OMERACT – WHAT IS NEW
Peter Tugwell on behalf of the OMERACT Executive and the OMERACT 2018 Australian Organizing Committee
OMERACT – WHAT IS NEW
1. May 2018 OMERACT Australia
2. Premeeting on Safety/Harms/Adverse Effects - pictograms
3. New Website
4. New Methods
   a. Domains – New Onion
   b. Instruments – SOMP
   c. Updates
5. Consensus Checklist
6. Publications: Over 1000 Peer Reviewed
7. Link with COMET and ICHOM
8. Next OMERACT Colorado Springs April 2020
14 OMERACT CONFERENCES

OMERACT 1992: Maastricht, The Netherlands
OMERACT 1994: Ottawa, Canada
OMERACT 1996: Cairns, Australia
OMERACT 1998: Cancun, Mexico
OMERACT 2000: Toulouse, France
OMERACT 2002: Gold Coast, Australia
OMERACT 2004: Asilomar, USA
OMERACT 2006: St. Julian’s Bay, Malta
OMERACT 2008: Kananaskis, Canada
OMERACT 2010: Kota Kinabalu, Borneo
OMERACT 2012: Pinehurst, USA
OMERACT 2014: Budapest, Berlin
OMERACT 2016: Whistler, Canada
OMERACT 2018: Terrigal, Australia
May 2018 OMERACT held its 14th meeting in Terrigal in Australia
170 attendees
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New Website Format: https://omeract.org/about

Over 1000 papers in peer-reviewed journals
New Website Format: https://omeract.org/about

About OMERACT

OMERACT (Outcome Measures in Rheumatology) is an independent initiative of international health professionals interested in outcome measures in rheumatology. Over the last 20 years, OMERACT has served a critical role in the development and validation of clinical and radiographic outcome measures in rheumatoid arthritis, osteoarthritis, psoriatic arthritis, fibromyalgia, and other rheumatic diseases. OMERACT is coordinated by an executive committee and supervised by a steering committee. OMERACT organizes consensus conferences every two years, and employs various other means to stimulate the development of consensus in outcome measurement within the context of musculoskeletal and autoimmune diseases.
The OMERACT Process

OMERACT strives to improve endpoint outcome measurement through a data driven, iterative consensus process involving relevant stakeholder groups. The work of OMERACT is facilitated by participants within various working groups who provide input on the development of the OMERACT research agendas. The individual research agendas focus on measurement issues considering Truth, Discrimination and Feasibility, the backbone of the OMERACT Filter. A powerful and important aspect of OMERACT is the integration of patients at each stage of the OMERACT process. This patient input along with clinical trialist insight, epidemiologist assessment, and industry perspective, has led OMERACT to be a unique decision making group in developing outcome measures for all types of clinical trials and observational research.

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

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

**Feasibility** Can the measure be applied easily, given constraints of time, money, and interpretability? This criterion addresses the pragmatic reality of the use of the measure, one that may be decisive in determining a measure’s success.

When OMERACT endorses a core set, it is because there is consensus amongst OMERACT participants that *the evidence to support this has been clearly demonstrated.*
New Website Format: https://omeract.org/about

Spirit of OMERACT

Each one of our 8 C’s can be related to one of the three factors

1. Consensus-Commitment
2. Communication: Respectful across 5Ps stakeholders esp patients
3. Collaboration (truly participatory across all disciplines/sectors, international representation,)
4. Critical (evidence driven)
5. Careful/conscientious (apply critical thinking, systematic)
6. Concrete outcomes (e.g. OMERACT Filter; Core Sets; Methods)
7. Continuous Learning- updated methods and core sets
8. Continuity – Planned succession through Fellowship Pgm
Spirit of OMERACT

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OMERACT Patient Involvement

Check out this great video
New Website Format: https://omeract.org/about

Kirkham et al BMJ 2017; 357
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Selected OMERACT Publications & Resources

The OMERACT Handbook
updated 2018-01-19

Chapter 3: Domain Selection & Workbook

Chapter 4: Instrument Selection & Workbook

OMERACT Glossary

Patients' Expectations and

The OMERACT Filter for Outcome
Resources

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The OMERACT Handbook updated 2018-01-19

Chapter 3: Domain Selection & Workbook

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OMERACT Glossary

Patients’ Expectations and

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New Website : YouTube White Board : new Onion!
OMERACT Domain Selection

