Technology Assessment

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MEASURING QUALITY OF LIFE FOR PATIENTS WITH AGE-RELATED MACULAR DEGENERATION

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1. Overview of Age-Related Macular Degeneration

Age-related macular degeneration (AMD) is a degenerative retinal disease that affects the central retina, or macula. It is the leading cause of irreversible visual loss and legal blindness in persons over 50 years of age in industrialized countries. AMD affects approximately 15 million people in the United States alone, and current estimates project this figure to increase by 50% by the year 2020.[1,2] AMD will affect over one quarter of those in a representative cohort in the Medicare program who survive at least 9 years.[3]

There are two major clinical forms of the disease, "wet" and "dry." The "dry" form initially consists of abnormalities in the retinal pigment epithelium and other layers of the internal structure of the eye ("drusen"). It can then worsen to more advanced forms of dry AMD, as evidenced by larger areas of confluent drusen formation ("soft drusen"), secondary pigmentary changes, and atrophy of large areas of the retinal pigment epithelium ("geographic atrophy"). This early dry phase may convert to the more severe "wet" form of the disease in 10 to 20% of patients. Wet AMD ("neovascular") is characterized by the development of abnormal blood vessels underneath the retina in the macular region, which subsequently bleed and then heal via normal mechanisms, resulting in scar tissue formation and the destruction of the overlying retinal layers responsible for sensing light. Approximately 1.75 million Americans (10% of those with AMD) have the advanced or late forms of the disease (wet AMD or geographic atrophy).[4]

AMD can have a devastating impact on many of the basic activities and intermediate activities of daily living such as driving, recognizing faces, dressing, self-care, and reading. Since the disease affects the elderly population, it robs many individuals in their retirement years of their

independence and may compound the effects of other chronic diseases. As such, blindness from causes such as AMD has traditionally been one of the three leading fears of Americans, after cancer and AIDS/HIV.[5]

Fortunately, several therapies are now available to combat the progression of the most severe forms of macular degeneration, particularly the wet form. Investigators have shown in the Age-Related Eye Disease Study (AREDS) that the progression from the severe dry form to the wet stage can be reduced by about 25% with the use of daily antioxidant vitamins with zinc supplements compared to placebo controls.[6] Once patients have the wet form, several therapies have been shown in randomized controlled trials to reduce the degree of associated visual loss compared to the natural history of the disease among controls without treatment, including standard argon laser;[7] photodynamic therapy combining intravenous administration of photosensitive agents coupled with specific nonthermal laser wavelengths to create more selective destruction of the neovascular complex;[8] the intraocular injection of vascular endothelial growth factor (VEGF) inhibitors;[9] and the intraocular injection of steroids.[10] Other therapies, such as submacular surgery and macular translocation surgery, have been studied as potential additions to the treatment options for eyes with more advanced AMD. While these treatments have offered hope to those seeking to preserve their vision or to arrest further progression of the disease, they also translate into significant use of health resources. Thus, it is important to understand the value of these benefits in terms that are meaningful to patients.

1.1 Assessing Visual Functioning and Health-Related Quality-of-Life Measures in Patients with AMD

The clinical presentation of patients with AMD, like that of patients with many other eye and systemic diseases, varies widely, even among patients with similar findings on traditional ophthalmic examination. Patients with similar visual acuities or comparable areas of affected macula often report different degrees of difficulties with their ability to perform visual tasks and other related functions.[11] This is not surprising given the wide variation in function associated with another common eye disease affecting central vision, such as cataracts.[12,13] Thus, assessing the patient's visual acuity and/or the clinical severity of diseases such as AMD may not always demonstrate the overall effect of the disease on the patient's visual abilities and related abilities to function with their eyesight.[14] For example, airline pilots may have functional requirements in their occupation that might be compromised even at measured visual acuities of 20/20. In another context, patients may have 20/20 acuity in office testing conditions, but cannot drive due to glare difficulties with oncoming headlights at night. Thus, visual acuity or contrast sensitivity alone may not adequately reflect the degree of functional impairment or difficulty someone experiences.

Patient-reported visual function and quality-of-life (QoL) measures have become useful adjuncts for evaluating the impact of a patient's visual functioning or disease state on that particular individual and the effects of therapeutic interventions on the individual's level of function. In particular, as patients, providers, and their families appreciate the central importance of "patient-centered care," greater attention will be focused on how individuals fare with their conditions

and how best to ameliorate the impact of their conditions on their abilities to function by using measures that extend beyond conventional physician-directed measures.

There are several potential methods for assessing the impact of eye diseases on individual patients. First, individuals can be observed while performing specific tasks that either replicate activities of daily living or are established proxies for such performance. A leading example is the Salisbury Eye Evaluation (SEE) project, in which West and colleagues[15] did such testing on several thousand community-dwelling elders in a population-based study. Other studies have performed related analyses on various clinic-based populations. Second, persons can also be asked to complete questionnaires about what they do and their perceptions of doing so, as with numerous studies assessing many questionnaires.

Such questionnaire instruments have been classically defined into either general health-related QoL questionnaires, such as the Medical Outcomes Study 36-Item Short Form Health Survey (SF-36), the Medical Outcomes Study 12-Item Short Form Health Survey (SF-12), the Sickness Impact Profile (SIP), EuroQol, and similar instruments, or into disease- or condition-specific instruments, such as those for specific eye diseases. Within eye diseases, there are two major forms of questionnaires for vision-related functioning or vision-related quality of life: 1) general vision-related instruments either designed or proven to be useful across a variety of eye conditions; or 2) eye disease-specific questionnaires designed and used (to date) only on one specific eye disease. Such questionnaires may include items concerning not just vision, but also patients' emotional reactions, ocular pain, or other domains adapted from general health-related QoL instruments.

Such patient-reported, eye-specific instruments have now been incorporated into every major clinical trial of interventions to improve the disease course and patient outcomes in patients with AMD and other major eye diseases sponsored by the National Institutes of Health (NIH)/National Eye Institute (NEI), resulting in important data that informs our analysis below. At the same time, they appear to be little used by clinicians, who continue to rely on traditional measures, such as visual acuity, in assessing the degree of success of their treatments. Such an appearance is likely to be misleading, however, for physicians continue to assess the impact of their patients' diseases and treatments through questions in their history-taking, even if they do not use a formal instrument to do so. Thus, it is an opportune time to assess the relative contributions, if any, of these varying methods and instruments to the assessment of the impact of AMD and treatments for AMD on patients.

1.2 Questions Posed by the Centers for Medicare and Medicaid Services Regarding Measuring Quality of Life for Patients with AMD

The present evaluation of quality of life for patients with AMD was designed to respond to three specific questions posed by the Centers for Medicare and Medicaid Services (CMS):

1) *What is the status of current methods of measuring quality of life of individuals with AMD?*
    a. *What QoL measurement methods have been used in the AMD population and in those with visual disabilities from AMD (e.g., self-reporting, proxy reporting, measuring performance, etc.)?*

b. *Have these QoL measuring methods been used across other eye disease populations?*

c. *What are the psychometric properties of these methods (e.g., reliability, validity, responsiveness, etc.)?*

2) *What are other factors that may influence responses using these methods?*

3) *How do these QoL measurement methods relate to traditional outcome measures (e.g., visual acuity, contrast, etc.)?*

In performing this assessment related to AMD and health-related quality of life, we chose to focus on those methods and instruments that have been used in AMD populations. Thus, the instruments considered under Question 1b are a subset of the instruments considered under Question 1a, not vice versa. In other words, while there are many instruments that have been used for eye diseases other than AMD, if they have not also been used for AMD they were not included in this report. Conversely, for those instruments that have been used in patients with AMD, applications to patients with other types of eye disease were also of interest. Accordingly, our search and inclusion strategies (described below) were first focused toward attempting to find and include all articles pertaining to patients with AMD, and then in finding applications of these instruments outside of AMD. In the following section, we describe the general methods of this assessment.

2. Methods

2.1 Overview

The methodological approach to this review was designed to support the Medicare Coverage Advisory Committee (MCAC) deliberations regarding whether specific health-related QoL methods or instruments provide meaningful information about outcomes in individuals with AMD and similar disorders, and the degree to which these instruments are scientifically credible (e.g., have good psychometric properties, including convergent validity when compared to objective visual assessments.) The goal was to provide the most direct responses possible to the key questions listed above. In particular, we sought to highlight literature that would be of greatest value for the purpose at hand, focusing on articles and studies that describe instruments used in sizable populations with well-characterized AMD (and related eye diseases that affect central vision).

2.2 Search Strategy

We searched MEDLINE from 1966 to September 2005 using a search strategy (detailed in Appendix A) that combined the two concepts "age-related macular degeneration" and "quality of life." The objective was to identify all studies that provided primary data regarding health-related quality of life among individuals with AMD and related conditions. For purposes of this review, related conditions included eye disorders that could lead to central visual loss, specifically diabetic macular edema, macular hole, cataracts, keratoconus, and corneal scarring. Diseases known to primarily affect vision other than central vision, such as glaucoma (with its impact being primarily visual field loss until late in the disease) were excluded from the primary analyses.

To identify the disease concept, we also used MeSH headings “macular degeneration,” “retinal degeneration,” “retinal diseases,” and “vision disorders (exploded).” We also used text word searching for the text string “vis$ adjacent to funct$”; this is designed to detect various spellings such as “visual function” or “visual functioning.” Finally, the two concepts were combined (Boolean “and”). The strategy was limited to articles published in the English language.

Additionally, we searched for reports by authors known to publish in this area, as well as articles uncovered by reviewing the bibliographies of review articles discovered in our search and studies that satisfied inclusion criteria. We also supplemented the search by performing additional literature searches with the names of the specific instruments e.g., “name of specific instrument” AND “vision” and “name of specific instrument” AND “eye” once they had been identified as having been used in AMD. Once the set of included instruments was finalized, we used similar methods to search for all applications of these instruments to patients with eye disease.

2.3 Inclusion Criteria

Articles were included if the study population had the diagnosis of AMD, were 18 years of age and older, and the sample included 10 or more subjects. In addition, we included articles regarding instruments or methods that were used in study subjects with other eye disorders where the instrument had also been used in some included study of AMD patients. For studies of psychometric properties, we included any study that assessed reliability (internal consistency, test-retest), validity (content, construct, concurrent, and discriminant), or responsiveness.

