopaedic societies in co-operation with public health authorities has generally proved to be efficient, and the newer registries have followed these models. However, as each national register should be an integral part of the public health system, it is necessary to adapt its basic concept to the specific national model concerned.

The registers considered in this article are based on a definition worked out by the European Arthroplasty Register (EAR) in co-operation with the established European registers and The European Federation of National Associations of Orthopaedics and Traumatology (EFORT). It defines the aims of the register as: (i) registration in a central database of all primary and revision operations performed in a defined geographical area; (ii) follow-up of the implant until it has to be revised or the patient dies or emigrates; and (iii) failure to be defined as a revision of at least one part of the implant.

The new national registers in Slovakia, Romania, Australia and Canada have already presented their first annual reports and publications. The number of annual reports and publications from registers in peer-reviewed journals has increased, and will continue to do so. It is highly desirable that such information should become increasingly available.

Basic principles of a register
Arthroplasty registers collect information about primary and revision operations performed in a defined geographical area, usually a single country. They automatically reflect the standards prevailing in these surgical procedures and in that particular public health system. Differences between countries might affect the outcome of the intervention. Experience with differences in cementing techniques or designs of implant, surgical approaches, regimes of rehabilitation, or general features of public health such as the availability of medical care, are examples. General epidemiological conditions such as the life expectancy of the population may also have to be taken into consideration in the evaluation of raw data.

The quality of the basic data is fundamental to all analyses. Completeness of registration is the most important parameter for assessing the quality of the registries. Communication and mechanisms of feedback comprise the annual report open to the public, and usually each participating department also has access to confidential reports, including a breakdown of the performance of that department compared to the national average or other benchmarks.

Within each department, this information forms an essential basis for an autonomous
and continuous process of improvement, the influence of which can be clearly gauged from the progress made in the individual countries.\textsuperscript{1,8,11} Public discussions about the potential for improvement in individual departments would certainly be counterproductive. When publishing results, it is therefore advisable to proceed sensitively with the mutual consent of all concerned.

**Examples of the evaluation of register publications and the value of statements**

Because of the specific characteristics of the data sets of registers which are better suited to control confounders within a country than are sample-based studies,\textsuperscript{19} inferior outcomes can be registered more quickly. An example of this was published by the Norwegian Arthroplasty Register.\textsuperscript{20} In the data from the first six years (1987 to 1993) a cohort of 2907 cementless stems was examined. Two of the implants used showed a statistically significant increase in the rates of re-operation after a short-term follow-up with relatively small numbers of cases, 210 and 173 primary implantations respectively. The use of these implants was then stopped. It was possible to identify implant-specific factors related to the increased rates of loosening. Such findings are of considerable value in other countries where a corresponding product is used.

In general, it is easier to reliably identify negative deviations from the average rather than positive ones, and the conclusions are more valid if data from several sources follow a similar distinctive pattern.

The situation becomes more difficult if the data do not represent a clear trend, or if the information from a foreign register contradicts the general experience in a given country. Such a situation arose when diverging data for the Alloclassic Stem were published in the 2006 Annual Report of the Australian Register.\textsuperscript{18}

Using similar acetabular components which were therefore unlikely to be the cause for the differences, a cohort designated as ‘Alloclassic SL’ showed revision rates of between 0.6% and 0.8% in the parameter ‘performance per 100 observed component years’. Another cohort designated ‘Alloclassic’ showed significantly higher rates of between 1.7% and 2.3%. In Central Europe, where this implant originated, good results have been seen in clinical studies with a long-term follow-up.\textsuperscript{20-26} The Australian results were of concern to the European user. Further investigation showed that the terminology used in the Australian report did not correspond with that used in Central Europe. Comparison of the two sets of data only became possible by referring to the manufacturer’s item numbers, because their product designations are not consistent worldwide. According to the Australian Register, the cohort ‘Alloclassic SL’ is largely homogenous and corresponds to the implant with the same name that is widely used in Europe. However, it was eventually established that the Australian series included a mixture of variants of the Alloclassic product family, such as those with an increased offset, the Alloclassic SLO (larger offset), and the Alloclassic SLL (longer stem), which is usually used in revisions. On the basis of this additional information the data stated in the register report were re-analysed but neither divergence in results because of the case mix nor an increased occurrence of revisions because of the use of a variant of the implant with an inferior performance could be clearly identified.

