Health Equity Considerations for Developing and Reporting Patient-reported Outcomes in Clinical Trials: A Report from the OMERACT Equity Special Interest Group

Jennifer Petkovic, Jennifer L. Barton, Caroline Flurey, Niti Goel, Christie M. Bartels, Cheryl Barnabe, Maarten P.T. de Wit, Anne Lyddiatt, Diane Lacaille, Vivian Welch, Annelies Boonen, Beverley Shea, Robin Christensen, Lara J. Maxwell, Willemina Campbell, Janet Jull, Karine Toupin-April, Jasvinder A. Singh, Charles H. Goldsmith, Antoine G. Sreih, Christoph Pohl, Catherine Hofstetter, Dorcas E. Beaton, Rachelle Buchbinder, Francis Guillemin, and Peter S. Tugwell

ABSTRACT. ***Objective.*** Despite advances integrating patient-centered outcomes into rheumatologic studies, concerns remain regarding their representativeness across diverse patient groups and how this affects equity. The Outcome Measures in Rheumatology (OMERACT) Equity Working Group aims to determine whether and how to address equity issues within the core outcome sets of domains and instruments.

Methods. We surveyed current and previous OMERACT meeting attendees and members of the Campbell and Cochrane Equity Group regarding whether to address equity issues within the OMERACT Filter 2.0 Core Outcome Sets and how to assess the appropriateness of domains, instruments, and measurement properties among diverse patients. At OMERACT 2016, results of the survey and a narrative review of differential psychosocial effects of rheumatoid arthritis (i.e., on men) were presented to stimulate discussion and develop a research agenda.

Results. We proposed 6 moments for which an equity lens could be added to the development, selection, or testing of patient-reported outcome measures (PROM): (1) recruitment, (2) domain selection, (3) feasibility in diverse settings, (4) instrument validity, (5) thresholds of meaning, and (6) consideration of statistical power of subgroup analyses for outcome reporting.

Conclusion. There is a need to (1) conduct a systematic review to assess how equity and population characteristics have been considered in PROM development and whether these differences influence the ranking of importance of outcome domains or a patient's response to questionnaire items, and (2) conduct the same survey described above with patients representing groups experiencing health inequities. (First Release February 15 2017; J Rheumatol 2017;44:1727–33; doi:10.3899/jrheum.160975)

Key Indexing Terms:
HEALTH EQUITY ARTHRITIS RHEUMATOLOGY
OUTCOME ASSESSMENT OMERACT

From the Bruyère Research Institute, University of Ottawa; Ottawa Hospital Research Institute and School of Epidemiology, Public Health and Preventative Medicine, University of Ottawa; Cochrane Musculoskeletal Group, University of Ottawa; Children's Hospital of Eastern Ontario Research Institute; Department of Pediatrics and School of Rehabilitation Sciences, University of Ottawa; Department of Medicine, Faculty of Medicine, University of Ottawa; Ottawa Hospital Research Institute, Clinical Epidemiology Program; Department of Epidemiology and Community Medicine, Faculty of Medicine, University of Ottawa, Ottawa; Musculoskeletal Health and Outcomes Research, Li Ka Shing Knowledge Institute, St. Michael's Hospital; Institute for Work and Health; Occupational Science and Occupational Therapy, Rehabilitation Sciences Institute, Institute of Health Policy Management and Evaluation, University of Toronto, Toronto, Ontario; Departments of Medicine and Community Health Sciences, University of Calgary, Calgary, Alberta; Division of Rheumatology Department of Medicine, University of British Columbia (UBC); Department of Occupational Science and Occupational Therapy, Faculty of Medicine, UBC, Vancouver; Arthritis Research Canada, Richmond; Faculty of Health Sciences, Simon Fraser University, Burnaby, British Columbia, Canada; Veterans Affairs Portland Health Care System, Oregon Health and Science University, Portland, Oregon; Division of Rheumatology, Duke University School of Medicine, Durham, North Carolina; Quintiles IMS, Denver, Colorado; Department of Medicine, Rheumatology Division, University of Wisconsin School of Medicine and Public Health, Madison, Wisconsin; University of Alabama at Birmingham; Birmingham Veterans Affairs Medical Center, Birmingham, Alabama; Department of Orthopedics, Mayo Clinic College of Medicine, Rochester, Minnesota; Penn Vasculitis Center, Division of Rheumatology, The University of Pennsylvania, Philadelphia, Pennsylvania, USA; University of the West of England, Bristol, UK; VU University Medical Centre, Department Medical Humanities, EMGO+ Research Institute, Amsterdam; Department Internal Medicine, Division of Rheumatology, Maastricht University Medical Center; Caphri Graduate School Maastricht University, Maastricht, the Netherlands;

