

Enhanced Patient Involvement and the Need to Revise the Core Set — Report from the Psoriatic Arthritis Working Group at OMERACT 2014

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ABSTRACT. Objective. To discuss the need for revision of the “core set” of domains to be included for assessment in psoriatic arthritis (PsA) randomized controlled trials and longitudinal observational studies, review work undertaken since the 2012 meeting of Outcome Measures for Rheumatology 11 (OMERACT 11) to include patient perspectives in this revision, and reassess proposed composite measures in the context of new research data and the OMERACT Filter 2.0 framework.

Methods. The OMERACT 12 (2014) PsA working group presented work completed over the last 2 years to incorporate patient involvement in PsA outcomes research, review the endorsed PsA core set based on the patient perspective as well as new research findings, and further develop PsA responder indices. Breakout groups then discussed 2 topics: (1) the need to revise the PsA core set, and opportunities to add, move, or merge existing domains to improve existing redundancy; and (2) how to incorporate the core set in a composite index. Breakout groups fed back to the working group before participant voting.

Results. Meeting participants endorsed the need to revise the PsA core set according to the OMERACT Filter 2.0 framework (100%), and the inclusion of disease impact (94%) and fatigue (72%) in the inner circle. Breakout group feedback suggested the core set revision was an opportunity to consolidate pathophysiologic aspects such as arthritis, enthesitis, dactylitis, spondylitis as “inflammatory musculoskeletal disease,” and nail and skin psoriasis as “psoriasis activity.”

Conclusion. Future work will focus on updating the PsA core set and development of responder indices with ongoing, meaningful involvement of patient research partners. (First Release May 1 2015; J Rheumatol 2015;42:2198–203; doi:10.3899/jrheum.141156)

Key Indexing Terms:

PSORIATIC ARTHRITIS OMERACT OUTCOME MEASUREMENT PATIENT PARTICIPATION

Psoriatic arthritis (PsA) is an inflammatory musculoskeletal disease occurring in 7–42% of patients with psoriasis¹.

Arthritis, enthesitis, dactylitis, spondylitis, and skin disease result in pain, stiffness, reduced mobility, impairment in

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physical function, and subsequent disability. PsA is now recognized as a disease that can be serious and progressive despite treatment, resulting in significant physical, psychological, functional, and social impairment^{2,3,4,5}. At the 2006 Outcome Measures in Rheumatology 8 (OMERACT 8) PsA module, consensus was achieved on a core set of domains to be assessed in randomized controlled trials (RCT) and longitudinal observational studies⁶. Research was subsequently directed toward development of outcome measures including composite and responder indices that would gather all the domains of psoriatic disease into a single measure^{7,8}. The Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) has compared existing and novel composite disease activity and responder measures in the GRAPPA Composite Exercise (GRACE) project^{9,10}.

OMERACT has taken a leadership position in the incorporation of the patient perspectives in rheumatology research, which is now embedded in the heart of the OMERACT process¹¹. This position is based on the recognition that inclusion of patient perspectives would improve selection and validation of domains and outcome measures for their assessment, as well as subsequent composite responder indices. Examples of this approach are evident in the rheumatoid arthritis initiatives that defined minimum clinically important differences in patient-reported outcomes and added health-related quality of life (HRQOL), fatigue, and participation to the “core set,” validated definitions of remission and subsequent efforts to investigate and assess disease flare^{12,13}. Complementing the work of OMERACT, the European League Against Rheumatism (EULAR) has produced recommendations on inclusion of the patient perspective in research projects¹⁴. The National Institute of Health Research in the United Kingdom has convened the INVOLVE group to promote patient involvement in all aspects of the National Health Service (www.invo.org.uk/resource-centre/research-project-database/), including research, and the US National Institutes of Health has established the Patient-Centered Outcomes Research Institute effort.

Aims of the Workshop

The aims of the workshop were to discuss the need for revision of the “core set” of domains to be included for assessment in PsA RCT and longitudinal observational studies, review work undertaken since OMERACT 11 (2012) to include patient perspectives in this revision, and reassess proposed composite measures — all in the context of new research data and the OMERACT Filter 2.0 framework.

