Patient Participation in Psoriasis and Psoriatic Arthritis Outcome Research: A Report from the GRAPPA 2013 Annual Meeting

Maarten de Wit, Willemina Campbell, Oliver FitzGerald, Dafna D. Gladman, Phillip S. Helliwell, Jana James, Chris Lindsay, Roland MacDonald, Neil J. McHugh, Philip J. Mease, Ana-Maria Orbai, Penélope Palominos, Andrew Parkinson, William Tillett, and Niti Goel

ABSTRACT. For the first time, 8 patients with psoriatic arthritis (PsA) participated as full delegates at the 2013 Annual Meeting of the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA). Patients were invited to provide their perspective for different sessions of the conference program. Before the conference, the patient delegates had a separate meeting to familiarize themselves with the conference program and to gain a better understanding of the vision and objectives of GRAPPA. During the conference, the patient group discussed options for increased involvement in research projects. Herein we summarize the presentations on patient participation in research, the experiences of the patient group, and plans to enhance the patient perspective in psoriasis and PsA research. (J Rheumatol 2014;41:1206–11; doi:10.3899/jrheum.140171)

Key Indexing Terms:
OUTCOME RESEARCH PSORIATIC ARTHRITIS PATIENT RESEARCH PARTNER PATIENT-REPORTED OUTCOMES PATIENT INVOLVEMENT

Until recently, patients have rarely been seen as collaborative partners in health research. Despite being the individuals affected most directly by a disease, patients traditionally have had minimal direct influence on research agendas, study design, study conduct, or data interpretation related to their disease state. Since the 1990s, recognition has been increasing among researchers, regulatory agencies, and patient groups that patients should play a more active role in health research1. For example, in December 2009, the US Food and Drug Administration (FDA) released its “Guidance for Industry Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims.” In it, the FDA clearly indicates the importance and requirement of patient involvement in the development of patient-reported outcome (PRO) measures to be used in therapeutic clinical trials2.

Becoming a patient research partner (PRP) is not an instantaneous process, nor is it a role that every patient wishes to assume. It involves attaining a deeper understanding of the disease as well as knowledge of the aims and conduct of medical research. Patients need to have resources and support to develop their skills as PRP. The Outcome Measures in Rheumatology (OMERACT) group, which is focused on the development and validation of rheumatologic outcome measures, has been a leader in integrating patients in research. The OMERACT glossary3 and guiding principles4 highlight the evolution of patients into PRP since 2002. Rheumatology health research as a whole has benefited, for example, by the PRP contribution to recognition of fatigue as an important outcome measure in rheumatology. Per the OMERACT Website: “...patient input along with clinical trialist insight, epidemiologist assessment, and industry perspective, has led OMERACT to...”
In the UK, both the public and patients were being involved in research agendas. He indicated that at the government level patients within the system, versus PRP, who contribute to patient involvement in research, delineating the differences orient them to the meeting content. Dr. Helliwell outlined Helliwell and Philip Mease provided the patient group with experiences.

Eight patients, all with PsA, came to its 2013 annual meeting. GRAPPA proposed by the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA). GRAPPA subsequently incorporated patients into its research agenda, and 8 patients, all with PsA, came to its 2013 annual meeting (see Table 1 for a summary of the patients’ experiences).

Prior to the meeting’s start, GRAPPA members Philip Helliwell and Philip Mease provided the patient group with the history behind their presence at the meeting and helped orient them to the meeting content. Dr. Helliwell outlined patient involvement in research, delineating the differences between patient representatives, who negotiate on behalf of patients within the system, versus PRP, who contribute to research agendas. He indicated that at the government level in the UK, both the public and patients were being involved in an initiative to improve research agendas and the speed with which findings were incorporated into clinical practice. He delineated the initial small steps required to introduce patient involvement to GRAPPA and facilitate their contributions. Dr. Mease then discussed the concepts behind a module of the meeting that focused on developing simple clinical criteria to help clinicians identify inflammatory arthritis, enthesitis, dactylitis, and spondylitis as distinct from degenerative, traumatic, or mechanical forms of these conditions. Because this module would include a nominal group exercise, the PRP input was important in the breakout and plenary sessions, providing a good example of the critical value of the patient perspective in the proceedings. Both GRAPPA members encouraged the patients to participate and ask questions throughout the conference and thanked them for their willingness to contribute.

