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Preference-Based Assessments

A Quality-Adjusted Life-Year Measure for Multiple Sclerosis: Developing a Patient-Reported Health State Classification System for a Multiple Sclerosis-Specific Preference-Based Measure

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ABSTRACT

Background: Increasingly, generic preference-based measures of health-related quality of life (HRQOL) are used to estimate quality-adjusted life-years to inform resource allocation decisions. Evidence suggests that generic measures may not be appropriate for multiple sclerosis (MS). **Objectives:** To report the first stage in the development of an MS-specific preference-based measure to quantify the impact of MS and its treatment: deriving a health state classification system, which is amenable to valuation, from the 29-item Multiple Sclerosis Impact Scale (MSIS-29), a widely used patient-reported outcome measure in MS. **Methods:** The dimensional structure of the MSIS-29 was determined using factor analysis and a conceptual framework of HRQOL in MS. Item performance was assessed, using Rasch analysis and psychometric criteria, to enable the selection of one item to represent each dimension of HRQOL covered by the MSIS-29. Analysis was undertaken using a sample (N = 529) from a longitudinal study of people with MS. Results were validated by repeating the analysis with a second sample (N = 528). **Results:** Factor analysis confirmed the

two-subscale structure of the MSIS-29. Both subscales covered several conceptually independent dimensions of HRQOL. Following Rasch and psychometric analysis, an eight-dimensional classification system named the MSIS-8D was developed. Each dimension was represented by one item with four response levels. **Conclusions:** Combining factor analysis with conceptual mapping, and Rasch analysis with psychometric criteria, provides a valid method of constructing a classification system for an MS-specific preference-based measure. The next stage is to obtain preference weights so that the measure can be used in studies investigating MS.

Keywords: health-related quality of life, health states, multiple sclerosis, preference-based measures of health, quality-adjusted life-years, Rasch analysis.

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Introduction

Cost-utility analysis is a frequently used technique for evaluating the cost-effectiveness of health care interventions, in which quality-adjusted life-years (QALYs) are used to compare the relative merits of treatment options in terms of their impact on both length and quality of life. QALYs are calculated by weighting each year of life according to its quality on a scale ranging from 1 (equivalent to full health) to 0 (equivalent to being dead). Increasingly, preference-based measures (PBMs) of health-related quality of life (HRQOL) are used to provide these quality weights. PBMs use a standardized classification system to describe a finite number of possible health states. Each unique health state is assigned a numerical quality weight, typically estimated by eliciting preferences between different health states from a sample of the general

population [1]. Cost-utility analyses commonly use generic PBMs, such as the EuroQol five-dimensional questionnaire [2], Short-Form 6D [3], or Health Utilities Index [4], which are considered applicable for all health conditions. The broad focus of these generic measures has given rise to debate around the extent to which they capture aspects of HRQOL of particular relevance to specific health conditions [5]. The assessment of QALYs in MS is one such case.

Multiple sclerosis (MS) is a neurological condition that affects the central nervous system. It is a complex and progressive condition causing a wide range of symptoms including spasticity, loss of mobility, fatigue, ataxia, and loss of vision. The incidence and severity of symptoms differ considerably between individuals and levels of disability increase as the disease progresses [6].

There is empirical evidence to suggest that generic measures may lack the relevance and sensitivity required to capture the

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many and varied effects of MS on people's HRQOL [7–9] and that they have limited ability to capture changes in HRQOL across the full range of condition severity [7,10–13]. A recent systematic review [14] reports an assessment of the psychometric properties of several generic PBMs when applied to MS, finding that each has its own limitations. The review concludes that the development of an MS-specific PBM is a possible area for future research.

Condition-specific PBMs (CSPBMs) focus on those aspects of health that are most relevant to the condition of interest, potentially providing greater sensitivity to differences and changes in HRQOL [1]. One approach is to develop a PBM from an existing condition-specific measure. This process has been reported for a range of conditions, including dementia [15], mental health problems [16], asthma [17], flushing [18], and overactive bladder [19]. Here, we describe the first stage in the development of a CSPBM for MS: deriving a health state classification system from the 29-item Multiple Sclerosis Impact Scale (MSIS-29).

