Australian Government
Australian Institute of Health and Welfare

Assessment of the Australian Rheumatology Association Database for national population health monitoring

Working paper

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Authoritative information and statistics to promote better health and wellbeing

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Australian Institute of Health and Welfare
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Abbreviations

ABS	Australian Bureau of Statistics
ACT	Australian Capital Territory
AIHW	Australian Institute of Health and Welfare
ARA	Australian Rheumatology Association
ARAD	Australian Rheumatology Association Database
AQoL	assessment of quality of life
bDMARDs	Biological disease-modifying anti-rheumatic drugs
DMARDs	Disease-modifying anti-rheumatic drugs
EQ-5D	A generic health-related quality-of-life measure developed by a group of largely European-based researchers
GPs	general practitioners
HAQ	Health Assessment Questionnaire
HREC	Human Research Ethics Committee
MBS	Medical Benefits Schedule
NT	Northern Territory
OPAL	Optimising Patient Outcomes in Australian Rheumatology
PBS	Pharmaceutical Benefits Scheme
QLD	Queensland
SF-36	36-Item Short Form Health Survey
SA	South Australia
TAS	Tasmania
VIC	Victoria
WA	Western Australia

Summary

A wide range of existing data sources could potentially be used to improve our understanding of arthritis in the Australian population. This working paper uses an assessment framework recently developed by the Australian Institute of Health and Welfare (AIHW) (AIHW 2014a) to assess the suitability of the Australian Rheumatology Association Database (ARAD) as a potential new data source for population health monitoring of inflammatory arthritis.

More than 400,000 Australians have rheumatoid arthritis, the most common form of inflammatory arthritis (ABS 2012). This auto-immune disease causes chronic inflammation, pain and swelling of the joints and can greatly reduce a person's quality of life.

The ARAD, managed by the Australian Rheumatology Association, is a national registry that collects health information from individuals with inflammatory arthritis. It was primarily established to monitor the benefits and safety of new treatments, particularly the biological disease-modifying anti-rheumatic drugs (bDMARDs).

The AIHW's assessment of the ARAD for the purpose of national population health monitoring is that:

- it has the potential to fill a range of identified data gaps in relation to key questions for monitoring arthritis, including treatment outcomes, disease progression, quality of life and economic impacts
- it has well established administrative and governance arrangements in place to ensure data quality and compliance with legislative requirements
- it has limited coverage which could potentially be improved by combining with, or linking to, other similar data sources
- on balance, it is a data source with the potential to provide useful information for population health monitoring of inflammatory arthritis, particularly if used in combination with, or linked to, other data sources.

1 Introduction

Within Australia, arthritis and other musculoskeletal conditions are highly prevalent, cause significant disability and generate substantial personal and health system costs. The Global Burden of Diseases Study 2010 ranked musculoskeletal disorders as the leading cause of disability in Australia and second only to cancer for overall disease burden (IHME 2010).

Population health monitoring of arthritis and other musculoskeletal conditions is necessary to determine existing health patterns and population groups at risk; current health service usage; and future demands on the health system. It helps provide the evidence base to inform policies and programs to help prevent and better manage these conditions.

It is a core role of the AIHW and its monitoring centres to explore the usefulness of a range of data sources for national monitoring purposes, to drive increased transparency and standardisation of national health datasets already in existence, and to develop standards for new datasets.

This working paper outlines the AIHW's assessment of the suitability of the Australian Rheumatology Association Database (ARAD) for monitoring arthritis. This assessment draws heavily on the Data Quality Framework of the Australian Bureau of Statistics (ABS) (ABS 2009).

1.1 What is inflammatory arthritis?

More than 400,000 Australians have rheumatoid arthritis, the most common form of inflammatory arthritis (ABS 2012). This auto-immune disease causes the body's immune system to mistakenly attack its own tissues, causing chronic inflammation, pain and swelling of the joints. It most commonly affects the hand joints and potentially leads to deformity and severe disability. Other forms of inflammatory arthritis include ankylosing spondylitis, juvenile idiopathic arthritis, and psoriatic arthritis.

The impact of inflammatory arthritis is generally long-lasting and can greatly reduce quality of life. It can affect an individual's physical, social and emotional functioning, and is associated with premature death. The peak onset for rheumatoid arthritis is in the fourth and fifth decades of life, thereby affecting individuals in their peak income-earning years (Buchbinder et al. 2007).

Previously, the primary forms of disease-modifying treatment for inflammatory arthritis were the disease-modifying anti-rheumatic drugs (DMARDs). These drugs had a long history of use and a well-known risk profile. Since 2003, newer drugs have been introduced to the market—biological disease-modifying anti-rheumatic drugs (bDMARDs). These newer drugs have been found to greatly improve the health outcomes of patients with severe inflammatory arthritis. While the short-term efficacy of these newer drugs is well established, the long-term outcomes are not yet well known (Briggs et al. 2009, Buchbinder et al. 2007).

bDMARDs have restricted access and can only be prescribed by rheumatologists and clinical immunologists. The availability of government-funded bDMARDs usage is restricted to patients who fail to achieve adequate responses to prior therapy and fulfil criteria for 'severe and active disease'. Prior approval by Medicare Australia is required before bDMARD treatment on the Pharmaceutical Benefits Scheme (PBS) can be initiated.

Due to the uncertainty surrounding the long-term outcomes of bDMARDs, several countries have established long-term observational studies via the establishment of health registries to monitor the long-term safety and efficacy of these drugs (Briggs et al. 2009). The Australian Rheumatology Association Database (ARAD) was established with the primary aim of determining the effectiveness and long-term safety of biological drugs used to treat inflammatory arthritis conditions.

