

COMMENTARY

Patients as Partners: Building on the Experience of Outcome Measures in Rheumatology

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Advising patients about managing and living with their conditions and explaining the risks and benefits of treatment choices are integral aspects of a clinician's medical practice. However, if descriptions of the potential outcomes are framed in terms patients do not understand or do not consider relevant, they may not be able to make informed decisions, and treating clinicians may fail to achieve these goals. When designing clinical trials, we must therefore include outcome measures that are meaningful to patients and correspond to their life experiences.

For the past 2 decades, the driving force for addressing issues regarding outcome measures in rheumatology has been Outcome Measures in Rheumatology (OMERACT), which is involved in the development and validation of core outcome measure sets in rheumatic diseases (1). OMERACT began as an informal gathering of researchers who were interested in outcome measures in rheumatology but evolved into a biennial 5-day working conference including a wide range of clinicians and clinical

research methodologists. Since 2002, patients have also been actively involved in order to incorporate their views regarding which outcome measures should be used to assess the benefits of treatment (2). Patient involvement has made a significant difference in terms of the issues taken up by research working groups, with fatigue measurement in rheumatoid arthritis (RA) being, perhaps, the best example (3). The importance of fatigue, which now is considered to be central to our understanding of the effects of inflammatory arthritis (4), had been effectively ignored by this group of committed researchers.

The call by patient participants to look more closely at fatigue as a component of RA resulted in a 10-year program of international research culminating in the incorporation of fatigue into the “core set” of measures for RA clinical trials. This would not have happened without the prolonged involvement of patient participants in OMERACT (5). Furthermore, the manner in which patients have subsequently contributed to the development of a new measurement of fatigue in RA has been described in detail (6). Following this lead, researchers developing the Rheumatoid Arthritis Impact of Disease (RAID) score (7) and the Psoriatic Arthritis Impact of Disease score (8) have done so in close partnership with patients. Important domains directly derived from the experience of patients were formulated using language that is understood by patients. In addition, patient research partners provided advice regarding the feasibility of the research protocols, the number of items to be included in questionnaires, the length of the recall periods, and methods for scoring.

Patient involvement in health care research has been advocated by national institutions for some time, perhaps most notably by the UK National Health Service through the INVOLVE program (9). In the US, the Patient-Centered Outcomes Research Institute (PCORI) was established in 2014 to “identify critical research questions, fund patient-centered comparative clinical effectiveness research . . . and disseminate the results in ways that

Outcome Measures in Rheumatology (OMERACT) is an international research group that is supported by registration fees and has received unrestricted funding from more than 23 pharmaceutical and clinical research companies over the past 2 years.

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Submitted for publication December 22, 2015; accepted in revised form March 8, 2016.

the end-users . . . will find useful and valuable” when making health care–related decisions (10). An increasing body of literature has demonstrated that involving patients as partners in research design, study implementation, and dissemination of results is worthwhile (11).

A collaboration with patients as research partners does not happen spontaneously. It has to be actively pursued and embedded in research planning. The way in which OMERACT has included patients as partners in its activities has become more sophisticated and fully integrated in the OMERACT filter (12). Initially, “10 nervous, bewildered individuals with one thing in common, rheumatoid arthritis” (13) came from 5 countries and contributed to ~15% of the programmed activities. Now, every aspect of its activities automatically requires the participation of patient partners, as described and explained in detail in the OMERACT handbook (14). This approach changes aspects of both the overall strategy and day-to-day procedures (15). For example, all (non-technical) research groups must include and provide financial support for patient partner involvement. This process of growth and development is likely to occur with other organizations that embrace patient participation.

Thus far, 64 different patients from 13 countries participated in 1 or more OMERACT conferences (average of 2 conferences). Their conditions have ranged from RA (the most common) to gout, Behçet’s syndrome, and vasculitis-associated interstitial lung disease. At times, patient participants have required an accompanying person, portable oxygen supplies, or other special arrangements. With accumulating experience, a number of innovations have been introduced to support patient partners at and between conferences. These include allocation of funding for patient support, production (by patient partners) of a glossary of research terms (1), an introductory session for patient participants before the start of conferences and daily briefing sessions from the coordinators of the different sections of the meeting, and a “buddy” system for new patient participants (16).

An in-depth analysis of how this support helps OMERACT to work (17) identified 3 key messages. First, making patient participation an integral part of the conference vision, structure, and program ensures that the patient perspective is captured effectively and efficiently. Second, tailored introductions and personalized training and support for patients are important conditions for successful engagement with patients. Third, chairs and moderators of small group discussions play a pivotal role in enabling patients to contribute to research and fostering the mutual learning processes for all participants.

Funding bodies (such as Arthritis Research UK and PCORI) are increasingly requiring grant applicants to include patients as partners in the research team and to show how those partners will be supported and empowered. Other professional organizations (such as the European League Against Rheumatism) and research collaborations (such as the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis) have established networks of patient research partners (18) and have made the participation of patients a common feature at their annual meetings (19). National rheumatology societies (such as the American College of Rheumatology) may also be considering the development of such links.

The experience with patient involvement over many years (20) offers some guidance and pointers to others wishing to develop similar types of collaborative partnerships with patients in research. Inevitably, new challenges emerge as old ones are overcome. For OMERACT, these currently include the following: ensuring that patient partnership between meetings is an almost automatic occurrence; widening representation of patient participants of different regional, cultural, and social backgrounds; and organizing education about collaboration for both researchers and patient research partners. However, it is clear that with appropriate commitment of will and resources, patients can be effective partners across the research continuum and in all forms of research endeavors.

AUTHOR CONTRIBUTIONS

All authors were involved in drafting the article, revising it critically for important intellectual content, and all authors approved the final version to be published.

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APPENDIX A : THE OMERACT EXECUTIVE COMMITTEE

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