Review of the Psoriatic Arthritis Working Group at OMERACT 12: A Report from the GRAPPA 2014 Annual Meeting

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ABSTRACT. At the 2014 annual meeting of the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA), the psoriatic arthritis (PsA) working group of OMERACT (Outcome Measures in Rheumatology) presented a review of the progress made at the OMERACT 12 meeting, held in 2014. Members of the PsA OMERACT working group presented work from the Patient Involvement in Outcome Measures for PsA initiative to improve the incorporation of patient research partners in PsA outcomes research, the results of discussions within the OMERACT breakout groups, and finally the voting results. The OMERACT 12 participants had endorsed the need to update the PsA core set according to the Filter 2.0 framework. The breakout group discussions identified potential opportunities for revising the core set, including consolidating existing redundancy within the core set, improving incorporation of the patient perspective, and including disease effects such as fatigue as a core criterion. GRAPPA members of the OMERACT working group now have a program of research to update the core set with the goal of seeking endorsement at OMERACT 13, to be held in 2016. (J Rheumatol 2015;42:1048–51; doi:10.3899/jrheum.150131)

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In 2006, at the eighth meeting of Outcome Measures in Rheumatology (OMERACT 8), members endorsed the psoriatic arthritis (PsA) core set of outcome measures to be used in randomized controlled trials and longitudinal observational studies[1]. Considerable work within the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) has been undertaken over the last 8 years to develop appropriate individual and composite responder indices to measure disease activity[2,3]. At the OMERACT 11 meeting in 2012, it became clear that much of the work of outcome measure development and domain selection had been undertaken with little or no incorporation of the patient perspective. The role of patients in outcome research is embedded at the heart of the OMERACT process[4,5], and has been accomplished through meaningful, ongoing inclusion of patient research partners (PRP). In rheumatoid arthritis (RA), the acknowledged benefits of patient involvement have included the improved determination of the minimum clinically important differences (MCID) in patient-reported outcomes, development of definitions of remission and flare, and inclusion of fatigue and participation to the RA core set[6,7].

A number of initiatives on both sides of the Atlantic are under way to firmly embed the patient perspective in wider health research. The US Congress has established the Patient-centered Outcomes Research Institute; the UK National Institute of Health Research has convened the

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INVOLVE group to promote patient involvement in the National Health Service; and the European League Against Rheumatism has published recommendations for inclusion of the patient perspective in research[8].

At the 2014 GRAPPA annual meeting, the PsA OMERACT working group presented a summary of the work of the Patient Involvement in Outcome Measures for Psoriatic Arthritis (PIOMPSA) group over the last 2 years. Results were also presented of the breakout group discussions and attendee voting at OMERACT 12, as well as a potential road map toward endorsement of a revised PsA core set at OMERACT 13 in 2016.

Presentations

OMERACT 12 psoriatic arthritis working group overview. Dr. Niti Goel introduced the PsA OMERACT working group comprising 2 fellows, 4 co-chairs, 3 PRP, 1 member of the OMERACT executive committee for liaison, and 2 additional GRAPPA member attendees (see Acknowledgment). The OMERACT PsA workshop consisted of presentations of the work undertaken since OMERACT 10, including the PIOMPSA initiative[9], the Psoriatic Arthritis Impact of Disease (PsAID) study[10], and the progress made toward development of composite disease activity measures[2]. Presentations at OMERACT were followed by breakout group discussions on the need to update the PsA core set and what revisions should be considered. Results from breakout groups were presented at a plenary session, followed by voting[11].

Review of the patient involvement initiative (PIOMPSA). The PIOMPSA effort was initiated in 2012 to improve incorporation of the patient perspective in PsA outcomes research within GRAPPA. The first meeting in Dublin, Ireland, included equal numbers of rheumatologists and PRP, and efforts have been made to preserve this balance to give PRP an equal voice at the proceedings[9]. The PIOMPSA group discussed the relative lack of patient input in the development of the PsA core set and outcome measure development. They also undertook a systematic literature review to define current levels of patient involvement together with developing a road map to enhance integration of patient perspectives in future PsA research. The group identified the need to revise the existing PsA core set, primarily to ensure incorporation of patient involvement in domain selection and prioritization, but additionally to integrate the considerable research progress from 2006 onward, including:

- The 68/66 (tender/swollen) joint count has been identified as the optimal joint count for PsA assessment in clinical trials[12]
- Tools to assess fatigue, enthesitis, dactylitis, and the measurement of axial disease have been developed and tested[13,14,15]
- The Psoriasis Activity and Severity Index has been shown to be reliable when performed by rheumatologists or dermatologists[16].

