Editorial

Knee registries

The first ever national patient registry was established in Norway in 1856 for the disease leprosy [1]. This formed part of a programme to control a disease which at that time was a major health problem not just in Norway but throughout the world. Whilst other disease specific registries followed, it was over a century before we saw a registry for a specific medical device-knee joint replacement.

The well-known business aphorism “if you can’t measure it, you can’t manage it” is generally credited to the Austrian–American management consultant Peter Drucker. Perhaps with this in mind, the Swedish Orthopaedic Society in 1975 commenced the Swedish Knee Arthroplasty Register with a small group of approximately 20 surgeons led by Prof Göran Bauer who regarded knee arthroplasty as a large scaled human experiment that should be monitored with respect to safety, outcomes and failure rates. Financing was initially with the Swedish Medical Research Council and with grants. Data was stored in a mainframe computer and included assessment of the Ahlbäck classification and follow up was at 1, 3, 6, and 10 years. Incomplete data collection altered the registry’s mindset believing complete information on a few variables was superior to incomplete information on many [2]. Subsequently many nations have followed suit with a state-of-the-art review in this issue describing 23 arthroplasty registries along with eight for ligament, four for osteotomy and three for articular cartilage surgery [3]. The Australian Orthopaedic Association commenced their National Joint Replacement Registry (AOANJRR) with an application to the National Government in March 1998. The specific aims were:

- Determine the demographic and diagnostic characteristics of patients undergoing joint replacement surgery.
- Provide accurate information on the types of prostheses for primary and revision replacement.
- Evaluate the effectiveness of different implants and techniques.
- Compare the results in the Australian Registry to other nations.
- Provide confidential outcome data to individual surgeons and hospitals.
- Educate Australian orthopaedic surgeons in the most effective prostheses and surgical techniques [4].

These lofty goals are consistent with just about every knee registry irrespective of the type of knee surgery being measured. We should ask if they have been reached. Should we continue with registries or are there better, more relevant and accurate methods to assess and ultimately improve our surgery.

A management consultant whose interests lay in better outcomes following knee surgery would ask these questions of registries. Which parameters are to be measured, how is the data to be stored and analysed and how will it be promulgated so that the expense and effort resulted in improvements? And finally-have registries made a difference? A cost benefit analysis should at the very least demonstrate that knee registries produce better outcomes for both patients and health systems whilst reducing costs. Measuring the correct parameters is important. To the sceptics who see few benefits in registries, the words of James Willbanks, a former USA soldier in his collection of essays on the Vietnam War ring true—“if you can’t count what’s important, you make what you can count important.” A picture of what’s truly happening in a particular hospital, region or nation requires all to participate—a challenge that has alluded some nations. For example, the largest joint registry in the world, the American Joint Replacement Registry (AJRR) in USA currently captures less than one half of all arthroplasty procedures in that nation and minority groups are underrepresented in the data. And the two most populous nations—India and China—do not have national registries. As a consequence, the majority of knee replacements worldwide are not captured.

Most registries are funded by national governments but few provide information on expenses and budgets. The AOANJRR is supported by the Australian Federal Government with an annual budget of approximately 2.6 million Australian Dollars. The Government then seeks reimbursement from the implant companies based on usage. The estimated cost per procedure is twenty-five Australian dollars which is dwarfed by the average total surgical cost of somewhere in the vicinity of $30,000 per patient. Despite that relatively small cost, one of the reasons for lower participation with the AJRR in the USA currently 28%—is that the expense is borne by individual hospitals and practices. Participation in the AJRR costs $4000 each year for each institution but there are also initial start-up costs, in time, effort and money, which are required to sync the AJRR to the institution’s electronic medical record [5].

In Latin America, the development of TKR registries has proved elusive-in part due to lack of funding but also to the difficulty in obtaining high levels of participation. Interestingly, the Argentine Arthroscopy Association have developed and published on their ACL registry demonstrating the value of large data sets on a specific surgical procedure [6]. A remaining challenge for Asia and much of Latin America is that many nations still lack a well-organized and well-documented registry. Whilst some countries including Japan, Iran, Taiwan, and Pakistan have managed to establish national registries, it is hoped more will do so in the future.

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Registries have been front and centre for the past 20 years and that there have been significant benefits is undoubtedly true. Implants with a higher-than-expected revision rate have been detected sooner than post market surveillance would allow and subsequently withdrawn, an example being the ASR hip. Outliers—either individual institutions or surgeons have been identified and counselled. Data on revision rates has seen changing trends in the performance of surgery, for example the incidence of patellar resurfacing at primary arthroplasty is climbing steadily in nations with a recently commenced registry such as Australia, which is likely a response to registry data [7], yet remains very low in nations with longer standing registries including Norway and Sweden [5]. Those critical of registries would suggest this could be considered over treating for some patients who may have a similar outcome with patellar bone preservation.