1.2 What information is needed for monitoring inflammatory arthritis?

Arthritis (including inflammatory arthritis) and other musculoskeletal conditions are chronic diseases for which information is required across the disease continuum to monitor the movement from wellness to mortality (see Figure 1.1). The different stages of disease progression include the well population; the at-risk/asymptomatic population; populations with a recent disease diagnosis; populations managing a chronic condition; populations receiving palliative care; and those who have died from the condition.

Various data sources could potentially be used to provide information relevant to understanding arthritis and musculoskeletal conditions. Many of these data sources were not developed specifically for monitoring these conditions but have the potential to be used for population health monitoring.

Information is needed to describe the situation at a particular point in time and also to track changes over time. These priority information areas translate into a set of 6 key questions for monitoring arthritis and other musculoskeletal conditions (see Box 1.1) (AIHW 2014b).

Box 1.1: Key questions for monitoring arthritis and other musculoskeletal conditions

1. **Risk factors:** What proportion of the population experiences modifiable risk factors associated with arthritis and other musculoskeletal conditions?
2. **Prevalence:** What is the prevalence of arthritis and other musculoskeletal conditions in the population?
3. **Prevention, management and treatment:** What prevention, management and treatment services do the population with arthritis and other musculoskeletal conditions receive?
4. **Quality of life:** How do arthritis and other musculoskeletal conditions affect an individual's quality of life?
5. **Disability and death:** To what extent are disability and death associated with arthritis and other musculoskeletal conditions?
6. **Health expenditure:** What is known about expenditure on arthritis and other musculoskeletal conditions?

Stage of disease continuum

	Well population	At-risk or asymptomatic	Diagnosis of disease	Management of chronic disease	Mortality
Level of prevention	Primary prevention	Secondary prevention/early detection	Disease management, tertiary prevention and rehabilitation		Disease management
Nature of intervention	Promotion of healthy behaviours and environments across the life course: • Promote weight control[(a)] • Promote joint injury or trauma prevention[(a)(c)] • Prevent smoking[(a)(b)] • Promote behaviours to improve bone health including nutrition, exercise and moderate alcohol consumption[(c)] • Address occupational risks[(d)] Universal and targeted approaches	Education programs Screening: • Bone mineral density screening[(c)] Identification of cases Periodic health examinations: • Promote weight control and joint injury prevention[(a)] • Early intervention, tailored to condition (for example, early recognition of symptoms and prompt referral to allied health/self-management[(a)(d)] or to specialist services as appropriate) • Intervene to prevent first fracture[(c)] Control risk factors	Treatment and acute care, including pain management Complications management including comorbidity Preserve function and independence Promote healthy lifestyle behaviours: • Initiate disease-modifying therapy early[(b)] • Support attendance at an educational program[(b)(c)] • Consider occupational intervention[(b)] • Identify people with minimal trauma fracture[(c)] • Intervene to prevent further fractures[(c)]	Continuing care Maintenance Optimise therapy and symptom relief: • Provide timely access to joint replacement surgery and multidisciplinary care[(a)(b)] Disability support and management Improve functioning (social and physical): • Self-management • Psychosocial support Intervene to prevent further fractures[(c)] Improve health-related quality of life	Manage pain and discomfort Improve health-related quality of life
Responsible sectors	Public health initiatives Primary health care Other sectors	Primary health care Public health initiatives	Specialist services Hospital care Primary health care	Primary health care Community care Specialist services	Hospital care Primary health care Community care
	Prevent movement to at-risk group	**Prevent/delay progression to complications**	**Prevent progression to established disease**	**Delay progression of complications**	

(a) Particularly relevant to osteoarthritis.

(b) Particularly relevant to rheumatoid arthritis.

(c) Particularly relevant to osteoporosis.

(d) Particularly relevant to back problems.

Source: Modified from DoHA & NAMSCAG 2004; National Public Health Partnership 2001.

Figure 1.1: Public health activities across the disease continuum for arthritis and other musculoskeletal conditions

1.3 What is the Australian Rheumatology Association Database?

The ARAD, managed by the Australian Rheumatology Association, is a national database that collects selected health information from individuals with inflammatory arthritis and from their clinicians. The specific aims of the ARAD are to:

- establish the short- and long-term effectiveness and safety of bDMARDS prescribed for rheumatoid arthritis and other inflammatory arthritis
- identify the relative contributions of disease factors and other treatments in any risks or benefits observed
- determine the economic impact of bDMARD therapy
- inform rheumatologists of their individual patient outcomes, together with de-identified summary data as a comparison
- evaluate the appropriateness of the stringent restrictions for the prescription of bDMARDS.

The ARAD collects information from patients every 6–12 months via questionnaires, including questions about medical history, medication history, responses to medication, physical functioning and patient-reported quality of life. Patients also provide consent to link their registry information with other relevant data sources such as cancer and death registries, the PBS and Medicare Benefits Schedule data. Patients and rheumatologists across Australia contribute to the ARAD and have provided data for up to 10 years.

1.4 Why assess the Australian Rheumatology Association Database?

The ARAD has not featured in current monitoring reports produced by the AIHW. This is partly because it is not part of the national data sources routinely used for monitoring purposes for which nationally agreed data standards and data flow arrangements exist (for example hospital and deaths data). The ARAD had also not been previously assessed to determine its strengths and limitations for population health monitoring, including its content, completeness and governance arrangements.

This working paper uses the AIHW's recently developed assessment framework (AIHW 2014a) to assess the suitability of the ARAD as a potential new data source for population health monitoring of inflammatory arthritis. The ARAD was selected for this demonstration project because:

- it focuses on inflammatory arthritis, a group of musculoskeletal conditions for which there is particularly limited information
- it holds detailed information about patient treatment and patient reported outcomes (quality of life) over time, both identified information gaps and priorities
- of its potential to support data linkage and thereby analysis of patient movements across health settings and patient outcomes (given its methodology includes consent arrangements to undertake linkage to other specified datasets).

