OMERACT 2018: International Consensus Conference on Outcome Measures in Rheumatology

In May of 2018, the biennial Outcome Measures in Rheumatology (OMERACT) Conference took place in Australia. OMERACT is an international network of health professionals focused on outcome measurement across randomized controlled trials and longitudinal observational studies¹. The objective of OMERACT is to improve outcome measures through a data-driven, iterative consensus process that first reaches consensus on the core domains to be measured and then aims to reach consensus on the instruments that meet the OMERACT criteria to be recommended as part of a core outcome measurement set². At this biennial international meeting, participants gather in a collegial interactive environment to develop and reach consensus on the core sets of patient-important outcomes for clinical studies in rheumatology through workshop activities and plenary voting.

It was an honor for the local organizing committee to host the OMERACT 2018 conference in Terrigal, Australia. Terrigal, “the place of little birds,” is the traditional land of the Darkinjung people. OMERACT was fortunate to be welcomed to the country by local Elder Gavi, have an opportunity to view artworks, artifacts, and bush medicine samples, and to witness traditional dances from indigenous students from the local high school.

There were numerous innovations and “firsts” at OMERACT 2018. In the lead-up to the meeting, for the first time, premeeting Webinars were hosted by the OMERACT Patient Leadership team³ to prepare patients for their active participation in their groups before, during, and after the meeting. The newly formed Technical Advisory Group reviewed all presenting groups’ workbooks prior to the meeting. The OMERACT secretariat held regular calls and virtual meetings to monitor and facilitate progress for the working groups (WG) seeking a vote at the meeting. So much input behind the scenes helped bring the meeting to fruition!

This year, a premeeting⁴ interactive discussion addressed drug safety from the patients’ perspective with patients, regulators (European Medicines Agency, US Food and Drug Administration, Pharmaceutical Benefits Advisory Committee), and OMERACT members. Important qualitative work was presented from the Glucocorticoid⁵ and the Drug Safety⁶ OMERACT WG, as well as contributions from the Standardised Outcomes in Nephrology for kidney disease outcomes and the Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events for oncology trials. The whole meeting was recorded in real-time and rapid fire by a talented cartoonist.

There were other firsts for this OMERACT meeting:

- the Emerging Leaders⁷ program, which was attended by returning fellows to further develop knowledge and skills as mentors and future WG and OMERACT leaders
- a virtual meeting by a WG with participants in Canada and France linked in
- the OMERACT Methodology debut (the approved methodology⁸ for reaching consensus first on core domain sets⁹ and then on core outcome measurement instruments¹⁰), through a whiteboard video on core domain set selection, along with the introduction of the OMERACT Summary of Measurement Properties table, which encapsulates the selection of instruments using the “OMERACT Filter: 3 pillars, 4 questions, 7 measurement properties, 1 answer”
- a now-famous *Jeopardy!*-style session led by the OMERACT Methodology and Technical Advisory team
- the first 2 instruments to receive OMERACT endorsement, presented by the Psoriatic Arthritis WG
- facilitator training, offered to enhance the facilitation and consensus-building process in the breakout groups, considering that consensus was the key theme for the meeting
- a session on reaching consensus through the Delphi process¹¹.

Our patient research partner commented on the open, free-flowing information and opinion exchange (including discussions that went well into the night), the equal participation of patients in the discussions, the attention being given to patient-centric measures such as adherence, and the emotional thought-provoking experience during discussions on the balance between risks and benefits from the patient perspective in the premeeting Drug Safety workshop.

There were 170 participants from 22 countries in attendance. Presentation at the biennial OMERACT meeting is dependent on WG making a submission and conducting sufficient work in the interim 2 years between meetings. Not all submissions could be accommodated in the final program and several groups opted to be Virtual OMERACT WG.

Five workshops were presented in the program, including voting for the core domain sets for juvenile idiopathic arthritis¹², shoulder disorders¹³, and osteoarthritis (OA) hip and knee¹⁴ update, and voting for 2 core psoriatic arthritis instruments^{15,16}, in addition to the Methodology Workshop introducing the OMERACT Methodology for instrument selection. All workshops were presented in a final Implementation and Knowledge Translation session to discuss how participants will spread the word to facilitate uptake of the new evidence generated from the WG activities

Table 1A. Outcome Measures in Rheumatology (OMERACT) core areas and core domains (inner circle of the OMERACT Onion) for joint health conditions.

