PURPOSE

The Australian Rheumatology Association Database (ARAD) has been established as a national arthritis database to provide valid and reliable longitudinal clinical data of arthritis sufferers in Australia, with the ultimate aim of providing better care and improving outcomes for patients. It became operational in August 2003.

SCOPE AND THE INVOLVEMENT OF ARA MEMBERS

The roles of ARAD will be to:

- Establish a specific cohort of all Australian arthritis patients receiving anti-tumour necrosis factor (TNF) and other biological disease modifying antirheumatic drug (DMARD) therapies together with a group of patients not receiving biological DMARD therapy to determine long-term safety and effectiveness of the biological therapies;
- Provide reports of patient outcomes to participating rheumatologists;
- Provide comparison with grouped de-identified data from other rheumatologists;
- Report on treatment side effects and reasons for stopping or changing therapy;
- Provide quality assurance for participating rheumatologists (Passive Quality Assurance CPD points - 0.5 per hour per patient);
- Evaluate the tight PBS restrictions for biological therapy in Australia – to help determine whether proposed cost-effectiveness is being met, whether the right target group are receiving the therapy and what effect treatment order has on outcomes;
- Compare Australian data with overseas registries to determine country-specific differences;
- Pool with overseas registries to obtain more accurate estimates of rare events;
- Provide a potential research resource of well-documented patients.
- Invite ARAD participants to participate in additional projects as they arise.

All rheumatologists in Australia may contribute patients to the database, including all patients on biologic therapy, as well as a control group of patients who are not receiving biologic therapy.

National registers have been established in other countries as an essential part of the prescribing process. For example, in April 2002, the UK’s National Institute for Clinical Excellence (NICE) granted approval for the use of anti-TNF therapies for the treatment of severe rheumatoid arthritis in the National Health Service, explicitly stating that prescription of these drugs should be accompanied by registration with the British Society for Rheumatology Biologics Register.

In Australia, although enrolment on a national register is not an essential requirement of the prescribing process, it is highly desirable. Australian data will provide information that is applicable to the Australian population with its different...
population characteristics and different background risks of complications such as skin cancers and melanoma. In addition, because of the tight PBS restrictions to prescribing of biological DMARD drugs in Australia, an Australian database will have the potential to provide unique data on outcomes in patients with more severe rheumatoid arthritis, ankylosing spondylitis and psoriatic arthritis.

**FUNDING**

ARAD was established with the financial support of industry and government partners. Further funding to meet the future costs of ARAD will be sought from industry partners and competitive national and government granting agencies.

The ARA membership will not be asked to fund ARAD unless such a request is passed at an AGM by more than 75% majority as outlined in the constitution.

**SUPPORT OF GOVERNMENT**

ARAD has the support of Medicare Australia and the Pharmaceutical Benefits Advisory Committee. Medicare Australia has agreed to provide ARAD with all requested health information including details contained within the authority request for biological therapy for an indefinite period upon receipt of the patient’s signed consent agreeing to release of their health information.

**REGISTRATION OF PATIENTS PRESCRIBED BIOLOGICAL AGENTS**

Figure 1 displays the process for registration of patients prescribed biological agents. At the time of prescribing biological DMARDs, rheumatologists are asked to explain the purpose of ARAD to their patients, and provide them with the ARAD permission to contact form (Attachment 1). The signed ARAD permission to contact form is sent to the ARAD data centre (mail, fax, email or online). Upon receipt, the patient is contacted by an ARAD research assistant who describes the ARAD project in more detail and sends the patient a detailed patient information and consent form (Attachment 2). Patients can self-refer by a similar process.

**REGISTRATION OF PATIENTS NOT PRESCRIBED BIOLOGICAL AGENTS**

A group of ‘non-biological’ patients will also be recruited from participating rheumatologists to achieve an Australia-wide representative sample by a similar process.

**FOLLOW UP**

Participants will complete further questionnaires at regular intervals. These ask about the development of any serious adverse events, changes to medication and quality of life.

Rheumatologists and other health care providers may be contacted periodically for further information as required.
At regular intervals, ARAD will perform data linkage with various registries including the Australian Institute of Health and Welfare database to monitor morbidity and mortality. International data linkage may also be performed.

OWNERSHIP OF ARAD AND ITS MANAGEMENT STRUCTURE

The ARA owns ARAD and controls access to the data and its release. The management structure of ARAD is shown in Figure 2.

ARAD has both a Steering Committee and a Management Committee. The Management Committee comprises the principal investigators. The ARAD Steering Committee conforms to the ARA committee structure and the Operating Principles and Technical Standards for Clinical Quality Registries. The Steering Committee comprises an ARA representative from each state, the Chair of the ARA Therapeutics, Quality Assurance, Scientific Committees, a member of the ARA Executive, a consumer representative from Arthritis Australia and members of the Management Committee (ex-officio). The Steering Committee reports to the ARA Executive.

MANAGEMENT

The ARA will contract an independent centre (currently Monash University CCREt) to manage the ARAD database. Data management will be pursuant to a contract drawn up under the direction of the ARA legal advisers and ARA Treasurer.

Data management activities for the project include: development and maintenance of high quality case record forms; provision of experienced data management staff trained in Standard Operating Procedures, systems and study procedures; ongoing development and maintenance of the ARAD database; provision of adequate quality assurance and quality control systems for database and data handling with written standard operating procedures; provision of data in a format able to be input into key software packages for analysis and provision of regular reporting of project status.