OMERACT Onion Example: Polymyalgia Rheumatica

- Outer Circle: Weakness, Physical Activity, Sleep
- Middle Circle: Patient global, Fatigue
- Inner Circle: Systemic Inflammation (lab blood tests), Physical Function, Pain, Stiffness

Hakim SL et al. The OMERACT Core Domain Set for Outcome Measures for Clinical Trials in Polymyalgia Rheumatica. *Rheumatol* Aug 2017
OMERACT Domain Selection

LET'S Recap...
1. DO DOMAINS FIRST
2. INVOLVE MULTIPLE STAKEHOLDERS
3. SEEK INTERNATIONAL PERSPECTIVE
### OMERACT Master Checklist for Developing Core Domain Sets

<table>
<thead>
<tr>
<th>#</th>
<th>OMERACT Core Domain Set Checklist Item</th>
<th>Stop</th>
<th>Caution</th>
<th>Go</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Core Domain Set selection</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Topic submitted and approved by Executive; Executive Embedded Mentor assigned</td>
<td>☑</td>
<td>☑</td>
<td>☑</td>
</tr>
<tr>
<td>2</td>
<td>Forming an OMERACT Working Group; agreement to adhere to OMERACT philosophy</td>
<td>☑</td>
<td></td>
<td>☑</td>
</tr>
<tr>
<td>3</td>
<td>Stakeholder groups and their contacts identified</td>
<td>☑</td>
<td></td>
<td>☑</td>
</tr>
<tr>
<td></td>
<td><strong>Develop Methods Protocol</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Describe PICOC (Population, Intervention, Control, Outcome, Context)</td>
<td>☑</td>
<td>☑</td>
<td>☑</td>
</tr>
<tr>
<td>5</td>
<td>Brainstorming session, determine potential gaps, check for existence of other core domain sets, design methods protocol for core domain set selection</td>
<td>☑</td>
<td></td>
<td>☑</td>
</tr>
<tr>
<td>6</td>
<td>Deliverable: Submission of protocol to Technical Advisory Group based on OMERACT Domain Workbook</td>
<td>☑</td>
<td></td>
<td>☑</td>
</tr>
<tr>
<td>7</td>
<td>Review and approval of protocol for domain selection and prioritization by Technical Advisory Group</td>
<td>☑</td>
<td></td>
<td>☑</td>
</tr>
<tr>
<td></td>
<td><strong>Core Domain Set selection</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Generate candidate domains covering each Core Area (by conducting literature reviews, and focus group &amp; surveys across all appropriate stakeholder groups)</td>
<td>☑</td>
<td>☑</td>
<td>☑</td>
</tr>
<tr>
<td>9</td>
<td>Prioritization of candidate domains through consensus process</td>
<td>☑</td>
<td></td>
<td>☑</td>
</tr>
<tr>
<td>10</td>
<td>Formulation of Draft Core Domains - at least 1 per Core Area, as well as for adverse events, and organized as per the OMERACT Onion</td>
<td>☑</td>
<td>☑</td>
<td>☑</td>
</tr>
<tr>
<td>11</td>
<td>Formulation of core contextual factors</td>
<td>☑</td>
<td></td>
<td>☑</td>
</tr>
<tr>
<td>12</td>
<td>Working Group agrees on the Draft Core Domain Set (record vote here)</td>
<td>☑</td>
<td></td>
<td>☑</td>
</tr>
<tr>
<td>13</td>
<td>Working Group finalizes &amp; submits Draft Core Domain Set to Technical Advisory Group (including submission of reports as per Domain Workbook and timeline for update cycle)</td>
<td>☑</td>
<td>☑</td>
<td>☑</td>
</tr>
<tr>
<td>14</td>
<td>Result of final vote by full OMERACT membership on Core Domain Set (currently requires a plenary vote at full OMERACT Meeting)</td>
<td>☑</td>
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### Psoriatic Arthritis