Musculoskeletal Statistics Unit, The Parker Institute; Frederiksberg Hospital, Copenhagen, Denmark; Department Internal Medicine II, Rheumatology, Schlosspark-Klinik Berlin, Charité — Medical University Berlin, Berlin, Germany; Monash Department of Clinical Epidemiology, Cabrini Institute and Department of Epidemiology and Preventive Medicine, School of Public Health and Preventive Medicine, Monash University, Melbourne, Australia; University of Lorraine, Nancy, France.

J.A. Singh has received research grants from Takeda and Savient, and consultant fees from Savient, Takeda, Regeneron, Merz, Iroko, Bioiberica, Crealta and Allergan pharmaceuticals, WebMD, UBM LLC, and the American College of Rheumatology. J.A. Singh serves as the principal investigator for an investigator-initiated study funded by Horizon pharmaceuticals through a grant to DINORA Inc., a 501 (c)(3) entity. J.A. Singh is a member of the executive of OMERACT, an organization that develops outcome measures in rheumatology and receives arms-length funding from 36 companies; a member of the American College of Rheumatology's (ACR) Annual Meeting Planning Committee; Chair of the ACR Meet-the-Professor Workshop and Study Group Subcommittee; and a member of the Veterans Affairs Rheumatology Field Advisory Committee. C. Bartels receives institutional peer-reviewed grant support from Independent Grants for Learning and Change (Pfizer) unrelated to this work.

J. Petkovic, MSc, Bruyère Research Institute, University of Ottawa; J.L. Barton, MD, Veterans Affairs Portland Health Care System, Oregon Health and Science University; C. Flurey, PhD, University of the West of England; N. Goel, MD, Division of Rheumatology, Duke University School of Medicine, and Advisory Services, Quintiles IMS, and Patient Research Partner; C.M. Bartels, MD, MS, Department of Medicine, Rheumatology Division, University of Wisconsin School of Medicine and Public Health; C. Barnabe, MD, Departments of Medicine and Community Health Sciences, University of Calgary; M.P. de Wit, PhD, Patient Researcher, VU University Medical Centre, Department Medical Humanities, EMGO+ Research Institute; A. Lyddiatt, Patient Research Partner; D. Lacaille, MD, MHSc, Professor, Division of Rheumatology Department of Medicine, UBC, and Senior Scientist, Arthritis Research Canada; V. Welch, PhD, Bruyère Research Institute, University of Ottawa; A. Boonen, MD, PhD, Department Internal Medicine, Division of Rheumatology Maastricht, University Medical Center, and Caphri Graduate School Maastricht University; B. Shea, PhD, Ottawa Hospital Research Institute and School of Epidemiology, Public Health and Preventative Medicine, University of Ottawa; R. Christensen, MSc, PhD, Musculoskeletal Statistics Unit, The Parker Institute, and Frederiksberg Hospital; L.J. Maxwell, PhD, Cochrane Musculoskeletal Group, University of Ottawa; W. Campbell, LLB, Patient Research Partner; J. Jull, PhD, Bruyere Research Institute; K. Toupin-April, PhD, Children's Hospital of Eastern Ontario Research Institute, and Department of Pediatrics and School of Rehabilitation Sciences, University of Ottawa; J.A. Singh, MBBS, MPH, Professor of Medicine and Epidemiology, University of Alabama at Birmingham, and Staff Physician, Birmingham Veterans Affairs Medical Center, and Research Collaborator, Department of Orthopedics, Mayo Clinic College of Medicine; C.H. Goldsmith, BSc, MSc, PhD, Faculty of Health Sciences, Simon Fraser University, and Adjunct Professor, Department of Occupational Science and Occupational Therapy, Faculty of Medicine, UBC; A.G. Sreih, MD, Penn Vasculitis Center, Division of Rheumatology, The University of Pennsylvania; C. Pohl, MD, Department of Internal Medicine II, Rheumatology, Schlosspark-Klinik Berlin, University Medicine Berlin; C. Hofstetter, Patient Research Partner; D.E. Beaton, PhD, Musculoskeletal Health and Outcomes Research, Li Ka Shing Knowledge Institute, St. Michael's Hospital, and Institute for Work and Health, and Occupational Science and Occupational Therapy, Rehabilitation Sciences Institute, Institute of Health Policy Management and Evaluation, University of Toronto; R. Buchbinder, PhD, Monash Department of Clinical Epidemiology, Cabrini Institute and Department of Epidemiology and Preventive Medicine, School of Public Health and Preventive Medicine, Monash University; F. Guillemin, MD, PhD, University of Lorraine; P.S. Tugwell, MD, MSc, Department of Medicine, Faculty of Medicine, University of Ottawa, and Ottawa Hospital Research Institute, Clinical Epidemiology Program, and Department of Epidemiology and Community Medicine, Faculty of Medicine, University of Ottawa, Ottawa.