2 Assessment of the ARAD

When identifying potential data sources for population health monitoring, it is important to ensure they are 'fit-for-purpose'. The AIHW's 3-step process to assess potential data sources for population health monitoring includes:

- **Step 1**—collecting information about the data source
- **Step 2**—identifying the potential to inform key monitoring areas
- **Step 3**—assessing the quality of the data, using a modified version of the Australian Bureau of Statistics (ABS) *Data Quality Framework* (ABS 2009), to determine its 'fitness-for-purpose' by establishing strengths and limitations.

Further details of the assessment process are outlined in the recent report *An AIHW framework for assessing data sources for population health monitoring* (AIHW 2014a). Steps 1 and 2 of the assessment framework for the ARAD were previously completed as part of the recently published report documenting potential data sources for monitoring musculoskeletal conditions (AIHW 2014b) and are included in tables 2.1 and 2.2 below.

Step 1—Collect data source information

Table 2.1: ARAD data source details (Step 1)

Name	Australian Rheumatology Association Database (ARAD)
Type of data source	Registry (national)
Brief description	The ARAD is primarily a national database for patients with inflammatory arthritis commencing treatment with bDMARDs following consultation with a rheumatologist. Also included in the database are patients with rheumatoid arthritis, juvenile idiopathic arthritis, ankylosing spondylitis and psoriatic arthritis who commenced treatment with bDMARDs as well as a 'control' group not on bDMARDs. The database contains information on participants' location, arthritis history, health status (including quality of life and other health conditions), and treatment history (including adverse reactions to medication). For some participants the database also contains information about arthritis status (including tender and swollen joint count) and markers of inflammation.
Purpose	To determine the effectiveness and safety of new biological drugs (bDMARDs) used to treat inflammatory arthritis.
Collection methodology	Information is collected from patients every 6 to 12 months via questionnaires. Ongoing permission is sought to collect information from state and national registries and all other relevant health records for the life of the registry.
Scope (theoretical coverage of relevant population)	Patients of participating rheumatologists. The study focuses on patients with inflammatory arthritis commencing treatment with bDMARDs, but also includes, as a control group, patients with inflammatory arthritis not taking this class of drugs.
Coverage (actual)	At December 2013, 3,170 participants completed questionnaires and a further 2,112 agreed to allow information to be gathered from state and national registries. Out of 342 registered rheumatologists in Australia, there are 268 participating in ARAD.
Geographic coverage	Australia.
Frequency/timing	Commenced in 2002 and is ongoing.
Basic collection count	Person.
Size	As at July 2013, there were over 5,000 participants and over 30,000 completed questionnaires.
Collection management organisation	Australian Rheumatology Association, with support from Monash University, Cabrini Health, Royal North Shore Hospital, University of Sydney, St George Hospital, University of New South Wales and the Centre for Clinical Research Excellence at Monash.
Further information	<http://www.arad.org.au/Public/Home.aspx>.

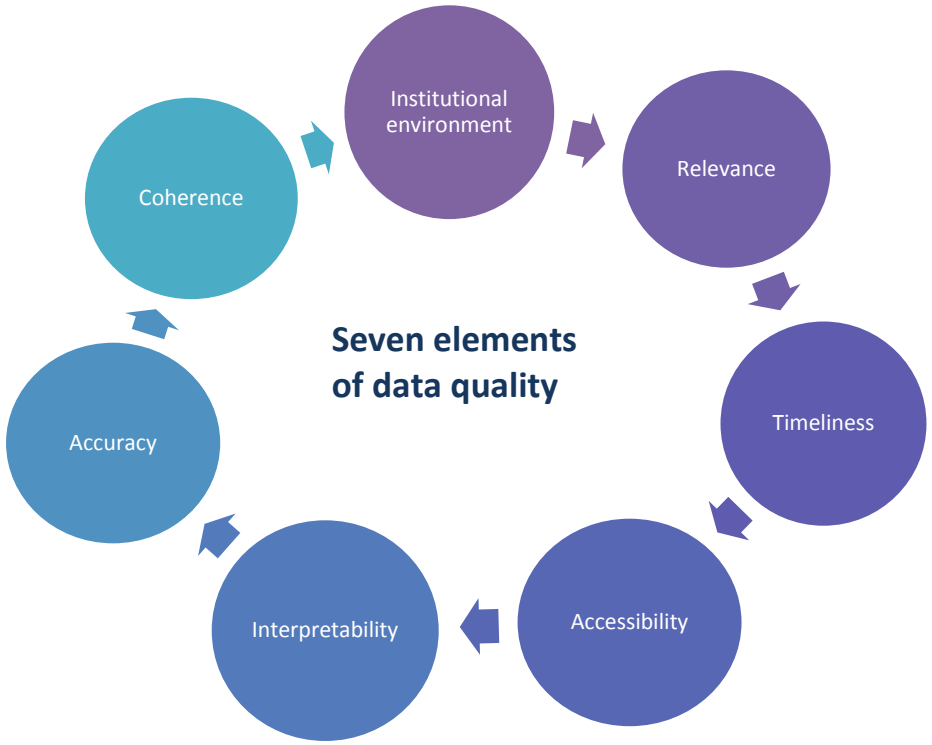
Step 2—Identify potential for data source to inform priority information areas

Table 2.2: Priority information areas for population health monitoring (Step 2)

Priority Information Area	Details
Risk factors	Information on all common comorbid conditions and potential triggers and risk factors such as smoking, alcohol, education, social status, occupational history.
Prevalence and incidence	No data regarding the diseases but collection of incidence data on adverse events, hospitalisations and new diseases such as cancer, serious infections, TB and so forth.
Prevention, treatment and management	Full information on treatment history, including medication use, complementary and over-the-counter treatments, hospitalisation and adverse drug reactions.
Quality of life	Comprehensive data on self-assessed quality of life using several standard instruments including a utility instrument.
Disability and death	Comprehensive data on disability burden via self-assessed disability tools. Death available by data linkage and carer reports.
Expenditure, costs	Full data on over-the-counter and complementary medicine use. It's also possible to link to the PBS in terms of drug utilisation, and to the MBS in terms of health services utilisation.
Socio demographics	Patient location, education, social factors, occupation history, pension status. Personal identifiers, such as name, date of birth, contact details, Medicare number and an alternative contact.

