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The Patient

Patient-Centered Outcomes Research



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Stakeholder Satisfaction with the Australian Rheumatology Association Database (ARAD)

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Abstract

Background: The Australian Rheumatology Association Database (ARAD) is a voluntary national registry for monitoring the long-term benefits and safety of biological disease-modifying anti-rheumatic drugs (bDMARDs) for inflammatory arthritis. Both rheumatologists and patients contribute data to the ARAD.

Objective: To evaluate the satisfaction of patients and rheumatologists with the ARAD.

Methods: Cross-sectional surveys were distributed to a random sample of 100 community-dwelling ARAD patients in 2007 and to rheumatologists attending the 2007 Australian Rheumatology Association (ARA) annual scientific meeting.

Survey questions included items about the usefulness of the ARAD, workload for participants, frequency of questionnaires, and experience of contact with ARAD staff.

Results: A total of 92.5% of patients perceived the ARAD as very important (scoring 9–10 on a numeric rating scale). Patients reported minimal difficulty in completing questionnaires, and 95.0% indicated that a 6-month interval between questionnaires was reasonable. Of responding rheumatologists, 32.3%, 62.1%, and 53.8% indicated that the ARAD was very important (scoring 8–10) with respect to clinical information, research, and the profession, respectively, while 68% of those participating in the ARAD reported that the workload

required to enroll patients was manageable and 30% found it difficult or onerous.

Conclusion: Key stakeholders in the ARAD view it as an important resource and are satisfied with its operations. Efforts will be directed towards assisting those rheumatologists who find the associated workload difficult and to improving the perceived clinical value of information available from the ARAD.

Background

The health outcomes of patients with uncontrolled severe inflammatory arthritis have improved markedly with the introduction into clinical practice of biological disease-modifying anti-rheumatic drugs (bDMARDs) including etanercept,^[1] infliximab,^[2] adalimumab,^[3] and anakinra.^[4] Like conventional DMARDs, long-term continuation of these agents is required to maintain effectiveness. While the long-term outcomes and risk profiles of conventional DMARDs have been extensively investigated, because of their relatively recent introduction, the long-term outcomes of biological agents in inflammatory arthritis is not yet well elucidated. For this reason, several countries, including Australia, have established long-term observational studies in the form of health registries for the purpose of monitoring the long-term safety and efficacy of bDMARDs used in routine clinical care.^[5] Health registries provide an ideal means of monitoring drug safety and efficacy in a 'real world' context since consumer participation is not restricted by rigid inclusion criteria, as is the case in randomized controlled trials (RCTs). For example, a recent study^[6] reported that only 5% of patients typically seen in practice would be eligible for inclusion in a bDMARD RCT.

Australian Rheumatology Association Database

The Australian Rheumatology Association Database (ARAD) was established in 2003, coinciding with the listing of bDMARDs for inflammatory arthritis on the Australian Pharmaceutical Benefits Scheme (PBS).^[5] This national database is partially funded by an Australian

National Health and Medical Research Council (NHMRC) Enabling Grant, and by industry through unrestricted grants paid to the ARA. The background, structure, and governance of the ARAD have been described previously.^[5]

As of May 2008, there were 2334 patients and 178 rheumatologists actively participating (67.9% of ARA member rheumatologists active in clinical practice) in the ARAD. While we cannot completely verify the generalizability of ARAD data to all Australians receiving biological therapy, the ARAD participants are drawn from all over Australia and from a variety of settings including hospital- and community-based care, and metropolitan, regional, and rural practices. We have also verified that the majority of eligible patients of participating rheumatologists are asked to participate in the ARAD, thus ensuring the internal validity of the database.^[7]

Currently, 194 (8.8%) participants have ceased completing questionnaires for the ARAD but continue to provide outcomes data through linkage of their details with Medicare Australia and national and state cancer and death registries. Unlike registries in some other countries (e.g. the British Society of Rheumatology Biologics Register [BSRBR]), participation in the ARAD by rheumatologists and patients is voluntary and data are derived predominantly from patient responses to 6-monthly questionnaires. It was understood at the creation of the ARAD that busy clinicians would not participate in the ARAD if it added significantly to their workload, particularly as prescription of bDMARDs in Australia is already time consuming and requires completion of authority request forms initially and every 6 months thereafter. Rheumatologists are therefore only required to complete basic details about their eligible

patients at the time of enrollment and to ask eligible patients to complete a 'permission to be contacted by the ARAD team' consent form. However, more information from rheumatologists is often sought to clarify or verify data provided by the patient.

