Adopting patient-centered care in standard practice: PROMs moving toward disease-specific era

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ABSTRACT

Past discussions about the challenges of using patient-reported outcome measures (PROMs) in clinical practice included clinicians' skepticism, time and resources for the implementation, validity of the PROMs, unfamiliarity with the interpretation of PROMs, and costs of implementation. However, these concerns are diminishing now as PROMs has confirmed its place in the management of patients with inflammatory arthritic conditions where there is no surrogate outcome measure available to capture the patient's well-being and response to treatment. Therefore, PROMs has been endorsed as a primary outcome in clinical trials. PROMs directly measure treatment benefit beyond survival, disease, and physiologic markers, and are often the outcomes of greatest importance to patients. Recently, PROMs has progressed from the generic phase into a "disease-specific" era. This article will discuss the evolving role of PROMs in the assessment and management of patients suffering from inflammatory arthritic conditions and how it can help in transforming patient-centered care concept into reality.

Introduction

Inflammatory arthritic condition and connective tissue diseases are characterised by a progressive inflammatory status which, when persistent, is often associated with radiographic progression (1, 2), systemic organ damage, functional debilities (3), work disability (4), and premature mortality (5). In rheumatoid arthritis, the most thoroughly assessed inflammatory arthritic conditions, these long-term outcomes tend to develop over 5–20 years, and therefore cannot function as endpoints in most clinical studies, which are usually conducted over 3–24 months. The recognition of the active inflammatory status early in the disease process, the window of opportunity, and the recently adopted *treat-to-target* concept (6) has changed the way we look at these conditions, its impact on the patients' lives and its short- as well as long-term management. In most of the short-term research trials, numerous articular, laboratory, functional, and questionnaire measures have been developed (7). These were considered able to provide reasonable surrogate markers for long-term outcomes (8) assuming that short-term improvements in these markers epitomise long-term control of inflammatory conditions.

In contrast to many chronic diseases, where a single *gold standard* measure, such as blood pressure in hypertension, haemoglobin A_1C in diabetes, and lipid profile in hyperlipidaemia, etc., is applicable to diagnosis, management, prognosis, and analyses of outcomes in all individual patients in clinical trials, clinical care, and long-term databases; in inflammatory arthritic conditions (excluding gouty arthritis), there is not a single gold standard measure to assess outcomes. This is applicable both in short-term trials such as joint and laboratory measures, as well as in long-term studies such as radiographic progression, disability, and death. The absence of such a gold standard measure highlighted the need for pooled indices as a valid tool (9, 10). However, so far, these tend to be complex, expensive and currently used in clinical trials but not in clinical care.

In an attempt to standardise inflammatory arthritic conditions such as RA and spondyloarthritis, clinical practice guidelines (11-13) have been published. Similarly, a core data set for management outcomes (14) was endorsed as a framework for all indices in rheumatology. Pharmacological and non-pharmacological treatment pathways, assessment of co-morbidities and health-related quality of life measures (HrQoL), as well as lifestyle advice and patient education, have been recommended. However, as the patients' response to management and the presence of risk factors may vary from one patient to another, the treatment concept has shifted to be *patient-centered* (15). On the other hand, another challenge arose, which is the fact that the patient's condition and development of new risk factors may change over time, requiring regular screening, assessment and monitoring of disease activity as well as risk factors in standard clinical practice. Patient-reported outcome measures (PROMs) stand firmly as a valid candidate to recode these changes in the standard outpatient rheumatology setting. Over the past years, the role of PROMs expanded from mere assessment of disease activity parameters, to playing an active role in the diagnosis, assessment of disease activity, monitoring of co-morbidities, adherence to therapy and patient self-management (16). PROMs also progressed from the generic phase into a *disease-specific* era. This article will discuss the evolving role of PROMs in the assessment and management of the patients suffering from inflammatory arthritic conditions and how it can help in transforming the patient-centered care concept into reality.

The evolving role of PROMs in standard practice

The WHO, international classification of functioning, disability and health (ICF), reported that future functional disability assessments are likely to become more sophisticated as the interaction among illness, functional ability, psychological status and society become increasingly recognised (17). A recent study also emphasised that functional limitation is a modifyable outcome of disease, and provides a measure of progress in developing and disseminating effective treatments (18). Therefore, the role of PROMs in the measurement of health outcomes in standard clinical practice has become increasingly important as it provides not only a record of their disease activity status but also an insight into the disease impact on the patients' lives and abilities. This includes information on impairments (symptoms and wellbeing), disability and handicapping (functioning), as well as quality of life (19, 20).