2.4 Abstraction

Articles were abstracted directly into evidence tables (Appendix B). The elements included in the abstraction were as follows:

Identifying information:

- First author (last name, first initial)
- ProCite number

Study characteristics:

- Country
- Year
- Context (e.g. clinical trial, cohort, cross-sectional study)
- Inclusion/exclusion criteria

Subject characteristics:

- Number of subjects
- Age
- AMD %
- AMD type (% wet/% dry)
- Laterality (unilateral/bilateral)
- Other eye disease %
- Objective measure(s) of function, (e.g., visual acuity)

Instrument characteristics:

- Instrument name
- How administered
- By whom (masked/unmasked)
- Mode of administration (phone, face-to-face, mail in, in office, observation)
- Respondent (patient only, patient or surrogate, surrogate only)
- Time points of administration (pre-/post-surgery)

Quality characteristics (see Appendix C for quality criteria);

- Meaningfully defined study population
- Protection from bias
- Consideration of statistical power

2.5 Summarizing Results

We approached the summarization of the literature by key questions:

- Question 1a: Results are listed by instrument for AMD and related patients.
- Question 1b: Same as Question 1a, but for non-AMD patients, using instruments and methods used in Question 1a.
- Question 1c: Psychometric properties (validity [content, construct, concurrent, discriminant], reliability [internal consistency, test-retest], and responsiveness).
- Question 2: Factors identified as affecting scores on instruments or methods measuring the impact of AMD on patients.

- Question 3: Relationship between QoL measure(s) and objective measure(s).

Note that for the sake of completeness, we also examined studies of direct utility measures. Since these policy-relevant measures are distinct from QoL measures, they are summarized under a separate heading within Section 3 ("Results").

2.6 Quality Criteria

In the absence of an established quality measure for health-related QoL instruments (other than the standard psychometric property criteria noted above), we assessed three characteristics deemed important in such studies (see Appendix C). First, we considered whether the study population was defined in a clinically meaningful way. To assess this, we noted whether the study quantified characteristics that were crucial to the interpretation of study results (e.g., the proportion of patients with AMD, and type of AMD [at least wet vs. dry, since the visual status and prognosis are significantly divergent between these two clinical forms]). Second, we assessed whether the study made an explicit effort to protect from bias. Here we focused on whether the individual responsible for the assessment was identified and had a stake in the result (e.g., the surgeon or assistant). Third, we noted if statistical power or sample size was specified as it related to analyses of interest. As an approximate rule of thumb, analyses with fewer than 100 subjects tend to have less ability to detect small(er) differences, analyses with 100 to 400 subjects tend to have a greater ability to do so, and analyses with more than 400 subjects tend to have the ability to find significance with small differences. As with other inquiries, the power and associated sample size issues should reflect the endpoint of interest, whether this is treatment effect as measured by visual acuity or by responses to a vision-related QoL instrument. Related

statistical issues arise when the variance in responses to a measure is greater or less than the variance in responses to other measures.

3. Results

3.1 QoL Instruments and AMD

Question 1a: What QoL measurement methods have been used in the AMD population and in those with visual disabilities from AMD?

The use of health-related QoL measures for the evaluation of AMD is a relatively recent concept, starting within the last 20 years. Vision-related, health-related quality of life can be conceptualized in various ways, primary among these being (a) observed task performance; (b) general health-related QoL measures applied, with or without modification, to patients with vision loss; and (c) vision-specific measures, including vision-specific measures of visual performance and vision-specific measures of health-related quality of life. Each of these can be contrasted with conventional clinical measures of visual performance, for example, provider-involved tests such as visual acuity or contrast sensitivity.

3.1.1 Observed Task Performance Measures

Relatively few studies have assessed objective task performance as a means of gauging the limitations of patients with AMD. Accordingly, discussion of this approach will be limited to the current section.

The SEE project is the largest population-based study among elders in the United States where participants were observed performing essential tasks such as face recognition, use of keys, mobility and obstacle avoidance, and reading, as well as being asked about their functioning through the administration of both general and vision-specific QoL instruments. Participants also received comprehensive assessments of their visual performance with conventional measures (provider-directed) such as visual acuity, contrast sensitivity, and visual fields.[15] *The project has not yet published data specific to patients with AMD, but those with AMD were included in the study sample*. The project has already generated several key findings: 1) in-office observation of task performance by elders closely parallels actual at-home task performance;[16] 2) observed task performance in reading correlates with self-reported difficulty in reading, but with significant variability from patient to patient;[17] and 3) in-office conventional examination measures and patient self-report of visual activities and functions provide complementary data.[14]

Several smaller studies (almost exclusively case series) have examined specific tasks, particularly reading and mobility.[18-20] These studies indicate that the size, severity, and location of the central vision loss ("scotoma") caused by advanced AMD play a particularly important role in modulating the impact of AMD on patient functioning. Studies that utilize direct observation of measured performance require greater levels of effort and participation on the part of both patients and observers (researchers or patient care providers), as well as the availability of standardized testing environments and equipment. Because of these issues, direct observation may not be practical in assessing functioning in ordinary clinical care or in standardized, large

sample-size studies. However, those patients who receive home visit assessments for safety and other visiting nurse services may be appropriate candidates for such measures.

3.1.2 General Health-Related QoL Measures

Rather than focus on observed task performance, researchers have typically measured visual functioning and health-related quality of life using questionnaires. Several studies have assessed the ability of global or general health-related QoL instruments such as the SF-36 and its variants (the SF-12 and the Medical Outcomes Study 20-Item Short Form [MOS-20]) to detect the impact of having AMD, worsening of AMD and visual performance, and the relative impact of treatment regimens to alter the natural history of AMD as measured by physiological parameters or conventional visual performance. Such global instruments detect physical, mental, and social impact across the spectrum of systemic and disease processes. It has been hypothesized that global measures may not be sensitive to detect subtle vision changes or treatment of eye conditions, as noted with cataracts,[12] and, indeed, the psychometric data support this conclusion[21-27] (see response to Question 1c), in particular regarding convergent validity with objective measures.[21-26,28-30] MEDLINE searches with "amd" or "armd" and the Quality of Well-Being Scale (QWB), EuroQol, and General Health Questionnaire (GHQ) separately did not uncover any published papers. A similar search with "amd" and the SIP revealed one paper.[31] For the present purposes, the modification of the SIP pertaining to patients with visual deficits is considered to be a global rather than a vision-specific measure.

Overall, because the vision-specific measures appear to have better performance relative to clinical features of AMD of importance to patients when compared to general QoL measures, the primary focus of our efforts will be on vision-specific approaches.

3.1.3 Vision-Specific Measures

During the last 15 years, a myriad of vision-specific instruments have been developed, both for specific eye diseases and for a spectrum of eye diseases. Some of these instruments assess visual function and visual abilities in the context of daily activities, and are termed patient-based measures of visual function. Other instruments assess patient reactions and concerns relative to their eye diseases, and are termed vision-related or vision-specific QoL measures.

Some of the instruments originally developed for cataract and cataract surgery assessment have subsequently been used in other eye diseases, including AMD. Two instruments, the National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) and the Vision Quality of Life Core Measure (VCM1), were expressly designed to be usable across major eye conditions of interest (cataract, glaucoma, macular degeneration, and diabetic retinopathy in the case of the NEI-VFQ), with additional questions for specific diseases in the NEI-VFQ ("additional module questions"). Others have recently been developed specifically for AMD. In a literature search of QoL instruments applied in the evaluation of AMD disease burden or effects of therapy, we found five such instruments, discussed below: 1) the Visual Function Index (VF-14); 2) the NEI-VFQ; 3) the Activities of Daily Vision Scale (ADVS); 4) the VCM1; and 5) the Daily Living Tasks Dependent on Vision (DLTV). Appendix D contains copies of these instruments, and Table 1 summarizes their content and administration features.

Table 1: Content and administration features of QoL instruments used with AMD patients

CONTENT	ADVS	DLTV	NEI-VFQ-25	VF-14	VCM1
How would you evaluate your general health?			√		
How would you evaluate your general vision?	√	√	√		
Do you experience any ocular pain?			√		
Do you have trouble seeing in dim light or at night?	√				
Can you see objects off to the side?		√	√		
Can you see moving objects at night?	√				
Are you confident using public transportation?	√				
Are you confident walking around your own neighborhood?		√			
Are you confident walking around an unfamiliar area?		√			
Do you have difficulty driving?			√	√	
Do you have difficulty driving in daytime?	√		√	√	
Do you have difficulty driving at night?	√		√	√	
Do you have difficulty driving in busy conditions?			√		
Do you have difficulty driving in unfamiliar areas?	√				
Do oncoming headlights bother you?	√				
Can you see things in the distance?	√	√	√	√	
Can you enjoy the scenery while traveling?		√			
Can you read signs across the street?		√	√	√	
Can you read signs during bright daylight?	√				
Can you read signs at night or in dim light?	√				
Can you read correspondence?		√			
Can you read food can labels?	√			√	
Can you read large-print materials?				√	
Can you read medicine bottle labels?	√	√		√	
Can you read the newspaper?	√	√		√	
Can you see television?		√	√	√	
Can you read the writing on television?	√				
Do you have difficulty walking downstairs?		√		√	
Do you have difficulty walking downstairs in bright daylight?	√				
Do you have difficulty walking downstairs in dim light or at night?	√		√		
Can you see the numbers on a phone?					
Can you see things that are close to you?	√	√	√	√	
Can you identify money in your wallet?		√			
Can see to pay bills accurately?			√		
Can you see to write checks?	√	√		√	
Can you tend to your own personal hygiene needs?		√	√		
Can you cut the food on your own plate?		√			
Do you have trouble finding Items on a crowded shelf?			√		
Can you pick out and match your own clothes?			√		
Can you pour yourself a drink?		√			
Can you prepare meals?	√	√	√	√	

CONTENT	ADVS	DLTV	NEI-VFQ-25	VF-14	VCM1
Can you thread a needle?	√				
Can you use a ruler/tape measure?	√				
Do you have difficulty using a screwdriver?	√				
Do you have difficulty doing fine handwork?			√	√	
Are you able to enjoy gardening?		√			
Can you see to play cards/games?	√			√	
Can you see to play sports?			√	√	
Can you recognize colors?			√		
Can you recognize faces?	√	√	√	√	
Can you see movies/sports events?			√		
Life Interference					√
Safety outside the home					√
Anger					√
Depression					√
Coping with everyday life					√
Inability to do preferred activities					√
Fear of deterioration in vision					√
Safety at home					√
Embarrassment					√
Loneliness					√
ADMINISTRATION					
Time to complete instrument			10 min. avg.		30-90 min.
Mode of administration:					
Phone interview	√		√	√	
Face-to-face interview	√	√	√	√	√
Mail questionnaire					
In-office questionnaire		√	√	√	√
Observation					
Scoring	See Note 1	See Note 2	See Note 3	See Note 4	See Note 5

Note 1: Items were examined with multiple (usually three) questions per item: the first to assess whether patient engages in the activity (if "not applicable" the answer was treated as missing data), the second to establish "no difficulty" (5) to "extreme difficulty" (2), and the third to ask whether the patient is unable to perform the activity because of poor vision (if not, it is missing data; if so, then the most disabled score [1] is assigned). For this study, all questions were equally weighted and scored in Likert fashion.