Address correspondence to Dr. J. Petkovic, 43 Bruyère St., Annex E, Room 302, Ottawa, Ontario K1N 5C8, Canada.
E-mail: jennifer.petkovic@uottawa.ca

Accepted for publication January 11, 2017.

Substantive patient input is required for both the selection of domains for the Outcome Measures in Rheumatology (OMERACT) core outcome sets as well as instruments to assess these domains, especially those that use patient-reported outcome measures (PROM)[1,2,3]. However, to date, the majority of core outcome domains and subsequently the corresponding PROM have been primarily developed with input from nondisadvantaged, well-educated patients or without consideration of potentially disadvantaged subgroups, and therefore may not represent other population groups[4]. While many OMERACT Working Groups have shown differences in how patients and healthcare professionals value different health outcomes[5,6,7,8], the OMERACT Equity Working Group aims to examine potential variations in values of socially disadvantaged patients. Health equity refers to the absence of avoidable and unfair differences in health outcomes[9]. This is important because disadvantaged individuals being offered treatment (e.g., pharmacologic, nonpharmacologic, surgical) may select different outcomes or weigh the relative importance of beneficial and harmful outcomes differently from nondisadvantaged patients. The OMERACT Equity Group uses the acronym "PROGRESS-Plus" to identify characteristics of disadvantage that may contribute to health inequities. PROGRESS refers to "Place of residence, Race/ethnicity/culture/language, Occupation, Gender/sex, Religion, Education, Socioeconomic status, and Social Capital" (e.g., social networks), while "Plus" refers to additional characteristics such as age or disability, features of relationships (in which 1 person has more control than the other), and time-dependent circumstances (in which a person may be temporarily disadvantaged)[10,11,12]. Kroon, *et al* added "health literacy" to PROGRESS-Plus in view of its relevance to health equity[13].

Previous research has shown that factors such as income, culture, and type of work can affect how people respond to questions about their health[14]. For example, differential item functioning analysis, which compares how questionnaire items function across population groups, showed that in India, the item "difficulty managing job" using ThyPRO, a thyroid-specific quality-of-life PROM, was rated as more important than in the other countries where the PROM was tested (Denmark, Italy, the Netherlands, Serbia, Sweden, and the United Kingdom)[15]. One possible explanation may be that the types of jobs held by the participating Indians were more dependent on good physical health, indicating that PROM development requires input from patients representing diverse populations.

Few studies of PROM in rheumatology have considered equity issues. The Health Assessment Questionnaire is a PROM that has been adapted to address linguistic and cultural issues[16,17,18,19,20]. Examples include the Thai version changing the item about taking a tub bath to lifting a water bowl to wash[16], the Bengali version changing the item about getting in and out of a car to getting in and out of a

rickshaw[21], and the Arabic version changing the item about vacuuming and yard work to praying from the standing position (kneeling)[20]. The Patient-Reported Outcomes Measurement Information System, a set of questionnaires administered through computer-adapted testing, has been developed with input from and with consideration of diverse populations within the United States, with validation across over 20 languages and cultures under way[22,23]. When using this system, clinicians are able to select specific questionnaires to address concerns of individual patients and can select items from an item bank based upon the respondent's previous answers[24]. The individualization of items to the patient highlights how equity issues may be addressed. Last, the OMERACT Worker Productivity Group has identified differences in outcomes of importance for patients with arthritis for those who are employed and those who are not, requiring different measures of participation[25].