The concept of the multidimensional nature of inflammatory rheumatic diseases was first brought to light with the observation of increased mortality in RA. Earlier reports (21, 22) noted the increased rates of cardiovascular and infection events and that, on average, the established RA patient has two or more co-morbid conditions. The chronic, debilitating, autoimmune nature of inflammatory arthritis affects the patient both directly or indirectly in almost all organ systems, from cardiovascular disorders and infections to increased risk of falling and osteoporotic fractures, depression, sexual dysfunction and gastrointestinal ulcers. Guidelines (11-13) have highlighted that it is the rheumatologists' responsibility to assess for these risks when treating the patient. The potential role of PROMs in the assessment of these co-morbidities in arthritic patients is another example of the evolving nature of PROMs. Recent PROMs questionnaires allow the treating clinician to assess for arthritis-associated co-morbidities at each visit. In its early stages, inflammatory arthritis patients may not have significant co-morbidities that warrant further management. However, as the disease progresses and becomes more active, the patient can be prone to one or more of these co-morbidities. Screening for these symptoms is highly recommended on a regular basis for every patient. This approach would facilitate, on-the-spot assessment for cardiovascular risk, falls risk, and osteoporosis, as well as depression (23-25). By incorporating such parameters, PROMs attained its multidimensional nature (Fig. 1), which takes into account not only how a person functions physically, mentally and socially, but also incorporates work ability, quality of life, disease activity and an evaluative component for self-helplessness that assesses

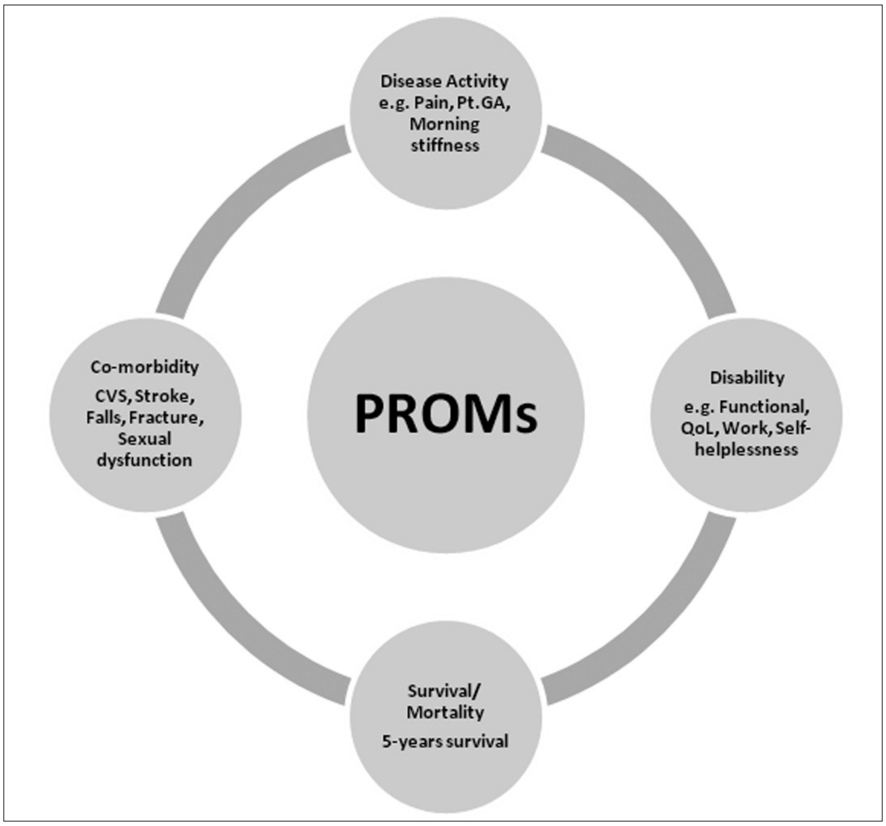

Fig. 1. Classification of outcome measures included in the multidimensional patient reported outcome measures.
PROMs: patient reported outcome measures. PtGA: Patient Global Assessment.

a person's satisfaction with his or her current health status (21, 26).