Step 3—Assess individual data quality elements

Step 3 of the AIHW's framework consists of assessing 7 data quality elements (see Figure 2.1).



Source: Adapted from the ABS's *Data Quality Framework* (ABS 2009).

Figure 2.1: Seven elements for assessing data quality (Step 3)

The 7 elements of data quality include the institutional environment; timeliness; accessibility; interpretability; relevance; accuracy; and coherence. Each individual data quality element will be assessed in the subsequent text and then an overall assessment of Step 3 presented at the end of the chapter, along with a summary table (see Table 2.4).

Institutional environment

Key questions in the assessment of the data collection's institutional environment are:

- Is the production and dissemination of data undertaken in an objective, professional and transparent manner?
- Is the agency producing the data independent and free from potential conflicts of interest?
- Are there sufficient resources for the collection and production of the data?
- Are there processes, staff and facilities in place to ensure data quality?
- Does the data source comply with privacy and legislative requirements for managing data?

Governance arrangements

The ARAD governance arrangements are shown in Figure 2.2. The Australian Rheumatology Association owns the ARAD and controls access to, and release of, the data contained within it. The management of the database is the responsibility of the ARAD management committee which reports directly to the executive. The ARAD scientific advisory committee also reports to the executive and is responsible for advising on policy and access to the data. Research proposals, which have ethics approval, are submitted to the scientific advisory committee.

The day-to-day management of the database is the responsibility of the project coordinator, 3 state research officers and a data management centre team comprising a database architect, data manager and research assistant. These appointees work in close association with the management committee. The Australian Rheumatology Association and Monash University administer the funds and an audited account is presented to the executive monthly and to the full membership annually.

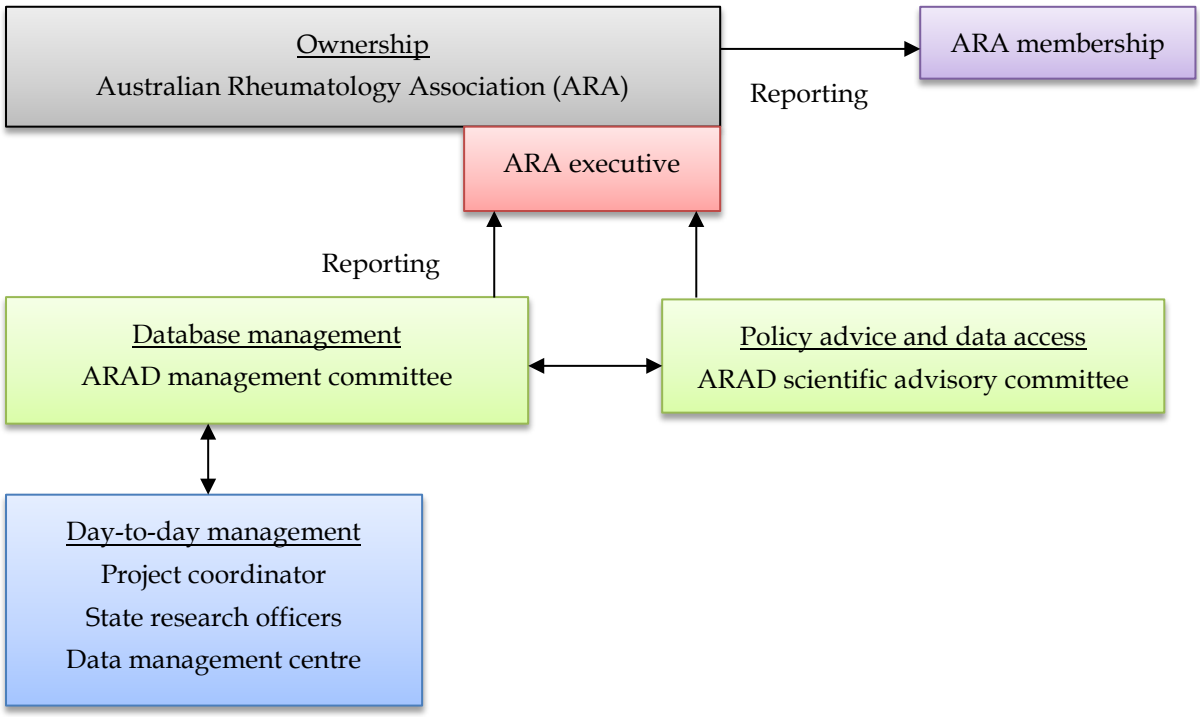


Figure 2.2: Australian Rheumatology Association Database governance arrangements

A preliminary assessment, undertaken by the AIHW of the ARAD against the Operating Principles for Clinical Quality Registries (ACSQHC 2010)—relevant here given the nature of this dataset—demonstrated a strong commitment by the ARAD management team to ensure the quality, comprehensiveness and usability of data collected. Many of these operating principles are consistent with the elements of the AIHW's data quality assessment framework.

