



Australian  
Orthopaedic  
Association  
National  
Joint  
Replacement  
Registry

# NATIONAL JOINT REPLACEMENT REGISTRY

## *Data Collection Information/Protocol*

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## **1. TITLE**

Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR)

## **2. INVESTIGATORS**

The Australian Orthopaedic Association National Joint Replacement Registry is an initiative of the Australian Orthopaedic Association (AOA). It is owned and managed by the AOA. The AOA Board of Directors is responsible for the management of the AOANJRR and has established the Registry Committee to oversee the AOANJRR.

The Registry Committee comprises of the:

AOA Registry Committee Chair (appointed by the AOA Board)

AOA Vice President

Registry Clinical Director

Registry Clinical Deputy Directors

Research Committee Chair

Board approved nominees from:

Foot and Ankle Society (where there is not expertise in AOANJRR)

Shoulder and Elbow Society (where there is not expertise in AOANJRR)

Spine Society of Australia

Neurosurgical Society of Australasia

President of the Arthroplasty Society of Australia

Representative of the Knee Society

State Branch Chair Committee Representative (where there is not a committee member from that state)

Consumer (patient) Representation – up to 3

The Registry Clinical Director and Deputy Registry Clinical Directors are responsible for the day-to-day clinical management of the AOANJRR. AOA employs an Executive Manager – Registry Services who is responsible for oversight of liaison with hospitals, industry and government to ensure effective data collection and site coordination.

The South Australian Health and Medical Research Institute (SAHMRI) is currently contracted by AOA to provide data management and analysis services to the AOANJRR.

## **3. INTRODUCTION**

AOA, the medical devices industry and Commonwealth Government recognises that the outcome of joint replacement surgery is an important health issue. Following a successful application by AOA in March 1998, the Commonwealth Government provided funding to establish the AOANJRR. The AOANJRR continues to be funded by the Commonwealth Government through the Department of Health and Aged Care cost recovery process. In June 2009, legislation was passed through Federal Parliament to permanently fund the AOANJRR, thus ensuring its long-term stability.

The purpose of the AOA National Joint Replacement Registry is to:

- Define the practice and improve outcomes of joint replacement surgery in Australia
- Provide an auditing facility to Australian orthopaedic surgeons that will enhance the success of joint replacement in Australia

Privacy and consent issues that are relevant to this application include:

1. The AOANJRR was first declared a Federal Quality Assurance Activity under the Commonwealth Health Insurance Act 1973 in 1999, and this continues to be maintained by the Registry ongoing (REFER ATTACHMENT 9 for the most recent declaration)
2. No direct patient contact is required by AOANJRR staff
3. Patient confidentiality will be maintained
4. Patients will be informed about the AOANJRR

5. Consent will be obtained using an 'opt out' approach
6. No individual patient, surgeon or institution will be identified in reports produced by the Registry
7. Data will be stored securely

During 1998, the Registry undertook a pilot study to determine the most appropriate method of data collection, transfer and analysis as well as finalising management arrangements for both the Registry and data. Information presented in this application is based on the results of this study.

#### **4. AOANJRR IMPLEMENTATION**

Implementation of the AOANJRR was undertaken in a staged manner commencing in South Australia in September 1999. Full national implementation was achieved by mid-2002. Initially hip and knee joint replacement data only was collected; however, following a request from the Commonwealth Government in 2006, data collection was expanded to include shoulder, elbow, wrist, ankle and spinal disc replacement. In November 2007, implementation of data collection of these additional joints commenced nationally. After a successful pilot in 2017 and subsequent rollout, knee osteotomy procedures have been included in the national data collection. The Registry is now in the process of obtaining approvals to collect ankle arthrodesis procedure data from all hospitals nationally.

#### **5. BACKGROUND TO THE AOANJRR**

Joint replacement surgery is a common procedure in Australia, with over 110,000 hip and knee replacements undertaken nationally each year. Approximately 10,000 other joint replacements such as shoulder, elbow, wrist, ankle and spinal disc replacement are undertaken each year. In addition, there are up to 1,200 knee osteotomy and up to 1,500 ankle arthrodesis procedures performed each year.