Evidence for registries changing behavior can be seen in the higher rates of total replacement over partial replacement in nations with a registry. For example, the rate of unicompartimental replacement (UKR) in Australia fell from a high of 14.5% of all knee replacements in 2003 to 6.2% in 2020 [8]. It is reasonable to infer surgeons prefer to maintain their low registry revision status by using an implant that is less likely to require revision than risk partial replacement with an implant that has twice the revision rate—even if the patient’s function may be better with the partial replacement.

Evidence Based Medicine has established randomised controlled trials (RCT) as the definitive method to answer research questions. However, an RCT is not always generalizable. Registries do tell us what is happening in the real world. If a surgeon were to ask a simple question such as—should the tibia always be cemented—a registry will give the answer with far greater numbers which are derived from the general orthopaedic population rather than a randomised trial with smaller numbers from an elite unit. However, registries and RCT’s are not mutually exclusive with registries having a significant involvement in some randomised studies. Two examples of nested studies within a registry in Australia are the CRISTAL trial comparing Aspirin with Enoxaparin for thrombo-prophylaxis in single TKR and another comparing alignment strategies, computer navigation and robotic surgery.

Whilst registry generated change in surgeon behaviour is usually beneficial, some potential negative consequences remain including the risk of bias as well as concerns about data quality [9]. Registry data does not make any allowance for the learning curve effect inherent in newer implants. Surgical techniques and implant technology evolve over time so that data provided in an earlier period may not reflect the revision risk at a later time. Another potential consequence is the prospect that patients with a higher risk of complications including revision having more difficulty finding a surgeon who will agree to operate. Similarly, a surgeon may inappropriately advise against his or her patient undergoing revision surgery when that procedure is indicated. Registry avoidance behaviour has been seen in Australia where patients undergoing debridement with implant retention do not have an exchange of the tibial polyethylene, thus not appearing in that surgeon’s registry data as a revision. Steps to detect such behavior and improve the accuracy of the registry have been taken with data linkage to review hospital admissions, surgical billing and antibiotic prescribing thereby improving data quality.

Another challenge is stratifying the varying circumstances in which surgery is performed and data collected. Teaching hospitals have joint replacements carried out under supervision by orthopaedic trainees who in most registries do not have an identifying number. Any subsequent revision will be allocated to the supervising surgeon. The potentially higher risk of revision following trainee performed surgery may result in an increased reluctance to allow trainees to operate. That same trainee will later commence practice potentially with less experience and typically with a small number of replacements in his/her early years of practice increasing the potential to become an outlier.

It must be pointed out that most replacement registries only measure a single outcome—revision of the implant, either partial or complete. Whilst this is a definite and solid end point, it does not capture some very unsatisfactory outcomes—from the stiff painful knee or the unstable knee that is never revised and even the patient with a vascular complication who has an amputation. The administration of suitable PROMS at 12 months will help registries identify outlying implants, institutions and individual surgeons as well as implants with better function. The New Zealand registry is commended for administering the Oxford Score in ten percent of its hip and knee replacement patients. The ceiling effect of some PROMS needs consideration and perhaps the Forgotten Joint Score could be used by those registries administering PROMS. Similarly, registries can improve our decision making by the collection of more data. The AOANJRR commenced collecting American Society of Anaesthesiologist score and BMI data in 2016 and this information along with data on medical comorbidities which have been shown to adversely affect outcomes of surgery will greatly enhance surgical decisions.

Comparing PROMS across international boundaries remains a challenge especially between Western populations and Asians [10]. Achieving painless daily activities such as walking, stair climbing and chair rise may denote a successful outcome in Western populations but more is demanded by Indian, Chinese, or Japanese populations whose routine activities of daily living and culture includes sitting cross-legged, crouching, and kneeling. Failure to achieve these activities may not be reflected in Western derived PROMS. Asians also tend to avoid revision replacement in part due to fear of a second surgery but also with a lack of facilities in rural areas, especially in less educated third world countries, which will confound the revision rate. Accordingly, local population based registries if available are more suitable in these regions rather than adopting the registry ideals from other countries [10].

What are the challenges that lie ahead for registries? All surgery is evolving. When the Swedish Knee Arthroplasty Registry began in 1975, neither computer navigation nor robots in the operating room were known or anticipated. Changes have occurred and more will come. Registries must continue to evolve—evaluating the newer techniques—currently the use of various robots remembering that they are not all the same—but also all the future changes that will inevitably occur. We are seeing a plethora of new alignment strategies with many surgeons moving away after several decades of mechanical alignment to kinematic alignment and to subtle variations including restricted kinematic alignment, inverse kinematic alignment and functional alignment. Whether the surgeon actually achieves the intended alignment is a separate issue that will require three-dimensional post operative imaging in further nested registry studies. Data ownership and more so its utilisation has the potential to be a major concern for registries now and in the future. Whilst registries have always had ownership of their data, individual surgeons may use the data unethically and governments and health authorities may similarly use data to exercise control over hospitals or individual surgeons. Appropriate legislation will help avoid these scenarios and help ensure participation. It is earnestly hoped that registries will keep pace with the changes in surgery as they occur and continue to fulfill their potential to provide all stakeholders with timely information that improves patient’s outcomes.

References
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