The MSIS-29 is a widely used measure of HRQOL in MS with strong psychometric properties. It consists of a physical subscale of 20 items and a psychological subscale of 9 items. Respondents are requested to report the impact of MS on their day-to-day lives over the preceding 2 weeks. The amended version, MSIS-29-v2, was used for this study; this has four response levels per item: “not at all,” “a little,” “moderately,” and “extremely.” The content of the instrument was based on qualitative work with people with MS and is designed to be suitable for all types of MS [20].

We begin by summarizing the basis on which we selected the MSIS-29, followed by methods used for the development of the classification system and results.

Measures of HRQOL for MS

Taking as a starting point that only patient-reported measures of HRQOL provide a suitable basis for the development of a classification system for a CSPBM [21], a systematic search of the literature was undertaken to identify existing MS-specific, patient-reported HRQOL instruments. The search identified 13 published reviews of HRQOL measures in MS, from which 17 individual measures were extracted. The existing literature [22–27] was used to develop criteria for assessing the quality of these 17 instruments. These criteria (Table 1) defined our prerequisites for any potential candidate measure for the CSPBM. A two-stage approach was used, first applying five initial criteria to narrow down the selection without need for detailed comparison of measures. Second, the remaining measures were compared against the remaining selection criteria.

At stage one, 14 measures were excluded [12,28–38]. Exclusions were primarily due to the development methodology not incorporating qualitative research with patients (NeuroQoL Quality of Life in Neurological Conditions Measure, MS Quality of Life Inventory, RAYS Quality of Life Scale for MS, Disability and Impact Profile, Health-Related Quality Of Life questionnaire for MS, MS Activities of Daily Living Scales, MS Quality of Life-54, Hamburg Quality of Life Questionnaire in MS, Functional Index for Living with MS, and Quality of life Index MS version) and/or recognized scale development techniques (MS Quality of Life Inventory, Quality of Life Questionnaire for MS, RAYS Quality of Life Scale for MS, Hamburg Quality of Life Questionnaire in MS, and MS Symptom Impact Diary).

Three candidate instruments remained after stage one: the MSIS-29 [23], the MS International Quality of Life questionnaire (MusiQoL) [39], and the Functional Assessment of MS (FAMS) [40]. On the basis of practical considerations, we decided not to progress further with the MusiQoL: its limited

Table 1 – Criteria for selection of an HRQOL instrument.

Acceptability	Single instrument, rather than battery of measures* Proportion of questionnaires completed Item missing data <10% High percentage of computable scale scores Floor and ceiling effects <20% per subscale Does the range of scores span the full-scale range?
Reliability	Mean score near scale midpoint Internal consistency (Cronbach $\alpha > 0.80$) Test-retest reliability ($r \geq 0.50$)
Construct validity	Convergent validity (correlation $r > 0.70$) Discriminant validity (correlation $r > 0.30$)
Internal validity	Group differences validity ($P < 0.05$) Moderate correlations between subscales ($0.30 < r < 0.70$)
Responsiveness	Effect size: large (>0.80) or moderate (>0.50)
Scale development and scaling assumptions	Recognized scale development techniques used to devise the instrument* Similar mean scores and variances Similar response option frequency distributions Similar and substantial item–total correlations ($r > 0.30$) Item–total exceed item–other correlations by ≥ 2 standard errors Skewness (–1 to +1)
Content/face validity	The underlying concept captured by the instrument is HRQOL* Instrument was constructed on the basis of qualitative work with patients* Extent to which instrument covers domains important for HRQOL in MS*
Practical considerations	Acceptability to clinicians/researchers; use in clinical trials Access to a data set that includes the measure

HRQOL, health-related quality of life; MS, multiple sclerosis.

* Indicates that this was used as a screening criterion (stage one).

use in clinical trials to date restricted the availability of evidence to support its responsiveness and acceptability [10]. Although we decided not to progress further with the MusiQoL, consideration of this instrument could be a productive area for future research.

At stage two, the MSIS-29 and the FAMS were considered in terms of the remaining criteria. Validation studies have confirmed the acceptability, reliability, validity, and responsiveness of the MSIS-29 [41–46] and the FAMS [40,47–53] for a range of MS types and clinical settings. Both instruments are well accepted by clinicians and researchers and have frequently been used in research and clinical trials [54]. Overall, there was more published

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