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Measuring quality of life in macular degeneration

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List of abbreviations

ADVS Activities of Daily Vision Scale

CNV choroidal neovascularisation

DTSQ Diabetes Treatment Satisfaction Questionnaire

EQ-5D EuroQol 5-dimension questionnaire

FS functional status

HS health status

HUI3 Health Utility Index 3

MacSSQ Macular Service Satisfaction Questionnaire

MacTSQ Macular Treatment Satisfaction Questionnaire

MD macular degeneration

NEI-VFQ National Eye Institute Visual Function Questionnaire

NICE National Institute for Health and Clinical Excellence

PRO patient-reported outcome

QALY quality adjusted life year

QoL quality of life

SF-36 Short Form 36

SG standard gamble

TTO time trade-off

VA visual acuity

W-BQ12 12-item Well-being Questionnaire

WHO World Health Organisation

Abstract

Patient-reported outcomes are increasingly used in research and clinical practice in ophthalmology as in other medical specialties. Measures of health status, psychological well-being, functional status, and visual function are frequently referred to as quality of life (QoL) measures and have been used as such in research into macular degeneration (MD). However, such patient-reported outcomes do not measure QoL, although the constructs may be related to or influence QoL. When inappropriate or insensitive measures are used as QoL measures, the findings can be misleading and may lead to incorrect management of patients. Care is needed in the selection of patient reported outcomes (PROs) for use in research and clinical practice to ensure that they are appropriate for the intended purpose. In addition, PROs should be psychometrically validated, demonstrating qualities including face, content and construct validity, internal consistency and test-retest reliability and responsiveness.

Utility values obtained using methods such as time trade-off and standard gamble are used to calculate quality adjusted life years and frequently referred to as QoL measures. However, they do not measure QoL and give no impression of the ways in which MD or any other medical condition impacts on QoL. For older people, such as those with MD, the questions are particularly difficult to answer.

PROs have shown that MD has a considerable negative impact on the lives of people with the condition and on their families. The use of PROs is valuable in assessing the impact of clinical and rehabilitative interventions and other services for people with MD. Ideally a complementary combination of PROs would used for evaluation purposes to ensure considerate, individually tailored and effective management of this group of patients.

Age-related macular degeneration

Age-related macular degeneration (MD) is a chronic, progressive eye disorder that mainly affects people over the age of 50. It is the leading cause of blindness in the Western world in people over 60 years and the third most common cause of blindness globally after cataract and glaucoma (WHO, 2004). Recently it was estimated that, in the UK, with a population of 59 million, approximately 417,000 people have some degree of MD, of whom 214,000 have sufficient impairment for registration as partially sighted or blind (Owen et al., 2003). With increasing longevity in the population the prevalence of MD is likely to grow (Owen et al., 2003).

MD affects the most sensitive part of the retina, the macula. The condition leads to loss of central vision needed for activities requiring fine vision such as reading, driving and recognising faces. Peripheral vision is usually retained but MD can impair proficiency in performing most activities in daily living and can make it more difficult for people to live independent lives. The effects of MD on vision are illustrated in Figures 1-3 (reproduced courtesy of the Macular Disease Society), which show a scene as perceived with normal vision, with mild MD and with moderately severe MD. In very severe cases central vision can be completely obliterated.

Figure 1 Scene as perceived with normal vision The scene is clear and there is no distortion

Figure 2 Scene as observed with mild MD. Vision is blurred and there is some distortion

Figure 3 Scene as observed with severe MD. The scene is very blurred and no detail is detectable in the centre of the picture

There are two types of MD. Dry MD (also called atrophic MD) accounts for about 85% of cases and generally develops slowly, often affecting both eyes simultaneously. Dry MD is characterised by fatty deposits behind the retina which cause the macula to thin and dry out. In general it causes less severe impairment than the more aggressive wet MD. Wet MD (also known as neovascular or exudative MD) is associated with rapidly deteriorating vision and severe impairment. It accounts for 90% of cases of severe visual impairment due to MD. Wet MD is caused by the growth of new blood vessels (a process known as choroidal neovascularisation [CNV]) behind the retina. These new blood vessels are weak and tend to leak, damaging the retinal cells and leading to scar tissue.

MD is a largely untreatable condition. Treatment is appropriate for a small percentage of people if they are diagnosed at an early stage with particular types of the wet form of the disease. Even then the treatment does not cure the condition but can limit its progress, at least for a time, although the newest treatments do offer some hope of improvement in vision for a proportion of patients. However, potential new treatments and rehabilitation interventions are continually being developed and tested.