**PRO**: Patient Reported Outcome  
**CLINRO**: Joint Count

### Table: SOMP: Summary of Measurement Properties

<table>
<thead>
<tr>
<th>Author/year</th>
<th>Truth</th>
<th>Feasibility</th>
<th>Truth</th>
<th>Discrimination</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>Domain match</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lennon 1991</td>
<td>+</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>McCartney 2004</td>
<td></td>
<td></td>
<td>+</td>
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<tr>
<td>Harrison 2004</td>
<td>+</td>
<td></td>
<td>+/−</td>
<td></td>
</tr>
<tr>
<td>Starr 2005</td>
<td>+</td>
<td></td>
<td>+/−</td>
<td>+</td>
</tr>
<tr>
<td>Best 2006</td>
<td>+</td>
<td></td>
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<td>+</td>
</tr>
<tr>
<td>Sutcliffe 2006</td>
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<tr>
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<td>−</td>
</tr>
<tr>
<td>Brooks 2015</td>
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<td></td>
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</tbody>
</table>

| Total available studies for each property | 2 | 0 | 1 | 2 | 6 | 2 | 6 |
| Total studies available for synthesis    | 2 | 0 | 1 | 2 | 6 | 2 | 6 |

**Rating (RAGW) [put on Master Checklist]**  
- Green  
- Amber  
- Red

**Overall rating for instrument across properties**

- Green
# SOMP: Summary of Measurement Properties

**Psoriatic Arthritis**

**PRO:** Patient Reported Outcome  
**CLINRO:** Joint Count

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<tr>
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<th>Feasibility Truth Test retest reliability</th>
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| Rating (RAGW) [put on Master Checklist] | Green | Green | Amber | Green | Green | Amber | Green |

Overall rating for instrument across properties

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7 Properties
### SOMP: Summary of Measurement Properties

#### 7 Properties

#### Psoriatic Arthritis

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- **Rating (RAGW) [put on Master Checklist]**: Green Green Amber Green Green Amber Green
- **Overall rating for instrument across properties**: Not endorsed
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UPDATING CORE SETS

- In Press:
  - The Journal of Rheumatology

- Title: The OMERACT-OARSI core set of outcome domains to measure in clinical trials for people with hip and/or knee osteoarthritis.

- Authors: Smith TO, Conaghan PG et al

- Objectives: To update the 1997 OMERACT Core Domain Outcome Set to measure in clinical trials with people who have hip and/or knee osteoarthritis (OA).
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7. ICHOM link-reactivated Nomenclature Confusion
8. Link with COMET
<table>
<thead>
<tr>
<th>RECOMMENDATION</th>
<th>Points to consider</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. What is the rationale for selecting the Delphi procedure?</td>
<td>For example: Initial Delphi for item generation, followed by consensus conference.</td>
</tr>
<tr>
<td>2. Is there a clear outline of the overall process involved and where the Delphi fits?</td>
<td>Working group should include participants from at least 3 continents.</td>
</tr>
<tr>
<td>3. How will items be generated and selected for inclusion in the Delphi survey?</td>
<td>Create your initial list of core domains or core instruments.</td>
</tr>
<tr>
<td></td>
<td>Starting with 70 items or less is recommended.</td>
</tr>
<tr>
<td></td>
<td>Should include:</td>
</tr>
<tr>
<td></td>
<td>• Working group brainstorm, Literature review, Stakeholder consultation through qualitative research such as focus groups or interviews</td>
</tr>
<tr>
<td>4. How many stakeholders (participant groups) will be involved in each step?</td>
<td>Primary stakeholders</td>
</tr>
<tr>
<td></td>
<td>• Patients (minimum n= 100)</td>
</tr>
<tr>
<td></td>
<td>• Clinicians (minimum n= 100)</td>
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Moving to Hybrid Virtual

Developing a preliminary definition and subdomains of flare in knee and hip osteoarthritis. Consensus building of the Flare-In-OA OMERACT group.

Guillemin, Francis
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   Clinical Trials.gov
   ICHOM
8. Link with COMET
Tower of Babel COS Nomenclature Initiative

- Core domain set
- Core outcome set
- Core outcome measurement set
- Standard set
- (sub) domain
- Outcome
- Outcome measure
- Measurement instrument
- Outcome measurement instrument
- Specific measurement
- Specific metric
- Method of aggregation
- Setting/scope
- Contextual factor
- Case-mix variable
- Health
- Health condition
- Health intervention

COMET
Clinicaltrials.gov
Cochrane
COSMIN
FDA
ICF (WHO International Classification of Function)
ICHOM (International Consortium for Health Outcomes Measurement)
OMERACT

“The curse of linguistic Limitation”
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Collaboration with COMET

Collaboration with COMET continues on a number of fronts including

- representation and presentations at each other’s meetings,
- comparing and contrasting methods,
- tailoring of the COMET Delphi Manager to OMERACT topics,
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15th OMERACT Conference
April 2020 OMERACT
Colorado Springs
Colorado USA

[Proposals due Dec 12 2018]