The goal of the Equity Special Interest Group at OMERACT 2016 was to develop a research agenda for addressing equity issues within the development of the Core Outcome Sets of Domain and Instruments.

MATERIALS AND METHODS

Prior to OMERACT 2016, we conducted a survey to seek opinions on (1) whether to attempt to address equity issues within the OMERACT Filter 2.0 Core Outcome Sets[26], and (2) how to assess the appropriateness and performance of the Core Set Instruments among diverse patients. The survey was developed by the Equity Working Group co-chairs with assistance from a patient research partner (PRP). We used the PROGRESS-Plus framework to develop the survey questions because it identifies population characteristics associated with inequities[11,27]. We conducted the survey online (using SurveyMonkey), and invited current and past OMERACT meeting participants (n = 781) and members of the Campbell and Cochrane Equity Methods Group (n = 780) to participate. We sent the same survey to both groups with slight changes to the background material to ensure that those who had not been involved with OMERACT received information required to complete the survey (e.g., links to the OMERACT glossary). We sent an e-mail reminder 1 week after the initial invitation to participate.

At OMERACT 2016, we organized a 1.5-h session that all registered participants were eligible to attend. The results of the survey as well as the results of a narrative review of the psychosocial effects of rheumatoid arthritis (RA) in different subpopulations were presented[28] to stimulate discussion and develop a research agenda for the next 2 years.

RESULTS

Survey. From the OMERACT membership list, 64 people responded (from 781), and 36 responded (from 780) from the equity membership list.

A summary of survey results is provided in Table 1. Support from both groups was greatest for considering place of residence (high- vs low-income country, rurality), occupation, and culture, and for testing current and future core outcome measures in specific diverse populations. Overall, most respondents reported that PROGRESS characteristics would affect the importance of different domains of health effect (minimum to maximum 39%–84%, depending on the PROGRESS factor).

In open comments, respondents identified several characteristics not included in the PROGRESS that OMERACT should consider (some of which are identified by the "Plus" of PROGRESS-Plus), including access to healthcare, access to social care, age, immigrant or refugee status, mental or physical disabilities, multiple comorbidities, poor access to transportation, psychological profile/mental health of patients (e.g., optimistic vs negative outlook), and sexual orientation. One respondent commented on the challenges for longitudinal studies when patient characteristics change over time, such as improvements in health literacy, changes in employment status, or changes in family commitments, and how these might be identified. One respondent cautioned that feasibility should be considered since it may not be possible to adjust/adapt the PROM for every population subgroup and doing so would hinder efforts to standardize measures.

The survey results indicated that the majority of respondents consider PROGRESS-Plus characteristics as important considerations for PROM developers. Respondents suggested that representatives of disadvantaged populations have an opportunity to answer this survey so that their input is included in the next steps.

One comment consistent among survey respondents was that while population characteristics matter, their importance in a randomized controlled trial (RCT) is not clear because differences between populations are minimized by randomization. This final comment was reiterated by participants at the OMERACT 2016 Equity session.

OMERACT 2016 Equity session. In total, 32 OMERACT delegates attended the session, including 6 PRP. The results of the survey were presented and the importance of equity issues in RCT was discussed. Discussion was further stimulated by the presentation of a narrative review of psychosocial effects of RA on men[28]. This review demonstrated potential differences between subgroups of a population and how, in this case, sex may influence the choice of outcome or patient responses. The review found that men and women experience different types of effect on their quality of life[28]. Specifically, women reported lower quality of life on items relating to emotional state than men, whereas men reported lower quality of life on items relating to social activity. Further, among individuals with RA and osteoarthritis, as well as healthy populations, women consistently scored worse than men on quality of life measures, indicating these measures may not be identifying issues important to men[28].