- MD is a progressive eye condition.
- MD mainly affects people over 50 years of age and incidence increases with age.
- MD is the leading cause of blindness in people over 60 in the western world.
- MD damages the central part of the retina, the macula, which is needed for fine vision.
- There are two types of MD. About 85% of cases are ‘dry MD’, which develops slowly. Wet MD, progresses rapidly and, although it accounts for only about 15% of cases of MD, it is the cause of 90% of cases of severe vision impairment due to MD.
- There is currently no treatment for dry MD. Wet MD can often be treated to halt progress of the condition. In some cases vision improves with treatment but there is no cure for MD.

Table 1. Key facts about macular degeneration (MD)

Measuring quality of life and other patient reported outcomes

It is important that appropriate patient reported outcomes (PROs) are used in the evaluation of new interventions. Many PROs are routinely referred to as 'quality of life (QoL) measures' but this ubiquitous term is often misused and, when it is, data referred to as QoL data can be misinterpreted. This can lead to incorrect assumptions about the effects of intervention (Bradley, 2001) and may even result in the inappropriate management of patients.

Although a great deal of QoL research is carried out there is little agreement about the definition of QoL. The one we prefer, which guides our own measurement of quality of life, is:

"Your quality of life is how good or bad you feel your life to be." (Bradley et al 1999)

Implicit in this definition is that QoL is a subjective perception and that QoL means different things to different people. Although many so-called QoL measures allow people to indicate their own perceived levels of whatever aspect of life is being measured, many do not allow individuals to report the relevance or importance of that aspect of life for them (Bradley, 2001).

Psychological well-being instruments measure mood but they are often referred to as measures of QoL. People who feel depressed and anxious are unlikely to describe their QoL as good. However, people whose psychological well-being is good may nevertheless feel that their QoL is severely damaged by MD. Some well-being scales, such as the Beck Depression Inventory (Beck et al 1961) measure only negative well-being (depression). Where people are not depressed to begin with, such a measure could show no improvement. Measures which also investigate positive well-being e.g. the positive well-being subscale of the 12-item Well-being Questionnaire [W-BQ12] (Mitchell & Bradley, 2001) which also measures energy and negative well-being (anxiety and depression), are more likely to detect improvement in psychological well-being.

Health status (HS) measures investigate subjective perceptions of health but unfortunately HS measures are often wrongly called QoL measures and this has caused great confusion and misleading conclusions (Bradley, 2001). HS is not QoL; although poor HS may be associated with impaired QoL, good HS does not indicate that QoL is good. HS measures such as the SF-36 (Ware et al 1993) are unsuitable as indicators of the impact of eye conditions on QoL because most of the domains investigated (e.g. pain, energy, appetite) are not affected by visual impairment (Mitchell & Bradley, 2006). The SF-36, and the shorter subset, SF-12, have been found to be sensitive to age-related eye disease including MD in some work (Knudtson et al., 2005) but not in others (Childs et al 2004; Stevenson et al 2005) and found to be only minimally responsive to change in visual acuity (VA) in patients with CNV over a period of 2 years (Childs, 2004). The SF-12 was also found not to be responsive to change (Cahill et al 2005). The health utility index (HUI-3) (Feeny et al 2002) includes an item concerned with vision and, unsurprisingly, proved more sensitive to vision impairment (Espallargues et al 2005) than the SF-12 and the EQ5D (Brooks, 1996) which investigates only five dimensions of health, none of which is vision. This disappointing performance of widely used HS measures in detailing impairment in people with MD and other eye conditions can be understood when it is appreciated that, for the most part, the general population do not think of problems with their eyesight when asked about their health. Patients may be registered blind with MD and still report that their health is excellent. If asked about their QoL they may nevertheless say it is badly affected by their MD. Quality of health is quite a different matter from QoL (Bradley, 2001) and this is particularly true for people with eye conditions, including people with MD. When the SF-36 and other HS measures show no impact of MD and are also wrongly referred to as QoL measures it may be mistakenly concluded that MD has no impact on QoL when all that has been shown is that MD has no impact on self-reports of health. The literature on MD abounds with studies that have used HS measures and wrongly referred to these as QoL measures (Mitchell & Bradley, 2006). It is essential that we recognise this problem and are not misled by the data.

