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Preference-Based Assessments

Improving the Measurement of QALYs in Dementia: Developing Patient- and Carer-Reported Health State Classification Systems Using Rasch Analysis

Brendan Mulhern, MRes[1,], Sarah C. Smith, PhD[2], Donna Rowen, PhD[1], John E. Brazier, PhD[1], Martin Knapp, PhD[3,4], Donna L. Lamping, PhD[2,†], Vanessa Loftus, MSc[4], Tracey A. Young, PhD[1], Robert J. Howard, MRCPsych[4], Sube Banerjee, FRCPsych[4]*

[1]Health Economics and Decision Science, School of Health and Related Research, University of Sheffield, Sheffield, UK; [2]Health Services Research and Policy, London School of Hygiene and Tropical Medicine, London, UK; [3]Personal Social Services Research Unit, London School of Economics and Political Science, London, UK; [4]Institute of Psychiatry, King's College London, De Crespigny Park, London, UK

ABSTRACT

Objectives: Cost-utility analysis is increasingly used to inform resource allocation. This requires a means of valuing health states before and after intervention. Although generic measures are typically used to generate values, these do not perform well with people with dementia. We report the development of a health state classification system amenable to valuation for use in studies of dementia, derived from the DEMQOL system, measure of health-related quality of life in dementia by patient self-report (DEMQOL) and carer proxy-report (DEMQOL-Proxy). **Methods:** Factor analysis was used to determine the dimensional structure of DEMQOL and DEMQOL-Proxy. Rasch analysis was subsequently used to investigate item performance across factors in terms of item-level ordering, functioning across subgroups, model fit, and severity-range coverage. This enabled the selection of one item from each factor for the classification system. A sample of people with a diagnosis of mild/moderate dementia (n = 644) and a sample of carers of those with mild/moderate dementia (n = 683) were used. **Results:** Factor analysis found different five-factor solutions for DEMQOL and DEMQOL-Proxy. Following item reduction and selection by using Rasch analysis, a five-dimension classification for DEMQOL and a four-dimension classification for DEMQOL-Proxy were developed. Each item contained four health state levels. **Conclusion:** Combining Rasch and classical psychometric analysis is a valid method of selecting items for dementia health state classifications from both the patient and carer perspectives. The next stage is to obtain preference weights so that the measure can be used in the economic evaluation of treatment, care, and support arrangements for dementia.

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

Introduction

In the economic evaluation of emerging health technologies or interventions, it is common to employ cost-utility analysis by using the cost per quality-adjusted life-year (QALY) gained to inform the allocation of resources. QALYs are used to measure the impact of an intervention on both quality and quantity of life. Quality of life is measured by using health state values that are scored using preference information typically gained from a representative sample of the general population.

Generic preference-based measures (PBMs) of health such as the EuroQol five-dimensional (EQ-5D) questionnaire [1,2], Short Form-6D (SF-6D) [3], and Health Utilities Index (HUI3) [4] are widely used as a means of generating health state values for use in the calculation of QALYs [5]. PBMs include dimensions of health and related response levels that enable respondents to indicate the severity of the problem they may be experiencing. For example, the EQ-5D questionnaire includes a five-dimension health state classification system (mobility, self-care, usual activities, pain/discomfort, anxiety/depression), each with three health state levels. Therefore, the EQ-5D questionnaire generates 243 health states, a selection of which has been valued to generate the preference weights used to calculate QALYs [2].

"Dementia" is a syndrome that may be caused by a number of illnesses in which there is progressive decline in multiple areas of function, including memory, reasoning, communication skills,

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Conflicts of interest: The authors have no conflicts of interest to report.

[†]Deceased.

[*] *Address correspondence to:* Brendan Mulhern, School of Health and Related Research, University of Sheffield, Regent Court, 30 Regent Street, Sheffield S1 4DA, UK.

E-mail: b.mulhern@sheffield.ac.uk.

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and the ability to carry out daily activities. Alongside this decline, individuals may develop behavioral and psychological symptoms such as agitation, aggression, wandering, shouting, repeated questioning, sleep disturbance, depression, and psychosis. Dementia not only has a major impact on those with the disorder but also has profound, negative effects on family members who provide the majority of care. Family carers are often elderly and frail themselves and have high levels of carer burden, depression and physical illness, and decreased quality of life [6–8].

Dementia is a common disorder in later life with prevalence rates increasing rapidly with age; for example, the rate is less than 1% for those younger than 69 years but rises to 30% for those older than 90 years. According to the World Alzheimer Report [9], there are currently 36 million people with dementia worldwide; this number is projected to exceed 60 million by 2032 and 115 million by 2050. Among the consequences is a projected rapid rise in the costs of care, support, and treatment. If expected trends in prevalence, staff costs, and (unpaid) carer availability are overlaid onto England's current care system, total health and social care expenditure will more than treble over a 30-year period from £17 billion [10] to more than £50 billion [11]. This highlights the strategic importance of dementia care and also the need for valid PBMs enabling the assessment of treatment and services that are developed to target this enormous health and social care challenge.

