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Editorial

EDITORIAL

HAQ and DAS28 for clinical trials over months and MDHAQ, RheuMetric and psycho-socio-economic measures for long-term observations over years?

In this issue of *Rheumatology* [1], investigators from DANBIO (Danish Biologics registry) report an algorithm for converting multidimensional HAQ physical function (MDHAQ-FN) [2] scores to equivalent values of prototypic HAQ-FN scores [3]. HAQ-FN includes 20 activities in eight categories of two or three items, scored 0–3; the highest scores within the eight categories are totalled 0–24 and divided by eight for a mean 0–3 HAQ-FN score [3]. MDHAQ-FN includes 10 activities, eight verbatim from each of the eight HAQ categories, and two complex activities, 'walk 3 km or 2 miles' and 'participate in recreation and sports as one would like', also scored 0–3, totalled 0–30 and divided by 3 for a 0–10 score [2].

The MDHAQ (Supplementary Fig. S1, available at *Rheumatology* online) was modified from the HAQ (Supplementary Fig. S2, available at *Rheumatology* online), largely based on patient feedback, to include one activity from each of eight HAQ categories that every ambulatory individual would like to perform every day [2]; for example, 'shampoo your hair' and 'run errands and shop' are not relevant to many patients [1, 2]. This strategy resulted in MDHAQ-FN scores being 10–15% lower than HAQ-FN scores. The algorithm corrects this problem [1], similarly to two other reports that address this matter [4, 5].

The 10-item MDHAQ-FN scale was *not* reduced from 20 HAQ-FN items for a shorter questionnaire, but rather to capture considerable clinically relevant additional information not available on the HAQ within the same two-page format. The full MDHAQ, beyond MDHAQ-FN, provides informative scores for fatigue, anxiety, depression, sleep quality, rheumatoid arthritis disease activity index (RADAI) painful joint count, 60-symptom checklist (for review of systems and possible medication adverse events) [2] and medical history information (recent illnesses, new medications, adverse events, falls, etc.). The full MDHAQ is completed by most patients in 5–10 min [2], perhaps 1–3 min more than the HAQ disability index (HAQ-DI), to improve doctor–patient communication and documentation, while saving time for both doctors and patients.

Three simple validated indices may be feasibly calculated from two to four MDHAQ component or composite scores in patients with RA and all diseases studied: RAPID3 (routine assessment of patient index data) assesses clinical status similarly to DAS28 (disease activity score 28) [2]. FAST4 (fibromyalgia assessment screening tool) agrees 90% with revised 2011 fibromyalgia criteria [6] to screen for fibromyalgia. MDS2 (MDHAQ depression screen) agrees 80% with two reference depression screening questionnaires, PHQ9 and HADS-D, similar to agreement of the two reference questionnaires with one another [7] to screen for depression. Comorbid fibromyalgia and/or depression are seen in 25–45% of people with RA [2]; they are easily diagnosed in some patients, but often underrecognized or unrecognized.

Disease activity score 28 (DAS28) and RA indices are elevated significantly by comorbid joint damage [8], fibromyalgia [9] and depression [10], even in the absence of substantial (or any) inflammatory activity [2]. DAS28 and other indices are effective to distinguish active from control treatments in clinical trials over 6–24 months [11, 12]. However, fewer than 10% of RA patients meet inclusion criteria for many clinical trials, and additional measures appear needed for routine care and long-term databases over 2–15 years [11, 12], particularly as index scores have not improved over the last decade in many settings [13], despite far stronger capacity to control inflammation than in the past.

DAS28 and all indices that include swollen and tender joint counts also may be elevated significantly by comorbidities. Joint damage may be assessed independently by scoring 'limited motion or deformity', in addition to 'swelling' and 'tenderness/pain on motion', as described in the initial report of a 28 joint count [14]. Pharmaceutical companies deleted 'limited motion/deformity' as usually irrelevant in clinical trials to detect control of inflammatory activity over 6–24 months, which may be appropriate. However, the rheumatology community has generally maintained deletion of "limited motion/deformity" in longitudinal databases over 2–15 years, which may be inappropriate, as inclusion could improve knowledge concerning the long-term course and outcomes of RA.

Another quantitative approach to assess joint (and other organ) damage, as well as patient distress (e.g. fibromyalgia, depression), is a physician RheuMetric clinical checklist (Supplementary Fig. S3, available at *Rheumatology* online) [15]. The physician assigns quantitative 0–10 visual numeric scale scores for overall global assessment, three subscales for inflammation or reversible findings, damage or irreversible findings, and patient distress or findings not explained by inflammation and/or damage, as well as other simple scores [15]. RheuMetric

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is completed by a physician in about 20–30 s. Scores for inflammation were higher than for joint damage in RA patients prior to 2012 but higher for damage than for inflammatory activity after 2015 [15, 16].

Patient questionnaires are a departure from a traditional 'biomedical model', the dominant paradigm of 20th century medicine, in which information from a patient is regarded as less important than information from health professionals. The value of this model is reinforced daily in acute care hospitals, the setting of most medical education and training. Many physicians, including rheumatologists, remain guided primarily by a biomedical model, and do not collect or review patient questionnaire scores at all, leaving laboratory tests as the only quantitative data to guide clinical decisions.

Patient questionnaires and physician checklists reflect a complementary 'biopsychosocial model', which incorporates psycho-socio-economic measures relevant to chronic diseases, long-term wellness and general health [17]. Patient physical function scores are far more significant than laboratory tests or imaging in the prognosis of most severe clinical outcomes of RA, such as work disability and premature mortality [2]. The incidence, prevalence, morbidity and mortality of RA and most diseases are strongly associated with years of formal education [18]. DAS28 scores are correlated with GDP per capita in 25 countries at levels ($r = 0.78$) as high as seen with any 'medical' measure [19]. Medical interventions account for $<20\%$ of health and disease, with the remainder explained by genetics, education, literacy, income, occupation, housing, environment, etc. [20].

Introduction of MDHAQ–FN builds on extensive innovation and accomplishments of DANBIO. Further new measures on the full MDHAQ and RheuMetric checklist for joint damage, patient distress, fibromyalgia, depression, and new public health and rheumatological strategies towards earlier diagnosis and treatment may advance knowledge of the course of RA, perhaps improving outcomes as complementary to new therapies.

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Data availability statement

Data are available upon reasonable request by any qualified researchers who engage in rigorous, independent scientific research, and will be provided following review and approval of a research proposal and Statistical Analysis Plan (SAP) and execution of a Data Sharing Agreement (DSA). All references relevant to the editorial are included in the article.

Supplementary data

Supplementary data are available at *Rheumatology* online.

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