Joint replacement has considerable success in alleviating pain and disability in individuals suffering a variety of major joint disorders. The procedure is most commonly performed in the elderly population; however, the success of the procedure has led to increased use in younger individuals. This, combined with an aging population has resulted in an increased incidence of primary joint replacement.

A large variety of prostheses have been developed and are currently available on the Australian market. However, prior to the implementation of the AOANJRR the mid to long-term survival of the majority of these was unknown. It is well established that there is considerable variation in outcome for different prostheses. Surgical technique and specific patient characteristics also affect outcome. Prior to establishing the AOANJRR, inadequate outcomes data for the majority of prostheses, as well as variability related to different surgical techniques and diagnostic groups, made it difficult for surgeons to identify the relative effectiveness of different prostheses and treatments.

Until the implementation of the AOANJRR there was no reliable information on the demographics of the population receiving joint replacement, the total number and type of joint replacements, the incidence of revision surgery and importantly the results of this surgery within Australia. The AOANJRR provides essential information necessary for resource planning and improved outcomes.

A national Registry simultaneously monitors all types of prosthetic design. It is the most effective method to determine which prostheses and surgical techniques are most successful for given demographic and diagnostic sub-groups. A number of registries have been established in other countries. The ability to identify factors important in achieving successful outcomes has resulted in both improved standards and significant cost savings. We cooperate closely with these international registries and the AOANJRR is a founding member of the International Society of Arthroplasty Registries (ISAR) which was established in 2004 to ensure effective cooperation and collaboration between registries.

In recent years the Australian Knee Society approached AOA to consider undertaking a pilot study to test collecting knee osteotomy data. Knee osteotomy can be undertaken prior to knee replacement in an attempt to delay or avoid this procedure. The long-term outcomes in Australia remain unknown. AOA agreed to undertake the pilot, and this has now been successfully completed and a decision was made to implement knee osteotomy data collection nationally. The primary outcome measure will be the time to subsequent knee replacement, this will be assessed using Registry data.

AOANJRR will be implementing a new, separate form for ankle arthroplasty. With this new form, AOANJRR will enhance its capabilities in data collection; also, as expressed by the Australian Orthopaedic Foot and Ankle Society, AOANJRR will be one of the first registries collecting comprehensive data on ankle replacement and arthrodesis which will lead to solid evidence to define criteria regarding the benefits of ankle replacement vs ankle arthrodesis for ankle osteoarthritis. It is anticipated data collection for this new form will begin in the first half of 2025.

## **6. SPECIFIC AIMS**

The specific aims of the AOANJRR include:

- Establish demographic data related to joint procedure surgery in Australia
- Provide accurate information on the usage of different types of prostheses
- Determine regional variation in the practice of joint procedures
- Identify the demographic and diagnostic characteristics of patients that affect outcomes
- Analyse the effectiveness of different prostheses and treatment of specific diagnoses
- Evaluate the effectiveness of the large variety of prostheses currently on the market by analysing their survival rates
- Educate orthopaedic surgeons on the most effective prostheses and techniques to improve patient outcomes
- Provide surgeons with an auditing facility
- Provide information that can instigate tracking of patients if necessary
- Provide information for comparison of the practice of joint replacement in Australia and other countries
- Analyse the outcome of knee osteotomy and ankle arthrodesis procedures

## **7. PARTICIPANT SELECTION AND EXCLUSION CRITERIA**

The AOANJRR receives data on all patients undergoing hip, knee, shoulder, elbow, wrist, ankle and spinal disc replacement nationally as well as patients undergoing knee osteotomy and ankle arthrodesis procedures including primary, revision/re-operation procedures. The only exclusions are those patients who notify the AOANJRR that they would prefer not to have their name and details of their joint procedures included in the AOANJRR database.

