This article considers the establishment, purpose and conduct of knee arthroplasty registers using the Swedish register as an example. The methods of collection of appropriate data, the cost, and the ways in which this information may be used are considered.

Arthroplasty of the knee using ivory implants was first undertaken in 1890. Later, metal spacers and acrylate hinges were used, but the real advance came in the 1970s with the principle of low-friction arthroplasty, initially developed for the hip by Charnley. In the early 1970s Bauer, who was Professor of Orthopaedics in Lund, Sweden, had the foresight to realise that there would be a need for a multicentre project to gather enough experience to judge the performance of the newly-designed knee implants. He became the major promoter in initiating the Swedish Knee Arthroplasty Project which was formally launched in 1975. The aim was to give early warning of inferior designs and present the average results based on the experience of a whole nation. Although individual institutions such as the Mayo Clinic had started registering their arthroplasties in 1969 the Swedish Knee Arthroplasty Register (SKAR) was the first national register of its type. Since then, national or regional arthroplasty registers have been established in many other countries (Table I).

Which data to collect?
The present registers can be defined as health technology audits which follow the results of specific surgical interventions. To be able to do this the most important variable to collect is a unique identifier for the patient. In Nordic countries every inhabitant has a social security number which is printed on every identity card and passport and is widely used by the inhabitants in their contact with companies and authorities. This number allows for the easy tracking of patients if they undergo revision in a new location and for tracking of those who die and those who leave the country permanently. When such an identifier is not available, follow-up is much more laborious and expensive. Although it is desirable to collect as much information as possible, in large multicentre registers there appears to be an inverse relationship between the amounts of information asked for and the quality of data delivered. The real value of information depends on the completeness and accuracy of the data. Many registers have had to give up their initial ambitious use of extensive datasets since the returns were so incomplete as to render the information useless. The SKAR learned early on to limit the dataset, but to try to ensure completeness of the information collected. If the results are to be compared with those of other registers, it is essential that similar variables are collected. In an effort to provide an international consensus on the collection of data, interpretation and reporting, a group from the various international registers has been meeting to prepare the establishment of an International Society of Arthroplasty Registries. It has suggested a core minimum dataset including the specific identification of all components used, details of the individual having surgery and of the operation itself (Table II).

The measure of outcome
The principle of register studies is to establish a prospective follow-up of patients after surgery with no predefined control as to who is included or of the implants used. The routines for follow-up are those practised at the participating units and thus may vary. This is quite different to the arrangements for therapeutic studies in which there are strict inclusion criteria and follow-up routines. The lack of predefined follow-up makes register studies unsuitable for studying results which depend on formal post-operative clinical or radio-
logical follow-up. However, there is one event which consistently brings the patient back to the hospital and can be precisely registered, namely the need for a revision operation. Although revision is a crude measure of failure, it is difficult to measure success or failure in the context of surgical intervention when the primary objectives of a treatment may be different. Even with seemingly obvious failures such as loosening, instability and wear, there is a lack of consensus on definitions, and clinically they may not be easily distinguished in elderly patients. Thus, the main outcome measure in register studies has been the need for revision as a measure of survival of the implant. This information in combination with a careful analysis of the reasons for revision has then been used as a measure of failure for the different procedures. This method has some disadvantages, as has been pointed out by Murray, Carr and Bulstrode. Failures which are not revised for medical or other reasons do not become registered and patients may be lost to follow-up. However, registers may access softer data by use of self-administered questionnaires and this practice will probably gain further popularity since it may deliver information about the patients who never come to revision.

**Registers versus randomised studies**

The randomised, controlled trial (RCT) provides the best evidence. However, it is a laborious and costly process and such trials are not suitable for large studies over a long period of time. Many of the RCTs which have been conducted on patients with knee arthroplasties have focused on matters which were not related to the implant. The outcome measures assessed were usually factors which could be determined in a relatively short time on a numerical scale, such as bleeding, level of pain, length of stay and range of movement. Most of the studies which have focused on implant- or fixation-related problems have often examined short-term factors such as early migration and post-operative alignment. Due to their limited methods of follow-up, register studies can never replace the RCT. However, the question is whether the RCT can replace register studies when it comes to long-term evaluation of different procedures. Considering the relatively low rate of revision of knee arthroplasty with an approximate cumulative revision rate of 5% at ten years, a very large number of patients is required in order to prove that there is a significant difference between two implants. In order to have an 80% chance of detecting a significant difference for an implant with a 30% worse revision rate (6.5% vs 5%) almost 4000 patients would have to be randomised and followed for ten years.

It is clearly difficult to arrange an RCT with these numbers of patients. There are relatively few large long-term RCTs and a search of the literature has not revealed any which compared two different types of implant.

**Registers versus focused longitudinal studies**

Perhaps focused longitudinal studies from large centres with a more controlled follow-up would be as good as or better than those with a register when investigating the outcome of arthroplasty. A large part of the long-term investigations published are of this type. However, such studies may not reflect the average results which may be achieved. It is customary to set inclusion criteria to make the groups studied as uniform as possible, and hence the results may not be valid for all types of disease or age groups. The studies are often started long after the surgeons have become acquainted with the instruments and implants and therefore do not reflect the learning curve which may affect early results. Also, the surgeons at centres performing such studies are more experienced and interested in this type of surgery than the general orthopaedic surgeon and therefore their results may be better, but provide information which cannot be readily generalised.
The publication bias

Studies published in the literature may not be a representative sample of all the studies performed since there may be a tendency for research with a positive outcome to become published more easily than that with a negative outcome. This may be due to journal bias but is probably mainly because researchers do not submit studies with a negative outcome.12

It is therefore not surprising that a large number of survival studies published from individual centres during the 1980s and 1990s described much better results for knee implants than those found on a national level in Sweden by the arthroplasty register. Many good results have originated from large centres in the USA, but figures show that the proportion of revisions performed for knee arthroplasty in the USA13 has been higher than that in Sweden (taken from the SKAR) (Fig. 1), indicating that many of the published results from individual centres do not reflect the average results.