Note 2: A core of 22 individual items each with a 4-point ordinal response scale. In addition to questions relating to specific tasks, patients were asked to describe their degree of confidence in performing certain of the tasks. Four further questions were posed, asking patients to rate their general health status on a scale of 1 to 10. They were also asked to rate their overall distance vision, to rate their overall near vision, and to state agreement or disagreement with the statement, "I have to be more careful because of my eye condition."

Note 3: Patient is asked to answer with range from "no difficulty at all" (1) to "stopped doing this because of eyesight" (5) or "because of other reasons" (6). There are two steps to scoring: original numeric values are re-coded according to a table (high scores represent better functioning). Each item is then converted to a 0 to 100 scale so that the lowest and highest possible scored are set at 0 and 100 points. In this format, scores represent the achieved percentage of the total possible score. Then items within each sub-scale are averaged together to create the 12 sub-

scale scores (instructions are in a table to assign which items contribute to a specific sub-scale). Missing data items are not taken into account when calculating the scale scores. Scores represent the average for all items in the sub-scale that the respondent answered.

Note 4: Patient is asked "do you have any difficulty, even with glasses" for each question. "Not applicable" is scored as missing data, "no" receives 4 points to "yes, and am unable to do the activity" receiving 0 points. For the driving portion of the instrument, scores are "no difficulty" (4) to "great deal of difficulty (1). Items are not included for scoring if person does not do the activity for some reason other than vision. Scores on all activities performed or not performed because of vision are then averaged (resulting value 0 to 4), and that value is multiplied by 25, giving a final score from 0 to 100.

Note 5: Patients were asked two forms of questions: "How much has your eyesight interfered with . . . ?" was scored from "not at all" (0) to "can't do because of eyesight" (5), with an additional score for "don't do for other reasons" (8). Another question "In the past month, how often have you . . . because of eyesight?" was scored from "not at all" (0) to "a lot of the time" (5). All items were, accordingly, scored on a 0-5 scale (with responses of not applicable treated as missing). It is recommended that results be presented at the level of the item or at the overall scale, but not the subscale. Presumably, the overall scale score is obtained by multiplying the number of non-missing items by 10, although this is not explicitly stated.

3.2 QoL Instruments and Non-AMD Eye Diseases

Question 1b: Have these QoL measuring methods been used across other eye disease populations?

The SF-36 and its variants (the MOS-20 and SF-12) have been used across a variety of eye conditions as well as in several large studies of defined clinical populations, such as the Medical Outcomes Study and several NEI trials, and in population-based studies such as the Beaver Dam Health Outcomes Study.[12,32-37] The QWB has also been used to assess impacts on patients and individuals with cataract surgery[38] and in the Beaver Dam Health Outcomes Study.[39] Literature searches targeting each of the other common global health-related QoL instruments – the SIP, EuroQol, and GHQ – with "vision" or "eye" revealed that no papers were published with the GHQ, five with the EuroQol (cataract surgery, diabetes eye disease, cytomegalovirus retinitis, and thyroid eye disease), and nine with the SIP (glaucoma, cataract surgery, and thyroid eye disease). In each study, the global measure was weakly, if at all, related to the presence of an eye disease and to changes in visual status. Interventions, particularly cataract surgery, were

often associated with significant changes, but generally in the form of amelioration of declines in global functioning that would otherwise occur.[12]

The NEI-VFQ, ADVS, and the VF-14 have been utilized across other eye diseases that affect central vision (Table 2). The NEI-VFQ has been used more generally, as it was specifically designed as an instrument for evaluation of many eye diseases and patterns of vision loss.[40] These instruments have generally been shown to vary significantly and appropriately in their scores relative to the severity of the eye condition in question, as measured by conventional measures which serve as proxies for functioning (e.g., visual acuity in cataracts) or by physiological measures of disease severity. Other diseases for which some version of the NEI-VFQ has been found responsive include glaucoma and its treatment, corneal diseases and surgery, diabetes and diabetes eye disease, retinitis pigmentosa, vascular occlusions in the retina, dry eyes, low vision services, optic neuritis, and several population-based studies and clinical trials.

The VF-14 and ADVS were independently developed but share significant overlap of items, since each was designed for cataract evaluation for surgery. Therefore, they have been used more commonly in conditions that affect central vision, but have also been used in other diseases such as glaucoma. The ADVS has been used to assess not only cataract surgery and glaucoma but also giant cell arteritis (unable to differentiate those with and without visual loss).[41]

The VF-14 has been commonly used and is a popular instrument given its brevity and ease of administration, as well as its desirable psychometric properties. It has been tested and validated

in patients with retinal disease including diabetic retinopathy. [42] It has also been validated in glaucoma, corneal transplants and keratoconus, dry eye patients, and those with nystagmus, low vision, after retinal detachment surgery.

The DLTV is a relatively newer instrument designed for AMD. As such, there have been no publications with the DLTV outside of the five papers assessing its performance in patients with AMD.

Table 2: QoL instruments used in AMD patients and in other eye disease patient populations

Instrument	Cataract	Other macular diseases	Corneal diseases
ADVS	Mangione[12]1994 Mangione[43]1995 Pesudovs[44] 1998 Superstein[45] 1999 McGwin[46] 2003 Pesudovs[47] 2003	None	None
NEI-VFQ	None	Tranos[48]2004 Tranos[35]2004 SSTRG[49]2005	Kymes[50] 2004 Fink[51] 2005
VCM1	Tinley[52] 2003	None	None
DLTV	None	None	None
VF-14	Steinberg[53] 1994 Steinberg[54] 1994 Damiano[13] 1995 Schein[55] 1995 Cassard[56] 1995 Desai[57] 1996 Alonso[58] 1997 Espallargues[59] 1998 Norregaard[60] 1998 Castells[61] 1999 Crabtree[62] 1999 Rose[63] 1999 Brydon[64] 2000 Lum[65] 2000 Lee[32] 2000 Lee[33] 2003 Norregaard[66] 2003 Mozaffarieh[67] 2004 Goyal[68] 2004 Aralikatti[69] 2004 Rosen[38] 2005 Mozaffarieh[70] 2005 Valderas[71] 2005 Lee[72] 2005	Linder[42] 1999	None

3.3 QoL Instruments and Psychometric Properties

Question 1c: What are the psychometric properties of these methods (e.g., reliability, validity, responsiveness, etc.)?

As noted previously, the impact of visual impairment potentially can be measured via patient-reported responses on instruments that are designed to capture visual functioning and the ability to complete vision-related tasks vision-related quality of life, as well as health status and quality of life in general. Psychometric properties of general health-related QoL measures such as the SF-36 and QWB are covered in considerable detail in other publications and are not included in this report, particularly since they have little if any relationship to the presence of eye diseases and changes in visual status associated with disease progression (see Section 3.1.2, "General Health-Related QoL Measures"). Similarly, the "vision-related" version of the SIP is not considered here, as this can primarily be considered to be a general QoL instrument. However, vision-specific QoL measures have consistently shown evidence of associations with AMD (and other eye diseases) and differences in visual status reflected in conventional measures of visual performance or physiological disease status. In addition, in studies of eye conditions they have demonstrated better discriminant validity and responsiveness than general QoL measures; for example, they were more responsive to efficacious interventions, such as cataract surgery, and better at distinguishing between the quality of life of groups with different degrees of visual impairment.[43] Details of the psychometric property studies are provided in the evidence tables (Appendix B).

The review article by Margolis and colleagues[73] provides an excellent overview of various methodological issues in the assessment of the psychometric properties of the instruments under consideration, and is particularly recommended. The review article by de Boer and colleagues[74] provides similar information. The principal characteristics examined for the five vision-specific QoL instruments used in patients with AMD include the following:

Reliability is the consistency with which an instrument measures a given property or behavior. Reliability includes internal consistency, reproducibility, and consistency of scaling.

Internal consistency is the extent to which all items measure the same construct. It is primarily assessed using Cronbach's alpha, and is secondarily assessed using item-total correlation coefficients, as well as an assessment of floor and ceiling effects. For the VF-14, internal consistency was also assessed using the number of items that patients rated as applicable to their situation. During the preliminary development of a scale (often the item reduction phase), internal consistency may also be assessed using factor analysis.

Reproducibility refers to the degree to which scores remain the same over time when the patient's true health status is unchanged. Reproducibility (also called test-retest reliability) is usually measured using an interclass correlation coefficient (ICC). Ideally, the assumption that the patient's true health status is unchanged will have been verified by direct observation or interview.

Consistency of scaling refers to the degree to which x-unit differences in one part of the scale have a meaning similar to x-unit differences in another part of the scale (e.g.,

whether a difference between scores of 3 and 5 has the same substantive interpretation as a difference between scores of 40 and 42). Scaling consistency is often measured using techniques of Rasch analysis and item response theory. Note that scaling consistency could reasonably be categorized separately.

Validity is the extent to which an instrument measures what it purports to measure. It can be expressed in several ways.

Content validity is the degree to which an instrument measures what it purports to assess – in this case, what is important to patients, clinicians, and other interested parties. The assessment of content validity is qualitative, in large part depending upon the quality of the processes used during instrument development. We comment on content validity only for instruments that have demonstrated good psychometric properties otherwise.

Construct validity evaluates how well a measure correlates with other indicators of similar and related constructs. In this application, such constructs often include objective measures of visual function, general health measures, and self-reported global items about quality of vision, satisfaction with vision, and the like. Construct validity can be further subdivided into convergent validity and discriminant validity, the former assessing the degree to which an instrument correlates with other measures of the same or similar constructs, and the latter assessing the degree to which the measure can discriminate between cases and controls, disease severity groups, or other groups that are expected to have different levels of vision-related quality of life. Construct validity is

typically measured by considering correlations and patterns between group means. The magnitude of differences between group means is sometimes quantified using effect sizes.

Responsiveness refers to the extent that an instrument can detect change in patients that are known to have a change in their underlying state of interest – in this case, their visual functioning and vision-related abilities or limitations to pursue or enjoy activities that cam be affected in some way by their vision. Responsiveness is usually assessed by comparing mean scores before and after an intervention (ideally, using difference scores calculated within a subject). The magnitude of differences between group means is sometimes quantified using effect sizes, particularly where scale scores are arranged on a numeric scale.

The above psychometric properties have been summarized in evidence tables for this report (Appendix B). Those instruments that have demonstrated particularly good psychometric properties in an extensive validation are also discussed in a more detailed summary below. Where instruments have been developed in both English and non-English versions our emphasis is on the version in English. The impact of different languages and the cultural milieu are discussed below in reference to Question 2 (Section 3.4).