## **8. AOANJRR PLAN AND DESIGN**

The AOANJRR identified the core information required to achieve the aims of the AOANJRR. This has been defined as the minimum data set.

The principal outcome measure is the time between primary and revision surgery. Existing registries such as the Swedish and Norwegian Joint Replacement Registries had shown this to be a very efficient measure when monitoring large numbers of joint procedures. These Registries were responsible for the early identification of a variety of prostheses and a particular form of bone cement that performed poorly. The experience of the AOANJRR has been similar.

Prior to establishment of the AOANJRR the databases of hospitals, health insurance companies, state health departments and orthopaedic companies were examined to determine the nature, quality, availability and relevance of this information to the AOANJRR. None of these databases were able to supply all the necessary details

required by the AOANJRR. It became apparent that the only way for the AOANJRR to collect the minimum data set was to introduce an independent method of data collection.

The existing databases remain important for use as a cross-reference tool that permits validation of different components of the AOANJRR data. The AOANJRR has been able to demonstrate that the combination of independent AOANJRR data collection and subsequent validation provides data accuracy approaching 100%.

### **Data Collection**

#### **Minimum Data Set**

The essential purpose of the minimum data set is to identify patients undergoing hip, knee, shoulder, elbow, wrist, ankle, spinal disc replacement, knee osteotomy and ankle arthrodesis procedures, and accurately link the patient to details of specific prostheses used. Data collection is undertaken successfully at all hospitals, both public and private, that undertake the applicable joint procedures listed above (REFER ATTACHMENT 1).

1. Patient details (name, date of birth, sex, address, post code, hospital unit record number and Medicare number)
2. Hospital
3. Surgeon code
4. Date of surgery
5. Primary or revision/ re-operation surgery
6. Diagnosis
7. Side of surgery
8. ASA Score, Height and Weight
9. Operative approach
10. Procedure details
11. Prostheses identification

#### **The Proforma**

Most hospitals do not have facilities to collect and transfer data electronically and therefore the minimum data set is collected on specifically designed colour coded proformas (REFER ATTACHMENTS 2 – 8).

| Proforma       | Colour |
|----------------|--------|
| Hip            | Yellow |
| Knee           | Green  |
| Knee Osteotomy | Teal   |
| Ankle          | Pink   |
| Shoulder       | Orange |
| Elbow & Wrist  | Purple |
| Spinal Disc    | Blue   |

The proforma are supplied to the hospitals by AOANJRR.

The data set provides information on a number of areas. These include patient identification and Medicare number. The Therapeutic Goods Administration has requested that the AOANJRR collect the Medicare number to assist with prostheses recall if required. Also, the operative diagnosis for primary or revision/re-operation surgery, hospital and surgeon code as well as prostheses identification by company name, catalogue and lot numbers are captured.

The catalogue and lot numbers are unique identifiers of specific size and type of prostheses. As such the use of these numbers allows for outcome analysis to be undertaken not only on particular prostheses but also specific features that may be

common to a variety of different prostheses. Data collection on cement and prostheses additions is also included as they are considered to be part of the prostheses.

Ease of use was a major consideration in the development of the proformas. Completing the forms involves using hospital and company labels to provide patient and prostheses identification and marking relevant boxes in relation to diagnosis, type and side of procedure. The pilot study demonstrated that using labels ensures the proforma is easy to use and reduces the need for handwriting, thereby minimising the risk of errors when transposing names and numbers and overcomes potential problems of illegibility. Spaces are provided for writing should labels not be unavailable.

### **Data Validation**

As mentioned previously, existing databases were examined to determine their relevance and availability to the AOANJRR. The combination of state health department, hospital, and orthopaedic company databases provides a very effective method of validation.

State health departments collect separation data on all patients both public and private. This information can be used to verify the number of joint procedures undertaken in each state or territory and more specifically is able to identify the number of primary and revision operations as well as re-operation procedures undertaken by each hospital. The separation data is accurate, although the AOANJRR has identified a small percentage of errors in this information. It is not possible to obtain date of surgery, side or prostheses details. It has however been a very useful data validation tool as it is able to quickly identify the AOANJRR capture rate for each hospital and to relate the procedure to the hospital's patient identity number.