The benefits of register studies

Registers have a number of benefits. They allow analysis of epidemiology and demography as well as of outcome. By monitoring the national results they are able to give an early warning of underperforming implants and methods. As results are being closely watched, surgeons are less likely to use methods or implants which have not been properly tested. By disseminating the findings and allowing hospitals to compare their results with those of the country as a whole, hospitals and surgeons are stimulated to perform their best. They enable surgeons to be advised regarding optimal methods, implants and selection of patients.

Patients can be informed of the potential outcome, why specific methods are preferred and when to wait or to proceed with surgery. Purchasers of medical care can be provided with information on how previous decisions and financing have affected volumes and results, and can be advised as to future trends regarding the need for primary and revision surgery. Finally, since the part, and Lot numbers are registered, implants can easily be tracked if recall is necessary.

Some drawbacks and how to address them

Data in the register may be biased by selection, be incomplete or erroneous. It is important that there are protocols regarding how data are gathered, how incomplete data are assessed and how they are treated and saved. Further, it should be possible to track all information to the original source and there should be protocols for validation. This not only makes the information credible but allows for early reaction to situations in which improvement is required.

Registers provide crude monitoring and are not suitable for detailed analyses regarding clinical outcome, but they provide information which can identify problem areas and are a basis for further in-depth analyses.

Registers may hinder evolution and progress by deterring the introduction of new methods and implants, forcing surgeons to use only implants which are well documented in the registers. While this may be the case, for hospitals not involved in research it may constitute a sensible approach. However, the example of mini-invasive surgery, which was quickly adopted in Sweden14 in spite of little scientific evidence, indicates that this is probably not a major concern.

Registration takes time, and in an effort to minimise this it is important to select carefully the variables needed and the timing of their registration, as well as involving staff other than physicians as much as possible. The minimal dataset form used by the SKAR can be completed by staff during the operation with the help of the surgeon who has only to answer a few questions.

Ownership and control

The ownership of a national register must depend on the legal, financial and organisational circumstances in each country. In Sweden, official health care is provided by the counties and the registers are formally owned by the Federation of Swedish County Councils.

The body in charge of collecting, analysing and interpreting data is perhaps more of an issue than the formal owner. Many of the present registers were started by orthopaedic societies and are being controlled by the profession. However, the Finnish Arthroplasty Register,15 the Canadian Joint Replacement Register16 and the England/Wales National Joint Registry17 were implemented by health authorities. However, no matter who is in charge there may be controversy regarding the issue of control and access. With the England/Wales National Joint Registry there has...
been widespread concern among consultants regarding the lack of orthopaedic representation in the steering committee and how the data were being used.\textsuperscript{18} By contrast, in Sweden the National Audit Office has recently complained that the data contained in the quality registers were difficult to access for the authorities and did not always contain data relevant for official quality control.\textsuperscript{19}

Hospital administrators and the profession seem to have differing opinions regarding the use of registers. It is important to realise that the first orthopaedic registers were initiated by interested surgeons who required information on outcome and complications. The purpose was to give an early warning on inferior methods and implants, to analyse what had gone wrong, to learn from mistakes and to be of assistance in the development of better methods and implants. Their scientific findings were mainly disseminated by articles in peer-reviewed journals and at national and international conferences.

In Sweden this contrasts with the requirements of the authorities and administrators of the present streamlined health-care systems. They mainly regard registers as benchmarking tools which can be used quickly to eliminate methods, implants, surgeons or hospitals which are found to be underperforming. While the goal of accessing efficacy and costs is praiseworthy, the deeper-lying purposes seem to be less of an issue and therefore there is a tendency to avoid in-depth analyses requiring medical insight. In an effort to achieve quick results, there is a trend for peer-reviewed publications to be replaced by administrative reports.

How can the wishes of both administrators and researchers be respected? Since many countries already have large central databases to keep track of patient treatment in hospitals, mainly for economic purposes, and as more and more medical records are being computerised, should not the information gathered in the present registers be combined into a super-database? Although theoretically attractive, this would be difficult. In Sweden, there are presently 57 different national registers and to agree on and to design a practical working system for all of them would be an enormous task. Further, the quality and control of the coding would still be a problem and such a registry could not respond to changes in the collection of variables.

Thus, it seems that individual registers will be around for some time to come. They should try to collect and to analyse data of interest to both researchers and administrators. It is important to realise that without proper research there will be no basis for real improvement in quality.

Registers have now become important tools in evidence-based practice. New implants and methods are constantly being introduced, some of which will not perform as expected. Registers will continue to be important tools for detecting problems and minimising damage for years to come. They are important for the specialty as a whole since a profession with good documentation is better equipped in the competition for strained medical resources. Purchasers of medical treatment are more willing to provide finance when the effects of previous funding can be shown, the results of treatment documented and future trends predicted.

References

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