

OMERACT 7 Workshop

# Progress Since OMERACT 6 on Including Patient Perspective in Rheumatoid Arthritis Outcome Assessment

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**ABSTRACT.** The first OMERACT Patient Perspective Workshop took place at OMERACT 6 in 2002. Through a series of meetings and discussion sessions a research agenda emerged and this report outlines progress made on this agenda. Work on identifying novel outcomes, instruments, and methods has shown similarities across European countries in the importance patients with rheumatoid arthritis (RA) attach to specific outcomes, in particular fatigue. Validation of an appropriate instrument to measure fatigue in patients with RA is currently being investigated. Frequent or repeated real-time assessment of symptoms such as pain and fatigue is becoming possible using electronic systems. An OMERACT Patient Panel has been established, and has produced a glossary for patients involved in supporting clinical research. In some centers, efforts are being made to provide Patient Research Partners with knowledge and skills that will enhance their contribution, and some of these approaches will be incorporated into OMERACT 7. The research agenda that was developed during the first Patient Perspective Workshop has stimulated new work in several areas. In addition, international attention has been drawn to the need to make sure that the patient's perspective is not lost among the technical expertise of rheumatology. (J Rheumatol 2005;32:2246-9)

*Key Indexing Terms:*

CONSUMER      INSTRUMENTS      FATIGUE      REAL-TIME ASSESSMENT

## Introduction

The objective of the patient perspective workshops at biannual OMERACT conferences has been to address the question of assessing the outcomes of intervention in rheumatoid arthritis (RA) from the perspective of those who experience the disease and incorporating such assessments into clinical

trial outcomes<sup>1</sup>. At the first workshop, held at OMERACT 6 in 2002, participants reviewed the current state of research in the area, identified the requirements for the development of valid instruments, delineated a research agenda that might attain these requirements, and motivated participants to undertake the appropriate research. Through a series of meetings and discussion sessions a research agenda emerged (Table 1). The purpose of this article is to outline progress made on this agenda. Many of the topics will be reported in full elsewhere, but this summary was used to provide a basis for further developments at the Patient Perspective Workshop at OMERACT 7 in 2004, where it was presented<sup>2</sup>. Several activities arising directly from the OMERACT 6 workshop, shown in Table 2, have helped to stimulate progress and widen the participation of researchers and patient participants.

## Progress on Identifying Novel Outcomes, Instruments, and Methods

**Outcomes.** Examining RA patient perspectives on outcome in several countries or cultures was one of the issues proposed at OMERACT 6 for further studies. Work on the importance of different outcomes to patients in the United Kingdom<sup>3</sup> was compared to a similar study carried out in

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Sweden (by M. Ahlmén and colleagues)<sup>4</sup>. Patient focus groups started from the questions, “What are the important outcomes from treatments?”, “How do you know when a treatment is working?”, and “What makes you satisfied or dissatisfied with treatments?”. Careful qualitative analysis allowed the identification of major themes, and those emerging from the Swedish study were compared to those in the UK study. Living a normal life, physical capacity, independence, and well-being were important in both studies. Many patients reported that the relative importance of out-

comes changes over time and depends on circumstances. British patients disclosed fear of the future, while Swedish patients announced that RA treatment called for the use of positive thinking. Thus in the UK and Sweden, the cultural differences between countries and healthcare systems do not change RA patients’ perspectives on important outcomes from treatment.

*Measures.* At OMERACT 6 patients identified fatigue as an important outcome. A quantitative study carried out in Ireland, on pain outcome and fatigue levels in RA, highlighted the importance of including fatigue as an outcome measure in RA. Women (n = 58) who participated in a quality of life cross-sectional study<sup>5</sup> were reevaluated after 4 years. The Arthritis Impact Measurement Scales 2 was used to measure 12 health status dimensions; a visual analog scale was used to measure current fatigue levels. A wide range of fatigue levels was seen. At baseline the cohort of women with established RA identified pain as the health status measure that most required improvement. They were not asked to consider the importance of fatigue at baseline, but this was included at followup, when fatigue rather than pain emerged as the health status measure that patients now prioritized for improvement. This work highlights the importance of fatigue as an outcome measure of disease and treatment impact.

Further support from this comes from the focus group study, where patients proposed fatigue in RA as an important and distressing outcome<sup>3</sup>. However, before we can provide assessment and treatment of fatigue for patients, we need to be able to measure fatigue. To do this, we need to identify current measures of fatigue that are available and assess how applicable those scales are to fatigue in RA. To achieve this, a systematic search of the literature for scales used to measure fatigue in RA is being undertaken (by M. Hehir and colleagues) using relevant databases and specified terms and combinations of terms. A total of 59 articles have been identified and are currently being scrutinized to establish what fatigue scales have been used in RA assessment and whether they are valid in this setting. The item content of the scales will be compared to the descriptors of fatigue emerging from qualitative studies with RA patients.