We report the results of two stakeholder satisfaction surveys of patients and Australian rheumatologists participating in the ARAD, performed as a requirement of the Enabling Grant funding and in recognition that a patient-centered approach is relevant in any evaluation of healthcare services.^[8] We also explored their views to determine the perceived importance of the database and to identify any barriers to participation in the registry so that we may continue to improve buy-in from both patients and rheumatologists and deliver a high-quality health resource.

Methods

A survey and reply-paid envelope were mailed to 100 (7.2% of the cohort at May 2007) ARAD patients. These patients were randomly selected according to a computer-generated randomization schedule written to identify 100 ARAD patients from the central ARAD database who met the following criteria:

1. the participants must have been enrolled in the ARAD for at least 12 months to ensure adequate exposure to the operations of the ARAD;
2. the participants must have returned at least three questionnaires (0-, 6-, 12-month time-points) to ensure that respondents had experience with, and were familiar with, completing the ARAD questionnaires.

A reminder letter was sent after 3 weeks to those patients who had not responded. Participants responded to questions regarding the importance of collecting health information, frequency of the ARAD questionnaires, the level of difficulty and time required to complete questionnaires, and contact experiences with ARAD staff.

At the same time, a brief, anonymous survey was distributed to delegates during a plenary

session at the May 2007 ARA Scientific Meeting in Sydney, asking rheumatologists to provide feedback on their views and experiences (if applicable) of the ARAD. A survey designed by the BSRBR for a similar purpose was used as a model.^[9] Rheumatologists responded to questions regarding their prescribing practices, the scientific and professional usefulness of the ARAD, enrolling patients into the ARAD, the workload associated with the ARAD, and the usefulness of biannual reports issued by the ARAD data center.

Surveys for both parties were designed using 11-point (0–10) numeric rating scales (NRS) and nominal response categories.

Approval to conduct the surveys was granted by the Human Research Ethics Committees of Cabrini Hospital (Melbourne, VIC, Australia) and St George Hospital (Sydney, NSW, Australia). Descriptive statistics were used to analyze the response data. Independent t-tests and chi-square tests were used to test differences in characteristics between the ARAD patient responders and non-responders. All data were analyzed using SPSS version 15.0 (Chicago, IL, USA).

Results

Patient Survey

A total of 80 ARAD participants (under the care of 42 rheumatologists) responded to the survey (80% response rate) and there were 20 non-responders (under the care of 16 rheumatologists). There were no significant differences in age, disease duration, or sex distribution between the responders and non-responders ($p > 0.05$; table I).

The ARAD was generally perceived by patients to be very important, with 92.5% indicating a score of 9 or 10. The perceived importance of collecting information on demographics, disease state, lifestyle factors, quality of life, medical history, and medication history was also high (figure 1). Questions were not perceived to be complex, and respondents reported minimal emotional and physical difficulty completing the questionnaires (figure 2).

Table I. Characteristics of the patient respondents and non-respondents

Diagnosis	Respondents (n=80)				Non-respondents (n=20)			
	n (%)	mean age [y (SD)]	mean disease duration [y (SD)]	female (%)	n (%)	mean age [y (SD)]	mean disease duration [y (SD)]	female (%)
Rheumatoid arthritis	75 (93.7)	57.8 (11.9)	17.5 (11.6)	64.0	17 (85.0)	54.2 (13.1)	17.9 (10.6)	68
Ankylosing spondylitis	4 (5.0)	54 (22.3)	13.7 (11.7)	0	2 (10.0)	65 (4.2)	38.5 (2.1)	0
Psoriatic arthritis	1 (1.3)	32	13	0	1 (5.0)	41	17	100

The majority of participants (n=76, 95.0%) indicated that 6 months was a reasonable time interval between questionnaires. The time required to complete the questionnaires varied; half the respondents (n=40) reported that completion of questionnaires took 10–20 minutes, 21 (26.3%)

took 20–30 minutes, 18 (22.6%) took 30–60 minutes, and 1 (1.3%) required more than an hour. Participants were generally very satisfied with introductory calls received from ARAD officers explaining the study requirements (data not shown).