Where substantial efforts at instrument validation have been applied to patients with AMD, we focus on these efforts. Where relatively fewer validation efforts specific to patients with AMD are available, our focus extends beyond AMD to include other vision-related conditions. Note

that studies in which quality of life is compared with measures of visual loss are discussed under Question 3.

It is important to recognize that there is no consensus on benchmarks for strength of conformance with psychometric criteria. Accordingly, adjectives corresponding to these criteria are qualitative. The work of Lamping et al.[75] provides an example of a typical set of benchmarks.

3.3.1 VF-14

The VF-14 was originally developed by Steinberg et al.[53] as an index of visual function in patients undergoing cataract surgery. Briefly, respondents are first asked whether they have any difficulty with various vision-related tasks (e.g., reading, even with glasses, a newspaper or a book). A category of "not applicable" is included. If the answer to the lead-in question is affirmative, the level of difficulty is placed on a 4-point scale (1 = a little, 2 = a moderate amount, 3 = a great deal, 4 = unable to perform activity). Scores for applicable items are averaged, then inflated to a 0 to 100 scale. Initial development included patient interviews. Most validation has taken place within the context of cataract surgery, but studies by Linder[42] and others included patients with AMD.

Internal consistency: Cronbach's alpha was high in the two studies pertaining to AMD; for example, 0.91 in Linder.[42] These figures were representative of the other studies and within the benchmarks typically recommended for an excellent instrument.

The remaining data on internal consistency pertains to patients undergoing cataract surgery. Item-total correlations were relatively modest, ranging from approximately 0.3 to 0.7, and were below benchmarks. Alonso[58] found that few patients believed all 14 items to be relevant, although Steinberg[53] found the median number of relevant items to be 12. Accordingly, most patients found most items to be relevant, which is probably all that is reasonably required. A factor analysis by Steinberg supported the notion that the 14 items comprise a single scale.

Reproducibility: There is no information available regarding reproducibility for English versions of the instrument. In a small study using the French version of the instrument,[76] the ICC was an encouragingly high value of 0.88.

Scaling consistency: Application of Rasch analysis to the VF-14 demonstrates reasonable interval scaling, though the scale as a whole may be able to be shortened to provide even greater efficiency in capturing data relative to cataract surgery.[77] Overall, these results support the conclusion that the instrument is internally consistent.

Construct validity: The evidence in favor of construct validity was consistent. Correlations with self-reported global items (trouble with vision, satisfaction with vision, quality of vision) were moderately strong (usually in the range of 0.4 to 0.6), and were higher than similar correlations between generic instruments and these same global items. There was a strong relationship between AMD severity and VF-14 total score.[22]

Responsiveness: The instrument is responsive to an intervention whose effectiveness is on the order of magnitude of cataract surgery. Alonso's estimate of an effect size of approximately 1 is representative.[58] No information about responsiveness is available from patients with AMD.

Overall: Among patients undergoing cataract surgery, although the item-total correlations for the scale were only moderate, the content validity and responsiveness of the instrument was solid, and thus the overall evidence for the validity of the VF-14 is strong. The evidence for the validity of the VF-14 in patients with AMD is less strong due to the limited number of studies in AMD with this instrument, although the consistency of the cross-sectional results provided by Linder[42] and MacKenzie[22] (which included AMD patients) and the cross-sectional validation results in patients undergoing cataract surgery is encouraging. It has not yet been demonstrated that the VF-14 is responsive to changes that would be attributable to AMD-specific interventions, particularly after adjustment for visual acuity.

This summary was based on evidence tables for those studies that included patients with AMD, namely Linder,[42] Sharma,[78] Riusala,[79] Armbrecht,[80]and Mackenzie;[22] evidence tables for two large studies in patients undergoing cataract surgery, namely Alonso[58] and Steinberg;[53] and various smaller studies in patients undergoing cataract surgery that provided substantively similar conclusions, namely Velozo,[77] Javitt,[81] Cassard,[56] Tielsch,[82] Desai,[57] Armbrecht,[83] Castells,[61] Nijkamp,[84] and Gresset.[76]

3.3.2 NEI-VFQ

A list of the items included in the NEI-VFQ is provided by Mangione and colleagues,[85] who give this description: "This measure includes multi-item scales to rate overall health on a 5-level scale that ranges from excellent to blind; multi-item scales that assess difficulty with near vision activities, difficulty with distance vision activities, limitations in social functioning due to vision, role limitations due to vision, dependency on others due to vision, mental health symptoms due to vision, future expectations for vision, driving difficulties, and pain and discomfort in or around the eyes; and single items to assess limitations with peripheral vision and color vision." Items were developed from patient focus groups representing a diverse set of visual conditions,[86] the intention being to develop a scale that can be generalized to all patients with vision deficits, regardless of cause. (Indeed, subgroup analyses performed during the validation of the initial NEI-VFQ-51 that presented the data by cause of visual deficit supported the conclusion that the scale could, in fact, be generalized in this way.) The content validity of this instrument is high.

The NEI-VFQ is noteworthy in that it has been validated in populations of patients with a diverse set of eye diseases. The initial validation was performed on a 51-item version of the form (NEI-VFQ-51). It should be noted that even in this long version most subscales have few items, which will tend to degrade measures such as Cronbach's alpha (which increases with the number of increasing items.) In any event, the largest validation study for the NEI-VFQ-51 had 583 patients. Attention then shifted to creating shorter versions of the instrument. The 39-item version of the form had a validation study with over 4,000 patients, and the 37-item version can be considered to be functionally equivalent to the version with 39 items (2 items were dropped, and the other 37 items retained as is). One of the studies of the 37-item version of the form

noted that subscale scores for the NEI-VFQ-25 were similar to those of the NEI-VFQ-37, and concluded that the 25-item version of the instrument was likely to exhibit similar performance in practice. The 25-item version of the instrument has been used in several large validation studies, for example, with sample sizes 4,119; 1,052; and 859.

It appears that, in practice, the version of the instrument that is most likely to be used is the NEI-VFQ-25. Accordingly, the following summary focuses on the 25-item version of the instrument. The psychometric properties of the 51-, 39-, 37- and 25-item versions of the instrument appear similar.

Internal consistency: Cronbach's alpha coefficients ranged from 0.47[87] to 0.81 when calculated at the level of the subscale, but were high (e.g., 0.92) when calculated for the total 25-item scale. Although certain subscales exhibit floor and ceiling effects, the overall score does not.

Reproducibility: Reproducibility was reasonable, with test-retest ICCs ranging from 0.68 to 0.91.[85] Lowest performance was for the driving scales, perhaps reflective of the diverse nature of the older population in driving, the difficulties of attribution of limitations in driving in this population, and the impact of other comorbid ocular or systemic diseases on driving.

Scaling consistency: Rasch analysis in patients with low vision administered the NEI-VFQ demonstrated that those items that deal with difficulty in performing tasks scale with good intervals between and among responses. However, as might be expected, those items that refer

to frequency or level of agreement with a statement (typically patient perceptions) did not scale with intervals.[88]

Construct validity: The evidence in favor of construct validity, such as Clemons,[89] was consistently strong. For example, high correlations were reported with visual function, the instrument successfully classified patients according to disease severity, and the pattern of correlations among the subscales was as anticipated.

Responsiveness: Although perhaps not as extensive as the evidence in favor of construct validity, the evidence in favor of responsiveness was solid. Scale scores tended to improve with intervention, and greater improvement in visual function was associated with greater improvement in the NEI-VFQ. While not responsive in every study, several studies demonstrated differences in NEI-VFQ scores even after adjustment for visual acuity. Further, across the range of developmental conditions (cataract, glaucoma, AMD, and diabetic retinopathy), as well as other conditions as diverse as corneal diseases and vascular occlusions of the retina, NEI-VFQ scores vary in the expected direction with differences in visual performance and disease state.

Overall: This scale exhibits excellent validity across a wide variety of patient groups, including those with AMD. The 25-item version of the scale performs similarly to longer versions. The reader is referred to the evidence tables (Appendix B) for additional details for studies including those by Massof,[88] Mangione,[85] Tranos,[48] Clemons,[89] Berdeaux,[90] Miskala,[91] Miskala,[92]

Miskala[25] Lindblad,[6] CAPT, [87] Mangione,[40] Brody,[93] Cahill,[29] Cahill,[28] Scilley,[94] Childs,[24] Dong,[23]and Tranos.[35]

3.3.3 ADVS

Internal consistency: One small study[95] reported evidence of the presence of strong ceiling effects. Otherwise, little information is available regarding the internal consistency of this scale.

Reproducibility: No information is available about the reproducibility of this scale.

Scaling consistency: Rasch analysis indicated that many of the items did not scale at equal intervals for cataract evaluation and cataract surgery.[47]

Construct validity: One large study[96] provided some evidence of construct validity, and in another smaller study,[97] both the ADVS subscales and overall scale correlated with scotopic sensitivity. However, the ADVS did not correlate highly with stage of AMD severity after correction for visual acuity.[86]

Responsiveness: Patients with cataract demonstrated good reliability and responsiveness of the ADVS pre- and post-cataract surgery.[86]

Overall: Although potentially promising, the ADVS has not been submitted to as extensive a validation as either the VF-14 or the NEI-VFQ. Further, unlike the VF-14 and NEI-VFQ, Rasch analysis has demonstrated areas of unequal scaling.

3.3.4 VCM1

This 10-item instrument is targeted toward vision-related patient perception of quality of life, the items including embarrassment, anger, depression, loneliness, fear of deterioration in vision, safety at home, safety outside the home, coping with everyday life, inability to do preferred activities, and life-interference, as related to patients' visual status. Initial development of the instrument was based on interviews with patients and providers,[98] and the content validity is good.

Internal consistency: The 10 items appear to load onto a single scale, with good internal consistency (Cronbach's alpha 0.93, item-total correlations 0.65 to 0.79).

Reproducibility: Reproducibility is good, with an ICC of 0.90.

Scaling consistency: No information is available regarding scaling consistency.

Construct validity: In a large study VCM1 scores were correlated with age and social class, and in a smaller study VCM1 scores were highly correlated with the VF-14 and moderately correlated with objective measures of visual function.

Responsiveness: Except perhaps for the results of a single trial that reports change between baseline and 12 months, but does not relate this change to other measures of vision,[26] no information is available regarding responsiveness.

Overall: Validation efforts to date, although not as extensive as those for the VF-14 or NEI-VFQ, have produced promising results regarding internal consistency, reproducibility, and construct validity. No information is available regarding scaling or responsiveness.