PROMs evolving from static to dynamic

In acute diseases in hospital settings (the primary setting of most traditional medical practice, education, training, and research) quantitative data regarding blood pressure, temperature and body weight come as a priority, whereas no data are collected concerning functional status or pain since success or failure of the treatment is obvious within a short period. However, in chronic diseases such as in the standard rheumatology outpatient setting (the primary locale of almost all contemporary rheumatologic care), such information is critical for the documentation of patient outcomes and results of care. An earlier report (27) highlighted that pain, function and RAPID scores, should be considered as vital signs in chronic diseases, analogous to pulse and temperature in acute disease and blood pressure and cholesterol in long-term health conditions. However, whilst more attention has been paid to the long-term value of PROMs (patient questionnaire is the most significant predictor of mortality in RA), its short-term value in routine clinical care, role in enhancing the patient-centered care approach, as well as improving patients' experience, has been recently highlighted. A recent report (24) emphasised the expansion of PROMs from the static phase of capturing and measuring outcomes at a single point of time to a more dynamic role. The potential disease-modifying role of PROMs was highlighted in a recent study (28) which looked into sharing the patients' previous PROMs records with them either in a paper or electronic format (visual feedback). The results of this study revealed that viewing previous PROMs records (1) helped the patients understand the effect of treatment on disease activity, (2) helped in medication adherence, (3) improved trust in the treating physician, (4) alleviated concerns about the future, and (5) helped in coping with daily life and disease. The financial implication of this visual feedback approach revealed how PROMs can play an important role in cost effectiveness (29). This was achieved by helping the patients to be more adherent to their medications and less likely to stop due to intolerance; need fewer visits to their GPs, as well as being able to go back to work. Another study (30) showed how PROMs can serve as a link between the disease outcomes and patient education. PROMs enabled the treating physician and the patient to identify the main points that need tackling. This integration of PROMs and patient education offered a new opportunity toward patient self-efficacy in disease management. This new dynamic role for PROMs helps to derive improvement not only in the quality of inflammatory arthritis care but also in the patients' reported experience.

PROMs: from generic to disease-specific

Quantitative measurement in many rheumatic diseases, has progressed following two inspiring conferences held in 1982 (9, 10) which endorsed proposals for outcome measures assessment in rheumatoid arthritis (30-36); osteoarthritis (37); fibromyalgia (38); systemic lupus erythematosus (39-44); ankylosing spondylitis (45, 46); as well as vasculitis (47-49). However, unfortunately, most rheumatology patient care continues to run largely without quantitative measures other than laboratory tests, which may not be available at the time of a patient visit and often give false positive or false negative results (50, 51).

According to Bowling (52), PROMs can be stratified in terms of their disease specificity (generic or disease specific), measurement objectives (discrimination, evaluation and prediction) and what they intend to measure (quality of life, health-related quality of life or health status) (53, 54). The multidimensional measurement scale involves more than one item of these outcome measures and therefore can be categorised broadly into 2 main categories: Generic health status and condition-specific measures (Fig. 2). Generic instruments comprise items intended to be relevant to the widest range of patients' conditions and the general population. On the other hand, condition-specific instruments are often more focused on a particular disease or health condition (*e.g.* rheumatoid arthritis or spondyloarthritis), a patient population (*e.g.* older adults), a specific problem or symptom (*e.g.* pain or fatigue), or a described function (*e.g.* activities of daily living) (55). Disease-specific tools tend to be multidimensional (56).

For any given area of health, condition-specific instruments may have greater clinical appeal due to incorporation of content specific to the particular conditions, and the likelihood of increased responsiveness to interventions. In view of the fact that there is no single measure which can serve as a gold standard in all patients suffering from inflammatory arthritic conditions, a mutual index of several measures has been recommended for assessment of disease activity and monitoring response to therapy. The most widely used indices in RA are the ACR Core Data Set, Disease Activity Score (DAS-28), and Clinical Disease Activity Index (CDAI) (30-36). In ankylosing spondylitis, BASDAI (57) was reported to be of great help to view a comprehensive picture of the disease activity of the patient. However, over the past few years, the Ankylosing Spondylitis Disease Activity Score (ASDAS) index was validated by the ASAS as the recommended tool for assessment of anklyosing spondylitis patients (46). ASDAS includes 4 patient-reported outcome measures (back pain, joint pain, patient global and morning stiffness) in addition to either ESR or CRP. In systemic lupus SLEDAI and ECLAM (39-44) are the most common tools used for assessment. Unfortunately, all of these indices which require formal quantitative measures, are not used at most visits to most rheumatologists (50, 51) and so far, the care of most patients suffering from inflammatory arthritis conditions is guided largely by non-quantitative impressions and laboratory measures rather than quantitative measures.