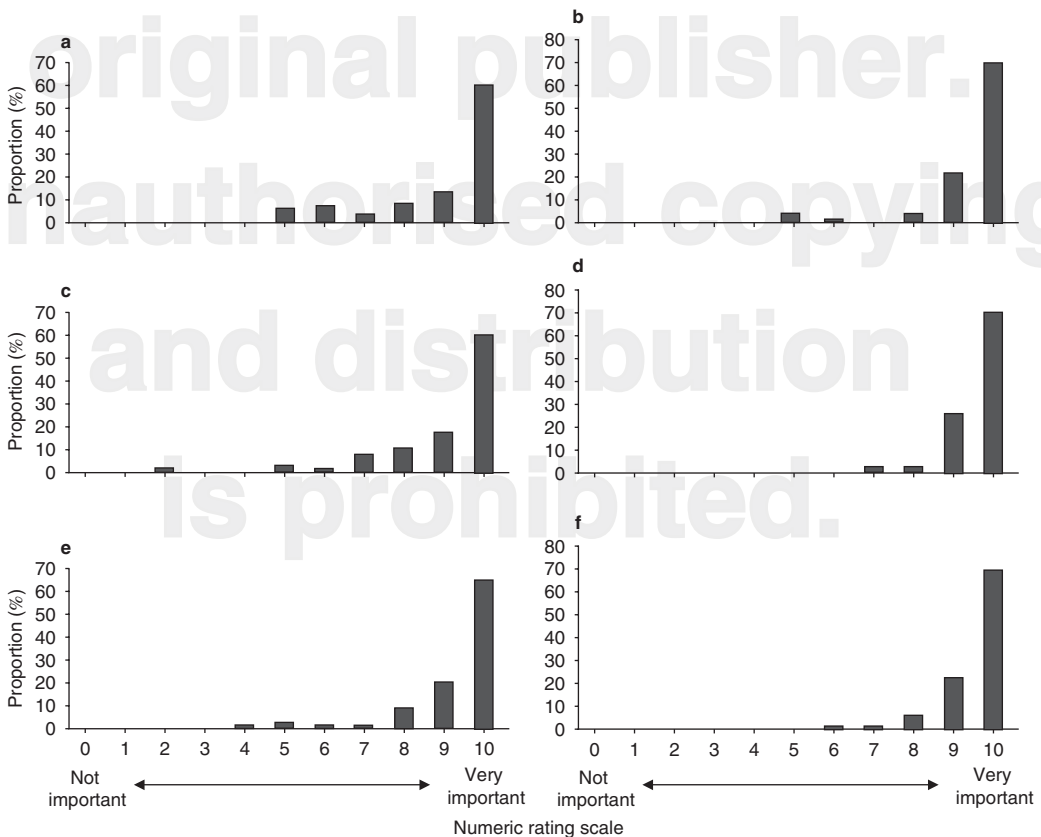


Fig. 1. Patient-perceived importance of collecting information on (a) demographics; (b) disease state; (c) lifestyle factors; (d) quality of life; (e) medical history; and (f) medication history. Data expressed as proportion of responses at each point on the numeric rating scale for each question (n=80, 79, 80, 79, 79, 80, respectively).

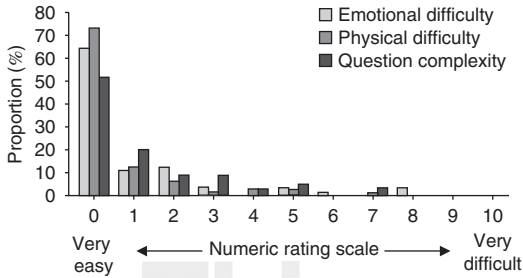


Fig. 2. Patient-perceived question complexity and physical and emotional difficulty in completing the questionnaires (n=80).

Rheumatologist Survey

The 2007 annual scientific meeting was attended by 200 registered ARA rheumatologists (55.7% of all 2007 ARA membership in Australia [n=359]), and 68 (34.0%) completed the survey. Of these, 63 (92.6%) were full ARA members, 4 (5.9%) were advanced trainees, and 1 (1.5%) was an associate member. This distribution broadly reflects the ARA Australian membership for 2007 (76.6% full members, 7.0% advanced trainees, 5.0% associate members, 3.9% honorary members, 3.3% non-medical members, 4.2% retired members). A majority (n=62, 91.2%), reported prescribing bDMARDs in clinical practice; of the five (7.4%) who did not prescribe bDMARDs, two were advanced trainees and one did not respond. Most rheumatologists who indicated that they prescribed bDMARDs had enrolled patients into the ARAD (n=53, 85.5%), while eight (12.9%) had not enrolled any patients, and one (1.6%) did not respond. Reasons cited for not enrolling patients in the ARAD were not knowing about it (n=2), not working in rheumatology (n=2), shortage of time (n=2), and no reason given (n=2).