Core Areas and Domains	RA ^a	PsA	Gout		OA		AS ^c	PMR	Shoulder	JIA
			Acute	Chronic	Hip and Knee	Hand				
Wolfe, <i>et al</i> ¹⁸ ; Boers, <i>et al</i> ² ; Boers, <i>et al</i> ⁸	Boers, <i>et al</i> ¹⁹ ; Felson, <i>et al</i> ²⁰ ; Kirwan, <i>et al</i> ²¹ ; Bykerk, <i>et al</i> ²²	Orbai, <i>et al</i> ^{23 b}	Schumacher, <i>et al</i> ²⁴		Smith, <i>et al</i> ²⁵	Kloppenburg, <i>et al</i> ²⁶	van der Heijde, <i>et al</i> ²⁷	Mackie, <i>et al</i> ²⁸	Ramiro, <i>et al</i> ¹³	Morgan, <i>et al</i> ¹²
Manifestations/abnormalities										
Symptoms ^g	X	X	X	X	X		X ^d	X	X	X
Pain	X	X					X ^f			
Fatigue										
Musculoskeletal signs										
Tenderness/pain	Joints	Joints, spine	Joints			Joints				Joints
Swelling	Joints	Joints	Joints			Joints	Peripheral joints ^e			Joints
Combined		Dactylitis, enthesitis ^h		Acute gout attack			Enthesitis ^e			
Stiffness							Spine ^d	X		
Performance							Spine mobility ^d			
Signs at other sites										
Skin/subcutis		Disease activity (skin and nail)		Tophi						
Other/multiple										
Global assessment (disease activity)										
Patient	X	X	X	X	X		X ^d		X	X
Physician	X									
Biomarkers										
Imaging	Damage ^k									
Soluble ^m	Systemic inflammation	Systemic inflammation		Serum urate		Damage ^l	Damage, spine and hip ^f	Systemic inflammation		
Life impact										
Health-related quality of life		X		X	X					
Physical function/disability	X	X	Activity limitation	Activity limitation			X ^d	X	X	X
Societal/resource use										
Lifespan/death ⁿ					X					
No. deaths		X							X	X

The clinical conditions included in this table are placed here as a way of separating the conditions into 2 tables. This does not imply a formal definition of "joint health conditions." ^aRA flare domains: pain, function, swollen joints, tender joints, patient global, physician global, laboratory tests, fatigue, stiffness, participation, self-management (Bykerk, *et al*¹⁴), ^bOrbai, *et al*²³ is an update of the work by Gladman 2005²⁹ and Gladman 2007³⁰. ^cAnkylosing spondylitis. Core set elements vary depending on focus of study: ^dincluded in all 3 core sets for DC-ART, SMARD/physical therapy, and clinical record keeping; ^eincluded in core sets for DC-ART and clinical record keeping; ^fincluded in DC-ART. ^gImpact of symptoms is specified, these would fall under Impact. ^hTheir assessment includes both swelling and pain. ⁱMandatory in specific circumstances: hand mobility mandatory in clinical trials of structure modification and observational studies. ^jMandatory in specific circumstances: juvenile idiopathic arthritis has domains that will be elicited if there are specific circumstances (i.e., eye involvement invokes assessment of uveitis). See reference for more complete list. ^kRadiographic damage measured in studies > 1 yr. ^lMandatory in specific circumstances: joint imaging mandatory in trials assessing interventions expected to change structure. ^mAcute-phase proteins were named for systemic inflammation. ⁿReporting of adverse events (including death) is mandatory in trials and death is a core area in OMERACT Filter 2. DC-ART: disease controlling-antirheumatic therapy; SMARD: symptom-modifying antirheumatic drugs; RA: rheumatoid arthritis; OA: osteoarthritis; JIA: juvenile idiopathic arthritis; AS: ankylosing spondylitis; PsA: psoriatic arthritis; PMR: polymyalgia rheumatica.

and the meeting decisions. Promoting dissemination and uptake of core outcome sets (COS) has become a more prominent focus of the past 2 OMERACT meetings. There is increasing emphasis on effective stakeholder engagement as critical to faster and broader use of completed COS by clinical researchers¹⁷. The importance of maintaining attention on this issue was highlighted by a pair of votes taken at the beginning of the final session on implementation and knowledge translation. While 76% of respondents believed that 90% of clinical trials should report all measures in each OMERACT COS, 62% of those surveyed estimated that <30% of clinical trials were in fact reporting COS developed by OMERACT. This suggests that further attention to dissemination and promoting uptake of all the COS endorsed by the OMERACT community since its inception (Table 1A and Table 1B^{18–37}) would be worthwhile. These tables summarize the core domains that have been endorsed across 17 clinical conditions.

WG selected for presentation as Special Interest Groups (SIG) included magnetic resonance imaging (MRI) in arthritis, pain, Behçet disease, stiffness, myositis, polymyalgia rheumatica/giant cell arteritis, the Study Group for Extreme Computed Tomography in Rheumatoid Arthritis (SPECTRA), contextual factors, hand OA, ultrasound, large vessel vasculitis, synovial, adherence, juvenile arthritis MRI, worker productivity, and longitudinal outcome studies. Another first was voting in SIG. On the final day, the Behçet disease and Myositis SIG conducted votes on their core domain sets. Virtual WG included shared decision making, OA flare, and adaptive trial designs in rheumatology. The meeting hosted 17 patients from Australia, England, Canada, the United States, and the Netherlands.

