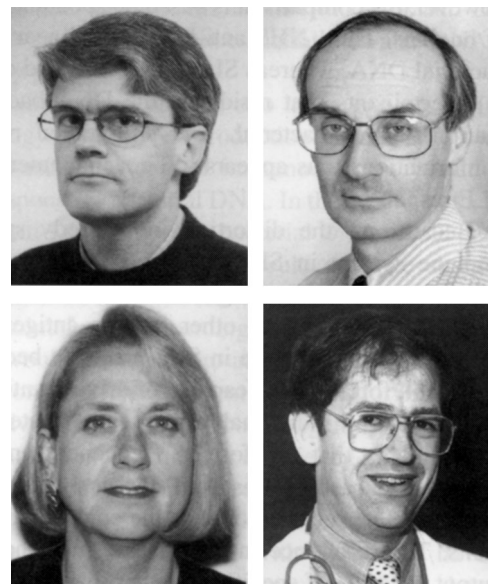


## The OMERACT Filter for Outcome Measures in Rheumatology



OMERACT stands for “Outcome Measures in Rheumatology.” The acronym was coined at an international consensus conference in Maastricht, The Netherlands, in 1992<sup>1</sup>. At this conference on Outcome Measures in Rheumatoid Arthritis Clinical Trials, initiatives that had been going on for over a decade culminated in a consensus over what was subsequently ratified as the “WHO/ILAR core set”<sup>2</sup>. Since then, OMERACT can be described as an informal gathering of professionals interested in outcome measurement in rheumatology. 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). OMERACT is linked to the Cochrane initiative, with advantages for the synthesis of results to give clinicians and patients the best estimate of benefit and risk.

OMERACT has since organized 2 other conferences, published several editions of a newsletter, and manages a discussion list on the Internet (contact: Belmonte@inf.uji.es). OMERACT II was held in Ottawa, Canada, in 1994; it focused on toxicity, generic health status, and economic evaluation<sup>3</sup>. It results in 3 ILAR task forces that are expected to produce recommendations in these areas.

OMERACT III was held in Cairns, Australia, in 1996; it focused on core sets of outcome measures in osteoarthritis and osteoporosis, and on psychosocial measures<sup>4</sup>. We are now completing preparations for the next conference, OMERACT IV, in Cancun, Mexico from April 16 to 20, 1998. (For information, please contact M. Boers). The conference will focus on longitudinal/observational studies, rheumatoid arthritis (response criteria and imaging), ankylosing spondylitis, and lupus erythematosus.

It is of note that the OMERACT process has been emulated by 2 other independent groups: one in the field of chronic juvenile arthritis<sup>5</sup>, and one in ankylosing spondylitis<sup>6</sup>. The former first developed a core set followed by response criteria, closely mimicking the process of the American College of Rheumatology and OMERACT for adult rheumatoid arthritis. The latter initially formulated a core set for ankylosing spondylitis, but has since decided to bring their process under the OMERACT umbrella.

### How does OMERACT work?

To reach consensus over what should be measured and how (i.e., what measures are applicable in trials for each clinical indication), OMERACT has developed the following procedure. First, the organizing committee polls experts and opinion leaders to generate interest in the topic at hand. These then form a committee to guide the subsequent process. From the general domains of health status defined by the “Ds” (discomfort, disability, dollar cost, death), specific domains are formulated for the topic in question. In each domain, measures are collected and tested for their applicability (see below). The domains and the applicable measures form the basis for the consensus guidelines.

The process is data driven. Literature reviews and validation studies are usually performed by small groups. The formulation and selection of the domains are made by larger committees, and the presentation of evidence (from literature and from targeted studies) and the final selection occur at the conference. Here, plenary presentations alternate with small group sessions where participants express their views and preferences. These views are brought back to the plenary session, where a final consensus is formulated, often with the help of interactive voting. Consensus does not

always imply agreement on measures or domains; it can also mean the formulation of a research agenda in areas where data driven decisions cannot be made. The process is iterative, in that guidelines are forever “preliminary,” based on the assumption that future data (sometimes a direct result of the research agenda) will serve to refine or modify them.