Functional status (FS) measures investigate respondents' ability to carry out activities of daily living such as self-care and eating. They may contain some items that are relevant to vision but they do not particularly investigate vision-related activities (e.g. reading, watching TV). Generally they do not include psychological domains such as confidence or worry. They do not necessarily correlate well with objective measures of vision or with QoL because FS measures only ask what a person can do, not whether they want or need to do those things or how important they are to their QoL. Nevertheless, using the Instrumental Activities of Daily Living scale, Williams et al (1998) demonstrated that, compared with visually unimpaired elderly people, patients with MD were 8 times more likely to report difficulty shopping, 13 times more likely to have difficulty managing finances, 4 times more likely to experience difficulties preparing meals, 12 times more likely to have problems using a telephone, and 9 times more likely to experience problems with light housework.

Vision-specific functional status (VF measures investigate vision-related tasks such as reading, writing, watching TV, recognising faces or driving. They are usually correlated with standard measures of vision such as VA. However, they do not differentiate between what is relevant and what is irrelevant to individual respondents, or what is important to QoL and what is not, and therefore they are not true QoL measures, although they are frequently referred to as such (Slakter & Stur, 2005). The impact on QoL of loss of or deteriorating near vision would be greater for someone who spent a lot of time reading and doing embroidery than for someone who preferred listening to music and swimming. VF measurement has also been shown to be influenced by general health (Miskala et al 2004). For example, the ability to prepare a meal may be affected by arthritis as well as by vision and, if the questionnaire does not specifically ask the respondent to consider only the effects of their vision on a task, co-morbidity may confound the scores and make results difficult to interpret. The Activities of Daily Vision Scale (ADVS) (Mangione et al 1992) was found to discriminate between mild and severe MD (overall score, near vision, daytime driving and glare) but not between mild and moderate MD (Mangione et al 1999).

The ADVS and some other VF measures investigate only visual function and do not include items relating to social or psychological functioning. Other VF measures, including the NEI-VFQ (Mangione et al 1998), which has been well validated in the MD population also investigates psychological aspects of visual impairment. As well as items pertaining strictly to function, the NEI-VFQ investigates social functioning, mental health and dependency. It differentiates between different eye conditions, and overall score and relevant subscale scores are correlated with VA. It has been shown to be responsive to change in VA over time (Lindblad & Clemons, 2005), but this was in a large study over a long period of time. It remains to be seen if the NEI-VFQ is sufficiently responsive to detect change in smaller samples. For a more comprehensive review of measures of FS and VF used in studies of vision impairment see Mitchell and Bradley (2006).

Vision-specific individualised quality of life measures: The MacDQoL is an individualised measure of the impact of MD on QoL (Mitchell & Bradley, 2004; Mitchell et al 2005, Mitchell et al, 2008). The MacDQoL, modeled on the ADDQoL for diabetes (Bradley et al1999) (which in turn was influenced by the generic SEIQoL [McGee et al 1991]) and developed alongside the RetDQoL for people with diabetic retinopathy (Woodcock et al 2004), examines both impact and importance of each domain on QoL and allows for variability in the relevance of specific domains to individual respondents (see other chapter by Mitchell and Bradley in this book on the MacDQoL for more detail on design and development). Impact and importance scores are multiplied to give weighted impact scores. The MacDQoL has two overview items (present QoL and MD-specific QoL) and 23 domain-specific items. It has been shown to differentiate between mild and moderate and mild and severe MD (measured by UK registration status: blind, partially-sighted or not registered) but, in common with visual function measures, not between moderate and severe. The overview items are also sensitive to severity of MD, the present QoL (generic) item less so than the MD-specific item, as would be expected. There are promising indications of the MacDQoL's responsiveness to change in a small sample (Mitchell et al, 2008), and some evidence that the MacDQoL is slightly more sensitive to VA impairment than the NEI-VFQ in a large multinational trial (Berdeaux et al 2006). Measuring both the impact and the importance of a domain of life to QoL leads to

considerable variability in scores and so it would not be surprising if correlations between the MacDQoL and measures of vision such as VA or contrast sensitivity were not as large as those between VA and vision function e.g. MacDQoL average weighted impact score correlates 0.45 with better eye distance VA (Mitchell et al 2005), NEI-VFQ distance vision score correlates 0.65 with better eye distance VA (Mangione et al 1998). This correlation between NEI-VFQ score and distance VA score would be expected to be high as with both measures the patients are being asked how well they can see. The MacDQoL measure captures the nature of the impact of MD on a person's life in a way that cannot be achieved with a vision function measure. If there is any loss of sensitivity to differences in VA, it is outweighed by the increased relevance of the QoL measure to the whole experience of MD including experience of any treatment and rehabilitation.

