

**Is the Quality Adjusted Life Year (QALY) as calculated with the EQ-5D a suitable
measure when looking at the wellbeing of carers of people with dementia?**

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Abstract

Aim/ Background: Advisory bodies, such as NICE in the UK, recommend using a generic instrument such as EQ-5D for measuring quality of life. The choice of instrument used to measure health related quality of life (HRQL) is therefore very important as it affects the calculations used to produce QALYs, and hence determine whether an intervention/ technology is considered cost-effective. However, generic instruments may not be sensitive enough to detect quality of life changes in certain populations, such as carers. This paper seeks to set out the issues surrounding the use of generic quality of life instruments to measure wellbeing in carers of people with dementia.

Methods: The strengths and weaknesses of the EQ-5D are discussed and the equity of QALYs is considered. An alternative capability measure, ICECAP-O, is introduced as a possible alternative for carers of people with dementia. The capability approach assesses an individual's capabilities to achieve an outcome whether or not they choose to carry out the functioning. The traditional maximisation goal is also forgone in favour of a more equitable aim of achieving the highest number of people attaining a minimum level of capability rather than maximising the overall level of capabilities within a society regardless of distribution.

Conclusion: The choice of instrument used to measure HRQL is important. Generic instruments have both strengths and weaknesses but when considering the use of alternative instruments for economic evaluation there is still the need for results to be converted into units that can be used in cross-programme comparison.

Introduction

Dementia is the term used to describe the collection of symptoms caused by damage to nerve cells in the brain. It is a progressive condition and symptoms can include memory loss, a decline in spatial awareness and reasoning ability, behavioural changes, communication difficulties and a decline in physical ability. There are many different types of dementia, the most common being Alzheimer's disease. Dementia predominantly affects older people and recent estimates put the number of people in the UK with dementia at over 800,000, a figure expected to rise with the ageing population (Luengo-Fernandez *et al.*, 2010). Figures released in early 2010 estimate the annual UK cost of dementia to be £23 billion (Luengo-Fernandez *et al.*, 2010), which is substantially higher than the previous estimate of £17 billion in 2007 (Knapp *et al.*, 2007). The cost to the economy is largely due to institutional care (£9 billion, 40%) and informal care provided by family and friends (£12 billion, 55%). The direct cost to the health service is considerably less at £1 billion, 5%.

Without the informal care sector, there would be a huge gap in funding for dementia care each year therefore it is imperative that carers are supported in their role. This support can take many forms, from clear information and signposting towards available help at the time of a dementia diagnosis; through to respite care for the person with dementia to enable the informal carer to have a break. As part of the dementia care guidelines produced jointly by The National Institute for Health and Clinical Excellence (NICE) and the Social Care Institute for Excellence (SCIE), it is recommended that health and social care managers should ensure that carers of people with dementia receive the assessment of needs that they are entitled to as outlined in the Carers (Equal Opportunities) Act 2004 (NICE, 2007). The assessment is carried out by Social Services with a purpose of identifying additional services

that the carer is entitled to in order to make their role easier, and at what cost these services will be made available. While the remit of NICE is very much focused on assessing cost-effectiveness, SCIE is an independent charity funded by the Department of Health with the aim of identifying and promoting good clinical practice. All SCIE reports include views of both formal and informal caregivers so the joint nature of the 2007 report with NICE allowed the opportunity for the voice of those involved with the day to day work of caregiving to be heard on a wider platform.

The NICE guide to technology appraisal, also known as the reference case, (NICE, 2008) provides an overview of the principles for assessing the clinical and cost-effectiveness of new and existing technologies. As part of the guidance, it is stated that clinical effectiveness should be reported in Quality Adjusted Life Years (QALYs) and *'an additional QALY should receive the same weight regardless of any other characteristics of the people receiving the health benefit'*. For interventions involving people with dementia, this can be interpreted as the QALY gain for the carer being of equal importance as that of the person with dementia. Carers are explicitly mentioned further on in the report, with the guidance being that *'the perspective on outcomes should be all direct health effects, whether for patients or, when relevant, other people (principally carers).'*

The choice of instrument used to measure health related quality of life (HRQL) is therefore very important as it affects the calculations used to produce QALYs, and hence determine whether an intervention/technology is considered cost-effective. NICE prefers the use of EQ-5D (EuroQoL, 1990), a preference-based generic instrument, to elicit changes in health

related quality of life; however the guidance notes that *'when EQ-5D utility data are not available, direct valuations of descriptions of health states based on standardised and validated HRQL measures included in the relevant clinical trial(s) may be submitted. In these cases, the valuation of descriptions should use the time trade-off method in a representative sample of the UK population, with 'full health' as the upper anchor, to retain methodological consistency with the methods used to value the EQ-5D.'*

This article discusses the suitability of EQ-5D for measuring quality of life in carers of people with dementia and presents an alternative in the form of ICECAP-O, a capability based instrument.