Hospital databases can be used to validate data collected on individual patients as well as additional verification of the number of patients undergoing joint procedures. The information already collected on hospital databases includes patient identification, date and type of surgery and in some hospitals, prostheses identification. Should any discrepancies occur between the minimum data set collected on individual patients or the number of patients identified as having had a joint procedure, we will liaise with a member of staff (see hospital involvement) who can access patient records, theatre operations registers, or databases for verification.

For accurate data analysis it is necessary to identify patients on the AOANJRR who have died and when this occurred. The National Death Index housed at the Australian Institute of Health and Welfare records all deaths in Australia. This information is entered against the AOANJRR data, allowing identification of those patients.

### **Data Transference (proforma)**

The most appropriate method for transferring data consists of photocopying the completed proforma, filing the photocopy in hospitals and returning the original to the AOANJRR by post using the AOANJRR reply paid service. The photocopies at the hospitals provide a source for cross-checking individual data should any discrepancies arise. Further to this, it provides a reference to identify that the correct number of proforma are returned to the AOANJRR. The photocopies need only be kept until the data has been validated and entered in the AOANJRR.

### **Hospital Involvement**

The principal role of hospitals is to ensure data collection. Surgeons and/or theatre staff are required to complete a proforma at the time of surgery. The proformas are then returned to the AOANJRR.

To achieve this effectively it was necessary to have a member of staff take on the role of hospital coordinator. This was usually a member of the theatre nursing staff. The hospital coordinator liaises closely with AOANJRR staff, provides direction to hospital staff, ensures efficient data collection, and is available to follow up any discrepancies. An

information manual to provide information on the AOANJRR and instructions on the collection and transference of data is provided to each hospital.

### ***Commencement of Data Collection***

Data collection commences as soon as practicable after receipt of hospital approval. Following approval, hospitals are required to nominate the hospital coordinator. The AOANJRR project coordinator subsequently contacts the appropriate personnel to establish effective liaison and provide education. Arrangements for delivery and return of the proforma will be made. After the nomination of the hospital coordinator and following discussion with AOANJRR staff, a convenient date for the commencement of data collection is determined.

## **9. EFFICACY**

Not Applicable

## **10. ETHICAL CONSIDERATIONS**

### ***Beneficiaries of the AOANJRR***

The principal beneficiaries of a national joint replacement registry are those individuals requiring joint procedures. The AOANJRR produces reports on a variety of factors that influence the outcome of joint procedures. The identification and use of prostheses and techniques associated with lower failure rates will in the long term contribute to significantly improved outcomes for patients undergoing joint procedures. Further to this, the identification of features related to improved prostheses survival provides important information for future research and development.

There are also benefits to the wider community. A decrease in the incidence of revision surgery and re-operation procedures and its associated morbidity, mortality and less successful outcomes will result in a significant reduction in health care costs.

Surgeons benefit, as the AOANJRR can provide a confidential secure audit of their joint procedure practice. It will also provide ongoing education in appropriate techniques and prostheses selection.

Hospitals stand to gain significant advantages. Involvement with the AOANJRR improves the accuracy of hospital data. The AOANJRR has been effective in identifying miscoding or non-identification of patients in hospital separation data. This has important funding implications. Furthermore, hospitals are legally required to accurately link prostheses by catalogue and lot number to individual patients. This is essential to permit recall of prostheses, which is necessary from time to time. It has been the experience of the AOANJRR that many hospitals do not record the information in a manner that is easily accessible if a recall is necessary. It is a simple matter for the AOANJRR to provide this information to a hospital in this situation. The Registry also provide standardised hospital reports which allows hospitals to identify how they are performing against national averages.

In addition, State and Federal Governments as well as hospitals will have access to accurate demographic and performance-based information. This is necessary for cost/benefit analysis, resource planning and allocation of funds. Furthermore, a mechanism that ensures monitoring and improvement of clinical standards has been established.