Participants discussed other examples, such as item performance by sex. While women tend to be more able to clearly express their emotion, men tend to imply emotion and can be more comfortable discussing anger than sadness; men's distress is often hidden or minimized[29]. A measure of depression designed to identify men's feelings of distress (asking about actions and thoughts rather than feelings) is more successful at diagnosing depression in men than traditional measures of depression[30].

Table 1. Summary of survey results. Values are n (%).

Questions	Total, n = 100		
	Yes	No	NR
Do you think (characteristic listed below) will affect the importance of health impact (pain, quality of life, functional limitations, etc.)?			
Place of residence (high-income, low-income country)	84 (84.0)	8 (8.0)	2 (2.0)
Place of residence (urban, rural, etc.)	83 (83.0)	11 (11.0)	2 (2.0)
Occupation (whether a person has a job: employed, out of work, longterm disability)	82 (82.0)	7 (7.0)	11 (11.0)
Occupation (type of job)	78 (78.0)	7 (7.0)	14 (14.0)
Culture	77 (77.0)	6 (6.0)	10 (10.0)
Socioeconomic status	71 (71.0)	8 (8.0)	17 (17.0)
Education	70 (70.0)	13 (13.0)	16 (16.0)
Social capital	70 (70.0)	10 (10.0)	18 (18.0)
Gender/sex	63 (63.0)	19 (19.0)	12 (12.0)
Ethnicity	53 (53.0)	29 (29.0)	10 (10.0)
Language	49 (49.0)	33 (33.0)	11 (11.0)
Religion	49 (49.0)	30 (30.0)	12 (12.0)
Race	39 (39.0)	33 (33.0)	8 (8.0)
Do you think current or future core outcome measures should be tested in specific diverse patient populations?	78 (78.0)	5 (5.0)	16 (16.0)
Do you think disadvantaged populations [such as those listed above] may benefit from more plain language, inclusive outcome measurement instruments?	67 (67.0)	8 (8.0)	16 (16.0)
Do you think that PROM need to be modified for use among immigrant populations within the country in which the PROM was developed?	56 (56.0)	21 (21.0)	11 (11.0)
In addition to the PROGRESS characteristics (listed above), are there other potentially disadvantaged groups that we need to consider within OMERACT?	25 (25.0)	39 (39.0)	20 (20.0)

NR: no response; numbers do not add to 100% because some respondents recorded comments other than yes or no (e.g., do not know); PROM: patient-reported outcome measures; PROGRESS: Place of residence, Race/ethnicity/culture/language, Occupation, Gender/sex, Religion, Education, Socioeconomic status, and Social Capital; OMERACT: Outcome Measures in Rheumatology.

These examples led to a group discussion of when to apply an equity lens to clinical trials and how these considerations may affect patient-reported outcomes.

Recommendations of OMERACT Equity session attendees. Participants suggested the addition of equity to the OMERACT Handbook and proposed 6 moments when an equity lens could be added when developing, selecting, or testing PROM within the context of an RCT (Figure 1):

(1) Recruitment: Ensure a diverse population with representation of groups with health inequities considering appropriate stratification for randomization.
(2) Domain selection: Ensure domains are relevant to groups who may experience health inequities.
(3) Feasibility in diverse setting: Are access, equipment, and ease of use reasonable across diverse settings including among populations with low health literacy?
(4) Instrument validity: Ensure instruments are validated in diverse populations.
(5) Thresholds of meaning: Ensure that these are valid for diverse individuals.
(6) Consideration of statistical power of subgroup analyses for outcome reporting: Following the Yusuf, *et al* criteria for credible subgroup analyses[31].

The participants suggested encouraging PROM developers to include the perceptions of population subgroups when developing a PROM. However, it was noted that developing PROM with modified or additional items for every population subgroup would make it impossible to compare results across populations without exhaustive cross-cultural validation. Instead, supplementary items could be added, if necessary. This requires research to determine which population characteristics make a difference and how these may be addressed.

The group discussed the importance of equity considerations in rheumatology trials. Overall, the group agreed that population characteristics are important considerations when planning a trial. Although there would likely be no effect on the internal validity of the results, population characteristics could affect the generalizability. Understanding whether the intervention is effective in specific population subgroups is important for the implementation of the intervention in practice. Therefore, the group agreed that testing PROM in diverse populations with representation from disadvantaged subgroups is essential as well as performing subgroup analyses, when appropriate. Table 2[20,32,33,34,35,36,37,38] presents examples of the effect of population characteristics and the potential effect on outcome identification and prioritization.