Specific multidimensional PROMs have been developed to capture those elements of health outcome measures of relevance to a specific patient group. Therefore, it represents the best available tool offering a quantitative "gestalt"

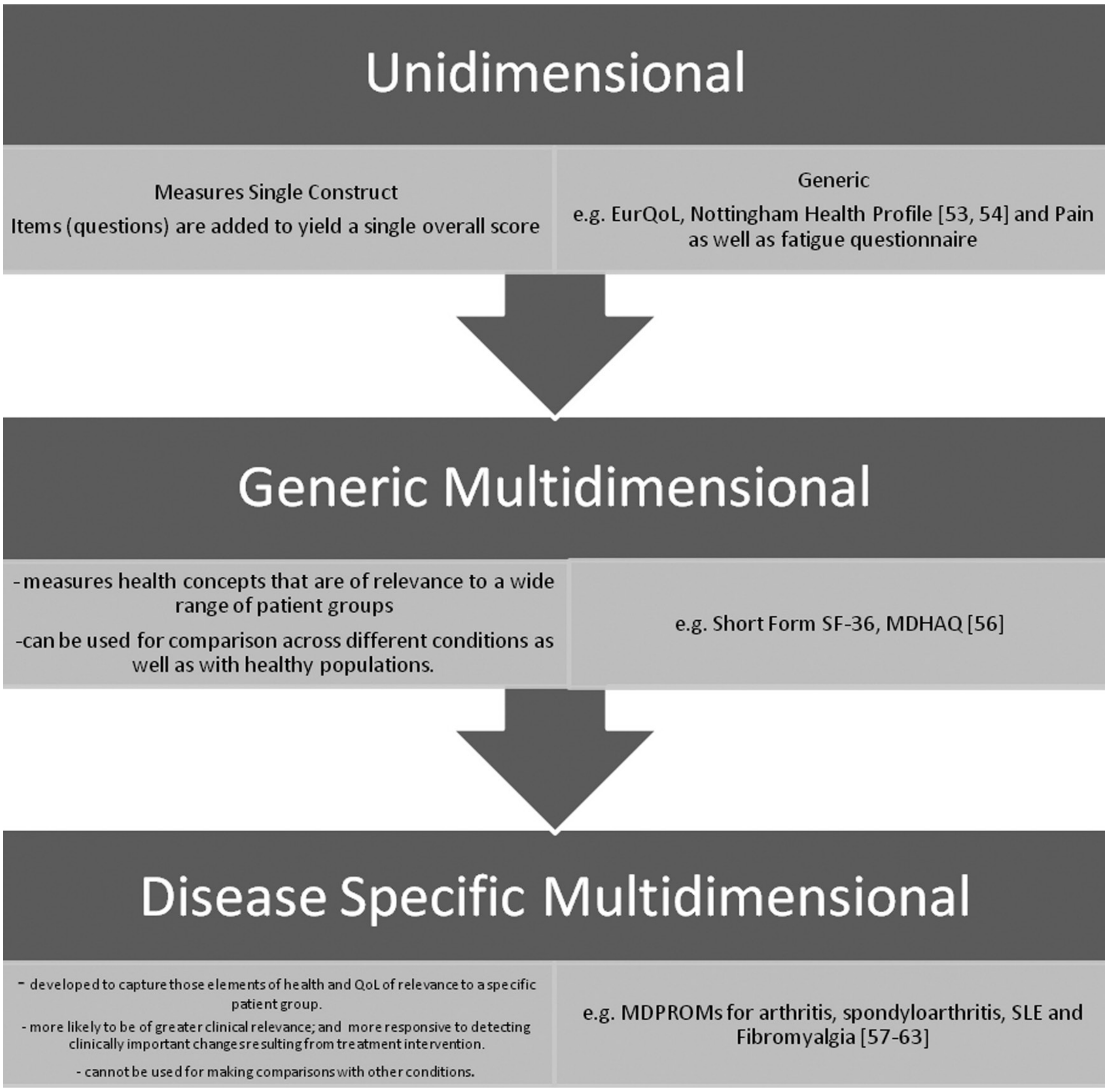

Fig. 2. Stages in the development of patient-reported outcome measures questionnaire.

impression of the outcome measures for a specific condition. Multidimensional PROMs questionnaire are already available for rheumatoid arthritis (58), spondyloarthritis (59), SLE (60, 61), osteoarthritis (62), low back pain (63) as well as fibromyalgia (64). In all these conditions, PROMs has shown both a diagnostic value in helping to identify those who might be suffering from early inflammatory condition and a therapeutic impact as it helps to monitor response to therapy over time (65).