3.3.5 DLTV

The DLTV was developed specifically for patients with AMD, began with patient focus groups, and has reasonable content validity. The complete 24-item instrument is provided by Hart.[99] Most items, all of which have four response categories, pertain to difficulty with tasks, two items pertain to confidence, and items are general.

Internal consistency: Factor analysis supports the distribution of items into subscales, and Cronbach's alphas for the dimensions range from 0.66 to 0.96. The internal consistency is reasonable to good.

Reproducibility: No data are available regarding reproducibility.

Scaling consistency: No data are available regarding scaling consistency.

Construct validity: Although not comprehensive, the information to date (mostly correlations with objective measures of visual acuity) supports the construct validity of the scale.

Responsiveness: No information is available regarding responsiveness.

Overall: Validation efforts to date, although not as extensive as those for the VF-14 or NEI-VFQ, have produced promising results regarding internal consistency and construct validity. Future investigation may be helpful in determining the level of usefulness of the DLTV. No information is available regarding reproducibility, scaling consistency, or responsiveness.

3.3.6 Summary

The psychometric properties of the vision-specific instruments described above are summarized in Table 3.

Table 3: Summary of psychometric properties for vision-specific instruments (details in evidence tables in Appendix B)

Property	VF-14[22,42,53,56-58,61,76-84]	NEI-VFQ[6,23-25,28,29,35,40,48,85,87-94]	ADVS[47,86,95-97]	VCM1[26,98]	DLTV[27,99-102]
Internal consistency	++	+/++	0	+/++	+/++
Reproducibility	0	+	NA	+	NA
Scaling consistency	+/0	+/0	+/0	NA	+/0
Construct validity	++	++	+	+	+
Responsiveness	+	+	+	NA	NA

NA = psychometric property was not assessed; 0 = assessed but little or no evidence in favor of this psychometric property; + = moderate evidence in favor of this psychometric property; ++ = strong evidence in favor of this psychometric property

3.4 QoL Instruments and Other Factors

Question 2: What are other factors that may influence responses using these methods?

When patients are asked to report their functioning, several factors can potentially influence how they respond other than their visual status alone. There are several studies that specifically address factors that influence responses on vision-specific QoL questionnaires in AMD patients.

These factors can center on the patient and their reactions to their disease, the presence of co-morbid systemic diseases and conditions, and the methods of measurement themselves.

First, patients may suffer significant emotional distress, depression, or fear upon an initial diagnosis of an eye disease, such that those factors color their reported perceptions of their abilities to function. Williams et al. examined this question in AMD patients with legal blindness in at least one eye using global health-related QoL measures along with the Profile of Mood States.[30] They correlated a shorter period of perceived vision loss with increased likelihood to report high levels of emotional distress and lower quality of life. Furthermore, those who were blind in one eye were even more significantly distressed than those who were blind in both eyes, as they feared vision loss in their unaffected eye. Thus, this study established both a time component from the time of diagnosis and a significant effect of mental and emotional states on QoL scores. This is reinforced by other studies establishing a significant incidence of depression in patients with AMD.[103] The same phenomenon is present in patients upon initial diagnosis in other diseases, such as glaucoma.[104] Because of this, and for simplicity and reliability, almost all developmental papers for vision-specific QoL instruments such as the NEI-VFQ include only those patients who have a stable disease state and were diagnosed for at least 3 to 4 months to maximize reliability and stability of responses.

Second, Owsley and McGwin[105] demonstrated that older persons who are depressed may have reduced scores on the NEI-VFQ-25 independent of the impact of vision problems. Similar findings were reported by Lee et al. in analyses of the SF-36 results from younger cohorts in the Medical Outcomes Study relative to visual symptoms and difficulty seeing, even inclusive of

other medical and systemic symptoms.[5] Thus, not only may AMD cause depression, but those who are depressed may score lower on the NEI-VFQ summary scores and on scores for distance vision, peripheral vision, vision-specific role difficulties, vision-specific dependency, and vision-specific mental health.[105] Of note, however, depression due to AMD can be ameliorated over 6 months by a self-management treatment strategy, but only for those who were initially depressed and not for those without depression, such that NEI-VFQ scores can rise in that subgroup with initial depression.[93] Patients who are informed of a serious illness or condition often become depressed for various time intervals, as exemplified by Kubler-Ross's five stages of grief.

Third, Miskala et al. hypothesized that a vision-specific instrument would be influenced by general health.[91,106] They examined the responses of 120 patients with advanced AMD in at least one eye to the NEI-VFQ and the SF-36. They correlated large decreases in the physical and/or mental components of the SF-36 with more modest decreases in the NEI-VFQ. Therefore, the authors recommended adjustment for general health when comparing NEI-VFQ scores across patient groups, suggesting that the SF-36 scores could act as such an adjustment factor.

Fourth, Frost et al. demonstrated that among an elderly population in the UK, vision-specific QoL impairment as measured by the VCM1 increased as age increased, social class decreased, and material deprivation increased, while sex and means of administration were not associated.[107] While it is likely that the prevalence of significant untreated ocular conditions that would impact upon VCM1 scores would increase in the lower socioeconomic strata, this does suggest the need for additional study to elucidate the causes of this finding. Of note, similar findings related to conventional measures of visual performance, such as visual acuity and legal

blindness and socioeconomic status, were found in the Baltimore Eye Study in the United States.[108]

Fifth, while several translations have been made of the NEI-VFQ (French, Italian, Spanish, Turkish, and many other languages) and have been found to have acceptable psychometric properties in the translated languages for patients with eye diseases (which may be a testimony more to the methods of translation than the instrument itself), Varma et al. in the Los Angeles Latino Eye Study demonstrated that a normal patient's native or preferred language (Spanish or English) has an independent association with the NEI-VFQ scores and psychometric properties.[109] Whether this holds for patients with AMD or other ocular diseases is unknown, but there is no reason to suspect that this difference would not persist. Thus, in ethnically and linguistically diverse populations, recognition that mean scores could vary based on whether an English or Spanish version is administered should be included in data analyses with instruments administered in more than one language.

Finally, standard psychometric considerations such as order of instrument administration have been assessed for some of the NIH/NEI Trials, such as the Submacular Surgery Trials Group.[110] Related issues such as mode of administration (face-to-face, phone, self-administered) and timing of administration during an interaction or afterwards likely behave similarly to other disease- or condition-specific instruments.[111]

3.5 QoL Instruments and Outcome Measures

Question 3: How do these QoL measurement methods relate to traditional outcome measures (e.g., visual acuity, contrast, etc.)?

We examined the relationship of QoL measurement methods to traditional outcome measures in the context of the instrument and the type of study (observational versus interventional). This allows us to evaluate the performance of various instruments as a direct correlation to the objective measures, and to test the instrument's responsiveness, or sensitivity to change over time.

3.5.1 NEI-VFQ

The NEI-VFQ has been extensively utilized in several studies of AMD. It has been introduced by the NEI into NEI-sponsored clinical trials, which has generated significant amounts of NEI-VFQ data.

3.5.1.1 Observational Studies

The study by Scilley et al. examined the NEI-VFQ results of a population of AMD patients seeking low-vision services.[94] They compared their population to other AMD patients and non-AMD patients seeking low-vision services. They found lower scores on the overall score and the near vision, distance vision, social functioning, and other subscales as compared to the control patients with similar levels of visual acuity. They concluded that AMD patients seeking low-vision services have decreased vision-specific QoL scores for their given visual acuity as compared to the control populations.

The other cross-sectional studies employing the NEI-VFQ in AMD were carried out in the enrollment phase of several interventional trials. The NEI's Age-Related Eye Disease Study was a large multicenter study designed to evaluate the effect of antioxidant vitamins and zinc on progression of early AMD. Investigators attempted to correlate NEI-VFQ scores with clinical measures of visual function.[89] They found lower scores in participants with advanced AMD in one or both eyes as compared with disease-free participants.

Another NEI trial investigating the effect of sub-threshold laser treatment of the macula in early AMD (Complications of Age-Related Macular Degeneration Prevention Trial) also performed a cross-sectional analysis of enrolled patients.[87] In this study, investigators found only a weak association between NEI-VFQ scores and measures of visual function, and no association with fundus features of clinical severity. This might have been due, in part, to the relatively homogeneous group of participants and variety of responses.

Another study obtained visual acuity and QoL measures on patients with late AMD enrolled in a trial investigating the outcome of submacular surgery on AMD (Submacular Surgery Trial).[23] These investigators established a strong association between visual acuity in the better eye with the NEI-VFQ scores but not with other global QoL measures (scores on the SF-36 and Hospital Anxiety and Depression Scale [HADS]). Furthermore, patients with bilateral disease scored six to 10 points lower than those with unilateral disease. Therefore, there was a more specific correlation of visual function with a vision-specific instrument, and the vision-specific instrument was impacted by bilaterality of disease. These correlations, while strong, remain only

moderate (0.2 to 0.4 in general), suggesting that visual acuity and the results with the NEI-VFQ are complementary in nature. Further, from a clinical perspective, the history of eyes with AMD is unpredictable, such that what is the worst eye may become the better eye for patients in the future.

The study by Berdeaux examined the correlation of the best eye's visual acuity and the worst eye's visual acuity with the NEI-VFQ.[90] Investigators enrolled patients about to undergo photodynamic therapy with verteporfin for late AMD. They found a strong association of the NEI-VFQ with the best eye's visual acuity and a weaker, yet still significant association with the worst eye's visual acuity. They concluded that even preserving vision in the worst eye may have an impact on vision-related quality of life.

Another study was drawn from the baseline characteristics of patients enrolled in a surgical trial for late AMD (macular translocation with 360° peripheral retinectomy).[29] Investigators found a positive correlation of NEI-VFQ with visual acuity and reading speed. Unlike the other patient populations, these were patients with uniformly bilateral late disease. Therefore, the population is more homogeneously affected than in prior studies.

3.5.1.2 Interventional Studies

The Submacular Surgery Trials Study Group published two papers on the results of submacular surgery on two types of advanced AMD (Group N, primarily neovascular, and Group B, primarily hemorrhagic subfoveal neovascularization).[24,25] In these trials there was a positive and significant relationship between visual acuity and NEI-VFQ scores. Although there was no

significant change in the final visual acuity between the treated and observation arms of the studies, patients with different levels of visual acuity had different NEI-VFQ scores. Similarly, there was no significant difference in the NEI-VFQ results between the different arms in both studies.

Three studies demonstrate responsiveness of the NEI-VFQ. The first is the AREDS Research Group's results in the patients that had progression of AMD with vision loss.[6] The NEI-VFQ score was responsive to AMD progression and vision decrease ($p < 0.001$ for each). A 15-letter visual acuity loss and progression to advanced AMD correlated with a decrease in overall NEI-VFQ score and changes of subscale scores of 10 points or more.

