

OMERACT IV: Fourth International Consensus Conference on Outcome Measures in Rheumatology

OMERACT stands for "Outcome Measures in Rheumatology." This acronym was coined at the first Outcome MEasures in Rheumatoid Arthritis Clinical Trials (OMERACT) international consensus conference held in Maastricht, The Netherlands, in 1992¹. At that meeting, initiatives that had been in progress for over a decade culminated in consensus on minimum outcome measures required for clinical trials in rheumatoid arthritis (RA), subsequently ratified as the "WHO/ILAR core set for clinical trials in RA."² Since then, OMERACT can be described as an informal gathering of professionals interested in outcome measurement in rheumatology as a whole. OMERACT strives to improve outcome measurement in rheumatology research through a data driven, iterative consensus process. OMERACT is chaired by an international committee and endorsed by the International League of Associations for Rheumatology (ILAR). OMERACT conferences have been held under the auspices of the World Health Organization (WHO).

Activities of the OMERACT initiative have been faithfully reported in this journal. These include proceedings of the 3 preceding OMERACT conferences^{1,3,4}, as well as a discussion list on the Internet (contact: Belmonte@ctv.es). OMERACT II was held in Ottawa, Canada, in 1994 and focused on toxicity, generic health status measures, and economic evaluation³. As an outgrowth of this meeting 3 ILAR task forces are expected to develop recommendations. OMERACT III, held in Cairns, Australia, in 1996, focused on core sets of outcome measures in osteoarthritis and osteoporosis clinical trials, as well as psychosocial measures in rheumatic diseases⁴. Most recently we presented the OMERACT Filter for Outcome Measures in Rheumatology⁵ as an introductory paper to the fourth OMERACT conference, held in Cancún, Mexico from April 16 to 20, 1998.

OMERACT IV was attended by 120 participants from 25 countries. The conference focused on domains and outcome measures appropriate to longitudinal and observational studies, RA response criteria and imaging, and domains and measures for clinical trials in ankylosing spondylitis and lupus erythematosus. As described⁵, each module was prepared by a committee of experts who collected relevant literature data for review by all participants prior to the

conference. At OMERACT IV, plenary presentations alternated with small group sessions where participants were encouraged to express their views and preferences, applying the OMERACT Filter whenever possible. Opinions were then brought back to the plenary session, where final statements were formulated, often with the help of interactive voting. The process is iterative, as consensus does not always imply agreement, but can also lead to the formulation of a research agenda, particularly in areas where data driven decisions cannot be made. The process is also iterative, in that guidelines are forever "preliminary," based on the assumption that future data (in part driven by the research agenda) will serve to refine or modify them.

With great pleasure we present the proceedings of OMERACT IV, which will appear in 4 parts over the next 4 issues of *The Journal*. In the introductory section several papers describe the progress in OMERACT activities initiated in the past, through the different task forces. The various modules follow:

The Longitudinal and Observational Studies module was chaired by Fred Wolfe and Marissa Lassere. Its purposes were to develop guidelines for the reporting requirements that allow one to understand what was done and to understand the biases and limitations of the studies; to describe broadly the statistical methods required for analyses of such studies; and to define the core variables and/or domains that should be collected, in general, in these studies.

The module for lupus was chaired by Vibeke Strand, Josef Smolen, and Peter Tugwell. Its purposes were to define a core set of outcome domains for lupus studies, either trials or observational studies, and to start the discussion on the development of a responder index for lupus.

The module for RA response criteria was chaired by David Felson and Piet van Riel. Its purpose was to compare the applicability of the 2 sets of response criteria proposed by the American College of Rheumatology and the European League for Rheumatology.

The module for RA imaging was chaired by Maarten Boers and Désirée van der Heijde. Its purposes were to discuss problems with current scoring methods of plain radiographs, and ways to improve them; to start the development of guidelines to validate new imaging methods; and

to start discussions on what constitutes a minimum clinically important difference in damage progression, with the minimum detectable difference as a starting point.

Finally, the module for ankylosing spondylitis was chaired by Désirée van der Heijde, Nicholas Bellamy, Maxime Dougados, and Sjef van der Linden. Its purposes were to broaden the consensus over the core set of measurement domains for ankylosing spondylitis studies formulated by the Assessment in AS Working Group⁶; and to start the selection of specific instruments in the domains of acute phase proteins, functional assessment, and imaging.

We feel the proceedings summary speaks for itself, and serves as a testimony to the hard work of all those involved in making OMERACT IV a success. Finally, we would like to take this opportunity to thank our corporate sponsors. Several representatives from industry have been staunch supporters of the OMERACT process from its initiation, and have provided valuable input, both content and financial, which has been essential for the continuity of OMERACT. OMERACT IV committee members and sponsors are listed on the following pages.

ADDENDUM: To subscribe to the OMERACT electronic distribution list send an E-mail message to listserv@nic.surfnet.nl with only the following text in the body of the message: `subscribe omeract firstname lastname`. Put your real first name and last name in the specified places.

You must also send a separate E-mail request stating your name, profession, and work address. On receipt of your request your name will be added and you will receive further instructions. Forward request to list owner: M. Belmonte, E-mail: belmonte@ctv.es

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