EQ-5D

The EQ-5D is one of the most commonly used instruments to measure health-related quality of life. It is a validated, preference-based instrument. It is also generic, which means that it can be applied to many different populations. It consists of two parts, a self-report questionnaire (EQ-5D) and a visual analogue scale (EQ-VAS). The EQ-5D questionnaire comprises five domains; mobility, self care; usual activities; pain and discomfort; and anxiety and depression. For each domain there are three levels of severity ranging from no problems, moderate problems to extreme problems. A scoring algorithm is then used to convert participants' responses into an index score which can be used to calculate a QALY. On the EQ-VAS, respondents are presented with a thermometer with markings from 0 to 100, 0 representing the worst imaginable health state and 100 the best imaginable health state. Respondents are asked to draw a line on the thermometer to mark the level they would

describe their health related quality of life as being. EQ-5D typically takes under ten minutes to complete.

One of the major strengths of the EQ-5D is its practicality. It can be administered by an interviewer or self-completed. When deciding which instruments to include in a trial there is a need to consider practicality as it is sensible to make sure that as many participants as possible can complete the questionnaires. The EQ-5D is brief and easy for participants to understand and self-complete. In a population such as carers of people with dementia it is important to recognise that time may be stretched already so there is a need to not overburden participants with overly long questionnaires.

While the EQ-5D covers physical domains well, there is only one question on mental health, which is on anxiety/ depression. Due to the dominance of physical domains, the EQ-5D isn't particularly sensitive to changes for groups such as carers of people with dementia, who might not expect to see any changes in their physical health over time but their quality of life is still going to be affected. Other aspects that can affect quality of life, such as relationships with others are ignored. However, there is some debate over whether these aspects of quality of life should be included in the measures that bodies such as NICE use to calculate cost-effectiveness; is it really the responsibility of the NHS to improve well-being in relationships?

The source of health state valuations used to create the scoring algorithm is also open to debate. EuroQoL used a sample from the general population, but there is a choice between

valuation by health professionals; the general population; patient groups; or a mixture of all three. An advantage of using patient preferences is that the respondents have a fuller knowledge of what it is like to be in the particular health state. Indeed, people who have experienced a particular poor health tend to place a higher value on that state than the general population would. This could be down to adaptation and indicate that the general population is valuing the imagined transition from their current health state to the lower state rather than valuing the long-term prospect of being in the state (Menzel *et al.*, 2002). The EQ-5D contains an item asking about usual activities which may cover the issue of transition and adaptation. Discrepancies in health state valuations may also occur when respondents are not presented with sufficient information about the states, leading to different interpretations of the descriptions. Using preferences of the general population can eliminate some difficulties associated with the use of patient groups e.g. the ethical issue of asking very ill patients to value states such as death, or the possibility of patient groups under-rating the values they would attach to low-health states in order to try and skew resource allocation towards those in very poor health.

Alternatives to EQ-5D

As discussed above, the EQ-5D is not faultless and health economists may need to look to other quality of life instruments when a population such as caregivers of people with dementia are involved. One alternative to using a generic instrument is to use a disease specific instrument.

The main advantage of a disease specific instrument is that it is very sensitive to changes associated with the disease in question. Therefore, studies do not need a large sample size to detect change, as might be needed when using a generic measure. It has been found in previous studies that generic measures have been poorer at detecting changes in quality of life compared to disease specific instruments (Pickard *et al.*, 2011).

However, a disadvantage of disease specific instruments is that co-morbidities may be overlooked. That is to say that they focus completely on the quality of life changes associated with one particular illness and ignore any separate health issues that a person may have. As people with dementia and their carers tend to be older, co-morbidities and side effects of an intervention are particularly relevant. Alternatively, population specific measures can be used. Population specific measures tend to cover a broader range of domains than disease specific instruments, with the additional benefit of being more sensitive than a generic instrument.

If a research team decided that the content of existing instruments did not adequately cover all items affecting quality of life for their study population there is the possibility of creating a new instrument. Researchers adopting this approach need to be aware of the balance between depth of instrument (e.g. number of items and number of levels for each item) and length of time and ease of completion for participants. Caution should be used with this approach as the applications for the resulting data will be limited- greater weight will always be placed on studies using widely accepted, validated instruments which allow for cross-programme comparison.

ICECAP-O

The World Health Organisation (WHO) defines health as ‘a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity’ (WHO, 2006). This reinforces the idea that we need to go beyond physical health measurement. Capability theory in Health Economics offers an opportunity to go beyond health gain measurement in terms of QALYs. In this case, to explore how people believe that not only their health related quality of life, but also their capability to benefit from such quality of life, in terms of activities that are important to them, are affected by interventions. Instruments that only consider health related quality of life measurements, such as EQ-5D, may underestimate the impact of interventions (Coast *et al*, 2008A). It may in addition be useful to measure capabilities rather than focus solely on health outcomes.

The capability approach assesses an individual’s capabilities to achieve an outcome whether or not they choose to carry out the functioning (Sen, 1993). There is a move from the goal of maximising the overall level of capability within society without regard to distribution, towards achieving the highest number of people attaining a minimum level of capability. Maximising output makes sense when talking about normal economic goods, but as capabilities cannot be distributed between individuals in a society maximisation is not necessarily a good goal to aim for (Coast *et al*, 2008B).