The study by Cahill demonstrated similar responsiveness of the NEI-VFQ.[28] However, in this study there was responsiveness to a significant increase in visual acuity in AMD. Investigators studied 50 patients who underwent macular translocation surgery for advanced AMD. The patients had a significant improvement in near visual acuity and reading speed, and a trend toward improvement in distance visual acuity. There was a corresponding increase in the composite NEI-VFQ score by 10 points and significant increases in many of the subscales. This study therefore demonstrated positive responsiveness of this vision-specific QoL instrument as a result of an intervention.

Brody et al.[93] used the NEI-VFQ as a secondary outcome measure in a trial of a self-management intervention aimed at primarily improving mood. While the primary outcome measure (Profile of Mood States) indicated some improvement, there were marginal changes in

the NEI-VFQ. The lack of responsiveness may more reflect the nature of the intervention than the responsiveness of the NEI-VFQ to changes in vision-related quality of life.

In summary, the NEI-VFQ is a vision-specific QoL instrument that has been evaluated in observational studies and numerous NEI-sponsored trials for AMD. It has demonstrated correlation with visual acuity and reading speed in these patients.

3.5.2 VF-14

The VF-14 was developed through funding by the Agency for Healthcare Research and Quality (AHRQ; formerly the Agency for Health Care Policy and Research [AHCPR]) to investigate QoL issues in patients with cataract and cataract surgery. The utility of the VF-14 instrument for AMD was examined in two observational studies and one interventional study in AMD. The study by MacKenzie[22] investigated the validity of the VF-14 in assessing visual function in patients with early and late AMD. Investigators found the instrument to have a stronger correlation with visual functional impairment than with visual acuity or AMD severity.

Riusala et al. studied the value of the VF-14 in patients with long-standing late AMD.[79] They found that the VF-14 correlated significantly with best-corrected visual acuity, contrast sensitivity, and global assessment scores of satisfaction with vision and quality of vision. Again, as in the previous study, the correlation of the VF-14 was stronger with global assessment scores than the VF-14 relative to other conventional objective measures. Therefore, investigators concluded that this instrument reflected a more complete assessment of the individual's function that objective measures alone.

The study by Armbrecht et al. evaluated the VF-14 in the context of a photodynamic therapy, a therapeutic intervention for late AMD.[80] Generally, this therapy reduces severity of vision loss in late AMD. All the patients in this study received the intervention, so no control group was available for comparison. Seventy-one percent of patients lost less than three lines of best-corrected visual acuity at distance, and these results were consistent with the observed visual acuity results with this treatment. The VF-14 showed significant decreases in the total score and in select items that correlated with the decrease in visual acuity and contrast sensitivity, and an increase in AMD lesion size.

In summary, the VF-14 instrument demonstrated a general correlation with visual acuity and contrast sensitivity in two non-interventional studies. An interventional study in which the expected outcomes were a decrease in visual acuity, decrease in contrast sensitivity, and increase in lesion size demonstrated a commensurate decrease in the overall VF-14 score, as well as in related subscales. Thus, there is a limited database to evaluate the adequacy of the VF-14 in AMD, though these studies demonstrate good performance.

3.5.3 ADVS

Scilley performed a comparative, cross-sectional study of patients with early AMD and relatively good vision with age-matched patients with good vision.[97] The major finding in this study was that there was a significant difference in the night driving, near vision, and glare disability in the AMD patients compared to the control patients.

Mangione et al. performed a cross-sectional, observational cohort sample of 201 patients with various stages of AMD.[21] Investigators correlated poorer ADVS scores with increased clinical severity of AMD. Of note, once visual acuity was taken into consideration, the clinical grading of maculopathy did not explain variations in visual functioning. Therefore, it appears that in these two observational studies, there was not a great correlation between visual acuity and the ADVS.

3.5.4 Summary

In summary (Table 4), it may be reasonable to conclude from the available data that the NEI-VFQ has demonstrated correlation with the traditional outcome measures of visual acuity, contrast sensitivity, and reading speed. It is also the only instrument that has demonstrated responsiveness. The VF-14 has been demonstrated to correlate with some traditional outcome measures, but there are limited data available.

Table 4: QoL instruments used in AMD patients and correlation with objective measures*

Instrument	Visual acuity	Contrast sensitivity	Reading speed	Clinical severity
ADVS	Mangione[21] 1999 +/+/- Scilley[97] 2002 +/+/-			Mangione[21] 1999 +/+/-
NEI-VFQ	**Clemons[89] 2003 +/+/+** **Scilley[94] 2004 +/0/-** **CAPT[87] 2004 +/+/+** SST[23] 2004 +/+/+ SST[24] 2004 +/+/+ SST[25] 2004 +/+/+ **Berdeaux[90] 2004 +/0/+** **Cahill[29] 2005 +/+/-** **Cahill[28] 2005 +/+/-** Brody[93] 2005 +/0/- **AREDS[6] 2005 +/+/+**	**CAPT[87] 2004 +/+/+**	**CAPT[87] 2004 +/+/+** **Cahill[28] 2005 +/+/-**	**AREDS[6] 2005 +/+/+**
VCM1	**Reeves[26] 2004 +/+/-**			
DLTV	**Hart[99] 1999 +/+/+** **McClure[102] 2000+/+/+** **Stevenson[101] 2003 +/+/+** **Stevenson[27] 2005 +/+/+**		**McClure[102] 2000+/+/+**	**Stevenson[27] 2005 +/+/+**
VF-14	MacKenzie[22] 2002 +/0/- **Riusala[79] 2003 +/0/-** **Armbrecht[80] 2005 +/0/-**		None	MacKenzie[22] 2002 +/0/-

* Bold denotes strong association with measured objective parameters; associated quality criteria denoted with +, 0, or - for "study population defined in meaningful way" / "instrument administered unbiased" / "statistical power or size specified"

3.6 Utility Assessment in AMD

The measures described above are of health states and values. Health states are general health conditions or particular dimensions of health, such as physical functioning, pain, and depression. Health preference relates to the desirability of a health state relative to other health states or disease outcomes. If the preference measurement question is asked under a condition of certainty, then a preference value is being ascertained (examples being the Time Trade-Off [TTO] or Rank and Scale [RS] techniques). If risk or uncertainty is incorporated into the preference measurement question, then utility is being assessed (an example being the Standard Gamble [SG] technique). While the SG is desirable as being consistent with the axioms of utility

theory, it is perceived to be difficult to understand and to administer (since some people are troubled in some way by the exercise requiring considering gambles that may lead to death), and thus the value technique of TTO is more often used as a utility surrogate.

Although not strictly speaking a health-related QoL measure, utility assessment is advocated as a way to establish an approximate equivalence between benefits in disparate health domains. Moreover, utility assessments can be used in calculating incremental cost-effectiveness ratios, a metric that can provide a rationale for allocating health resources.

In AMD, we identified two research groups that published their experience with utility assessment.[78,112-119] The original work by Brown[112] is representative. He noted that TTO is more palatable to patients than SG. The results did not correlate with visual acuity in the worse eye, but correlated moderately well with visual acuity in the better eye ($r^2 = 0.23$), and the response was not affected by age, level of education, sex, race, length of time of visual loss, cause of visual loss (predominantly diabetic retinopathy), or other comorbidities. However, experience with these measures in visual disorders is limited; in addition to studies of relatively few (and apparently often overlapping) subjects, we did not identify any clinical trials in AMD in which utility assessment was directly used in comparing treatment alternatives. Further, the two research groups obtained different values for the same level of visual acuity (69, 112-119).

Utility analyses have been conducted with other eye diseases in various contexts, particularly around the area of cataracts and cataract surgery in many different countries. In these studies, impaired vision was found to be significantly related to reduced utility scores, especially with the

use of TTO when it was feasible. Since utility assessment is of potential value in a policy context, further work in this area is appropriate, being cognizant of the limitations present in utility analyses.[120]

4. Clinical Implications

As described in Section 1, the key clinical issue in AMD is whether the biological impact of treatments corresponds to differences that patients care about. Usually, this issue is formulated as a question of "clinically important differences." In the literature, clinically important differences are assessed in various ways, the two primary approaches being termed distribution-based and anchor-based.[121] In the distribution-based approach, either change scores (longitudinal designs) or differences between group means (cross-sectional designs) are compared against statistically derived benchmarks, usually reported in standard deviation units. For cross-sectional designs, differences of 0.2 standard deviation units are considered to be small, differences of 0.5 standard deviation units are considered to be moderate, and differences of 0.8 standard deviation units are considered to be large. The VF-14 total score has an approximate standard deviation of 20;[58] accordingly, these benchmarks are 4, 10, and 16. The NEI-VFQ-25 total score has an approximate standard deviation of 14;[89] accordingly, these benchmarks are 3, 7, and 11. Standard deviation for subscale scores is larger; thus, so are the corresponding distribution-based effect size anchors. In practice, these standard deviations also depend on the population under study.

Anchor-based approaches compare observed changes (longitudinal designs) or between-group differences (cross-sectional designs) with either patient or clinician report. For example, in a

longitudinal design (e.g., an assessment of cataract surgery) an anchor-based approach based on patient report would be to select the subset of patients that reported overall improvement in their quality of life (e.g., using a global item) and then calculate the mean change in the QoL measure in question. Following this same idea, the minimal clinically important difference can be estimated by performing a similar calculation for the subset of patients reporting small improvements in overall quality of life. As an example of a clinician-reported approach, suppose that the question under consideration is whether a 10-unit difference in the NEI-VFQ is clinically important. Two typical patients could be envisioned, differing in their NEI-VFQ scores by 10 units, the pattern of the differences in their items analyzed, and an assessment made whether this difference represents something likely to be meaningful to patients.

In the literature, the question of clinically meaningful difference in eye disease is far from resolved. To get some sense of what score differences mean, we offer three observations. First, from studies of cataract surgery,[6,56] an intervention with a vivid improvement, QoL measures improve by an order of 1 standard deviation unit. Thus, a clinically meaningful difference is certainly below this value.