Funding

The database was initially funded from unconditional educational grants to the Australian Rheumatology Association from pharmaceutical companies involved with new therapies for arthritis, including the bDMARDs. In 2006, maintenance and further development of the ARAD was funded by a National Health and Medical Research Council Enabling Grant (Number 384330) and by Monash University. The ARAD is currently funded via unconditional educational grants from pharmaceutical companies. Sustainability of funding has been identified as a key issue by the ARAD management team.

Ethics approval

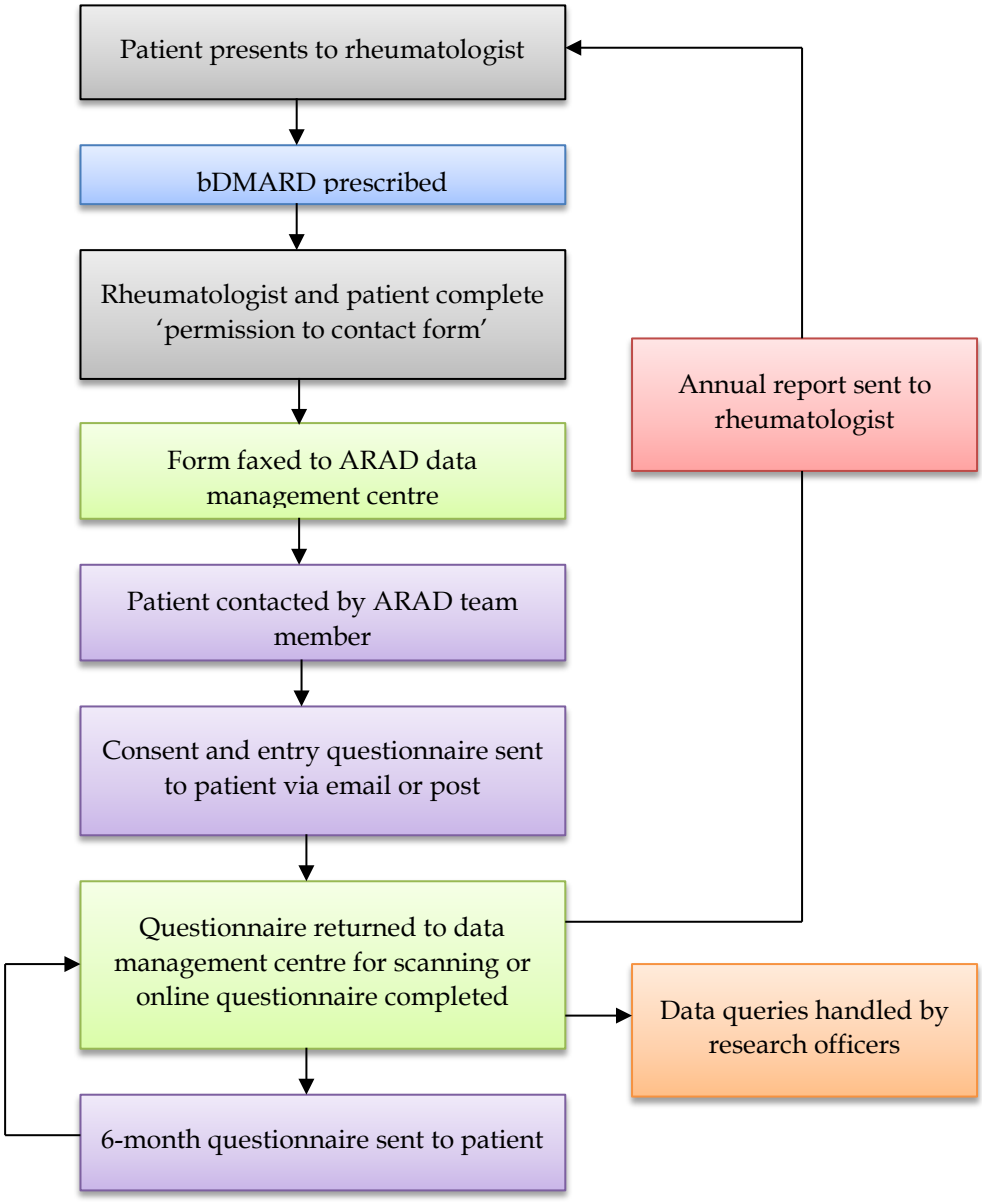
Ethics approval for the ARAD has been obtained from 23 committees and organisations across Australia (see Appendix 1). The primary ethics committee for the ARAD is that of the Cabrini Hospital. As part of the ethics approval process, ARAD personnel need to be familiar with, and abide by, the requirements set out in relevant privacy legislation, the National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research.

Recruitment and data collection

The recruitment and data collection process is shown in Figure 2.3. Patients visiting a rheumatologist and subsequently prescribed bDMARDs are invited to participate in the ARAD by the rheumatologist.

The patient provides their contact details and signs to receive information on the ARAD. These documents are sent to the ARAD Data Management Centre. The relevant state research officer then contacts the patient and provides further information and the standardised baseline questionnaire for self-completion. Patient consent is also obtained to access their Medicare and national/state health registry data for data linkage (National Death Index; Australian Cancer Database; state and territory cancer registries).

Follow-up questionnaires are mailed every 6 months. Patients with inflammatory arthritis not taking a bDMARD are also asked to participate as study controls. (Note that those in the control group may have less severe inflammatory arthritis at the time of recruitment and so caution needs to be exercised when making comparisons.)



Source: Buchbinder et al. 2007.