As is now customary for OMERACT meetings, educational workshops were conducted for the 17 patient research partners, 23 newbies (first-time attendees)³⁸, and 26 fellows (all of whom had presented an abstract on OMERACT-related

Table 1B. Outcome Measures in Rheumatology (OMERACT) core areas and core domains (inner circle of the OMERACT Onion) for systemic rheumatologic health conditions.

Core Areas and Domains Wolfe, <i>et al</i> ¹⁸ ; Boers, <i>et al</i> ² ; Boers, <i>et al</i> ⁸	SLE Smolen, <i>et al</i> ³¹	AAV Merkel, <i>et al</i> ³²	FM Syndrome Mease, <i>et al</i> ³³	Osteoporosis ^a Sambrook, <i>et al</i> ³⁴	CTD-ILD Khanna, <i>et al</i> ³⁵	Myositis Regardt, <i>et al</i> ³⁶	Behçet Disease Hatemi, <i>et al</i> ³⁷
Manifestations/abnormalities							
Symptoms ^c							
Pain			X			X	
Fatigue			X			X	
Sleep			X				
Other					Dyspnea, cough	Symptoms in muscle, joints ^f , lung ^f	
Musculoskeletal signs							
Tenderness/pain			Joint				
Deformity				Fractures ^c , height ^c			
Signs at other sites							
Skin/subcutis						X ^f	
Other/multiple	Disease activity	Disease activity					Disease activity ^g
Global assessment (disease activity)							
Patient			X				
Biomarkers							
Imaging				Fractures ^c	Lung damage		
Soluble				Bone metabolism ^{b,c}			
Other/multiple	Organ damage	Organ damage		BMD ^{b,c,d}	Lung physiology		New organ involvement ^g
Life impact							
Health-related quality of life	X	X	X		X		X
Physical function/disability			X		X	X	
Societal/resource use							
Lifespan/death ^h							
No. deaths	X	X			X	X	X

The clinical conditions included in this table are placed here as a way of separating the conditions into 2 tables. This does not imply a formal definition of “systemic rheumatologic health conditions.” ^aOsteoporosis: core set depends on focus, ^bcore domains for randomized trials where prevention of rapid bone loss is the primary aim, ^ccore domains for randomized clinical trials of therapies for treating high-risk patients for osteoporotic fractures, ^dBMD measured at 2 sites: hip and spine, ^eIf impact of symptoms is specified, these would fall under Impact, ^fMandatory in specific circumstances: these domains should be measured in trials targeting either or all these symptoms, ^gOrgan systems named to be mandatory in specific circumstances: mucocutaneous, eye, central nervous system, vascular, musculoskeletal, gastrointestinal, ^hReporting of adverse events (including death) is mandatory in trials. SLE: systemic lupus erythematosus; AAV: antineutrophil cytoplasmic antibody–associated vasculitis; CTD-ILD: connective tissue disease–interstitial lung disease; BMD: bone mineral density; FM: fibromyalgia.

work and received feedback from colleagues and experienced OMERACT mentors).

The “little birds” came into their own with the first Twitter competition, with the top tweeter receiving a discount on registration for the 2020 meeting. Tweets with the hashtag “#omeract2018” reached 52,374 people with 105,548 impressions.

Additional information and publications by WG can be found on the OMERACT Website³⁹. Also available is The OMERACT Handbook, which contains both methodological and organizational information, and has encouraged participants to become more engaged with the process by explaining various OMERACT procedures and practices. The OMERACT Handbook is available at www.omeracthandbook.org⁴⁰ and will continue to be a major resource for all those interested in outcome measure development. The Handbook is a “living” document to be updated as new methodology evidence comes to light, and clinicians and researchers involved in OMERACT activities are to monitor it for these updates.