The importance of the ARAD was rated as 8–10 on the NRS for rheumatology research, for providing clinically useful information about individual patients, and for the profession by 62.1%, 32.3%, and 53.8% of respondents, respectively (figure 3). The workload required to participate in the ARAD (asked of the 53 participating rheumatologists) was regarded as manageable by 34 (68%), difficult by 11 (22.0%), very onerous by 4 (8%), and impossible by 1 (2.0%);

3 did not respond. Perceived ease/difficulty of enrolling patients into the ARAD varied (e.g. 33.3% indicated that it was very easy [0–2 on NRS] vs 11.8% who indicated it was very difficult [8–10 on NRS]; figure 4). Some rheumatologists (n=21, 39.6%) indicated that they had contacted the ARAD staff for assistance with recruitment or for additional resources, and they were generally very satisfied with the outcome (data not shown).

A total of 44 (83.0%) rheumatologists reported having received biannual ARAD reports, while 6 (11.3%) had not; 3 (5.7%) did not respond. Most respondents who reported having received a report found them to be useful (51.3% of responses falling between 7 and 10 on the NRS. A small proportion of respondents (n=5, 11.4%) who had received a report indicated that they would prefer to see more information presented and/or to receive reports more frequently.

Discussion

The results of these surveys indicate that the key stakeholders of the ARAD, both patients receiving biological therapy and their treating rheumatologists, were generally satisfied with the database. The majority of rheumatologists who participated in this survey viewed the ARAD as an important resource for research, clinical information, and the rheumatology profession in Australia, while similar views were obtained from

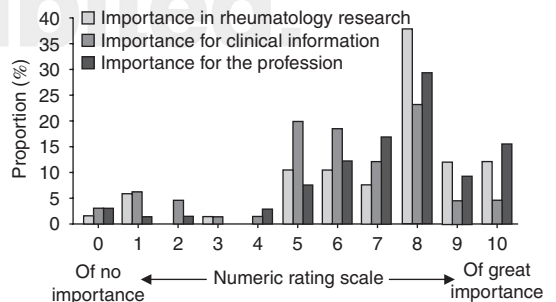


Fig. 3. Rheumatologist-perceived importance of the Australian Rheumatology Association Database for rheumatology research (n=66), for providing clinical information about individual patients (n=65), and for the rheumatology profession (n=65). Data presented as the proportion of responses at each interval in each domain.

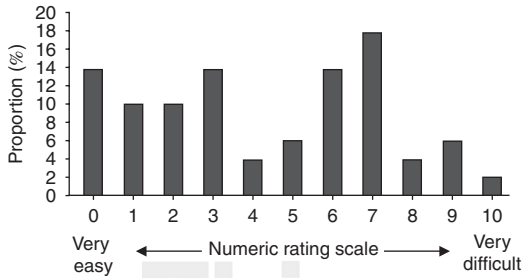


Fig. 4. Rheumatologist-perceived level of difficulty in enrolling patients into the Australian Rheumatology Association Database (n=51).

patients with respect to the importance of the ARAD. Although the rheumatologist response rate was low (34.0%), it was comparable to the response rate (26.7%) of a similar survey conducted by the BSRBR.^[9] In hindsight, it may have been more appropriate to survey rheumatologists in ways other than, or in addition to, those attending a single session of the annual scientific meeting of the ARA, although this mode was selected to minimize any disruption to the delegates.