Figure 2.3: ARAD recruitment and data collection processes

Data collection and entry

The ARAD data are protected through secure access and transfer controls, in line with relevant legislation, regulation, standards and guidelines. Skilled data entry personnel check the data and correct errors. The ARAD data are stored in a password protected-database and data are transferred via a secure file transfer system. Participants receive an individual link to their online questionnaire and log in with their date of birth and postcode.

Relevance

Key questions in the assessment of the data collection's relevance are:

- Does the data collection measure the concept identified by the end user of the data?
- Is the data source representative of the target population identified by the end user of the data?

Data collected through the ARAD

The ARAD questionnaire has been designed to ensure collection of all the data elements needed to assess the safety and effectiveness of biological drugs used to treat inflammatory arthritis. Of potential relevance for population health monitoring, the ARAD collects detailed information over time about patient treatment and patient-reported outcomes (quality of life) from individuals with inflammatory arthritis. This has been acknowledged as an identified data gap for monitoring purposes (AIHW 2014b).

Data collected also includes lifestyle risk factors (for example, smoking, alcohol consumption and weight) and comorbidities (for example, heart disease and diabetes) which allows for these factors to be controlled for in any analysis. The data currently collected as part of the ARAD from the rheumatologist, patient and through record linkage are presented in Table 2.3.

Table 2.3: Data collected at as part of the Australian Rheumatology Association Database

Rheumatologist data	Patient data	Record linkage data
Rheumatologist ID code	Patient identifying information (Medicare number, date of birth)	Australian Cancer Database
Diagnosis	Demography (age, gender, race, marital status, education)	Medicare Australia
bDMARD prescribed	History of arthritis	National Death Index
Baseline erythrocyte sedimentation rate	Medical history (illness, infection, cancer, symptoms)	State and territory cancer registries
Baseline C-reactive protein	Smoking and alcohol consumption history	
Baseline joint count	Medication history	
Chest x-ray result	Reasons for ceasing medication for arthritis	
Mantoux test result	Adverse events	
	Global evaluation of disease activity	
	Health Assessment Questionnaire	
	Assessment of quality of life	
	Short Form–36 Health Survey	
	European Quality of Life Survey	

For the initial data entry, the rheumatologist provides clinical data, while the patient provides identifying information, demographic details and information on their medical history. Patients provide information on risk factors; disease type and years of arthritis symptoms; medication history; and health-related quality-of-life measures.

Quality-of-life instruments include: the 36-Item Short Form Health Survey (SF-36), the Assessment of Quality of Life (AQoL), the EQ-5D, and arthritis-specific disability assessed by the 'physical function' scale of the Health Assessment Questionnaire (HAQ). This data source has an extensive amount of personal information linked to medication use and health outcomes.

Representativeness of the target population

As shown in Figure 2.3, the recruitment and data-collection process relies on a number of important steps. Coverage is therefore dependent on:

- sufferers of inflammatory arthritis visiting a rheumatologist
- these patients being prescribed bDMARDs (only once the above condition is met)
- the rheumatologist informing the patient about ARAD, completing a 'permission to contact' form and providing clinical data
- the patient completing the baseline questionnaire
- the patient completing 6-monthly questionnaires.

This is visually represented in Figure 2.4.

Note: There is a pathway for self-referral; however, the uptake is small through this process.

Figure 2.4: Coverage of the Australian Rheumatology Association Database

It is difficult to completely verify the generalisability of ARAD data to all Australians receiving biological drug therapy for inflammatory arthritis. However, ARAD participants are drawn from all over Australia and from a variety of settings including hospital and community-based care, and from metropolitan, regional, and rural practices. Participants appear to be nationally representative (Williams et al. 2011). It has been verified that the majority of eligible patients of participating rheumatologists are asked to participate in the ARAD (Briggs et al. 2009).

Participant numbers

Participants are thought to represent about a quarter of all patients with inflammatory arthritis who have been exposed to biologic therapy in Australia. As such, a degree of selection bias may exist, with further investigation needed to determine the comparability of those in the ARAD with those not in the ARAD. As at February 2014, 3,102 participants are completing questionnaires and a further 2,137 have agreed to allow information to be gathered from state and national registries (1,558 of whom have completed at least 1 questionnaire). There are 35,000 completed questionnaires in total. Just 276 patients signed up in 2013, down from 440 in 2012 and 1,434 in 2007. About 15% of participants have not been exposed to bDMARDs and serve as a control group.

The number of participants completing questionnaires every 6 months decreases over time and so retention is difficult. As at January 2014, there is a 79.6% response rate for online and 73% response rate for paper follow–up questionnaires. Out of 342 registered rheumatologists in Australia, 268 are participating in the ARAD (approximately 75%). However, just 55 rheumatologists provided patients to the ARAD in 2013 (ARAD 2013).

Timeliness

Key questions in the assessment of the data collection's timeliness are:

- Are the data up-to-date and current?
- Are there likely to be subsequent surveys or data collections?

Participants completing paper-based surveys are entered into the database within 1 week and there is no delay in the availability of data submitted by online participants. Once the data have been entered into the system, many items are automatically flagged for validation, such as cancer reports, serious infections, incomplete bDMARD medication dates and hospitalisations. These data queries may take up to 1 month depending on the ease of contact with the patient and/or health provider. It is anticipated that, subject to funding, data collection will be ongoing.

Accessibility

Key questions in the assessment of the data collection's accessibility are:

- Are there processes in place to facilitate data access?
- Can the data source be provided in a timeframe suited to the user's requirements?
- Are the data available in suitable formats?
- Are data available at costs affordable to the user's project?

Procedures are in place for external researchers to access the ARAD database. Researchers need to submit an expression of interest form, a research proposal and ethics approval from the researcher's institution to the ARAD Scientific Advisory Committee for consideration. If

access to patient personal information is required then an 'ARAD Confidentiality Agreement for External Researchers' must be completed and signed by all project staff before the information can be released.