PROMs: a new potential diagnostic role

The development of specific PROMs paved the way for a new potential role for PROMs in the diagnosis of their rheumatic disorder. Fibromyalgia is one of the examples depicting how PROMs can facilitate the diagnosis as well as disease activity assessment in one go. The modified 2010 ACR criteria for fibromyalgia (66) shifted the diagnostic role of somatic symptoms assessment from the physician to the patient and allowed subjects to rate specific self-reported symptoms (widespread pain index and symptom severity). Yet, fibromyalgia patients need further assessment in particular for associated co-morbidities and impact of the disease on the patient's life. PROMs offered the answer to this difficult challenge. A recent study (64) presented in the EULAR conference 2014, depicted a reliable and valid PROMs instrument for assessment of patients suffering from fibromyalgia which integrated the ACR diagnostic guidelines as well as the approved outcome measures. The results supported the value of completion of the PROMs questionnaire, which is not only helpful in the patient diagnoses based on the new ACR guidelines, but also provides a quantitative documented record by the patient at each visit to the clinic. PROMs also provided clues toward a phased treatment regimen tailored to the patient needs depending on the severity of fibromyalgia symptoms as well as the patient's preferences and comorbidities.

The diagnostic role of PROMs in early inflammatory arthritis, was emphasised in another study (65). The study presented a scoring system (EPISA) to predict those suffering from persistent inflammatory arthritis. Two of the 3 suggested parameters (duration of morning stiffness and percentage of change in the HAQ score over 3 months) are extracted mainly from PROMs. Identifying patients with inflammatory arthritis early in the disease course, would have a significant impact on altering the disease process with early intervention.

Embedding PROMs in the decision making process

The expansion in use of economic evaluation by health agencies has mirrored the growing recognition of the usefulness of health-related quality of life as an important indicator of outcome of disease treatment among clinicians and patients (67-69). Patient-reported experience measures (PREMs) became an independent assessment tool to measure management outcomes (70). A cornerstone of such analysis is the Quality-Adjusted Life-Year (QALY), which is formed by the arithmetic product of quantity and quality of life. Such economic implication raised the issue of shared decision-making between the patient and the treating physician as the recommended approach in clinical practice. Shared decision making is a process in which patients are encouraged to participate in selecting appropriate treatments or management options. The constituent elements of QALY are: health-related quality of life measures and survival. In UK, the mechanics for collecting patient-based HrQoL assessments have been presaged in the National Health Service from 2009 requiring both pre- and post-surgery patient-reported outcome measures assessment of health status in selected procedures (71). Embedding such data within national health information systems would facilitate an easier interpretation of QALY-based information. Furthermore, assimilating HrQoL into routine clinical rheumatology practice will assist not only the quality of care provided but also the longer-term development of other uses for those data. This represents another new evolving role for PROMs which can facilitate incorporating information on HrQoL and quality of life in treatment decision-making, improving the relevance of the QALY as a composite measure to those groups of users. Data derived from a PROMs questionnaire should provide the guide for the treating clinician in making decisions about different clinical inputs as well as for monitoring the outcomes and response to treatment. By implementing PROMs routinely in standard clinical practice, it can help to set up a management plan tailored to the patient's needs. In addition to its value in providing a baseline assessment of the health status, quality of life, and patient satisfaction or well-being, it helps to improve the patient-physician communication, identifying new co-morbidities that might have developed over the past few months prior to the clinic visit and the assessment of different procedures effectiveness.

In conclusion, assessments based on patients' opinion (PROMs) have received increasing recognition as being critically important end points in both clinical trials and standard rheumatology practice in the last decade. The role PROMs expanded from merely assessing disease activity parameters at a certain time of management, to playing an active role in the diagnosis, assessment of disease activity, monitoring of comorbidities, adherence to therapy and patient self-management. PROMs also evolved from the generic phase into a disease-specific era. Embedding PROMs in the decision-making process has facilitated filling the gap between the standard clinical practice and the growing role of health economics.

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