ETHICAL SUPERVISION

Ethical approval for the ARAD project has been granted by the Cabrini Hospital Human Research Ethics Committee, Melbourne; Royal North Shore Hospital Human Research Ethics Committee, Sydney; and South Eastern Health Human Research Ethics Committee Southern Section, St George Hospital, Sydney; Medicare Australia; AIHW; and all state cancer registries. Additional Ethics Committees have granted ethical approval (See xx).

As an ARA activity, this ethical approval covers individual clinicians who contribute patients to ARAD. Individual clinicians may also seek further ethical approval from their own institutions as required.

Research proposals requesting access to identifiable data will require ethical approval from the researcher’s institution as well as ethical approval from one of the following:
- the Cabrini Hospital Human Research Ethics Committee, Melbourne; Royal North
Shore Hospital Human Research Ethics Committee, Sydney; and South Eastern Health Human Research Ethics Committee Southern Section, St George Hospital.

**CONFIDENTIALITY, PRIVACY AND LEGAL LIABILITY**

ARAD complies with the Australian Commission on Safety and Quality in Health Care Operating Principles for Clinical Quality Registries and Commonwealth and State privacy laws.

All ARAD research staff are trained appropriately and sign confidentiality agreements.

Only de-identified patient data will be made available to third parties. No ARAD patient personal information will be released to third parties without explicit patient consent.

An ARAD manual describing ARAD data collection and management processes is continually being updated. All policies concerning consent, requests for involvement, follow up and data management and privacy are available upon request.

The ARA executive accepts legal liability for ARAD as covered under the ARA insurance policy.

A Register of complaints/enquiries will be kept by the Chair of the Quality and Safety Committee who will be responsible for follow up of any complaints. Details of any complaints and enquiries will be reported to the ARA executive.

**ACCESS TO INFORMATION**

The ARAD Steering Committee may grant access to de-identified data only. ARAD participants may be invited to participate in external research projects if approval has been granted by both the ARAD Steering Committee and relevant HRECs. Initial contact for those studies will be made by ARAD personnel.

Identifying information of participants will not be available for any purpose other than reports of health benefits and harms to their treating rheumatologist or other recipient nominated in writing by the participating patient and rheumatologist.

No ARAD identification details will be released to third parties without consent (written or electronic) of ARAD participants. All third parties must sign ARAD and any other relevant confidentiality agreements.

Industry partners have no rights to directly access the data. They may receive reports of grouped non-identifiable data upon request.

The process for external projects:-

1. Researchers write to ARAD Steering Committee with proposal;
2. Researchers can either wait till they have ethics approval and funding before submission or be processing approvals concurrently but the program will not proceed until ethics clearance and funding are available;
3. Proposal also contingent on ARAD staff having time to provide the service;
4. ARA Executive to be informed of all projects;
5. ARAD newsletter to participants and updates in ARA e-bulletin to notify members and patients of ongoing projects;
6. Rheumatologists will be notified of proposed studies;
7. Steering committee to make recommendation about need for individual patient approval from the ARAD participant’s treating rheumatologist on a case by case basis;
8. Steering committee, in collaboration with ARAD PIs, to make a recommendation about level of funding required for the project to proceed;
9. Authorship to be discussed a priori between researchers, ARAD Management and ARAD Steering Committee and decided on a case-by-case basis in accordance with international guidelines.

**Reporting to contributing rheumatologists**

Rheumatologists who have contributed patients to ARAD will receive updates. These will comprise a summary of de-identified pooled data as well as a summary of data concerning their contributed patients including health outcomes and major adverse events.

It will also be possible to provide individual raw data for analysis to the patients’ own rheumatologist upon request. For rheumatologists who work within a group, such as a hospital department, it will also be possible to provide de-identified grouped data. In this instance, they should apply in writing to the ARAD Scientific Advisory Committee. If approved, the ARAD Steering Committee would provide written consent to the CCREt who would then provide the de-identified grouped data report for the specified group.

**Reporting to ARA Council, ARA members and ARA Executive**

The ARAD management committee will report to the ARA Council and Annual General Meeting on an annual basis and to the ARA Executive on a quarterly basis (or more frequently as required). The report will comprise progress re database numbers, details of any studies and details of any outcomes.

**Publications**

The ARAD Principal Investigators will determine publication policy for all research reports relating to ARAD, including authors and order of authors on a case-by-case basis.

**TERMINATION OF PROJECT**

In the event that the project is terminated, for any reason, it will be the responsibility of the ARAD Management Committee, Steering committee and ARA Executive, to reach a consensus about the dispersion of any remaining funds and the data collected.
Figure 1: The process for registration of patients prescribed biological agents

ARA

Rheumatologist

Eligible for anti-TNF therapy
Explain purpose of ARAD

Patient

Completes PBS forms

PBS

Signs ARAD Permission for
Release of information

Consent Form and all
questionnaires

Fax to 1-800 number

ARA

Co-ordinators

Patient Information
& Consent Form;
Baseline questionnaire
Figure 2: The management structure of ARAD

- ARA ownership

- ARA executive
  - ARAD Steering Committee
    - Management Committee
    - ARA Representative from each state
    - Chair of Therapeutics, Quality & Safety, Scientific, Exec
    - Consumer

- ARAD Management Team
  - Single Data Management Centre currently Monash University CCREt
  - ARAD Project Manager and State Coordinators

- Participating Patients
- Participating Rheumatologists

- Q&S, Therapeutics, Scientific, Central Finance, IT Committees