Research proposals need to be approved by the ARAD Steering Committee before data requirements are sent to the data management centre. The average time for this process is about 6 weeks.

ARAD data formats

Data are generally provided in STATA format. However, if requested, data may also be available in other formats including Excel and SPSS. When the data file contains identifiable information, the file is transferred via a secure website (to which users are granted access with a username and password), in accordance with the *Health Records Act 2010* and *Privacy Act 1988*.

Interpretability

Key question in the assessment of the data collection's interpretability are:

- Are metadata available to support appropriate interpretation of the data?

A data dictionary/definitions manual is provided along with the dataset. This identifies the variables used in the data file and the corresponding item on the survey. The codes for each variable are also specified.

Accuracy

Key questions in the assessment of the data collection's accuracy are:

- Do the data reflect the condition or situation they were designed to measure?
- Are potential or acknowledged sources of error described?

To ensure the success of the registry, the process of quality control and data validation undergoes continued development and refinement. Researchers take a random sample of rheumatologist records to assess the concordance of patient responses concerning history of malignancy and adverse events to arthritis medications They also determine concordance through record linkage with the State cancer registries through the Australian Cancer Database.

In addition, the ARAD data query system identifies missing data when the questionnaire arrives at the data management centre. Other processes to ensure database quality include:

- minimising selection bias by developing a tracking log for participating rheumatologists to ensure all patients starting bDMARDs are invited to participate in ARAD
- regularly updating the standard operating procedure manual to reduce the number of data queries
- regularly updating database programs to identify any contradictory information provided by patients
- developing a spontaneous reporting scheme for rheumatologists to report adverse events. Information about adverse events is also to be forwarded to the Adverse Drug Reactions Advisory Committee.

Coherence

Key questions in the assessment of the data collection's coherence are:

- Does the data source use standard concepts, classifications and target populations?
- Does the data source use methodologies comparable with other data collections?

The ARAD uses standard data collection measures and standardised quality-of-life questionnaires, where applicable, to enable meaningful comparisons to be made and to enable linkage to other Australian and overseas arthritis registries and databases. The ARAD is supported by a data definitions manual which provides a reference for the ARAD field definitions and codes. This publically available manual ensures a consistent approach to data collection and entry.

Observational and longitudinal observational studies can provide information about the course and outcome of long term conditions that are difficult to obtain from other types of studies, such as randomised controlled trials. To help ensure the comparability between different longitudinal studies, it is useful to include agreed core variables. The data collected through the ARAD meet the Outcome Measures in the Rheumatology IV preliminary core set of domains for longitudinal observational studies in rheumatology.

Linkage to other registries and databases enables validation and verification of data reported by participants.

Summary assessment

A summary of the AIHW's assessment of the 7 data-quality elements of the ARAD are presented in Table 2.4. This assessment shows a strong commitment by the ARAD management team to ensure the quality, comprehensiveness and usability of data collected for ARAD. The production and dissemination of the ARAD data are undertaken in an objective, professional and transparent manner. There are also administrative and governance processes in place to ensure data quality and compliance with legislative requirements.

While the concept measured by the ARAD is highly relevant for the purpose of monitoring arthritis, the registry only includes about 25% of all patients with inflammatory arthritis taking bDMARDs with the participation of about 75% of rheumatologists in Australia. Consequently, the data source is considered to be only partially representative for national monitoring purposes.

The ARAD would provide timely data, in suitable formats with sufficient supporting information (metadata), to allow correct interpretations to be made. The ARAD data source would also provide relevant information on treatment, quality of life and disease progression.

The ARAD has been designed to collect the necessary data elements for assessing the safety and effectiveness of biological drugs used to treat inflammatory arthritis. To ensure the accuracy and quality of the data, the ARAD uses standard data collection measures to enable meaningful comparisons to be made and to enable linkage to other registries and databases.

Table 2.4: Assessment of the ARAD's 'fitness for purpose' for national monitoring of musculoskeletal conditions (Step 3)

Data quality element	Key question	Yes	Partially	No
Institutional environment	Is the production and dissemination of data undertaken in an objective, professional and transparent manner?	x		
	Is the agency producing the data independent and free from potential conflicts of interest?		x	
	Are there sufficient resources for the collection and production of the data?		x	
	Are there processes, staff and facilities in place to ensure data quality?	x		
	Does the data source comply with privacy and legislative requirements for managing data?	x		
Relevance	Does the data collection measure the concept identified by the end user of the data?	x		
	Is the data source representative of the target population identified by the end user of the data?		x	
Timeliness	Are the data up-to-date and current?	x		
	Are there likely to be subsequent surveys or data collections?	x		
Accessibility	Are there processes in place to facilitate data access (e.g. ethics committees where appropriate; data transmission arrangements)	x		
	Can the data source be provided in a timeframe suited to the user's requirements?	x		
	Are the data available in suitable formats?	x		
	Are data available at costs affordable to the user's project?	x		
Interpretability	Are metadata available to support correct interpretation of the data?	x		
Accuracy	Do the data reflect the condition or situation they were designed to measure?	x		
	Are potential or acknowledged sources of error described?	x		
Coherence	Does the data source use standard concepts, classifications and target populations?	x		
	Does the data source use methodologies comparable with other data collections?	x		

3 Findings

This working paper uses the AIHW's newly developed assessment framework for population health data sources (AIHW 2014a) to assess the suitability of the ARAD as a potential data source for population health monitoring of inflammatory arthritis.