Hemiarthroplasties are recorded in both the Australian and the Romanian registers. These implants are normally used to treat fractures of the femoral neck in the elderly, as the duration of surgery is short and this reduces the problems of anaesthesia and operative trauma in frail patients. Problems with acetabular erosion would not be relevant in these patients in view of their limited life expectancy.

For economic reasons, and because of the limited availability of implants in some rural hospitals in Romania, these implants have sometimes also been used in younger patients for the treatment of osteoarthritis causing some controversy within the national orthopaedic society. According to the register, 13% of patients who received this implant were under the age of 65. The highest incidence of revision procedures was in patients between 65 and 74 years of age. As a result of the relatively short period of time that registers have been active, both primary and revision operations have been recorded only for a small group of patients. A comparison between the Romanian and Australian registers confirms that the indications for treatment differ in the two countries. However, if the average life expectancy in these countries is included in the analysis, the rate of revision following the use of hemiarthroplasties is the same.

**Discussion**

It is difficult for a register, whose annual report is primarily drawn up for orthopaedic surgeons and the healthcare system of a certain country, to address all the demands of foreign readers. Those who live and work within a certain system are aware of the circumstances prevailing in the country concerned. An exhaustive explanation would considerably and unnecessarily extend the length of the report of a national register. Furthermore, only part of the information is available to the public and to international readers. The data of national registers for users outside the actual area to which they relate cannot usefully be processed by local authors alone. This would require co-operation between the authors of the reports of a national register, who have access to the basic information, and interested persons from abroad. Discussions at conferences could foster co-operation, and those holding key positions in national arthroplasty registers must be willing to invest much time and energy in order to make appropriate presentations. It is, however, obvious, that despite great commitment, the possibilities of direct contact are limited.

Specific questions could be dealt with by contributions in peer-reviewed journals. However, even this pathway is unlikely to fulfil the needs of interested readers and to make
use of the wealth of information contained in a register. Authors from a national register are familiar with their own national data set, but reference values from other countries should be collected and evaluated.

This is a complex task that can only be fulfilled in cooperation with all the partners involved and demands considerable resources. The EFORT and the EAR have addressed this issue and are attempting to generate added value for the international scientific community. Besides analysis of the results from different international registers, this should in future also comprise compiling background information about the circumstances under which the data have been collected and analysed. These activities are complex and must be considered in the long term.

The standardisation of product designations on an international scale would help in allowing conclusions to be drawn from registers in different countries. This would help in the preparation and interpretation of meta-analyses from literature published in peer-reviewed journals. Realistically, manufacturers are unlikely to change their practice in product designation and marketing for this reason in the short term. However, ideally a reference database should be established to determine exactly which information should be evaluated.

Registers allow for a relatively quick recording of increased revision rates for implants and detailed analysis of these cases. The patients concerned and departments holding relevant information, such as medical histories and radiographs, could be identified via a register. Studies of this kind could offer valuable information with regard to mechanisms of failure. The registration of increased rates of loosening depends principally on the number of primary operations performed and the divergence of the cohort from the mean value, taken as a reference. Identification of potential influencing factors may require further evaluation, as more detailed information would be needed than is currently available in the register datasets.

Problems encountered with a specific implant might have fundamental causes which could also affect further similar products from other manufacturers. Low-carbide metal-on-metal bearings are an example. The analysis and publication of such mechanisms could provide valuable information in the selection of currently available products and facilitate the improvement of future designs. However, these opportunities are limited at present. It will be necessary to address the legal aspects and funds would be required outside the regular budgets of national registers or EFORT-EAR. Such analyses are not part of the core activities of registers nor national public health institutions, which largely provide the financial support for national registers. However, such information could, for instance, be helpful for the work of European Union (EU) authorities responsible for licensing and product safety.

Whether implant manufacturers could also be involved in such co-operation remains to be seen. At present, no such cooperation exists.

Within the EU, projects have been launched to investigate and redefine outcome measurement in the field of medicine, with the experience gained by registers in the orthopaedic field playing an essential role. The reclassification of joint implants into Risk Class III will most probably lead to changes in EU monitoring.

The aim when establishing registers of this type both in Europe and worldwide is to provide physicians with information of the highest quality. The best way to achieve this is through extensive co-operation of the various specialties within arthroplasty registers and scientific societies.

We thank all who have collected and documented the data and contributed to the success of registers and to further developments in arthroplasty. We also thank the staff of the Scandinavian registers who willingly shared their experience and have committed themselves to participate in the establishment of registers in further countries. Finally, our acknowledgement is due to EFORT for its commitment to supporting registers, their development and their scientific work from the very beginning of supranational activities.

References