Updating the core set in light of these research findings would facilitate patient representation. It would also allow an opportunity for movement or incorporation of domains important to patients such as fatigue, dactylitis, and participation (work/leisure activities) that were not previously included[9,17]. Dr. Goel acknowledged that the PRP role within GRAPPA needed to be formalized through the work done in the Building Bridges initiative[18].

Update of the PSA core set, breakout group discussion, and voting. Dr. William Tillett reviewed the results of the 2014 OMERACT 12 breakout discussions and voting. The existing PsA core set, endorsed at OMERACT 8 in 2006, was reviewed (Figure 1)[1] and compared with the new OMERACT Filter 2.0[19]. The new structure encourages researchers to consider domains within 4 core areas: pathophysiological manifestations, life impact, resource use, and death (Figure 2)[19]. Domains are then placed within concentric spheres by decreasing importance and/or availability of applicable instruments and finally for the research agenda. The core (central) sphere should contain at least 1 domain from each of the 4 core areas. The middle sphere could contain several additional domains that may not be applicable for the central sphere but could be useful dependent on the individual study question. The final, outer sphere could be reserved for additional domains of interest in the research agenda. Participants at the OMERACT workshop breakout groups were given a copy of the existing PsA core set and asked to consider the need for its revision and if so, what changes to consider.

Feedback from the breakout groups identified a number of themes. There was general agreement on the need to revise the PsA core set, which would present opportunities to improve the existing set. An opportunity to amend existing redundancy within the core area of pathophysiology was discussed. An umbrella term such as inflammatory musculoskeletal disease for arthritis, enthesitis, dactylitis, and axial disease could be considered. Psoriasis activity may be considered as an encompassing term for skin and nail disease, and biomarkers for acute-phase reactants. Life effect concepts emerging from the breakout discussions included a strong message to retain in the core set pain, health-related quality of life, physical function, and patient global, while adding fatigue, which attendees noted had also been ranked highly in the PsAID study[10]. Debate followed regarding the potential overlap of domains included in the patient global measure as well as fatigue, with recognition of the increasing evidence that it is legitimate to move items such as dactylitis[20], fatigue[21], and enthesitis[22] from former positions in the second circle to higher prioritization in the inner circle, especially because tools had been developed and tested since the initial core set was created.

The proposal to revise the PsA core set was endorsed with a 100% vote by the OMERACT workshop participants — notably the first time a unanimous vote had been achieved

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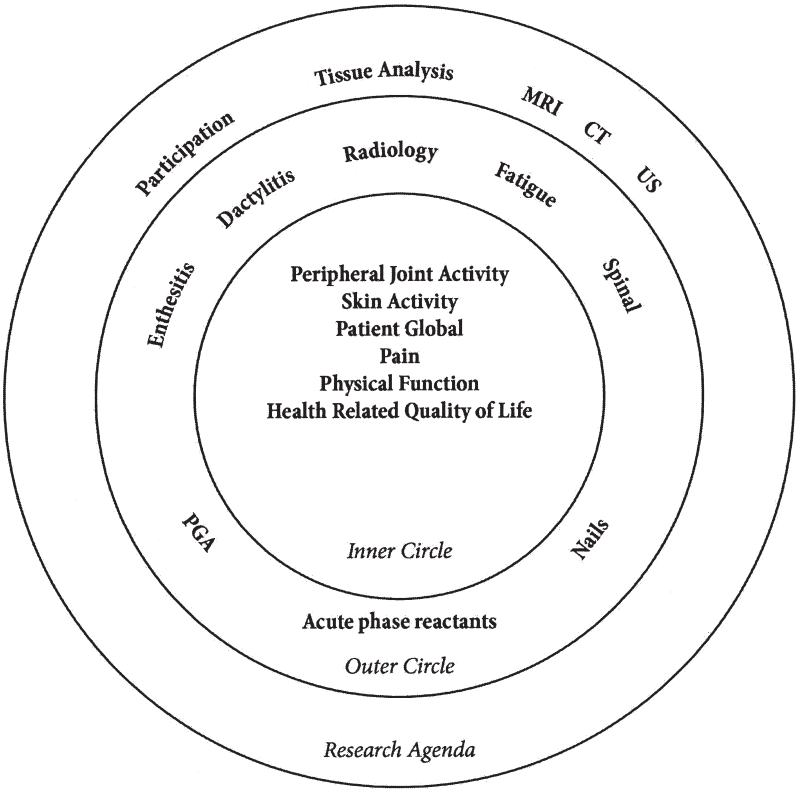