Assessment findings for steps 1 and 2

The ARAD is a voluntary national registry that collects longitudinal health information, including quality-of-life measures, from individuals with inflammatory arthritis. The database, managed by the Australian Rheumatology Association, monitors the benefits and safety of new treatments, particularly the bDMARD drugs. (Database details are included in Table 2.1).

There is a known information gap relating to information on the treatment and management of arthritis and the resultant impact on quality of life (AIHW 2014b). The ARAD has the potential to fill a range of data gaps in relation to key questions for monitoring arthritis and other musculoskeletal conditions, namely those relating to treatment outcomes, disease progression, quality of life and economic impacts. (Database details are included in Table 2.2).

Assessment findings for step 3

The AIHW's assessment of the ARAD 'fitness-for-purpose' for population health monitoring is summarised in Table 2.4. The assessment shows that the ARAD has well-established administrative and governance arrangements in place to ensure data quality and compliance with privacy and legislative requirements. The concepts measured and collected in the ARAD are considered relevant for the key monitoring areas for arthritis, such as treatment outcomes and quality of life for individuals with inflammatory arthritis.

The AIHW has determined that the ARAD is likely to provide timely data, in suitable formats with sufficient supporting information (metadata) to allow correct interpretations to be made. The ARAD also uses standard data-collection measures and so meaningful comparisons and linkages can be made to other registries and databases.

One potential limitation of the database is its coverage. Participants are thought to represent about a quarter of all patients with inflammatory arthritis who have been exposed to biologic therapy in Australia. Difficulties in retaining participants have been noted and recently numbers participating in the ARAD have declined slightly.

Possible future uses of the ARAD

Potential future uses of the ARAD for population health monitoring of arthritis could include investigating the following:

- recipients of joint replacement surgery, through data linkage using patients on DMARDs as controls
- patterns of death among people using bDMARDs, by linking ARAD to the National Death Index
- long-term adverse effects of bDMARDs, by linking ARAD with cancer registries
- disease progression of patients treated with bDMARD medication, by linking ARAD to the MBS/PBS, using patients on DMARDs as controls.

‘On balance’ assessment

Potential to inform policy

When assessing the usefulness of the ARAD, it is important to first establish its suitability and relevance to help inform policy questions and to fill information gaps. There is a known information gap relating to information on the treatment and management of arthritis and the resultant impact on quality of life (AIHW 2014b).

Improving treatment and care for people with inflammatory arthritis can help prevent or slow disease progression, reduce pain, preserve independence and improve quality of life. Early diagnosis of rheumatoid arthritis, the most common form of inflammatory arthritis, can alter the course of the disease, prevent or delay joint damage and improve long-term outcomes. If poorly treated, inflammatory arthritis can be highly disabling and can cause progressive and irreversible joint damage and loss of function.

More than half (58%) of all people with rheumatoid arthritis are of working age (25 to 64 years). Within 5 years of diagnosis, up to 20% of people can no longer work due to their condition (Arthritis Australia 2014).

The AIHW notes that the ARAD contains relevant data on self-assessed quality of life using several standard instruments, including a utility instrument. In addition, the ARAD also contains data on treatment outcomes, disease progression and employment status for people with inflammatory arthritis.

Data source assessment of ‘fitness for purpose’

Once it is established that a data source has the potential to provide policy-relevant information, the next step is to undertake further assessment to determine if the data source is ‘fit-for purpose’(that is, suitable for population health monitoring). As noted in Chapter 2, the AIHW’s assessment of the ARAD shows the production and dissemination of the ARAD data are undertaken in an objective, professional and transparent manner and that governance processes are in place to ensure data quality and compliance.

There are particular data quality elements where the dataset presents some challenges in terms of its suitability of population health monitoring. This includes the potential perception of its independence (based on the funding involvement of pharmaceutical companies); the lack of secure ongoing funding; and the incomplete coverage of the desired target population (which may affect the representativeness of findings).

Benefits of data linkage

The coverage of the ARAD could be improved by linking to other similar data sources such as the Optimising Patient Outcomes in Australian RheumatoLogy (OPAL) database. When considering potential uses for data linkage, it is important to specify the purpose of the data linkage and identify what policies it may contribute to.

Data linkage of the ARAD to other data sources, such as the MBS/PBS and cancer registry data, could also provide valuable information on patient movements across health settings, disease progression and treatment outcomes. Rheumatoid arthritis is also associated with increased mortality (Arthritis Australia 2014) and this could be further investigated by linking the ARAD with the National Death Index.

Overall assessment

Despite its incomplete coverage, the AIHW considers the ARAD has the potential to help fill identified data gaps relevant for national population health monitoring of musculoskeletal conditions.

Appendix 1

The ARAD Human Research Ethics Committee (HREC) approvals (as of January 2014)

Institutes/Hospitals

1. ACT Health HREC
2. Australian Institute of Health & Welfare Ethics Committee
3. Cabrini Hospital HREC
4. The Cancer Council New South Wales and New South Wales Health HREC
5. Western Australian Health HREC
6. Department of Veterans' Affairs HREC
7. Monash University Research Ethics Committee
8. Northern Sydney Local Health District Human Research Ethics Committee
9. Princess Margaret Hospital (WA) HREC
10. Royal Children's Hospital Victoria HREC
11. South Australia Department of Health HREC
12. South Eastern Sydney Local Health District HREC
13. St Vincent's Hospital (Melbourne) HREC
14. The Tasmania Health and Medical HREC
15. The Women's & Children's Health Network HREC
16. Sydney Children's Hospitals Network HREC

Cancer registries

17. Australian Capital Territory Cancer Registry
18. Queensland Cancer/Department of Health
19. Northern Territory Department of Health
20. Victoria Cancer Council
21. Tasmania Cancer Registry
22. South Australia Cancer Registry
23. Western Australia Cancer Registry

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