

# The Impact Triad (Severity, Importance, Self-management) as a Method of Enhancing Measurement of Personal Life Impact of Rheumatic Diseases

Clinical trials in rheumatoid arthritis (RA) currently focus on measuring severity of functional disability, patient global assessment, pain, and morning stiffness<sup>1</sup>. However, the inclusion of patient-reported outcome measures (PROM) to assess the impact of illness has been recognized as an important development, and collaboration with patients in developing PROM is becoming mandatory<sup>2</sup>. While it is recognized that patients and professionals may have different values and priorities<sup>3</sup>, discussion continues about how to incorporate outcomes that are important to patients.

Recent collaborations with patients in the conception of outcome measures have revealed 3 aspects of impact that require assessment. These are the severity of an outcome, its importance to the patient, and patient ability to self-manage (Figure 1). We provide 3 examples of how this impact triad emerged in recent RA research and discuss how the concept may influence the development of future instruments.

The first example comes from extensive focus group data exploring a patient definition of flare in RA<sup>4</sup>. The emergent definition included 3 components: as symptom intensity increased (i.e., severity), symptoms were sufficiently different from normal background variations (i.e., became important), and the actions patients took to deal with them failed

(i.e., self-management). This resulted in a tipping point being reached where medical help was sought for uncontrolled flare. The patients' complex model of flare goes beyond a simple increase in the number of swollen joints or the intensity of pain, to include these additional considerations. Therefore, the future development of a flare instrument will require not only items on the severity of flare-related symptoms, but also items on how these are different from patients' perceptions of normal background symptoms and items on the controllability of symptoms.

The second example comes from the development of a set of RA patient priorities in pharmacological interventions (RAPP-PI)<sup>5</sup>. Treatment outcomes elicited from in-depth interviews with patients were prioritized through nominal groups and a UK-based postal survey. The analysis from the survey illustrated that patient outcome priorities (importance) were influenced by 2 main groups of variables: disease severity and different aspects of self-managing. For example, improvement of mobility was selected as a priority about 3 times more frequently by those with moderate and severe disability than by those with mild disability. In another example, reduction of fatigue was prioritized twice as often by those managing moderately and those not managing compared to those who considered they were managing well. Therefore, it is important to consider how symptom severity and self-management may influence patient priorities or the importance of outcomes.

The third example comes from the development of 3 numerical rating scales (NRS)/visual analog scales (VAS) developed alongside the Bristol Rheumatoid Arthritis Fatigue Multidimensional Questionnaire (BRAFM-DQ)<sup>6</sup>. Focus groups of RA patients concluded that it is essential to measure 3 aspects of fatigue: severity, coping, and effect on life. Exploratory analysis on validation data showed that patients experiencing similar levels of fatigue had different profiles for these 3 aspects (Figure 2). For example, 2 female patients (A and B) had similar high scores for severity and effect (importance), but markedly different coping (self-management) scores of 8/10 (high) versus 1/10. Patients C and D (male) both had moderate fatigue severity (6/10) with little effect on their lives (2/10 and 3/10) but while patient C would require no support for coping



Figure 1. The impact triad.

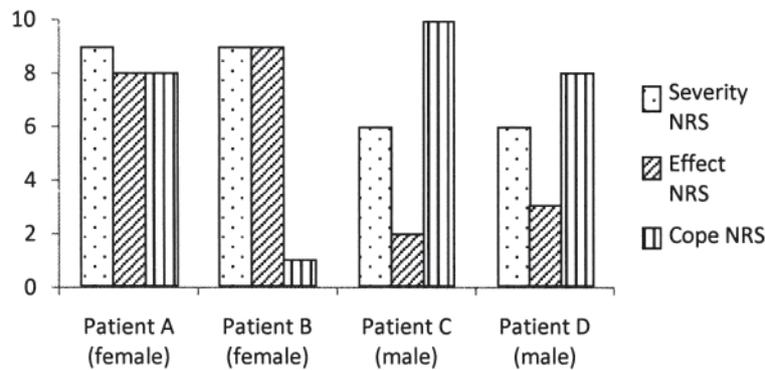


Figure 2. Bristol RA fatigue profiles. NRS: numerical rating scales.

(10/10), patient D still perceived his coping was not optimum (8/10).