Figure 1. Domains for psoriatic arthritis. CT: computed tomography; MRI: magnetic resonance imaging; PGA: physician's global assessment; US: ultrasound. From: Gladman, et al. J Rheumatol 2007;34:1167-70[1].

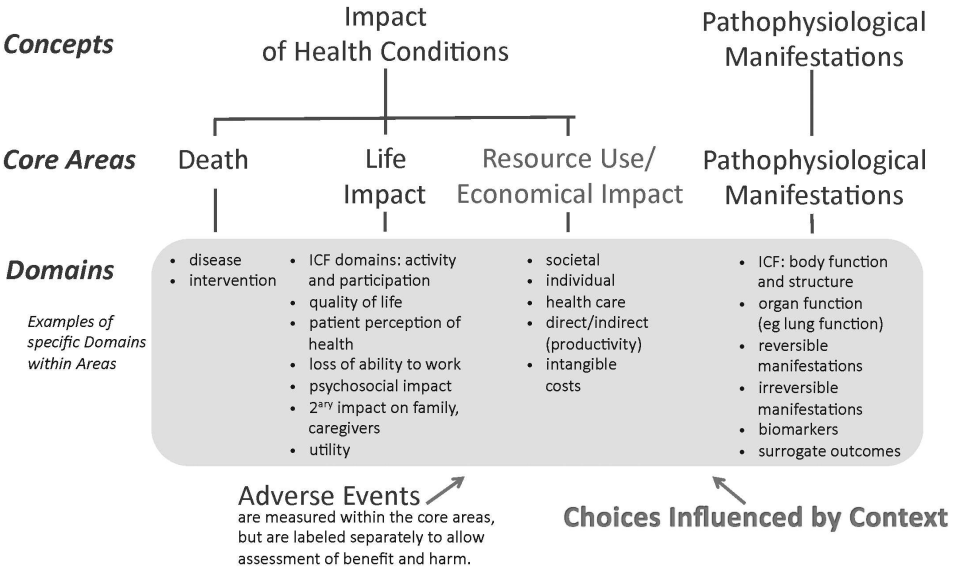

Figure 2. Conceptual framework for core areas. From Boers, et al. J Clin Epidemiol 2014;67:745-53[19]; with permission.

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within OMERACT. The PsA core set will therefore be the first to undergo revision using the OMERACT Filter 2.0. Consensus was also achieved on retaining the patient global within the core set (endorsed with 70% vote) as well as adding fatigue (endorsed with 72% vote).

At the 2014 OMERACT 12 PsA workshop there was unanimous endorsement for the need to update the PsA core set. The results of the OMERACT breakout group discussions highlighted opportunities to involve patients as well as add, move, or merge existing domains to improve existing redundancy. Over the next 2 years, GRAPPA working group members will focus on revising the PsA core set according to the OMERACT Filter 2.0, with the goal of seeking endorsement at OMERACT 13 in 2016.

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The OMERACT working group: Co-chairs: Oliver FitzGerald, Dafna D. Gladman, Philip S. Helliwell, Philip J. Mease; OMERACT liaison: Vibeke Strand; Fellows: William Tillett, Lihi Eder; Patient Research Partners: Maarten de Wit, Ina Campbell, Niti Goel; and GRAPPA attendees: Alexis Ogdie, Anna-Maria Orbai.

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