The selection of applicable domains and measures follows the guidelines for validity formulated by Tugwell and Bombardier, based on their study of measurement methodology in psychology, but focused towards trials<sup>7</sup>. In theory, measurement in medicine can be done for 3 main purposes: to classify, to prognosticate, and to measure change over time. In psychology, the concepts of validity and reliability have been developed with the view that measurement is mainly done to discriminate between states, and to prognosticate from a single measurement. For example, an intelligence test can be done on children at the end of primary school to suggest the level of secondary schooling. In trials, however, measurement of change is the objective, e.g., to monitor treatment effect. Thus, the concept of responsiveness or sensitivity to change becomes important, but its nomenclature and methodology have not been as well developed. In selecting measures validity is not the only issue: feasibility will determine which of the valid measures can actually be applied.

The above paragraph is a condensed version of discussions held at OMERACT. Coupled with the confusion over non-intuitive terminology and nomenclature (over which there is no consensus), we have found it useful to develop what we now call the “OMERACT filter” for applicability of measures in a certain setting. The word “applicable” is intended to include all aspects necessary for proper selection of a measure.

The OMERACT filter can easily be memorized in only three words: Truth, Discrimination, and Feasibility. Each word represents a question to be answered of the measure, in each of its intended settings:

*Truth.* Is the measure truthful, does it measure what is intended? Is the result unbiased and relevant? The word captures issues of face, content, construct, and criterion validity.

*Discrimination.* Does the measure discriminate between situations of interest? The situations can be states at one time (for classification or prognosis) or states at different times (to measure change). The word captures issues of reliability and sensitivity to change.

*Feasibility.* Can the measure be applied easily, given constraints of time, money, and interpretability? The word captures an essential element in the selection of measures,

one that may be decisive in determining a measure’s success.

In conclusion, OMERACT strives to improve outcome measurement in rheumatology through a data driven, iterative consensus process. If nothing else, it has made the selection of outcome measures more explicit, and served to place the issues around validity of measurement squarely where they belong: in the minds of clinical researchers.

**MAARTEN BOERS**, MD, MSc, PhD,  
Professor, Department of Clinical Epidemiology,  
Vrije Universiteit,  
PO Box 7057,  
1007 MB Amsterdam, The Netherlands;

**PETER BROOKS**, MD, FRACP, FAFR-CM, FAFPHM,  
Professor, Department of Medicine,  
University of New South Wales,  
St. Vincent’s Hospital  
Darlinghurst, NSW, Australia;

**C. VIBEKE STRAND**, MD, FACP,  
Clinical Associate Professor,  
Division of Immunology,  
Stanford University,  
San Francisco, CA, USA;

**PETER TUGWELL**, MD, MSc, FRCPC,  
Professor, Department of Medicine,  
University of Ottawa,  
Ottawa, Canada

*Address reprint requests to Dr. Boers.*

## REFERENCES

1. Boers M, Tugwell P for the OMERACT Committee, Conference on Outcome Measures in Rheumatoid Arthritis Clinical Trials. *J Rheumatol* 1993;20:526-91.
2. Boers M, Tugwell P, Felson DT, et al. WHO and ILAR core endpoints for symptom modifying antirheumatic drugs in rheumatoid arthritis clinical trials. *J Rheumatol* 1994;21 Suppl 41:86-9.
3. Tugwell P, Brooks P, Boers M. OMERACT II: Conference on Outcome Measures in Rheumatoid Arthritis Clinical Trials. *J Rheumatol* 1995;22:979-99; 1185-207; 1339-433.
4. Brooks P, Tugwell P, Boers M. OMERACT III: Conference on Outcome Measures in Rheumatoid Arthritis Clinical Trials. *J Rheumatol* 1997;24:763-802; 979-1001; 1206-37.
5. Giannini EH, Ruperto N, Ravelli A, et al. Preliminary definition of improvement in juvenile arthritis. *Arthritis Rheum* 1997;40:1202-9.
6. van der Heijde DMFM, Bellamy N, Calin A, Dougados M, Khan MA, van der Linden S. Preliminary core sets for endpoints in ankylosing spondylitis. *J Rheumatol* 1997;24:2225-9.
7. Tugwell P, Bombardier C. A methodologic framework for developing and selecting endpoints in clinical trials. *J Rheumatol* 1982;9:758-62.