The value of PROs

In the literature on MD, well-being, health status, functional status and visual function have all been referred to more or less inappropriately as QoL. We have argued that the use of such measures can be misleading, resulting in misinterpretation of findings. Nevertheless, PRO instruments other than QoL measures provide valuable data and, together, a variety of types of measure can give a fuller picture of the effect of MD on people's lives. Many PROs contain items which could appropriately be included in measures of more than one construct. Figure 4 illustrates the complex relationship between different types of PRO. Some measures, such as most health status questionnaires (e.g. SF-36 [Ware et al 1993], EQ5D [Brooks, 1996]) are clearly not helpful in evaluating the effects of MD. The SF-36 is a comprehensively validated and widely used measure and it may be that it is selected purely on the grounds of its ubiquity. If it is not expected to yield relevant results, however, it is an unnecessary burden on participants and is likely to give an underestimation of the benefits of an intervention designed to improve vision. In any study or clinical trial, careful thought must be given to the choice of measures to ensure that the data collected are the data that are required to answer the research question or investigate the effect of an intervention. A treatment for MD may result in enhanced visual function but, if the treatment is

very unpleasant, has to be repeated regularly and is anticipated with trepidation by some patients and refused by others, then it might do substantial damage to QoL in spite of having the potential to improve visual function. The work reported here indicates that, in many cases, there is widespread confusion about the term ‘quality of life’ and, generally, the choice of questionnaire indicates that it is defined inadequately. Choice of PRO instrument notwithstanding, measuring the impact of vision impairment is complicated by the involvement of a second eye and the interactions between the two eyes’ visual status (Slakter & Stur, 2005).

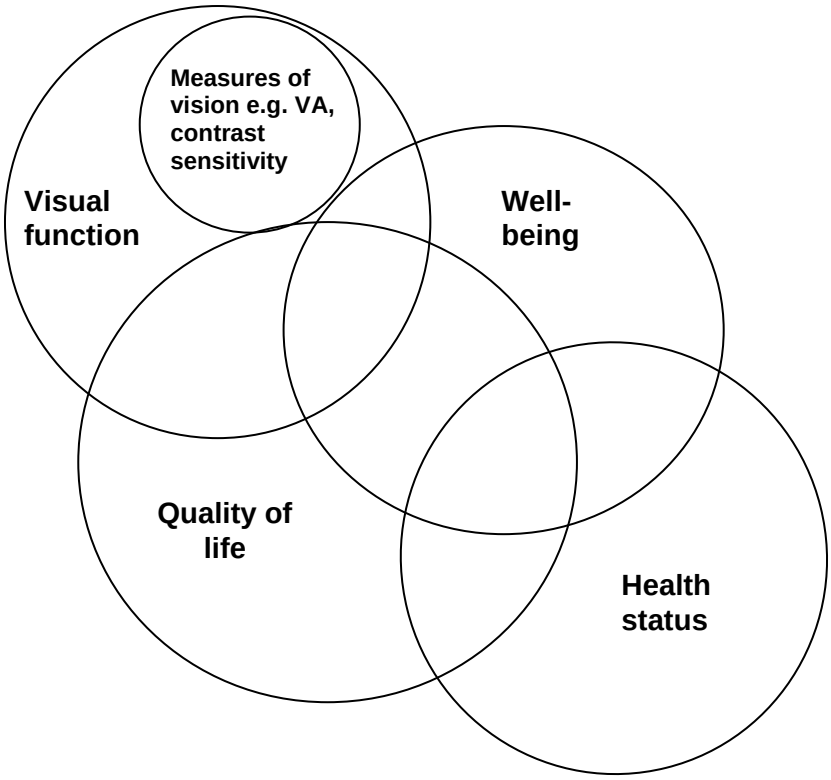

Figure 4 Venn diagram to show the relationship between PROs. The more the circles overlap, the stronger the relationship between constructs

MD-specific patient satisfaction measures related to quality of life

The factors that contribute to QoL are many and varied. For people with MD, the way in which their condition is managed and treated is likely to impact on their QoL. Two measures have recently been developed to investigate MD patient satisfaction.