Table 1. OMERACT 6 Patient Perspective Workshop research agenda.

1. Identify novel outcomes and instruments of relevance
“Well-being”/“fatigue”/sleep pattern
Standardized patient RA diaries
Low disease activity state
Use of information technology for repeated measurement
Check in several countries (cultures)
Patient feedback from questionnaires
Weighting for priorities or impact
2. Terminology and current knowledge
Glossary
List of terms to define
Review existing definitions
Professional/patient glossary review group
Work particularly on fatigue/well-being as related to RA literature review
Systematic
Linked to glossary development
Publishable in itself
Leading to Cochrane reviews of appropriate outcomes
Register of current work
3. The role of the patient
Developing patient expertise
Specific educational and communication support
Mechanisms of dissemination and representation
OMERACT patient panel
Patients as writers/editors
Plain-language editing
Defining research agenda in patient terms
Patient review group for current measures
Relevance
Linguistics
Comprehension

Table 2. Activities arising from the OMERACT 6 Patient Perspective Workshop.

EULAR 2002	Full program session “New Outcome Measures” including relevant presentations from OMERACT 6
ACR 2002	Formation of ACR Patient Perspective Study Group and first meeting on “Incorporating the Patient Perspective in Standardized Outcome Assessment in Rheumatoid Arthritis — an Emerging Prospect?”
	Patient perspective researchers progress and planning meeting
EULAR 2003	Full program session “The Patient Perspective in the Assessment of Functioning, Disability and Health”
	Full program session “User-Centered Research”
	OMERACT Patient Panel established
ACR 2003	ACR Patient Perspective Study Group meeting “Measuring Fatigue and other Patient-centered Outcomes in Rheumatoid Arthritis”
	Patient perspective researchers progress and planning meeting
	OMERACT 7 Patient Perspective Workshop planning meeting
BSR 2004	Two programmed sessions including patient participants

EULAR: European League Against Rheumatism, ACR: American College of Rheumatology, BSR: British Society for Rheumatology.

A special issue of *Arthritis Care & Research* (AC&R) devoted to presenting summary reviews of over 100 measures of patient outcomes that have been commonly used in rheumatology research was published in October 2003<sup>6</sup>. In the AC&R special issue, over 21 sections representing different types of outcomes measures are presented, including the outcomes of interest identified by this group at OMERACT 6, including fatigue, well-being, and sleep. The majority of the measures are patient-focused, i.e., outcomes are assessed from the patient's perspective. Accompanying reviews are intended to help researchers and clinicians choose appropriate outcomes measures for their particular situations and patient groups. The summaries include information regarding how to obtain, administer, and score the instrument and relevant psychometric properties, and whenever possible, Internet URL links are provided so that copies of the instrument may be viewed using a web browser. For sections in which multiple instruments are reviewed, a table is presented to provide an overview and comparison of the instruments. This AC&R volume should be invaluable to both researchers and clinicians who want to measure patient-focused outcomes.

**Methods.** Patients with RA participating at OMERACT have expressed a need for more frequent measurement of relevant outcomes, due to variations of symptoms during the day and from day to day. Using electronic information technology to capture frequent variation in the burden of disease may provide an opportunity to do this. Patients also suggested that there might be a potential for improvement in their own disease control if they have access to frequent measurements of their disease status. One system takes advantage of the mobile telephone network and uses a pen-based personal digital assistant (PDA) with wireless transfer of data to a server in the hospital. Initial findings were presented by Kvien and colleagues<sup>7</sup> from 40 patients who completed a daily questionnaire, alternately 3 weeks on PDA and 3 weeks on a paper version, each twice over a total of 12 weeks. This showed the PDA system to be valid and reliable, and opens the way to wider use.

### **Progress on Terminology and Current Knowledge**

During OMERACT 6 it was recognized that occasionally patients were struggling to follow some of the information given during the presentations and discussions because of the natural use of abbreviations. Further, even as they became used to some of the abbreviations, patient participants did not always comprehend their meaning. Consequently, they requested a glossary of commonly used rheumatology and research terms that was "simple, shared, direct, communicated and understood by all." This point was reemphasized by patients attending EULAR 2003, who stated that accessibility related not only to buildings but also to language and consequently Patient Research Partners required a user-friendly glossary.