Second, visual acuity can be a useful reference point. In Table 5 we provide ranges of QoL responses for the VF-14 and the NEI-VFQ for different levels of visual acuity. We see a general correspondence between acuity and quality of life; individuals with acuity worse than 20/200, the threshold for legal blindness, on average experience roughly a 50-point drop compared with individuals with no or mild visual acuity deficit. Further, for both instruments, a 10-point drop corresponds to a 15-letter visual acuity loss.[3,82]

Table 5: Mean QoL results by categories of visual acuity

Visual acuity in better eye (reference)	VF-14[53,78,82]	NEI-VFQ[89,91]
20/20 to 20/40	83, 83, 90	94, 81
20/50 to 20/70	73, 76, 79	
20/80 to 20/100	70, 74, 51	52
≤ 20/200	69, 34	46

Third, the scores in the QoL instruments have concrete interpretations that give some sense of the practical implications of specific point drops (or, conversely, point rises). The following are illustrative examples. For the NEI-VFQ, regarding work or hobbies ("How much difficulty do you have doing work or hobbies that require you to see well up close, such as cooking, sewing, fixing things around the house, or using hand tools?"), a change in response from "No difficulty at all" to "Stopped doing this because of your eyesight" corresponds to a 4-point drop. A change in response from "Driving" to "Not driving because of eyesight" corresponds to a 4-point drop. Relating to impact on perception, for example a change in response to the statement "I worry about doing things that will embarrass myself or others because of my eyesight" from "definitely false" to "definitely true" corresponds to a 4-point drop. Change in frequency of performance of an activity leads to NEI-VFQ score reductions. For example, if the response to "Are you limited in how long you can work or do other activities because of your vision?" changes from "None of the time" to "Some of the time," the NEI-VFQ score drops by 2 points; from "None of the time" to "All of the time" leads to a 4-point drop. The impact of limitations on score is similar for the VF-14. For example, for the question "Do you have any difficulty even with glasses writing checks or filling out forms?," a change from "No" to "Yes with a great deal of difficulty" reduces score by roughly 5 points, as does a similar effect on reading a newspaper or book. (Note that if an individual does not perform the activity for reasons other than vision, it is not

included in the score and the remaining elements are renormalized to keep the score from 0 to 100.)

5. Summary

The current review supports the following conclusions regarding the specific questions posed by CMS:

1. **There are several validated and clinically responsive vision-specific instruments for measuring health-related quality of life in individuals with AMD, including the NEI-VFQ and the VF-14 questionnaires.** General health-related QoL instruments such as the SF-36, SIP, or similar instruments are generally insensitive to the presence of specific eye diseases, although they may be more responsive to visual symptoms. As such, vision-specific, patient-based survey instruments both have been widely used and shown to be sensitive to differences in visual status and functioning among patients with AMD and various levels of severity of AMD. The use of observational testing of actual performance appears promising but has not been published in randomized clinical trials in patients with AMD to date, but case series evidence suggests that observed reading performance may be a useful adjunct related to important patient-centered considerations.

2. **These vision-specific QoL measuring methods have been successfully applied to other eye diseases affecting central vision.** In particular, the NEI-VFQ and VF-14 have been widely used in other eye diseases, such as cataract, diabetic macular edema, diabetic retinopathy, vein occlusion, and corneal diseases. As such, their use provides an ability

to compare the impact of AMD with other eye diseases and the attendant treatments to each other. This also provides additional support for the use of these instruments to provide additional information in assessing the impact of disease and treatments on patients with AMD.

3. **These methods, in particular the NEI-VFQ and VF-14, have appropriate psychometric properties for use in AMD and other diseases affecting central vision.** In many different analyses among different populations, the scales and summary (unweighted) scores of the VF-14 and NEI-VFQ have been found to be reliable (both internal consistency among scales and test-retest over time and across methods), valid (content, construct, concurrent, discriminant), and responsive to important clinical and functioning dimensions. Importantly, the questions in the NEI-VFQ related to difficulty have been found to be valid by Rasch analysis as well, although the psychological and emotional scales were not assessable by Rasch analysis. The NEI-VFQ includes psychosocial issues in addition to activity or task difficulty.

4. **The NEI-VFQ and VF-14 have been found to correlate moderately (0.2 to 0.4 generally) with traditional visual performance measures such as visual acuity, reading speed, and contrast sensitivity. The NEI-VFQ has been further tested in therapeutic interventions and found to have excellent responsiveness in trials in which visual (and anatomical) improvement has occurred as well as in trials in which these parameters have deteriorated. Ten-point differences in overall or subset scores have correlated with 15-letter changes in visual acuity in patients with**

macular degeneration. Use of the NEI-VFQ has also revealed similar levels of relationship between changes in the NEI-VFQ and visual acuity in population based studies as well as AMD patients.

5. **Vision-specific QoL instruments may provide complementary information to conventional measurement tools such as visual acuity, and may provide a more patient-centered orientation to assessing functioning among patients with AMD.** Evidence for the complementary nature of these measures comes from several findings. First, the NEI-VFQ and VF-14 have been found to correlate only moderately (0.3 to 0.4 typically) with visual acuity, reading speed, and contrast sensitivity, suggesting that they reflect somewhat different dimensions. Second, scores on the VF-14 are more highly correlated with overall satisfaction with or quality of vision (and satisfaction after cataract surgery) than the traditional performance measure of visual acuity. Third, correlations with visual acuity and disease severity are better for later stages of disease and visual acuity loss, suggesting that greater variance in NEI-VFQ scores among patients in early stages without significant visual acuity loss reflect patient difficulties and perceptual issues not reflected in visual acuity and other traditional measures. As such, the choice of primary endpoints may differ based on the specific questions being asked. While there is a direct relationship between conventional measurement tools such as visual acuity and contrast sensitivity to observed performance on important activities such as using a key, reading, and mobility, there is also an imprecise relationship among these conventional measures and patient self-reported visual functioning as measured by questionnaire instruments. Using conventional measures, patient reported functioning, or

a combination may depend on the relative importance of assessing patient functioning as opposed to physician measured and more "objective" measures of visual abilities. Finally, these QoL measures assess the impact of disease on the person level and can reflect the full impact of the disease on the person, including emotional effects and the side effects of treatment.

6. **Consideration should be given to including adjustments for time since diagnosis, depression, general health status, socioeconomic status (pending additional investigation), language used in the instrument (if applicable), and standard psychometric issues such as questionnaire order and mode of administration in analyzing scores with the vision-specific QoL instruments.**

7. **Additional work is needed to understand the relationship of proxy measures such as the vision-specific QoL instruments with actual observed or "objective" performance on the part of patients with AMD and on other potential outcomes measures for treatment or rehabilitation of AMD related deficits.** While small studies assessing a specific task have been performed, analysis of the SEE project and other datasets may provide an invaluable contribution to our understanding of the impact of AMD on patient functioning and general abilities to function. Additional work on the value of depression and other psychosocial and emotional measures as independent outcomes endpoints would also be helpful.

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Appendix A. Search Strategy

Database: Ovid MEDLINE(R) <1966 to August Week 2 2005>

Search Strategy:

---

1 exp retinal diseases/ (includes Macular Degeneration/ and retinal degeneration/)

2 exp vision disorders/

3 (vis$ adj1 funct$).mp.

4 1 or 2 or 3

5 "Quality of Life"/

6 4 and 5

7 sharma s$.au.

8 coleman a$.au.

9 brown m$.au.

10 brown g$.au.

11 aspinall p$.au.

12 owsley c$.au.

13 mangione c$.au.

14 bressler n$.au.

15 steinberg e$.au.

16 or/7-15

17 16 and 4

18 16 and 5

19 17 or 18

20 6 or 19

21 limit 20 to english language

22 limit 21 to humans

23 limit 22 to abstracts

Appendix B

Evidence Tables

Evidence Table 1: Activities of Daily Vision Scale (ADVS)

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Elliott 2000 #4650	**Geographical location:** Canada **Dates:** Unknown **Context:** □ Clinical trial □ Cohort □ Cross sectional X Longitudinal **Inclusion/Exclusion criteria:** Cataract patients were recruited from four local ophthalmologists who performed extraction in the Waterloo Canada area. Subjects had to be scheduled for cataract surgery within one month and had no signs of comorbid ocular disease or significant neuromuschular skeletal or radioascular disorder that could interfere with mobility.	**Population size (n):** N=18 (first eye surgery) N=25 second eye surgery N=25 control Eye dx: Not reported **AMD:** 0 Other central vision loss (by type): Cataract: 100% **AMD Type:** Not reported **Laterality:** □ Unilateral X Bilateral **Objective Measure(s) of function (e.g., visual acuity):** Operated eye High contrast VA (logMAR): 0.54 ± 0.36 Log CS: 0.92 ±0.50 Disability glare: 5.2 ± 3.8	**Instrument/Technique Name:** ADVS-20 **Method of administration:** Self-report **By whom:** □ Masked □ Unmasked X Unknown **Mode of administration:** X Phone interview □ Face to face interview □ Mail questionnaire □ In office questionnaire □ Observation X Other (physical exam) **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of administration:** Pre-op and post-op	**Question 1C: psychometric properties (validity, reliability, responsiveness)** Internal consistency: The ADVS evidenced ceiling effects. Responsiveness: As might be expected, patients with first eye surgery improved more than those with second eye surgery. Notes: This study, of patients scheduled for cataract surgery and age-matched controls, is too small and uses too few forms of validation to provide much support for the validity of these 2 instruments. This study also included another instrument, the SRS, which had similar results but will be excluded because it has not been applied to patients with AMD.	**Quality assessment:** Meaningfully defined study population: - Protection from bias: 0 Consideration of statistical power: - **This article is relevant to:** □ Question 1A □ Question 1B X Question 1C □ Question 2 □ Question 3

Evidence Table 1: Activities of Daily Vision Scale (ADVS) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Mangione 1999 #1730	**Geographical location:** Boston, MA **Dates:** 7/92-9/93 **Context:** □ Clinical trial □ Cohort X Cross sectional □ Other **Inclusion/Exclusion criteria:** Age > 45 AMD (drusen, RPE changes, geogr atrophy, exudative dz) Vision > 20/200 in at least one eye	**Population size (n):** 201 Eye dx: Not reported **AMD:** 100% **AMD Type:** 17% wet 83% dry **Laterality:** □ Unilateral X Bilateral **Objective Measure(s) of function (e.g., visual acuity):** Mild ARM: 64% Moderate ARM: 31% Severe ARM: 5% Visual acuity: Better eye: 20/25 Worse eye: 20/40	**Instrument/Technique Name:** ADVS; SF-36 **Method of administration:** **By whom:** □ Masked X Unmasked □ Unknown **Mode of administration:** □ Phone interview X Face to face interview □ Mail questionnaire □ In office questionnaire □ Observation □ Other **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate **Time points of administration:** NA	**Question 1A: Instrument scores in AMD patients:** Construct Validity ADVS: Mild (128) / Moderate (62) / Severe (11) / P value Day Driving: 86 / 79 / 65 / < 0.05 Night driving: 60 / 53 / 33 / Near vision: 82 / 80 / 64 / < 0.05 Far vision: 84 / 81 / 72 / Glare: 77 / 77 / 58 / < 0.05 Overall: 80 / 77 / 62 / < 0.05 SF-36: Mild (128) / Moderate (62) / Severe (11) / P value Physical functioning: 79 / 80 / 79 / Role-physical: 67 / 76 / 77 / Bodily pain: 73 / 75 / 82 / General Health: 68 / 68 / 63 / Vitality: 61 / 59 / 66 / Social functioning: 92 / 92 / 99 / Role-emotional: 82 / 87 / 88 / Mental Health: 75 / 74 / 73 / Physical Compont.: -0.35 / -0.23 / -0.19 / Mental Compont.: -0.22 / 0.18 / 0.32 /	**Quality assessment:** Meaningfully defined study population: + Protection from bias: + Consideration of statistical power: - **This article is relevant to:** **X**Question 1A □ Question 1B X Question 1C □ Question 2 X Question 3