Workshop Presentations

Review of the PIOMPSA patient involvement initiative. During OMERACT 11, the PsA working group received feedback on the limited amount of patient involvement in work presented at the workshop. Directly after this, the Patient Involvement in Outcome Measures for Psoriatic

Arthritis (PIOMPSA) effort was initiated, which included 4 face-to-face meetings over a period of 2 years. The first meeting in Dublin, Ireland, included 3 patient research partners (PRP), 3 rheumatologists, and 1 nurse researcher. The group identified the lack of patient input in development of the core set and proposed composite measures. Based on these conclusions, a road map was formulated to enhance integration of patient perspectives in this research and their incorporation into the next OMERACT workshop (2014). A first priority was to conduct a systematic literature review to evaluate levels of patient involvement in previous identification of domains and development of core set outcome measures.

Results of the systematic literature review¹⁵ were presented and discussed at a second meeting in Bath, UK, which included 5 PRP and 5 rheumatologists. They concluded, based on the systematic literature review and the Psoriatic Arthritis Impact of Disease (PsAID) study, that it was necessary to revise the PsA core set because important domains such as fatigue, dactylitis, and participation (work as well as family/social/leisure activities) were not included and needed to be considered¹⁶. It was agreed that continuing dialog with PRP within GRAPPA was essential. Eight patients attended the subsequent annual GRAPPA conference in Toronto in 2013 and participated in several plenary and breakout sessions, published in a separate report¹⁷. Three months prior to the OMERACT 12 meeting, a fourth meeting was organized in Leeds to discuss ongoing research projects, evaluate the PIOMPSA initiative, and prepare for the PsA workshop. Seven PRP, 10 rheumatologists, and 2 health professionals, representing 4 European countries, Canada, and the United States endorsed the concept of PRP involvement. The group recognized the importance of formalizing the future role of PRP in GRAPPA, the OMERACT working group, and other research initiatives.

Review of the PsA core set. The process was outlined for development of core outcome domains for PsA initiated during the inaugural meeting of GRAPPA in August 2003; further discussion and ratification of the “core set” as well as the research agenda were conducted at OMERACT 7 in May 2004¹⁸. The research agenda included a long list of items: optimization of joint count and skin assessments; development of tools to define structural damage and imaging modalities to assess inflammation and damage; instruments to assess axial manifestations, dactylitis, and enthesitis; ensuring patient’s global assessments (PtGA) evaluated both skin and joint involvement; development of instruments to assess participation; development of tools to measure fatigue; and ultimately, composite responder indices. The concept of participation in life events, not just work, within and outside the home was first introduced at that meeting.

Several of GRAPPA’s research goals have since been achieved. The 68/66 (tender/swollen) joint count was identified as appropriate to use in PsA¹⁹. The Psoriasis

Activity and Severity Index (PASI) was demonstrated reliable by both rheumatologists and dermatologists²⁰. The World Health Organization tool for the classification of disability, functioning, and health was tested in PsA but found to be somewhat cumbersome²¹. Tools to assess enthesitis and dactylitis have been developed and tested²². Axial disease assessment measures were evaluated in PsA²³. The Functional Assessment of Chronic Illness Therapy-fatigue scale (FACIT fatigue) demonstrated reproducible results that correlated with other fatigue measures as well as with disease activity in patients with PsA²⁴.

Subsequently, at OMERACT 9 (2008), a final “core set” of domains for assessment in PsA was presented for voting, which included peripheral joint activity (using the 68/66 tender/swollen joint count), skin activity (by PASI or body surface area), PtGA [by 0–10 visual analog scale (VAS) or numerical rating scale], patient pain (VAS), physical function [by Health Assessment Questionnaire (HAQ)] and HRQOL [by Medical Outcomes Study Short Form-36 (SF-36)]. These were considered the core domains that must be assessed in all RCT and longitudinal observational studies. The following were highly recommended but not mandatory: dactylitis, enthesitis, axial disease, radiography, nail disease, fatigue, physician’s global assessment, and acute-phase reactants. Imaging modalities such as ultrasound, computed tomography, and magnetic resonance imaging, participation, and tissue analysis were included in the research agenda⁶. PtGA was recommended for inclusion as an overall question, as well as separate questions regarding skin and musculoskeletal manifestations²⁵.