### ***Data Management and Confidentiality***

SAHMRI undertakes data entry, validation and analysis as well as providing secure data storage.

The data management and analysis work was moved from the University of Adelaide to SAHMRI in December 2015. Staff include; data managers, database programmers, statisticians and data assistants. SAHMRI is engaged in an increasing variety of research



including clinical studies, pharmaco-epidemiological studies, consultations and cohort studies.

The list of personnel with access to identified Registry information is as follows:

- Registry Clinical Director, Deputy and Assistant Deputy Registry Clinical Directors
- AOANJRR Managers
- AOANJRR Administrative Staff
- SAHMRI AOANJRR project staff including data manager and data assistants

Declaration of the project as a Federal Quality Assurance Activity ensures that AOANJRR and SAHMRI staff are bound to maintain confidentiality. In addition, the contract between the Commonwealth and AOA to establish the AOANJRR prohibits the release of identified data. As a consequence, AOANJRR published reports only contain de-identified data. This includes any data request reports prepared by the AOANJRR. Confidentiality not only applies to individual patients but also includes surgeons and hospitals.

SAHMRI has security systems to limit access to SAHMRI staff allocated to the AOANJRR and listed Registry staff only. There are policies and procedures in place as well as software barriers to protect personal information. These include the use of codes, passwords and encryption.

The proformas used for data collection are stored in a secure locked area at SAHMRI. After a period of time the forms are scanned and stored electronically. As with all data these are securely stored. All data will be retained in accordance with good scientific practice.

### ***Confidentiality and Privacy of Patients***

Joint replacement patients are not contacted directly by the AOANJRR. No individual patient is identified during analysis or in the reports and publications produced by the AOANJRR. Patient operative and prostheses data are managed in accordance with the Guidelines for the Protection of Privacy in the Conduct of Medical Research. Personal data collected is for use by the AOANJRR only.

### ***Surgeon Confidentiality***

It will not be possible to identify surgeons in the reports published by the AOANJRR.

### ***Patient Consent***

The AOANJRR uses an 'opt out' approach to patient consent i.e. patients are automatically enrolled unless they choose to 'opt out'. This is the most appropriate method for the AOANJRR for two reasons: -

- No direct patient contact is required
- The large number of joint procedures undertaken in Australia

Important aspects to the 'opt out' approach include the availability of information and clearly defined avenues should a patient wish to have their name removed. If this is the case the patient contacts the AOANJRR to ensure that their details are not included.

The participant information sheet is required to be given to patients when consent for joint procedure surgery is being sought in either surgeons' rooms or hospitals. This sheet provides information on joint procedures and the AOANJRR as well as contact details and a tollfree number.

Although it is important to include as many patients as possible, we understand that not all patients are comfortable with providing their personal details on a central registry. The

information sheet provides directions and an avenue for withdrawal at any time for patients that do not want their name registered.

### **Federal Quality Assurance Activity Declaration**

The AOANJRR was declared a Federal Quality Assurance Activity and this declaration continues to be maintained by the Registry. This ensures freedom from subpoena and absolute confidentiality of information held by the AOANJRR (REFER ATTACHMENT 9).

The Quality Assurance legislation is part of the Health Insurance Act of 1973. This Act was amended in 1992 to include quality assurance confidentiality. The Act operates on the underlying assumption that quality assurance activities are in the public interest. A declaration as a quality assurance activity by the Federal Minister for Health and Aged Care which prohibits the disclosure of information that identifies individual patients or health care providers, that is known solely as a result of the declared quality assurance activity. It is not possible to provide identifying information to any individual or organisation including the government.

To encourage efficient quality assurance activities "Part VC-Quality Assurance Confidentiality" contains the following provisions:

- a) Prohibiting:
  - 1. The disclosure of information that became known solely as a result of those activities; or
  - 2. The production to a court of a document that was brought into existence solely for the purposes of those activities; and
- b) Protecting certain persons engaging in those activities in good faith from civil liability in respect of those activities.