Workshop participants suggested conducting a systematic review to assess equity considerations in PROM development and whether population differences have been found to influence the importance of outcome measures or a patient's response to questionnaire items. Other potential projects suggested during the session include:

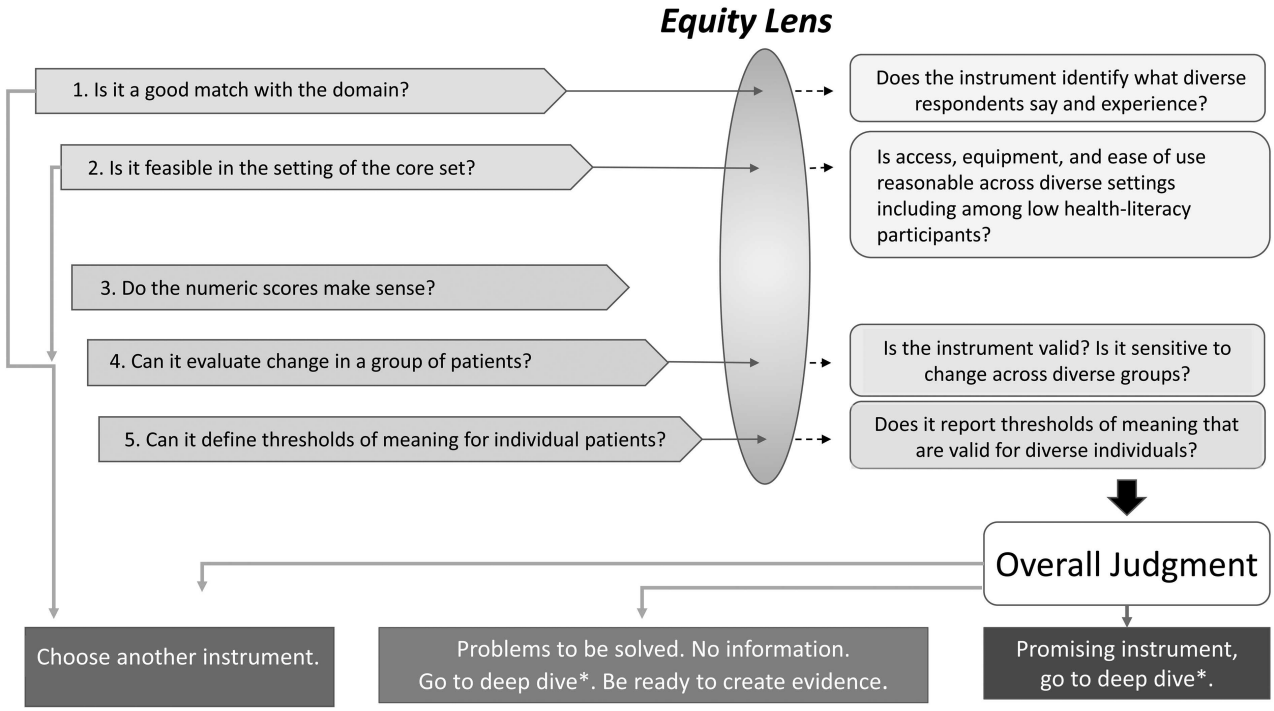

Figure 1. Proposed equity lens for the Outcome Measures in Rheumatology Filter 2.0. * Deep dive refers to a full evaluation of core outcome measurement sets.

(1) Testing a few instruments in diverse patient populations to see whether there are differences in responses;
(2) Comparing results from completed trials with different subpopulations and similar severity of disease with a treatment of known efficacy to see whether there are differences in PROM responses;
(3) Encouraging OMERACT PROM developers to consider studying equity when testing new PROM; and
(4) Conducting a metaepidemiological study assessing the empirical evidence from trials included in the Cochrane musculoskeletal reviews to look for potential effect modification associated with PROGRESS-Plus characteristics.