### Patient Involvement in Outcome Research

Four oral presentations were given during a 1-h plenary session chaired by Niti Goel and Oliver FitzGerald to introduce the concept of patient participation in outcome research. Neil McHugh summarized preliminary work undertaken by the Patient Involvement in Outcome Measures for Psoriatic Arthritis (PIOMPSA) group. He emphasized the need to incorporate patient input into PsA research and further explained recently developed composite outcome measures identified at the OMERACT 2012 meeting. PIOMPSA, first convened by Dr. FitzGerald in August 2012 and including 3 rheumatologists, a nurse researcher, and 3 patients with PsA, was charged with providing a roadmap to address these needs. The main conclusions, based on findings from the ongoing Psoriatic Arthritis Impact of Disease (PsAID) study, were that some of the items identified by patients as being most important in terms of disease effect are not measured directly in the newer composite measures. PIOMPSA members also agreed to undertake a systematic literature review to definitively confirm levels of patient involvement in previous domain identification and outcome measure development. Finally, the group recommended that PsA patient perspectives should be incorporated in the planned PsA workshop at OMERACT 2014.

A further meeting of the PIOMPSA group was convened by Dr. McHugh in February 2013 and attended by 5 rheumatologists and 5 patients. William Tillett presented results of a systematic literature review, which confirmed minimal and no patient input, respectively, into current PsA outcome measures and the original Delphi process for definition of the OMERACT core domains for PsA. A key meeting conclusion was that the OMERACT PsA core set may need revision, with fatigue and dactylitis considered for inclusion. Support existed conceptually for a minimal core set composite index, and possibly an expanded index to encompass broader domains. These would be incorporated...
The better able they are to make informed choices. Although a skilled professional in her own field, working full-time as an engineer designing railway signaling systems, she was concerned that the “medical speak” would leave her behind. However, she was surprised by her own level of understanding and felt gratified that when patients sought clarification, they were not made to feel inferior.

As a patient participant, Ms. James wanted to ensure that researchers recognize that some aspects of arthritis that they rank as important may lead to developing treatments that only partially affect the features that arthritis patients consider important. Patients can provide a complementary perspective on all areas of treatment for both psoriasis and PsA.

Finally, Dr. FitzGerald highlighted examples where patient involvement might prevent a potential mismatch between the preferences, expectations, and experiences of patients and of professionals. One study demonstrated that although a good correlation exists for PsA disease activity assessments between patients and physicians, the latter usually evaluate the disease as less active than do patients. This study also showed that patients with PsA attribute 50% of global disease burden to rheumatic symptoms, 25% to skin symptoms, and 25% to additional symptoms such as fatigue. These findings were confirmed by the aforementioned PsAID study. At least 3 of the 4 most important domains (pain, skin problems, fatigue, and work/leisure capacity) are not directly measured in each of the newer composite scores (Figure 1), although pain, skin problems, and fatigue are likely indirectly measured in the Patient Global visual analog scale. The differences in patients’ and physicians’ perspectives emphasize the importance of incorporating PRO in future PsA research.

To achieve this end, an important development in recent years is the involvement of PRP, persons with “a relevant disease who operate as active research team members on an equal basis with professional researchers, adding the benefit of their experiential knowledge to any phase of the project.” The European League Against Rheumatism (EULAR) has published recommendations that provide practical guidance for research partner involvement, capturing the (1) role of PRP, (2) phase of involvement, (3) recommended number, (4) recruitment, (5) selection, (6) support, (7) training, and (8) acknowledgment. With these guiding principles in mind, patients’ input was sought at the GRAPPA meeting, especially at the breakout sessions on treatment recommendations and on the definition of musculoskeletal inflammation. Dr. FitzGerald ended by emphasizing that time was needed to get to know each other, develop an appreciation of the value of patient participation, and develop a research agenda to involve patients.

Discussion after the plenary session focused on whether PRP are representative of the general population of patients with PsA and on experiences of patient involvement in community-based participatory research.
During this GRAPPA conference, Dr. Tillett presented the findings of the systematic literature review initially presented at the PIOMPSA meeting in February 2013 that sought to determine the level of patient participation in the development of PsA outcome measures and OMERACT disease domains. Sixty-three articles relating to 26 outcome measures were identified. Only 1 outcome measure, the Psoriatic Arthritis Quality of Life (PsAQoL) questionnaire, described any patient involvement in the development process. PsAQoL content was developed from initial qualitative interviews with patients with PsA and revised for clarity using feedback from PRP. Three articles relating to the development of PsA disease domains were identified, 2 of which reported GRAPPA exercises determining the original identification of disease domains, and during which there was no patient involvement. The other reflected a final consensus on domains achieved at OMERACT 8 (2006) where 4 patients with PsA participated as full delegates, with 1 presenting a personal story of living with PsA prior to the final voting exercise. The review demonstrated that much of the PsA disease domain and outcome measure development was conducted without substantial patient involvement.