The MacSSQ (Bradley & Mitchell, 2006) is a measure of macular clinic service satisfaction. It is intended for use with MD patients, both newly diagnosed and returning. People with MD informed the content and design of the measure, which contains 35 items pertaining to a wide variety of aspects of clinic service. It is intended for use in eye clinics so that shortcomings in the service that may not be recognised or considered important by clinic staff may be highlighted. It is hoped that findings from such service evaluation may prompt changes in the clinics leading to increased patient satisfaction. Psychometric development and validation is being carried out on the MacSSQ in 2008.

The MacTSQ (Mitchell et al 2007) is a measure of satisfaction with treatment for MD. It is modeled on the Diabetes Treatment Satisfaction Questionnaire (DTSQ) (Bradley, 1994; Bradley et al 2007) which is widely used internationally. There are currently several possible treatments for wet MD and it is likely that the future will bring new developments in treatment for both wet and dry MD. The MacTSQ is a 16-item measure that investigates patient satisfaction with aspects of treatment including provision of information about the treatment, diagnostic tests, apprehension about the treatment, pain and side effects associated with the treatment, cost and convenience of treatment. It is anticipated that the measure will be valuable in clinical trials to assess the acceptability of treatments to patients. Psychometric development and validation of the MacTSQ will be conducted on data to be collected from clinical trials starting shortly.

Validation of questionnaires

Measures of health status, functional status, visual function and well-being are not, in themselves, QoL measures. However, they are all concerned with aspects of life that may be important to QoL.

The value of questionnaire data collected depends on the psychometric properties of the measure. Psychometric properties that are regarded as important in a measure include those presented in Table 2 (Margolis et al 2002). In addition to these psychometric properties, the burden placed upon respondents (length of questionnaire, complexity of language, relevance of the questions) and that on administrators should be considered. Where questionnaires are designed in one language and translated into other languages, linguistic validation is required, including cultural adaptation where needed. Forward and backward translations are necessary (preferably reviewed by the questionnaire author) to ensure that the translations have not introduced semantic discrepancies. Clinician review can be helpful and cognitive debriefing interviews with people who have MD are needed to ensure that the translated items and instructions are understood as intended. Psychometric evaluation of each language version is necessary, at least on first use, before analysing data from multiple languages as one dataset.

Property	Definition	Considerations
Internal consistency reliability	The extent to which the items contribute to measuring the same construct (a reliability coefficient is calculated).	Only cases with complete data are valid for use in calculating internal consistency reliability
Test-retest reliability	The extent to which scores remain stable over time when no change has occurred (i.e. when there has been no change in vision, no treatment for MD or rehabilitation).	An appropriate time lapse between baseline and follow-up data collection is important. Two weeks is probably too short for patients to have forgotten their previous responses. Three months or more would be more appropriate.
Content validity	The extent to which the topic of interest is comprehensively and appropriately investigated by the measure.	It is important to involve patients in the design of a patient reported outcome measure in order to ensure content validity.
Face validity	The extent to which the questionnaire appears to measure what it is intended to measure.	Researchers designing questionnaires should consider the questions carefully and avoid ambiguity. Researchers considering the use of the measure should consider whether the items are suitable for their purposes.
Construct validity	Hypotheses concerning the relationship of questionnaire scores to other measures (such as VA or contrast sensitivity) are tested.	Ability to discriminate between levels of disease severity (e.g. between people who are registered blind, partially sighted or not registered) is important, particularly for a visual function measure, which would be expected to correlate strongly with disease severity.
Responsiveness	Sensitivity to real change over time (e.g. deterioration in VA or contrast sensitivity).	Care is needed in deciding what constitutes significant change.
Interpretability	The extent to which change scores can be interpreted and explained.	Selecting the most appropriate PRO measure is critical. Health status and utility measures are not suitable for investigating quality of life, particularly for people with MD.

Table 2. Psychometric properties desirable in scales to measure patient-reported outcomes. Some psychometric properties are investigated using statistical procedures and others must be determined by examination of content and consideration of the design process.

The method of administration is a further consideration that is particularly important in visually impaired populations. Self-completion (pen and paper) has been found to elicit poorer scores than interview administration in some questionnaires but not in others (Mitchell et al 2004). Where scores differ, using two implementation methods in one study may result in people with worse vision, and therefore having interview administration, under-reporting impairment compared with people self-completing the measure. This would confound the results. Generally it is better to use only one administration method in any one study.