These proposed projects will allow us to analyze the differences in responses by patients with varying population characteristics and potential disadvantage.

DISCUSSION

Over the next 2 years, we will:

(1) Conduct a systematic review to assess how equity and population characteristics have been considered in PROM development and whether these differences have been found to influence the ranking of importance of outcome measures or a patient's response to questionnaire items, and

(2) Conduct a questionnaire similar to the one used in our study with patients representing groups experiencing health inequities by inviting them to respond to the same survey described above. Interviews may be required to reach disadvantaged population groups.

Strengths of our survey include participation by multinational patients and researchers. However, our survey also has limitations. Although we had strong input from the OMERACT PRP and many of the participating clinicians have experience in the care of disadvantaged patients, we did not have the opportunity to include disadvantaged patients in the survey. Our survey had a low response rate, but this is usual for physician and expert surveys. Those who did respond are more likely to have an interest in health equity, which means they likely have a good understanding of equity issues and would respond that equity is important to consider in PROM.

The OMERACT Equity Working Group strongly endorsed continuing equity work within OMERACT. We agreed that there are subgroups of the population who may experience different effects of an intervention and for whom the importance of outcomes may vary. Our task going forward is to identify how these potential population differences can be measured. The most pressing research agenda item is to conduct a systematic review to assess how equity and population characteristics have been and should be considered in designing and evaluating RCT to avoid unnecessary, unfair disadvantage to subpopulations. We will investigate how these have been considered in PROM

Table 2. PROGRESS characteristics and potential effect on outcome identification and prioritization.

PROGRESS Characteristics	Example	Effect on Outcome Identification and Prioritization
Place of residence	Treatment that requires frequent trips to the hospital, health center, or specialist.	The patient may prioritize outcomes in their condition (e.g., reduced symptom severity, improved function) differently if they are unable to comply with the treatment schedule (e.g., because of a long distance to the health center) or may not receive appropriate followup care (e.g., advice regarding changes to dosage or side effect management, may not have access to a specialist).
Race/ethnicity/culture/language	There are cultural differences in how fatigue is experienced (e.g., Egyptian patients describe effects of fatigue as mostly physical while other populations, e.g., United Kingdom, Sweden, describe both physical and mental effects)[32,33].	The outcome measure may not accurately identify the different conceptualizations and meanings of fatigue in all groups within the population.
Occupation	A patient's type of work (e.g., manual labor) can affect outcomes.	In cancer-related work studies, manual laborers reported greater difficulty returning to work after treatment; therefore, greater improvements in other outcomes (e.g., pain, function) may be required to accurately assess return to work[34].
Gender/Sex	A patient's sex may affect their experience with pain[35].	Depending on sex, a patient may prioritize pain relief over function or other outcome.
Religion	Religious customs may place important physical demands on patients (e.g., kneeling to pray)[20].	For some religious patients, these outcomes may become more important than others (e.g., ability to kneel to pray may be more important than overall pain).
Education	Low education of patients makes it difficult to ensure an accurate response when administering a standard PROM[36].	Patients may respond to questions inaccurately due to poor comprehension or misunderstanding which can affect the interpretation of their responses (e.g., quality of life, disease severity)[37].
Socioeconomic status	An effective but expensive intervention.	Some people who cannot afford an expensive intervention may, therefore, place more value on other outcomes addressed through less expensive interventions (e.g., disease severity assessed with magnetic resonance imaging vs quality of life and function)[36, 38].
Social capital	An intrusive intervention that requires recovery time (e.g., major surgery).	Whether a patient has support (e.g., from friends and family) both physically and emotionally during and following treatment may affect how they perceive outcomes.

PROGRESS: Place of residence, Race/ethnicity/culture/language, Occupation, Gender/sex, Religion, Education, Socioeconomic status, and Social Capital; PROM: patient-reported outcome measures.

development, whether these differences influence outcome measure selection or patient's responses to questionnaire items, and will invite participation of diverse patient representatives. These results will inform guidance for applying an equity lens to PROM development that will be provided in the OMERACT Handbook. A draft of this guidance will be presented at OMERACT 2018. Continuing this work will ensure that potentially disadvantaged patients are considered in PROM development so that we can measure their experience, an effort that could contribute to more equitable care.

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