Review of composite measures in PsA. As traditional RA-based outcome measures typically applied have not addressed important and varied phenotypic manifestations of PsA, 3 new composite measures have been proposed. The Composite Psoriatic Disease Activity Index and GRACE are modular cutoff-based measures, and the Psoriatic Arthritis Disease Activity Score is a weighted index⁹. Domains included in these indices are presented in Table 1. Analyses of several RCT datasets have demonstrated better performance of these composite indices compared with traditional measures created for RA, such as the 28-joint count Disease Activity Score (DAS28)²⁶. Further, response criteria developed for each of the measures indicate that they can predict radiographic progression²⁷. Although patients were

only indirectly involved in their development, domains of concern to patients, identified in the recently published PsAID study¹⁶, are addressed by all 3 of these proposed indices through PtGA, HRQOL, and function.

Review of the PsAID study. Results were presented of the EULAR initiative to elaborate and validate a new composite score to assess the effect of disease in PsA¹⁶. Because currently, patient-perceived effect of PsA is assessed through generic questionnaires such as the HAQ or SF-36, the objective was to develop a questionnaire to calculate a score, reflecting the effect of PsA based on patients’ perspectives. This PsAID questionnaire is a patient-derived patient-reported outcome. PRP were involved throughout its development process, from conception and study contact through to reporting, using methodology developed for the Rheumatoid Arthritis Impact of Disease instrument²⁸. Two versions of the PsAID questionnaire were developed and include both physical and psychological domains: 1 version for clinical practice (12 domains of health) and 1 for RCT (9 domains; Table 2). Pain, fatigue, and skin problems had the highest relative importance. The validation study demonstrated that PsAID scores had good psychometric properties.

Two versions of a questionnaire to assess the effect of PsA on patients’ lives have been developed and validated, with PRP collaboration. This new questionnaire will facilitate better assessment of patients’ perspectives in PsA, in RCT as well as in clinical practice. PsAID questionnaire versions are available online free of charge with available translations²⁹.

Discussion at OMERACT 12 (2014)

PRP involvement in PsA outcome research. The workshop presented a review of progress and outcomes regarding PRP involvement in PsA outcome research over the past 2 years since OMERACT 11. It was recognized that this involvement is still in an exploratory phase of how to optimize PRP participation in the different working group and research initiatives¹⁷.

Revision of the PsA core set. One of the first major outcomes from the PIOMPSA group was the need to revise the existing PsA core set with meaningful patient involvement. At OMERACT 12, the proposal to revise the core set was strongly endorsed with a 100% vote by workshop participants (Table 3). The voting results for this item as well as for the individual domains to include are reported in Table 3.

Table 1. Domains covered by the CPDAI, PASDAS, and GRACE indices.

	Patient VAS Global	Physician VAS Global	Joints	Skin	Enthesitis	Dactylitis	Spine	HRQOL	Function
CPDAI	X	X	✓	✓	✓	✓	✓	✓	✓
PASDAS	✓	✓	✓	X	✓	✓	X	✓	X
GRACE	✓	X	✓	✓	X	X	X	✓	✓

✓: Included in the index. X: Not included in the index. CPDAI: Composite Psoriatic Disease Activity Index; GRACE: GRAppa Composite Exercise; PASDAS: Psoriatic Arthritis Disease Activity Score; VAS: visual analog scale; HRQOL: health-related quality of life.

Table 2. Domains of impact of disease assessed by the PsAID questionnaire for patients with PsA.

Domain	Short Defining Statement
Pain	Pain in joints and spine and skin
Skin problems	Skin problems, including itching
Fatigue	Being physically tired, but also mental fatigue, lack of energy
Ability to work/leisure	Ability to work and/or to do leisure activities
Functional capacity	Capacity to perform daily physical activities, loss of independence
Feeling of discomfort	Discomfort and annoyance with everyday tasks
Sleep disturbance	Sleep quality, sleep interruptions
Anxiety, fear, and uncertainty	For example, about the future, treatments, fear of loneliness
Coping	Adjustment to the disease, managing, being in charge, making do with the disease
Embarrassment and/or shame due to appearance*	Feeling embarrassed/ashamed due to appearance
Social participation*	Participating fully in social activities
Depression*	Feeling sad or depressed

*Not included in the PsAID questionnaire for clinical trials. PsAID: Psoriatic Arthritis Impact of Disease.

Table 3. Results of the psoriatic arthritis workshop voting.