The ICECAP-O index of capability was developed as an instrument to measure attributes of quality of life rather than influences on quality of life e.g. health. An individual’s quality of

life does not necessarily diminish through degradation of health but instead diminishes through being limited in what one can do as a result of poor health i.e. the individual values the activities that they can undertake rather than health itself. In this sense the EQ-5D is only a proxy measure for quality of life rather than a direct measure- health has an impact on the ability of an individual to undertake activities that they value but health in itself is not a defining attribute of quality of life (Grewal *et al.*, 2006).

The ICECAP-O index is intended to be a more encompassing well-being measure as it contains domains that people value in their lives rather than only looking at physical or mental health domains as a proxy for quality of life. With items such as love/friendship; thinking about the future; doing things that make you feel valued; enjoyment and independence the domains covered are very different to EQ-5D.

Whereas the EQ-5D was developed as a generic instrument, the ICECAP-O was developed as a population specific instrument with domains that older people find important (Coast *et al.*, 2008C). Considering the areas that are of importance to older people is relevant when assessing the quality of life of carers of people with dementia as the majority of informal carers are in the 45-64 age bracket, and many are themselves elderly. Use of instruments such as the ICECAP-O should enable decision-makers to compare the value of health and social services that may improve the quality of life of an individual without necessarily improving their health, to interventions that impact on both health and quality of life (Coast *et al.*, 2008C).

General Discussion

A recent systematic review of EQ-5D use in carers of people with dementia found that carers rated their pain/ discomfort and anxiety/depression lower than the general population scores for these domains. EQ-VAS levels were also lower than the general population (Hounsome *et al.*, 2011). One would expect caregiving to have a noticeable impact on quality of life; this could be either negative (restricted independence) or positive (a closer relationship). A study of carers of older people in Sweden introduced the concept of an R-QALY, a QALY weighted by the effect that caring for an elderly relative has on a person (Davidson *et al.*, 2008). The authors calculated the R-QALY as having a weight of -0.015, indicating carers had a lower quality of life than the general population. The results support the NICE assertion that the need for the effects of interventions on relatives to be considered as well as the direct effects on participants.

Health economists have in recent years been exploring the equity of QALYs. At present NICE assesses interventions based on a cost-effectiveness threshold of £20,000- £30,000 per QALY gained. Judging the equity of the distribution of resulting QALYs is not a huge part of the process. As the traditional maximisation goal is waived with the capability approach there is the opportunity for discussion about a more equitable allocation process. A report investigating societal preferences for QALY distribution was published in 2008 (Dolan *et al.*, 2008). Respondents from the general public were asked to choose between two groups of patients with varying attributes who they would hypothetically favour giving additional NHS treatment to. The attributes of the patient groups included age, social class, whether or not they had dependents, length of time with illness, current quality of life level and the cause of illness (natural vs. NHS negligence). Results from the focus group stage showed that the

public favoured giving additional treatment (and hence QALYs) to patients from a lower social class, those with dependents, those who had been ill for a longer length of time and those who were ill due to NHS negligence. The revealed societal preference of favouring those with dependents can be interpreted as favouring not only parents with young children but also carers of vulnerable or elderly adults.

Whichever instrument is used to measure quality of life, NICE prefers results to be converted into a QALY to allow comparison across different illnesses and interventions to be made (NICE, 2008). In order to satisfy the QALY methodology, quality weights must be based on preferences; anchored on a scale which contains full health and death points, and measured on an interval scale (Drummond *et al.*, 2005). For the EQ-5D full health is anchored at 1 and death is 0. The scale continues below 0 as it was found that there are health states that the population deemed to be worse than death. Whilst the ICECAP-O is anchored on a scale similarly to EQ-5D, 0 represents no capability rather than death and 1 represents full capability rather than full health. Another difference is that ICECAP-O does not have scores below 0.

An algorithm that can be used to convert ICECAP-O scores into a QALY is not yet available. Without the ability to convert scores into a QALY, results from a study cannot be compared directly to other interventions using different instruments. One way around this is to perform a mapping exercise of ICECAP-O scores onto EQ-5D scores. To be valid this would require a large data set which is not always possible due to financial and time constraints. While the lack of QALY conversion algorithm isn't ideal it won't invalidate the results of the

interventions using ICECAP-O, it will only limit the ability to undertake cross-programme comparisons until a QALY conversion algorithm is established.

Until a QALY conversion algorithm is available, researchers can ask participants to complete ICECAP-O and EQ-5D. This allows researchers the best of both worlds; a QALY that can be used in comparisons with other interventions and an instrument that is better able to detect changes of quality of life for carers of people with dementia. As both questionnaires are brief the extra burden to participants of completing two instruments is minimal.

Discussion point

This paper has been written as part of a PhD exploring QoL for carers of people with dementia. ICECAP-O has been used alongside EQ-5D in two trials (REMCARE and FAMCARE) and this paper is planned as the justification for the inclusion of ICECAP-O. As there is little original theory presented, what would HESG members suggest doing to increase the publication potential of the paper?

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