There is debate around the extent to which generic PBMs fully capture aspects of quality of life associated with some medical conditions [12], and the validity of using generic PBMs in dementia is uncertain. It has been suggested that the EQ-5D questionnaire does not sufficiently cover the impact of changes in cognitive functioning on quality of life [13,14]. Although the cognitive challenges of dementia—including deficits in memory, insight, language, and interpretation—would be expected to impact on an instrument‘s performance, there has been little validation of these generic instruments for this condition. A cognitive dimension has been developed for the EQ-5D questionnaire, but utility values for the EQ-5D questionnaire incorporating this component are not available [15]. Differences in response have also been found between people with dementia and family carers, with patients reporting higher utility scores than carer proxies report [16,17].

To increase the accuracy and validity of assessment there has been interest in developing PBMs from condition-specific measures to target medical conditions more effectively in terms of health-related quality of life (HRQoL) [18]. This is because nonpreference-based condition-specific measures are widely used in trials but cannot be used for cost-effectiveness analysis. The first stage of this is the development of a health state classification system amenable to valuation from an existing condition-specific measure. This has recently been carried out for a range of conditions including overactive bladder syndrome [19], urinary incontinence [20], flushing symptoms [21], asthma [22], common mental health problems [23], and cancer [24], demonstrating that classification systems can be developed across a range of conditions with a range of associated symptoms and HRQoL impacts. The second stage is to value a set of the health states generated by using a standardized preference elicitation technique [25].

In response to the debate about the economic evaluation of dementia, we describe the first stage of the development of condition-specific PBMs for self-report by people with dementia and for proxy-report by carers. The first stage is to apply classical psychometric and Rasch analysis [26] to develop reduced health state classification systems from the DEMQOL system, a measure of HRQoL in dementia by patient self-report (DEMQOL) and carer proxy-report (DEMQOL-Proxy) [27,28], that are amenable to valuation using a standard preference elicitation technique. Using Rasch alongside classical psychometric techniques is an accepted method of developing HRQoL instruments [29]. Reduced classification systems are used because in their original form the DEMQOL and DEMQOL-Proxy contain too many items to carry out valuation. The analyses applied here to determine the dimensional structure of each instrument and subsequently to select one item for each dimension have been reported elsewhere [19]. This study, however, is the first to use this process to develop a classification system for dementia and also the first for a proxy-reported quality-of-life instrument.

Methods

The DEMQOL system

The DEMQOL system was developed to generate a measure of HRQoL for people with dementia by using patient self-report and carer proxy-report [27,28]. It consists of two interviewer-administered instruments: DEMQOL (self-reported by the patient) and DEMQOL-Proxy (proxy-reported by a carer). The system was developed to be used across all types of dementias, care arrangements, and levels of severity. The psychometric properties of the DEMQOL system have shown it to be both reliable and valid, and as such it provides a solid evidence basis for the development of a health state classification system for people with dementia by self- and proxy-report.

DEMQOL

DEMQOL was developed from a conceptual framework that includes health and well-being, cognitive functioning, social relationships, daily activities, and self-concept [30]. Items were drafted to represent each of the conceptual framework domains and were piloted with patients and carers. Following piloting, standard psychometric analyses were used to reduce the number of items. The instrument consists of 28 items answered on a four-point Likert scale (a lot/quite a bit/a little/not at all) and administered by an interviewer using response cards. All items refer to the last week. Items are scored from 1 to 4, generating a total score between 28 and 112, with higher scores indicative of better HRQoL. A global quality-of-life item is also included, but it does not contribute to the overall score. Factor analyses during the development phase of the instrument were limited and not conclusive. A four-factor solution, however, was defined (daily activities, memory, positive emotion, and negative emotion). In the original psychometric evaluation, there was some evidence of content validity (four of the original conceptual domains were represented in the item-reduced version). DEMQOL was also found to have high internal consistency and test-retest reliability, and there was some evidence for convergent and discriminant validity in patients with mild or moderate dementia (defined by a Mini-Mental State Examination [31] score of $\geq$10 alongside a definite diagnosis of dementia). Factor analyses established a four-factor solution (defined as daily activities, memory, positive emotion, and negative emotion). The factors, however, did not fully support the original conceptual framework.

DEMQOL-Proxy

DEMQOL-Proxy was developed from the same conceptual framework and piloting and item-reduction process, with items worded for carers. It contains 31 items, like DEMQOL scored 1 to 4 (score range 31–124), and is interviewer administered using response cards (an additional global quality-of-life item is included but it does not contribute to the overall score). All items refer to the last week. The original psychometric evaluation found that DEMQOL-Proxy has acceptable content validity (all five conceptual domains are represented). DEMQOL-Proxy displays high levels of acceptability, reliability, and validity across the full range of dementia severity. Factor analysis suggested a two-factor solution (functioning and emotion), but this did not support the original conceptual framework.