The protection provided by the declaration assures surgeons, hospitals and Government that information supplied to the Registry remains confidential and secure.

The declaration of the AOANJRR as a Federal Quality Assurance Activity is for a five-year period but covers information collected during this period indefinitely. It is necessary for the AOANJRR to renew the declaration every five years.

## **11. DRUGS**

Not Applicable

## **12. SAFETY AND ECOLOGICAL CONSIDERATIONS**

Not Applicable

## **13. ANALYSIS AND REPORTING OF RESULTS**

Results of analysis of AOANJRR data are published in an Annual Report. No patient, surgeon or hospital are identified in the reports. Analyses are performed to provide accurate demographic data. In addition, a wide variety of factors that potentially influence outcomes of joint procedures are also examined. The data are presented in the form of descriptive statistics and survival analysis. The AOANJRR identifies survival rates not only for different prostheses but also examines other specific features that influence survival outcomes of joint procedures. Reports are produced annually as well as ad hoc reports, as required. The reports are provided to surgeons and other interested parties such as Government departments, hospitals and orthopaedic companies.

The AOANJRR is able to provide surgeons with a confidential, secure audit of their own joint procedures on record.

## **14. INDEMNITY**

AOA has indemnity insurance to cover the AOANJRR. This was a requirement of the Commonwealth Government for AOANJRR funding.

## **15. GOVERNANCE OF THE AOANJRR**

The governance of the AOANJRR is both transparent and accountable. The AOA Board of Directors is responsible for ensuring that the contractual obligations are fulfilled. When the AOANJRR was implemented, the Board established the AOANJRR Committee to oversee and develop policies for the operation of the AOANJRR.

This committee reports directly to the AOA Board of Directors and comprises:

- AOA Registry Committee Chair (appointed by the AOA Board)
- AOA Vice President
- Registry Clinical Director
- Registry Clinical Deputy Directors
- Research Committee Chair
- Board approved nominees from:
  - Foot and Ankle Society (where there is not expertise in AOANJRR)
  - Shoulder and Elbow Society (where there is not expertise in AOANJRR)
  - Spine Society of Australia
  - Neurosurgical Society of Australasia
  - President of the Arthroplasty Society of Australia
  - Representative of the Knee Society
  - State Branch Chair Committee Representative (where there is not a committee member from that state)
  - Consumer (patient) Representation – up to 3

The AOANJRR Committee meets four times a year.

The day-to-day activities will be managed by Registry Management Group. This group consists of the project investigators (Registry Clinical Director, Deputy Registry Clinical Director and Assistant Deputy Registry Clinical Directors) and Registry managers. The group meets fortnightly.

AOANJRR reports directly to the Board of the AOA through the AOA Registry Committee as well as to the Australian Commonwealth Department of Health and Aged Care through the AOA CEO. AOANJRR provides progress reports both to AOA and the Department of Health and Aged Care multiple times per year as required through the funding agreement requirements.

AOA currently contracts the South Australian Health and Medical Research Institute (SAHMRI), to provide data management and analysis services to the AOANJRR.

The AOANJRR is located in the SAHMRI building, North Terrace, Adelaide.

## **16. AOANJRR REPORTING**

Each year the AOANJRR reports on the outcomes of joint replacement surgery in Australia. The annual and supplementary reports provide information on patient demographics and outcomes including morbidity and mortality as well as prostheses effectiveness and survival rate. Government departments and other interested parties such as surgeons, hospitals, health insurance companies and orthopaedic manufacturing companies are provided with an electronic copy of the annual report. The annual report is also publicly available on the AOANJRR website together with all supplementary reports.

In addition, the AOANJRR produces additional reports from orthopaedic surgeons, hospitals, government departments, academic institutions and orthopaedic companies.

Reports are also provided by AOA to the Commonwealth Department of Health & Aged Care as outlined within the funding agreement requirements. These reports detail the activities of the AOANJRR and include a financial statement.