Proposal	Endorsement
The need to revise core set	100%
Items that should be included in the core set	
• Items covering impact of disease	94%
• Fatigue	72%
• Dactylitis	70%
• Enthesitis	56%
• Systemic inflammation (e.g., CRP)	53%
Should participation be further investigated for inclusion in the core set?	57%

CRP: C-reactive protein.

Revision of the core set offers an opportunity to examine its face validity, discrimination, feasibility, redundancy, consolidation, and movement of domains based on PRP collaboration. This will be the first core set revised using the OMERACT Filter 2.0³⁰. Filter 2.0 directs us to consider concepts of disease under themes of “life impact” and “pathophysiology” separately.

Life impact concepts emerging from the breakout discussions included a strong message to retain pain, HRQOL, function, and PtGA in the core set while adding fatigue. There was debate within the breakout groups on potential overlap of domains identified in the PtGA measure as well as fatigue. Fatigue, ranked highly by patients in the PsAID study¹⁶, was confirmed as an important domain although concern was raised from the breakout groups regarding availability of appropriate measures for its assessment in PsA. Consensus was achieved on retaining PtGA within the core set (endorsed with 70% vote) as well as adding fatigue (endorsed with 72% vote). There is now increasing evidence that it is legitimate to move items such as fatigue³¹, enthesitis³², and dactylitis³³ from former positions in the second circle to higher prioritization in the inner circle. Fatigue is now being systematically

assessed in clinical trials with instruments that are multi-dimensional, reliable, and sensitive to change as well as having been considered highly important in the patient focus groups that led to its importance as a domain in the PsAID^{16,34}. Of the pivotal phase 3 registry trials in the last 10 years, only the drugs leflunomide and etanercept did not have all 3 domains measured, but these trials were designed prior to having outcome measures for enthesitis and dactylitis^{8,34}. Subsequently etanercept did obtain enthesitis data in a phase 4 trial³⁵. Thus, fatigue, enthesitis, and dactylitis have been measured in at least 1 or more key trials for each biologic agent.

Within the OMERACT defined field of “pathophysiology,” revision of the core set was considered to be an opportunity to amend existing redundancy in the PsA core set by utilizing “inflammatory musculoskeletal disease” as an umbrella term for arthritis, enthesitis, dactylitis, and axial disease. Similarly the term “psoriasis activity” may encompass skin and nail disease. Acute phase reactants were thought to be an important marker for prognosis but are possibly better recorded under the umbrella of biomarkers.

Composite indices. At OMERACT 10 (2010) there was support for the concept of gathering all aspects of PsA into a composite disease activity measure. Novel and existing composite measures were debated at OMERACT 11 (2012) with agreement that existing measures used in other diseases such as the Disease Activity Score-28 or Disease Activity in Reactive Arthritis were unsuitable in PsA because they were designed to measure only articular disease. Further, it was felt that it should be feasible to encompass all clinical domains in a disease activity and responder index³⁶. At OMERACT 11 there was discussion (without agreement) in relation to whether PtGA or physician global measures were sufficient to encompass the assessment of other domains such as skin, enthesitis, dactylitis, or axial disease. At this OMERACT 12 PsA workshop, there was still support for the

need for a composite measure in PsA together with recognition that original information on specific domains should be preserved for subanalyses in RCT. Some clinicians expressed concerns that including multiple domains in 1 measure may result in overlap and redundancy, and that overall disease activity may be underestimated. Alternatively, there was a body of opinion that the balance of parsimony (not covering the core set) and face validity (complete coverage of the core set) could be achieved in a composite measure, which should be data driven. At the plenary voting at this OMERACT 12, there was a majority opinion (67%) that existing measures did not reflect the full core set, with no consensus on whether composite measures should function as a responder index, encompass the full core set, or indeed both. There were concerns expressed by both the PsA working group and those voting at the plenary that there was insufficient time to adequately discuss and vote on composite measures, which will therefore be tabled for future GRAPPA and OMERACT meetings.

At this PsA workshop, there was acknowledgment of progress made toward sustained and meaningful PRP involvement in PsA outcome measure research through the activities of the GRAPPA, the PIOMPSA, and PsAID groups. There was voting agreement on the need to update the PsA core set according to the new OMERACT Filter 2.0 update cycle and that this was an opportunity to involve patients as well as to add, move, or merge existing domains to reduce existing redundancy. Work over the next 2 years will focus on this revision of the PsA core set combined with modification of composite measures with meaningful and sustained involvement of PRP.

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