In the 3 examples, patients have used different terminology to explain the influence of how they deal with RA: self-management, managing, and coping. In Figure 1, we have selected self-management as a substantive term, suitable to be considered alongside severity and importance. Self-management is a broad concept, which is used to include both actions taken by individuals to meet their social, emotional, and psychological needs<sup>7</sup> and collaborative partnerships between patients and health professionals<sup>8</sup>. Patients have identified self-management as a process initiated to bring about order in their lives: identifying and understanding what is attainable; mobilizing resources in order to maintain independence and a sense of control; managing the shift in self-identity, and deciding the place that the condition has in one's life; and adapting in response to a growing understanding of one's bodily responses<sup>9</sup>. While the ability to self-manage may act as a buffer to the other constructs of severity and importance, the participants in the examples outlined above did not make this distinction between impact and a buffering determinant. Severity and importance may also act as buffers in some scenarios; for example, where the importance of avoiding side effects of medications affects adherence, resulting in more active disease and the need for more effective self-management strategies. This editorial suggests that from a patient perspective, impact is some combination of the 3 aspects of their experience: severity, importance, and self-management. As such, we cannot yet comment on the relationship between the 3, but can discuss the implications for measurement.

Traditional severity-based measures such as the Disease Activity Score<sup>10</sup> have until now functioned well in the process of selecting new pharmaceutical agents for development and documenting their clinical benefit. However, it has become apparent that a broader measurement of impact is to be expected now where patients have collaborated in the development of PROM. For example, for the RA Impact of Disease (RAID) score European patients selected pain, functional disability, fatigue, emotional well-being, sleep,

coping, and physical well-being as the most important domains<sup>11</sup>. In the RAPP-PI UK study, pain, activities of daily living, joint damage, mobility, life enjoyment, independence, fatigue, and valued activities were prioritized<sup>5</sup>. So how can the impact triad of severity, importance, and self-management be measured to capture the patient perspective of impact comprehensively? Can they be incorporated into one instrument or should they be measured separately?

The BRAF NRS/VAS scales provide one example based on fatigue, constructing an NRS/VAS to measure each aspect of the triad. However, this approach implies that 3 NRS/VAS would be required for each item in complex constructs such as disability. Other approaches to determining the importance of outcomes to patients include: asking each participant what is individually important (individualized measures, e.g., the MACTAR Questionnaire<sup>12</sup> and the Schedule for Evaluation of Individual Quality of Life instrument<sup>13</sup>), assessing the importance of specified items within an instrument [importance and preference scales, e.g., Personal Impact Health Assessment Questionnaire (PI HAQ)]<sup>14</sup>, and determining priority outcomes for a majority of patients and standardizing a collection of these outcomes across trials (patient priority indices or core sets, e.g., RAPP-PI<sup>5</sup>, RAID<sup>11</sup>; Table 1). Individualized measures enable patients to specify their individual concerns, but most involve semistructured interviews and are time-consuming to complete, and the data are more difficult to report<sup>15</sup>.

Importance scales have been developed to provide greater discrimination of impact. For example, each item in the PI HAQ is weighted by the importance it has for each patient<sup>14</sup>. Patients with the same high score of 2.5/3 on the HAQ were shown to have varying scores of personal impact on the PI HAQ (2.0–8.0/9)<sup>14</sup>. Seror, *et al*<sup>16</sup> found that severity and importance scores were only weakly correlated, and therefore importance scores could provide complementary information. Ten Klooster, *et al*<sup>17</sup> assessed RA patient priorities before and after 12-month treatment with anti-tumor necrosis factor using the Arthritis Impact Measurement Scales 2 (AIMS2) priority list (choosing 3 out of 12 speci-

Table 1. Description of instruments.