LYN MARCH , PhD,

Sydney Medical School,
Institute of Bone and Joint Research, and
Department of Rheumatology,
Royal North Shore Hospital,
St. Leonards, Australia;

BETHAN RICHARDS , MBBS (Hons), MSc,

Department of Rheumatology,
Royal Prince Alfred Hospital, and
Sydney Medical School,
University of Sydney,
Sydney, Australia;

MICHAEL GILL,

OMERACT Patient Research Partner,
Dragon Claw,
Canberra, Australia;

PETER M. BROOKS , MD,

Centre for Health Policy,
School of Population and Global Health,
The University of Melbourne,
Melbourne, Victoria, Australia;

BEVERLEY J. SHEA , PhD,

Ottawa Hospital Research Institute,
Clinical Epidemiology Program,
Ottawa, Ontario, Canada;

DORCAS E. BEATON , PhD,

Institute for Work and Health, and
Institute for Health Policy Management and Evaluation,
University of Toronto,
Toronto, Ontario, Canada;

LARA J. MAXWELL , PhD,

Centre for Practice-Changing Research,
Ottawa Hospital Research Institute, and
University of Ottawa,
Ottawa, Ontario, Canada;

SEAN R. TUNIS , MD, MSc,

Center for Medical Technology Policy (CMTP),
World Trade Center Baltimore,
Baltimore, Maryland, USA;

SHAWNA GROSSKLEG ,

Secretariat, OMERACT,
University of Ottawa,
Ottawa, Ontario, Canada;

PETER TUGWELL , MD,

Division of Rheumatology, Department of Medicine,
and School of Epidemiology and Public Health,
Faculty of Medicine,
University of Ottawa, and
Clinical Epidemiology Program,
Ottawa Hospital Research Institute,
Ottawa, Ontario, Canada.

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Esperanza Naredo, Spain	Maria Simona Stoenu, Belgium	Silvia Magni-Manzoni, Italy
Ethan Craig, USA	Maria Suarez-Almazor, USA	Simon Krabbe, Denmark
Féline Kroon, the Netherlands	Marieke (Maria) Voshaar, the Netherlands	Sofia Ramiro, the Netherlands
Florian Berghea, Romania	Marion Kortekaas, the Netherlands	Staeva Teodora, USA
Francis Guillemin, France	Marion Van Rossum, Canada	Stephanie Finzel, Germany
George Bruyn, the Netherlands	Mark Campbell, Canada	Susan Bartlett, Canada
George Wells, Canada	Matthew Page, UK	Susan Beard, Australia
Geraldine Hassett, Australia	Max Yates, UK	Susan Goodman, USA
Gillian Hawker, Canada	Meagan Walsh, Australia	Susan Humphrey-Murto, Canada
Gulen Hatemi, Turkey	Merrilee Needham, Australia	Susanne Juhl Pedersen, Denmark
Heidi Siddle, UK	Michael Gill, Australia	Suzanne Verstappen, UK
Helen Keen, Australia	Mihir Wechalekar, Australia	Tanaz Kermani, USA
Helene Alexanderson, Sweden	Mikkel Østergaard, Denmark	Tarimobo Michael Otobo, Canada
Hubert Van Hoogstraten, USA	Mirkamal Tolend, Canada	Teemu Karjalainen, Australia
Ida Kristin Haugen, Norway	Mirosława Nowak, USA	Thasia Woodworth, USA
Ilfta Sahbudin, UK	Nele Herregods, Belgium	Therese Dawson, Australia
Ingrid De Groot, the Netherlands	Niti Goel, USA	Thomas (Tom) Buttel, Australia
Jacob Jaremko, Canada	Pamela Richards, UK	Tiffany Westrich-Robertson, USA
Jane Munro, Australia	Paul Bird, Australia	Toby Smith, UK
Janet Maynard, USA	Peter Brooks, Australia	Todd Fox, Switzerland
Jasvinder Singh, USA	Peter Merkel, USA	Ulf Sundin, Norway
Jelena Vojinovic, Serbia	Peter Tugwell, Canada	Umut Kalyoncu, Turkey
Jennifer Horonjeff, USA	Peter Wong, Australia	Ursula Heilmeyer, Germany
Jessica Leung, Australia	Philip Conaghan, UK	Vibeke Strand, USA
Jo Bell, Australia	Philip Mease, USA	Victor Sloan, USA
Joanna Robson, UK	Premarani Sinnathurai, Australia	Victoria Evans, Australia
Joel Gagnier, USA	Rachel Black, Australia	Victoria Navarro Compán, Spain
Jonathan Cheah, USA	Rachelle Buchbinder, Australia	Violeta Vlad, Romania
José Bernardo Negrón Torres, Spain	Rafi Haner Direskeneli, Turkey	Vivian Bykerk, USA
Kathie Tymms, Australia	Reuben Escorpizo, USA	Walter Maksymowycz, Canada
Kathleen Wyrwich, USA	Richard Crew, UK	Wen-Hung Chen, USA
Kathryn Stok, Australia	Richard Holland, Australia	William Tillett, UK
Kayte Andersen, Canada	Richard Vesely, UK	Xavier Valencia, USA
Kenta Misaki, Japan	Robert Holt, USA	Ying Ying Leung, Singapore
Lara Fallon, Canada	Robert Lambert, UK	Yongdong Zhao, USA
Lara Maxwell, Canada	Robert Landewé, the Netherlands	