It was during EULAR 2003 that the OMERACT patient panel was established, and one of their tasks was to compile a glossary. Patients identified and developed a list of terms and abbreviations, and 2 of the members (P. Richards and M. de Wit) set about compiling the definitions, which were obtained from a variety of sources. Their sources included clinicians, journals, and the Internet. When all of the appropriate definitions had been obtained, the glossary was sent to a clinician, a researcher, and to a patient for verification. Once that process was completed, the glossary was distributed to Patient Research Partners via e-mail, and a hard copy was made available during OMERACT 7 and is now accessible on the OMERACT website ("OMERACT Glossary" available from: <http://reuma.rediris.es/omeract/docs/>)

### **Progress on the Role of the Patient in Outcomes Research**

The ways in which patients can be useful partners in outcomes research was reviewed (by E. Quest). Patients can make valuable contributions to developing a research agenda and can suggest ways to make delivery of patient care more effective. As a result of patient involvement in OMERACT 6, an international OMERACT patient panel has been formed to make further use of patients in a variety of situations. There are issues about barriers to involvement, including competence and confidence to participate, and the problems of technical and clinical language. It was patients themselves who constructed a glossary and produced several newsletters (see below). There has been greater involvement by patients as partners in research at several of the centers where OMERACT participants work, not only as subjects but also in the field of suggesting and directing topics for research. Outside OMERACT, patients are gradually being asked by researchers to give presentations at meetings, to participate in steering groups, and to be coauthors on research reviews. This has been encouraged by the patient involvement in OMERACT.

Arrangements for patient involvement at OMERACT 7 have advanced compared to the previous meeting. A larger number of patients from a greater range of countries are participating, new participants at OMERACT have been provided with personal support from patients with previous experience, patients are involved specifically in more sessions, and appropriate arrangements have been made in advance for any medical needs.

Following the establishment of the OMERACT Patient Panel, members decided to produce an occasional newsletter to keep developments moving forward. Five issues have been produced (by M. de Wit and P. Richards) and circulated by e-mail (available from <http://reuma.rediris.es/omeract/docs/>). The primary aim of the newsletter is to be a resource for Patient Research Partners. However, it should benefit all those patients and professionals interested in patient-centered outcomes. Another aim is to encourage the commitment of other clinicians and researchers to identify patients who can

get involved in research at the beginning of a project rather than merely endorsing it at the end. A further aspect of the newsletter will be to enable Patient Research Partners to share their experiences, primarily focusing on experiences in relation to involvement in and contribution to research.

Patients' direct experience of their illness and their experience of being subjects in research projects provide them with a unique insight in areas of applied clinical research. One group (J. Kirwan and colleagues) reported on how they had several Patient Research Partners at their center, helping to develop or manage a range of research projects. Recognizing the fear patients may have of being unable to contribute for a variety of reasons, they had addressed some of these issues by holding 2 Patient Research Partners' education days, as follows.

#### Why Patients May Fear Involvement as Research Partners

- Feeling that their views are not taken seriously
- Concern that they have nothing useful to contribute
- Worry that a lack of expertise in research will bar them from contributing
- Feeling that they may not understand the medical terms/language being used
- Concern that physical symptoms, disability, or other limitations make them unable to become involved.

These included information about clinical research and discussions about how patients and researchers feel when their relationship is changed from a clinical encounter to a working meeting, then back again to a clinical encounter. Although these events were popular and useful, Patient Research Partners will require more training, support, and financial provision if they are to fulfill their potential. The group hope to examine published work in the field and learn from current initiatives in rheumatology, other areas of medicine (e.g., cancer therapy), the UK National Health Service, and granting agencies (e.g., the UK Medical Research Council). Funding for a project combining this with qualitative exploration of patient research partner needs is actively being sought.

#### Discussion

The research agenda that was developed in 2002 during the Patient Perspective Workshop at OMERACT 6 has stimulated new work in several areas. The present article is limited to progress made by those able to attend and contribute to the 2004 Workshop. The most obvious areas of importance are the measurement of fatigue and the use of information technology in outcome assessment, the development of the patient glossary, and improvements in the support provided to Patient Research Partners. In addition, international attention has been drawn to the need to make sure that the patient's perspective is not lost among the technical expertise of rheumatology. Some areas of the research agenda are still being taken forward, and progress will emerge in the coming years. In the meantime, the Patient Perspective Workshop at OMERACT 7 will be able to build on what has been achieved so far.

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### Articles presented at OMERACT 7 Conference Asilomar, California, May 8–12, 2004

#### Modules

- Minimal Disease Activity for RA
- OMERACT Working Group on Safety
- Ankylosing Spondylitis: Imaging

#### Workshops

- Patient Perspective in Outcome Measurement
- Outcome Measures in Psoriatic Arthritis
- Outcome Measures in Fibromyalgia Syndrome

#### Special Interest Groups

- Concomitant Therapies
- Gout
- Measurement of Erosion Size/JSN
- Magnetic Resonance Imaging
- Psychoeducational Self-Management Interventions
- Reconciling Subject Differences in RCT
- Synovial Tissue
- Ultrasound Imaging
- Vasculitis

Part 1 appeared in the October issue and Part 3 will appear in the December issue of *The Journal*.

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