OMERACT 2016 — International Consensus Conference on Outcome Measures in Rheumatology Clinical Trials

In May of 2016, the biennial Outcome Measures in Rheumatology (OMERACT) Conference took place in Whistler, British Columbia, Canada. OMERACT is an international network of health professionals focused on outcome measurement across randomized controlled trials and longitudinal observational studies. The objective of OMERACT is to improve outcome measures through a data-driven, iterative consensus process. At OMERACT's biennial international meetings, participants gather in a collegial interactive environment to develop core sets of patient-important outcomes for clinical studies in rheumatology.

OMERACT has published over 1000 peer-reviewed articles. It has 42 active working groups (Table 1). The number grows with every meeting, demonstrating the continuing need for this work.

OMERACT has published 10 core outcome sets [ankylosing spondylitis, fibromyalgia, gout (acute and chronic), systemic lupus erythematosus, osteoarthritis, osteoporosis, psoriatic arthritis (PsA), rheumatoid arthritis (RA), vasculitis] — the evidence is accumulating that their uptake in published clinical trials is increasing, for example, the RA Core Set is now used in over 80% of published RA trials (www.bmj.com/content/357/bmj.j2262).

The 2016 Whistler meeting was a success, with nearly 200 participants intensively participating in 5 workshops: Flare in RA, Polymyalgia Rheumatica, PsA, Antineutrophil Cytoplasmic Antibody Vasculitis, Shared Decision Making, and 16 Special Interest Groups on the program. These consisted of a variety of short presentations and small group discussions, while maintaining the ambiance of a true multidisciplinary, collaborative, friendly yet rigorous process of outcome measure development. Patient contribution continues to play a fundamental part in the OMERACT process; it not only improves the results of OMERACT research, but also gives a new perspective that is clinically relevant to the topic being researched. OMERACT 2016 hosted 21 patients from Australia, Canada, Europe, and the United States. In addition to patients, OMERACT participants came from a range of backgrounds and expertise, including clinicians and rheumatology trainees, clinical outcome methodologists who work in academic environments, regulatory agencies, pharmaceutical and biotech companies, or clinical research organizations. While some OMERACT 2016 participants reside in Canada, the majority of participants of the meeting traveled to Whistler from North America, Europe, Asia, and Australia.

Table 1. OMERACT active Working Groups (n = 42).

Disease
ANCA Vasculitis (Core Set)
Behçet Syndrome
Ankylosing Spondylitis — Reference Case
Connective Tissue Diseases — Interstitial Lung Disease
Fibromyalgia (Core Set)
Flares in Osteoarthritis
Flares in Rheumatoid Arthritis
Glucocorticoid Adverse Events
Gout
Hand Osteoarthritis
International Classification of Functioning, Disability and Health
Juvenile Inflammatory Arthritis Core Set
Large Vessel Vasculitis
Myositis
Osteoarthritis (Core Set)
Osteoporosis (Core Set)
Pain
Polymyalgia Rheumatica (PMR)
Psoriatic Arthritis
Remission in Rheumatoid Arthritis — Patient Perspective
Rheumatoid Arthritis (Core Set)
Shoulder Pain Outcome Measures
Systemic Lupus Erythematosus
Total Joint Replacement
Imaging and Biomarkers
Gout Biomarker Group
Magnetic Resonance Imaging in Arthritis
Juvenile Arthritis Magnetic Resonance Imaging
Soluble Biomarkers
Study grouP for x-trEme Computed Tomography in Rheumatoid Arthritis
Statistical Analysis of Radiographic Data in Rheumatoid Arthritis Clinical Trials
Synovial Tissues in Randomized Clinical Trials
Ultrasound
Methods
Adaptive Clinical Trial Design
Item Response Theory and Computerized Adaptive Testing
Consensus for Consensus
Contextual Factors
Critical Outcomes in Longitudinal Studies
Safety in Rheumatology Clinical Trials Working Group
Equity
Quality-adjusted Life-years
Rasch Model and Minimal Important Difference
Health Literacy
Medication Adherence
Instrumentation Across Diseases
Shared Decision Making
Stiffness
Worker Productivity

OMERACT: Outcome Measures in Rheumatology; ANCA: antineutrophil cytoplasmic antibody.

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One major focus of the meeting was the operationalization of the instrument selection part of the new OMERACT Filter 2.0 that incorporates a number of clinimetric advances that have occurred since the original OMERACT Filter. Truth, discrimination, and feasibility continue to be the pillars of the OMERACT Filter unique to OMERACT, but as part of the transition to the new Filter 2.1, to select the most promising instruments, participants presented data more detailed than previously on concept match (content validity and face validity of "truth") and feasibility (practical aspects of length, time to complete, burden, difficulty, and cost). After small group discussions, draft recommendations were brought to a plenary for a vote at this stage. We called this an "eyeball vote" because it was the first scan of the potential for this instrument.

Three Working Groups brought instruments forward at this stage: Flare RA, PsA, and ANCA Vasculitis. All received the votes they needed to move forward into a full review of published evidence and/or creation of evidence as needed for the OMERACT Filter. Based on feedback from the OMERACT community, this "eyeball vote" will be integrated into a more streamlined 1-stage process (watch for Filter 2.1).

Dissemination and promoting uptake of core sets known as "knowledge translation" was another major focus of the meeting. Led by 2 international leaders, Dr. Sean Tunis and Dr. Ian Graham in a special workshop, participants were invited to propose and discuss recommendations for the OMERACT community to (1) strengthen stakeholder involvement in the core outcome set development process, and (2) promote dissemination and implementation of core outcome sets with a specific focus on the potential role of post-regulatory decision makers.

Additional information and publications by Working Groups can also be found in The OMERACT Handbook. The OMERACT Handbook, which contains both methodological and organizational information (currently available on the OMERACT Website: www.omeract.org), has encouraged participants to become more engaged with the process by explaining various OMERACT procedures and practices. The OMERACT Handbook is currently being reviewed, and soon an updated version will be available (www.omeract.org) and will continue as a major reference resource for all those interested in outcome measure development.

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- Part 1: Introduction, Workshops, Special Sessions
- Part 2: Special Interest Groups, Part 1
- Part 3: Special Interest Groups, Part 2

Part 2 will appear in the November issue.

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