2.3 QALYs and other manipulations of PROs

A limitation of condition-specific or vision-specific measures of health status, functional status and QoL, even when they are interpreted appropriately, is that the scores are not comparable across diverse medical specialties. One use for outcome measures is to assess the relative cost-effectiveness of different treatments and to inform decisions concerning allocation of limited funds. Such a measure, that could be used across all medical conditions and allow direct comparison, would be an asset for health economists. One technique that is adopted increasingly to make such comparisons is utility assessment. Utility values (also called preference measures) are quantitative expressions of preference for given health states. A scale is used with utility values ranging from 0 to 1 where 0 represents death and 1 represents perfect health. Techniques used for eliciting this value include time trade-off (TTO) and standard gamble (SG). They are usually obtained during an interview using particular questions, which are shown in Table 2. The utility value obtained is used in conjunction with an estimate of life expectancy to calculate Quality Adjusted Life Years (QALYs). QALYs are estimates of life expectancy in full health. One year of life in a health state rated as perfect health (utility value of 1) = 1 QALY. Two years of life in a health state with a utility value of 0.5 = 1 QALY. Cost per QALY can be calculated if the cost of treatment is known. Such costs can be calculated for any clinical intervention, and have been used by medical decision makers such as the UK National Institute for Health and Clinical Excellence (NICE) to make choices between

treatments. Health economists argue that non-preference PROs correlate poorly with preference measures and so are not suitable for use in economic evaluation. It could be argued that preference measures, although convenient for calculating QALYs, do not correlate well with non-preference based QoL measures as they do not measure QoL.

Technique	Question(s) asked	Sample response
Standard Gamble (SG)	A new treatment is available. When it works it always restores normal vision for the rest of your life but failure results in immediate death. The alternative to treatment is the certain continuation of your present visual status for the rest of your life. What percentage risk of death, if any, would you be willing to accept before refusing the treatment?	20% risk of death
SG utility calculation		1.0 – 0.2 = 0.8
Time trade-off (TTO) a)	How many more years do you expect to live	15 years
b)	Imagine that there is a new treatment for MD. It always works but it reduces the length of your life. How many of your remaining years would you be willing to give up if you could have this treatment and enjoy normal vision for the rest of your life?	3 years
TTO utility calculation		1.0 – 3/15 or 1 – 0.2 = 0.8

Table 2 Standard Gamble and Time-trade off questions and utility calculations
Participants are asked SG or TTO questions about a health state or medical condition and their responses are used to calculate utility values for that health state.

A number of studies have reported utility values for MD using TTO or SG techniques e.g. Brown, Sharma, Brown et al (2000a), Brown, Brown and Sharma (2000b) and there has been reasonable concordance in the findings. Nevertheless the method has attracted criticism. For example, there is some debate about whose values are the most appropriate: patients', doctors' or those of the taxpaying general public (De Wit et al 2000). The general public may be unaware of the impact of some medical conditions unless they themselves are affected by the condition. There can be marked differences in the values of patients, doctors and the public and the decision to use one

group rather than another will therefore be likely to affect the results obtained. It has also been reported that demographic data may be more predictive in determining health state utilities than the health states themselves (Dolan & Roberts, 2002). Some studies have reported less than impressive response rates e.g. Brown, Brown, Sharma et al (2001). Others have not reported response rates (e.g. Brown et al 2000c). TTO questions are often posed to MD patients during an eye clinic appointment while they wait to see the ophthalmologist following dilation of the pupils. Patients may feel vulnerable at this time and reluctant to express unwillingness to take part. When participants in a UK study were asked TTO questions during a telephone interview while they were in their own home, at a time convenient to them, response rates were a cause for concern (Mitchell & Bradley, 2005). A large proportion of people who did respond (38%) said they would trade no time for perfect vision. Unsolicited comments from participants indicated that they thought the questions ridiculous, too hypothetical or objectionable for religious or other reasons. People said they would not trade time because they were carers or because they wanted to see their grandchildren grow up. Nevertheless, it is likely that improvement in their MD would improve their QoL. There was no relationship between utility values and vision status (registration as blind, partially sighted or not registered) whereas, in the same study, vision status was significantly associated with MacDQoL scores. Another UK study (Hill et al 2005) demonstrated that 50% of participants with varying severity of MD were not prepared to trade any time for perfect vision and, after removing scores where no time was traded, there was no relationship between TTO utility values and VA. It is likely that the questions posed in the TTO method would be particularly difficult for elderly people to answer given their shorter life expectancies. The comparability of TTO responses to questions about ‘perfect health’ and those referring to ‘perfect vision’ (see Table 2 for wording of TTO questions) is doubtful. A person with poor vision and poor general health might view things differently from a person who has poor vision but otherwise good health.