### Patient Participation in Future PRO Research

In a separate session, several researchers requested particular input on their research from the PRP. Dr. Tillett presented preliminary data from the Long Term Outcomes in Psoriatic Arthritis II (LOPAS II) study, a prospective observational evaluation of work disability (WD) in 400 patients with PsA recruited from 23 hospitals across the UK. There is increasing recognition that WD is an important patient-centered QoL outcome that needs further investigation. A review of patients with PsA suggests that levels of WD are high (16–39%) and are associated with a range of clinical and social factors. Interpretation of the existing data is hampered by the small number of reports, heterogeneity of data collected, and posthoc analyses. LOPAS II is investigating the burden, associations, and the effect of treatment on WD. The patient group reviewed the study findings, made suggestions for future research, and agreed to review subsequent research proposals.

Ana-Maria Orbai introduced the Patient-Reported Outcomes Measurement Information System (PROMIS) initiated by the US National Institutes of Health. In a pilot study at the Johns Hopkins Arthritis Center, patients with PsA using a tablet completed 10 PROMIS computer adaptive test instruments in 10 min on average. The instruments assessed physical health (pain, physical function, fatigue, sleep quality), emotional health (depression, anger, anxiety), and social health (participation, satisfaction with roles), domains all identified as important to patients with PsA in a prior study. Preliminary data suggested that impairments in physical function and levels of pain and fatigue may be significantly higher in patients with PsA than in the general population. A subsequent planned mixed methods study, i.e., qualitative research followed by quantitative data collection, was presented and the PRP agreed to review the initial draft proposal and to continue to contribute to the development of the study after the meeting.

Penélope Palominos highlighted that although 75% of patients with PsA recruited from 23 hospitals across the UK...
recent PsA articles in PubMed (2006–2010) reported use of at least 1 PRO\textsuperscript{23}, little knowledge exists regarding patients’ beliefs about PsA and its treatment. In other rheumatic diseases, evidence indicates that patients’ beliefs influence their adherence to therapy\textsuperscript{24,25,26}, coping patterns\textsuperscript{27,28}, disease effect\textsuperscript{29}, and side effects from therapy\textsuperscript{30}. A systematic literature review about beliefs and perceptions of patients with PsA and other inflammatory arthropathies is ongoing, and a qualitative study is to be conducted in Brazil and France to gain knowledge on patients’ beliefs about PsA. The patient delegates were invited to collaborate in the latter effort by providing their opinions about the project and potential questions for inclusion in the semistructured interviews.

Finally, the patient group members gathered to evaluate their experiences during the conference. They formulated recommendations for GRAPPA to optimize the involvement of patients at future conferences (Table 2).

The official presence of patients for the first time at the GRAPPA Annual Meeting was an important first step in incorporating their voice into GRAPPA’s research agenda. Moving forward, PsA PRP will be involved in future research initiatives with GRAPPA such as PIOMPSA, the development and validation of composite measures, the definition of musculoskeletal inflammation, and the development of updated treatment guidelines, as well as the PsA workshop at OMERACT 12 held in May 2014.

Table 2. Recommendations from the GRAPPA 2013 patient participants.

<table>
<thead>
<tr>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meeting logistics</td>
</tr>
<tr>
<td>Provide premeeting time for patients to orient them to the meeting (potentially by phone)</td>
</tr>
<tr>
<td>Provide access to background information before the meeting</td>
</tr>
<tr>
<td>Provide reimbursement for accommodation, meals, airfare, and airport transportation</td>
</tr>
<tr>
<td>Appoint a patient group supporter from among the researchers</td>
</tr>
<tr>
<td>Breakout sessions</td>
</tr>
<tr>
<td>Identify sessions where patient input is needed or desired and adjust session layout</td>
</tr>
<tr>
<td>Offer patients the opportunity to participate and ask questions</td>
</tr>
<tr>
<td>Consider instruction or training for facilitators to ensure patient participation</td>
</tr>
<tr>
<td>Provide flipcharts for discussion points</td>
</tr>
<tr>
<td>Presenters</td>
</tr>
<tr>
<td>Provide handouts or e-mail information to patients in advance, to identify the patient input required at the meeting, and to involve patients in postmeeting activities</td>
</tr>
<tr>
<td>Patient research partners</td>
</tr>
<tr>
<td>Research partners should be supportive of one another within the patient group</td>
</tr>
<tr>
<td>GRAPPA</td>
</tr>
<tr>
<td>Consider appointing 1 or 2 patients to the GRAPPA Steering Committee</td>
</tr>
<tr>
<td>Consider involving patient participants with psoriasis, suggested by dermatologists</td>
</tr>
</tbody>
</table>

REFERENCES

GRAPPA: Annual Meeting of the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis.