Instrument	Full Title	Major Features
AIMS-2	Arthritis Impact Measurement Scales 2	45 items covering 9 domains: mobility, physical activity, dexterity, household activities, activities of daily living, anxiety, depression, social activity, pain
BRAF-MDQ	Bristol RA Fatigue Multidimensional Questionnaire	20 items covering 4 domains: physical fatigue, living with fatigue, cognition fatigue, emotional fatigue
MACTAR	McMaster Toronto Arthritis Patient Preference Disability Questionnaire	Functional index, including change in 5 impaired activities selected by each patient in a baseline interview
PI-HAQ	Personal Impact Health Assessment Questionnaire	Measures individual values for 20 activities of daily living in the HAQ, to provide impact scores of disability
RAID	RA Impact of Disease score	Composite of 7 numerical rating scales (pain, functional capacity, fatigue, physical and emotional well-being, quality of sleep, coping)
RAPP-PI	RA Patient Priorities in Pharmaceutical Interventions	Set of 8 priorities (pain, activities of daily living, joint damage, mobility, life enjoyment, independence, fatigue, and valued activities)
RASE	RA Self-Efficacy questionnaire	28 items measuring beliefs in the ability to use specific types of self-management for specific purposes
SEIQOL	Schedule for the Evaluation of Individual Quality of Life	Interview-based questionnaire, eliciting 5 areas most important in determining quality of life and assessing satisfaction in each

fied areas). In the group data, for example, pain and hand/finger function was prioritized higher at baseline than at followup (baseline 88.4%, followup 71.1%; 57.2%, 43.4%), while the priority for household tasks increased (16.2%, 24.3%). Thus, the AIMS2 can provide a measurement of both severity and importance (priority). However, without an assessment of self-management it cannot be determined to what extent these priorities also changed due to adaptation rather than treatment efficacy alone.

It is conceivable that each item in a questionnaire could be weighted not only for importance, but also for participants' ability to self-manage. Although this approach may be worth pursuing, it is uncertain how much extra sensitivity would be provided at the expense of extra participant and scorer burden in busy clinical and research settings. However, this would allow the relationship between the 3 aspects of the impact triad to be determined independently for each symptom such as fatigue, pain, and stiffness. An alternative is to use a self-management instrument that assesses beliefs about the overall ability to manage a health condition. An example is the 28-item RA Self Efficacy (RASE) questionnaire, which measures beliefs in the ability to use specific types of self-management for specific purposes<sup>18</sup>. Although the RASE gives a global score, we recognize that beliefs about self-management, like self-efficacy, might be item-specific. It is important to use a disease-specific instrument since self-management will address the symptoms and impairment specific to the condition.

Another approach may be to measure response shift (changes in the meaning of one's self-evaluation of a target construct), such as illness, ability to cope with pain, or fatigue. Studies in non-rheumatologic conditions show that response shift masks treatment impact and estimates of quality of life over relatively short periods<sup>19,20</sup>. In clinical trials, data on self-management of different outcomes would ensure that true treatment efficacy is determined. However, in non-pharmacological trials, it may be the self-management of outcomes that is the target of an intervention, and a generic scale may not provide sufficient detail about change in specific symptoms.

Whether the triad adequately captures the aspects of impact can be tested in a number of ways. One, which we aim to test, is based on the 8 outcome priorities identified in the RAPP-PI study<sup>5</sup>. Where they do not currently exist, NRS to address the severity, importance assigned by an individual, ability to self-manage, and impact of these 8 priority outcomes will be developed. The 4 NRS for each of the 8 priorities will then be tested, and the relationship of the combined components of the impact triad to the impact NRS for each outcome will be explored. We anticipate that the triad will be preserved in this construction. By limiting the outcomes to the 8 RAPP-PI priorities selected by patients, the development of an impact instrument that is feasible to administer and relevant to patients is more likely. Cross-sectional studies will be informative, but applying the impact triad measurements in longitudinal studies would be more

informative, and interventional studies offer the most informative option for investigating the triad. It would be of particular interest to measure the triad for interventions in which changing the patient's ability to self-manage (rather than reducing the severity of the underlying condition) was the primary aim.

Thus we propose the concept of the impact triad for consideration in the further development of PROM. The notion of measuring severity, importance, and self-management of symptoms to characterize the personal life impact of illness has emerged through incorporating the patient perspective in a variety of research settings with RA patients. We propose that future developments should incorporate the notion of the triad a priori, and this should be abandoned only if an appropriate psychometric analysis demonstrates unidimensionality in the outcome being assessed. With the potential increase in discriminatory power of measuring impact using the triad, interventions may become more targeted to different profiles of patients and efficacy of treatments assessed more accurately. However, the best method of incorporating the impact triad into routine measurements has yet to be determined.

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