Opinions differ as to whether utility values should be obtained from patients, health professionals or the tax-paying general public. Generally, the public overestimate the impact of medical conditions on QoL compared with patients but it has been shown that MD is an exception to this

rule: both the public and health professionals report higher utility values for MD than do patients (Stein et al 2003). This perhaps reflects an underestimation of the impact of the loss of central vision and an overestimation of the value of peripheral vision. Whatever the reason, a comparison of utility values across diseases when the utilities have been obtained from the public would mitigate against resources being allocated for treatment and rehabilitation of people who have MD.

Utility measures and QALYs are increasingly used to estimate so called 'QoL' gains or losses. However, the QALY values obtained using TTO and SG methods are not measuring QoL (Slakter & Stur, 2005) and the measures give no impression of the ways in which MD impacts on people's lives. There are many reasons why a person may not want to relinquish any years of life in spite of serious visual impairment but this does not imply that they are content with the present situation or that their QoL would not be much better without their vision problems. When such measures are obtained from members of the public who have no awareness of living with MD the results are so far removed from the patients' experiences as to be completely irrelevant to QoL measurement. These inadequate and inappropriate measures and others like them have been the preferred instruments for 'QoL' measurement and continue to be used uncritically in organisations such as the UK's NICE, dominated by health economists who are committed to such inferential methods of measurement, unaware of the importance of psychological factors and unaccustomed to listening to patients' accounts of their own experiences and descriptions of the impact of MD on their lives.

The use of PROs

The use of QoL, well-being and vision function measures in assessing the value of changes to the services offered to people with MD will help to ensure that management of this group of patients is considerate, sensitive to individual needs and effective. Slakter and Stur (2005) asserted that, ideally, different trials should use the same measures to enable comparison of the effects. It would be premature to recommend a specific set of measures for use in all trials, as some of the instruments are relatively new, though it is clear that health status measures such as the SF-36 are

of little relevance and utility values derived using TTO and SG methods are misleading and best avoided. A variety of visual function measures is available, with the NEI-VFQ being well established as a useful measure of visual function in MD. The W-BQ12 measure of well-being is psychometrically evaluated for people with MD (Mitchell & Bradley, 2001). There is growing evidence for the usefulness of the relatively recent MacDQoL measure of the impact of MD on quality of life which was developed specifically for people with MD (Berdeaux et al 2006; Mitchell & Bradley, 2004; Mitchell et al 2005) Such measures of well-being and quality of life are urgently needed in clinical trials in addition to measures of visual function in a context of continuing evaluation of their sensitivity to change in response to treatments and rehabilitation for MD.

It is well documented that MD has a damaging effect on many aspects of people's lives. The loss of central vision associated with MD impairs critical aspects of visual function including reading, driving, recognising faces, watching TV and other near vision activities. Impaired visual function affects different people in different ways. Not all aspects of impairment will be important to all people with MD but evidence from studies using the MacDQoL shows that loss of visual function will affect all people with MD in some way. The extent to which MD impacts QoL will be influenced by individual lifestyles and personal characteristics as well as by factors such as social support, co-morbidity and access to rehabilitation services. The use of effective and appropriate patient-reported outcome measures in evaluating treatment, rehabilitation and management will be invaluable in the maintenance of good quality of life for people with MD.

Summary points

- Macular degeneration is a chronic, progressive eye condition that mainly affects people over the age of 50. It is the leading cause of blindness in people over 60 years in the Western world. A minority of cases is treatable but this improves impaired vision for only a proportion of treated patients.

- Several different types of patient reported outcome measures, including measures of health status, psychological well-being, functional status and visual function are inappropriately used as measures of quality of life in the study of MD.
- When inappropriate PROs are used the findings may be misinterpreted and conclusions may be misleading
- Utility measures, used in economic analysis, do not measure quality of life and give no flavour of the experience of living with MD.
- Care should be taken in the selection of PROs for use research and clinical practice so that relevant, psychometrically validated measures are used, enabling effective interpretation of the data.

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