Although previous surveys of patient/participant satisfaction have been reported for patient-health professional internet-based interfaces,^[10,11] community pharmacy operations,^[8] pre-natal nutritional intervention programs,^[12] nutrition programs for HIV community clinics,^[13] and residential childcare facilities,^[14] the current study is the first to report patient satisfaction for a health registry. The ARAD was generally highly regarded by patients in terms of its importance, personal contact with ARAD staff, and did not impose a significant burden. Indeed, the high response rate for the patient survey may reflect this positive attitude, while previous research has demonstrated a positive correlation between overall satisfaction and the perceived importance of health services provided and usefulness of communication.^[15]

In this study, the ARAD participants were randomly selected on the basis that they were enrolled in the ARAD for at least 12 months and had completed at least three sequential questionnaires. These criteria were chosen to ensure that respondents had sufficient experience with

the operations of the ARAD, some contact with ARAD staff, and familiarity with ARAD communications such as the questionnaire and newsletter, to enable them to answer the satisfaction survey adequately. It may be equally important to canvas the viewpoints of those participants who have withdrawn from active participation in the ARAD but whose health records are still tracked through national health registries, and those patients who are more recently enrolled in the database and have completed fewer than three questionnaires. This could be a focus of future satisfaction audits.

The majority of those rheumatologists who participated in the ARAD (n=53) reported that the workload to enroll patients into the ARAD is manageable. Nonetheless, about 10% indicated that the ARAD workload was very onerous or impossible and/or reported difficulty in enrolling patients into the database. Since conducting this survey, ARAD research officers have assisted several rheumatologists in identifying and recruiting suitable patients into the ARAD.

In contrast with the ARAD, where rheumatologist participation is voluntary and most information is collected from the patient, participation in the BSRBR is mandatory for rheumatologists who prescribe bDMARDs, and involves periodically submitting patient-specific data. Not surprisingly, the perceived workload reported by rheumatologists in our study was less than that perceived by British rheumatologists enrolling patients into the BSRBR.^[9]

Rheumatologists rated the importance of clinical information provided by the ARAD as lower than the perceived importance of ARAD data for research and the rheumatology profession. Nonetheless, 83.1% of all rheumatologists surveyed rated the importance of the clinical information as ≥ 5 on the NRS (figure 3) and >50% of participating rheumatologists rated the usefulness of biannual reports, which contain aggregate and patient-specific clinical information, as 7–10 on the NRS. While it is expected that more clinical information will be provided to rheumatologists as the ARAD expands and more analyses are conducted, it will also be important for the ARAD Advisory Committee to maintain

open channels of communication with practicing rheumatologists to ensure that clinically useful information is provided. In order to keep the responder burden of the satisfaction survey low, we did not ask rheumatologists to elaborate on which clinical information they considered to be most and least useful. This may be an important avenue to explore in the future.

Long-term observational databases such as the ARAD provide important information not obtainable by other means. By carefully collecting data about patients and outcomes from routine clinical care, the long-term safety of new drug therapies can be assessed in the 'real world' including the incidence and risk factors for adverse events such as malignancy and infection, which are particularly relevant to bDMARDs. Moreover, long-term effects on important outcomes, including cardiovascular disease and mortality, can be measured.^[16,17] This approach for adverse events is more robust than spontaneous reporting schemes, such as that of the Australian Drug Reactions Advisory Committee (ADRAC).^[18] Spontaneous reporting schemes lack a comparison group, which makes it difficult to estimate the incidence of adverse events. Only a small proportion of adverse events are ever reported, and information is often incomplete, which may lead to underestimation of the true incidence.^[19] Furthermore, spontaneous reporting schemes are unable to identify potential adverse events, which might be expected to represent the natural course of a disease or already have a high prevalence in the community, for example infections.

Conclusion

The long-term sustainability of the ARAD will depend upon the availability of long-term funding as well as the ongoing support of rheumatologists and their patients. We are already introducing or considering strategies such as direct patient enrollment and direct internet-based data entry to reduce rheumatologist and participant burdens. Both clinician and patient stakeholders have indicated that they consider the ARAD to be a valuable resource. While the Australian Federal Government makes expensive

bDMARDs available to eligible patients with arthritis through the PBS, there is presently no onus on them to monitor long-term outcomes of new drugs that they subsidize to ensure that this money is well spent. As more new and expensive drugs are government subsidized, provision of funding to long-term observational registries such as the ARAD, set up and managed by clinicians with expertise in epidemiology and registry management, will be highly worthwhile. It is hoped that the generally positive stakeholder perception of the ARAD will persuade policy makers to consider long-term funding arrangements for registries such as this. It will also be important to periodically review satisfaction of key stakeholders in the ARAD to ensure continued delivery of an efficient and high-quality registry that provides a valuable resource for both clinical information and research.

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Dr Andrew Briggs was project manager for the ARAD at the time the survey data were collected.

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