Evidence Table 1: Activities of Daily Vision Scale (ADVS) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Mangione 1998 #2180	**Geographical location:** Ann Arbor, MI; Birmingham, MI; Boston, MA; Los Angeles, CA; Madison WI; San Francisco, CA **Dates:** 1998 **Context:** □ Clinical trial □ Cohort X Cross sectional □ Longitudinal **Inclusion/Exclusion criteria:** Diverse convenience sample for focus group	**Population size (n):** 246 Age Mean (range over conditions): 68 (40 - 77) % female: 55 Eye dx: Not reported **AMD:** 35 (14%) Other central vision loss (by type): AMD : 35 (14%) Glaucoma : 82 (33%) DR : 58 (24%) Cataract : 42 (17%) CMV retinitis : 17 (7%) Low vision: 12 (5%) **AMD Type:** Not reported **Laterality:** Not reported **Objective Measure(s) of function (e.g., visual acuity):** 20/40 or better: 139 (76%) 20/50 or worse: 43 (23%)	**Instrument/Technique Name:** ADVS **Method of administration:** **By whom:** X Masked □ Unmasked □ Unknown **Mode of administration:** X Phone interview □ Face to face interview □ Mail questionnaire □ Iin office questionnaire □ Observation X Other (physical exam) **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of administration:** NA (cross sectional)	**Question 1C: psychometric properties (validity, reliability, responsiveness)** Validity: Extensive interviews Reliability not assessed Responsiveness not tested	**General comments:** Apparently a convenience sample **Quality assessment:** Meaningfully defined study population: - Protection from bias: + Consideration of statistical power: - **This article is relevant to:** □ Question 1A □ Question 1B X Question 1C □ Question 2 □ Question 3

Evidence Table 1: Activities of Daily Vision Scale (ADVS) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Pesudovs 2003 #8520	**Geographical location:** United Kingdom **Dates:** Unknown **Context:** □ Clinical trial □ Cohort X Cross sectional □ Longitudinal **Inclusion/Exclusion criteria:** Patients awaiting cataract surgery. No patients had comorbid eye disease.	**Population size (n):** 43 18 bilateral cataract 25 one pseudophakic eye and were awaiting second eye surgery Eye dx: Not reported **AMD:** Not reported **AMD Type:** Not reported **Laterality:** Not reported **Objective Measure(s) of function (e.g., visual acuity):**	**Instrument/Technique Name:** ADVS **Method of administration:** **By whom:** □ Masked □ Unmasked X Unknown **Mode of administration:** □ Phone interview □ Face to face interview □ Mail questionnaire X In office questionnaire (assumed) □ Observation □ Other **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of administration:** NA (cross sectional)	**Question 1C: psychometric properties (validity, reliability, responsiveness)** Internal consistency: Cronbach's alpha = .92. Construct validity: Correlation with visual acuity and contrast sensitivity ranged from .41 to .50. Scaling consistency: Rasch analysis, including an assessment of missing data, ceiling effects and Rasch statistics suggested that 15 of the 22 ADVS items performed better than the others. It was also recommended that the number of response categories be reduced. Responsiveness:	**Quality assessment:** Meaningfully defined study population: Protection from bias: 0 Consideration of statistical power: + (low power) **This article is relevant to:** □ Question 1A □ Question 1B X Question 1C □ Question 2 □ Question 3

Evidence Table 1: Activities of Daily Vision Scale (ADVS) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Scilley 2002 #4020	**Geographical location:** Birmingham, AL **Dates:** **Context:** □ Clinical trial □ Cohort X Cross sectional □ Other **Inclusion/Exclusion criteria:** Patients: Age > 55 ARM in at least one eye (drusen) Acuity ≥ 20/60 No CNV or geographic atrophy Controls: Age > 55 No drusen Vision ≥ 20/35	**Population size (n):** 92 Gp 1: Early AMD Fellow < 20/60 Gp 2: Early AMD Fellow ≥20/60 Gp 3: Normal controls Age: Gp 1: 71 (66-75) Gp 2: 75 (69-83) Gp 3: 68 (57-74) Eye dx: Not reported **AMD:** 100% **AMD Type:** 0% wet 100%dry **Laterality:** □ Unilateral X Bilateral **Objective Measure(s) of function (e.g., visual acuity):** logMAR vision: Gp1: 0.22 (0.10/0.40) Gp2: 0.08 (-0.01/0.20) Gp3: -0.04 (-0.10/0.04) Scotopic sensitivity: Gp 1: 40.6 (32.4/44.3) Gp 2: 43.5 (41.0/46.2) Gp 3: 44.2 (41.5/46.0)	**Instrument/Technique Name:** ADVS **Method of administration:** **By whom:** □ Masked X Unmasked □ Unknown **Mode of administration:** □ Phone interview X Face to face interview □ Mail questionnaire □ In office questionnaire □ Observation □ Other **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate **Time points of administration:** NA (cross sectional)	**Question 1A: Instrument scores in AMD patients:** **ADVS** / **Early AMD Fellow < 20/60** / **Early AMD Fellow ≥ 20/60** / **Con-trols** / **P value** **Day driving** / **83.3** / **100** / **100** / **<.001** **Night driving** / **58.3** / **81.3** / **100** / **<.001** **Near vision** / **73.4** / **96.6** / **100** / **<.001** **Far vision** / **66.7** / **91.7** / **100** / **.011** **Glare** / **64.6** / **91.7** / **100** / **<.001** **Overall** / **74.0** / **93.1** / **96.7** / **<.001** **Question 3: Relationship between QOL measures (s) and objective measures** Acuity < 20/25 in both eyes associated with difficulty on all ADVS subscales (see table above). Poor scotopic sensitivity associated with difficulty on night driving subscale (OR 6.6) but not other subscales.	**Quality assessment:** Meaningfully defined study population: + Protection from bias: + Consideration of statistical power: - **This article is relevant to:** X Question 1A □ Question 1B □ Question 1C □ Question 2 X Question 3

Evidence Table 1: Activities of Daily Vision Scale (ADVS) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
West 1997 #8200	**Geographical location:** Maryland **Dates:** 1993 **Context:** □ Clinical trial □ Cohort X Cross sectional □ Longitudinal **Inclusion/Exclusion criteria:** Random sample of 2500 aged 65-84 years of age from Medicare database. Individuals were eligible if they were 65-84 yrs old as of 7/1993 residing in the eligible zip codes of Salisbury metropolitan area and alive at time of contact; must be non-institutionalized, be able to communicate with interviewer and travel to clinic for vision tests and pass a mental health test.	**Population size (n):** 2500 65-69 yrs. 36.8 70-74 31.3 75-79 21 80-84 10.9 % female 57.9 % AA 26.4 Eye dx: Not reported **AMD:** **AMD Type:** Not reported **Laterality:** Not reported **Objective Measure(s) of function (e.g., visual acuity):** Binocular vision worse than 20/40 6.9%	**Instrument/Technique Name:** ADVS **Method of administration:** **By whom:** X Masked □ Unmasked □ Unknown **Mode of administration:** □ Phone interview X Face to face interview □ Mail questionnaire □ In office questionnaire □ Observation X Other (physical exam) **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of administration:** NA (cross sectional)	**Question 1C: psychometric properties (validity, reliability, responsiveness)** Construct validity: ADVS scores decreased with increasing age and were correlated (in a multivariate model) with visual acuity. Notes: This large study, conducted in a general population sample, provides some evidence in favor of the construct validity of the instrument.	**Quality assessment:** Meaningfully defined study population: + Protection from bias: + Consideration of statistical power: + **This article is relevant to:** □ Question 1A □ Question 1B X Question 1C □ Question 2 □ Question 3

Evidence Table 2: Daily Living Tasks Dependent on Vision (DLTV)

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Hart 1999 #8180	**Geographical location:** Belfast, N Ireland **Dates:** Unknown **Context:** □ Clinical trial □ Cohort X Cross sectional □ Longitudinal **Inclusion/Exclusion criteria:** a) elderly patients attending a macular degeneration clinic; b) patients about to undergo cataract surgery; c) patients attending a GP geriatric screening unit; d) elderly patients attending a local hospital's rehabilitation unit. All subjects were over 55 years. The c and d groups were required to have visual acuity of 6/12 or better in each eye, have no visual complaints and be able to read a daily newspaper with current spectacles. These two groups formed the control group.	**Population size (n):** 103 (34 AMD) Age (mean): AMD: 74 Cataract: 73.7 Sex: AMD: 64.7% female Cataract: 75.7% female Eye dx: Not reported AMD**:** 33% **AMD Type:** Not reported **Laterality:** □ Unilateral □ Bilateral **Objective Measure(s) of function (e.g., visual acuity):**	**Instrument/Technique Name:** DLTV **Method of administration:** **By whom:** □ Masked □ Unmasked X Unknown **Mode of administration:** □ Phone interview □ Face to face interview □ Mail questionnaire X In office questionnaire □ Observation X Other (physical exam) **Respondent:** □ Only patient □ Patient or surrogate □ Only surrogate X Unknown **Time points of administration:** NA (cross sectional)	**Question 1C: psychometric properties (validity, reliability, responsiveness)** Internal consistency: A factor analysis (not described in detail) identified 3 putative dimensions. Construct validity: All items were correlated with measures of visual acuity (typically, .3 to .7) Notes: This instrument provides some support for the construct validity of the measure.	**Quality assessment:** Meaningfully defined study population: + Protection from bias: o Consideration of statistical power: +, but small **This article is relevant to:** □ Question 1A □ Question 1B X Question 1C □ Question 2 □ Question 3

Evidence Table 2: Daily Living Tasks Dependent on Vision (DLTV) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Hart 2005 #8510	**Geographical location:** Belfast, UK **Dates:** 12/95- 9/98 **Context:** □ Clinical trial □ Cohort X Cross sectional □ Longitudinal **Inclusion/Exclusion criteria:** AMD patients	**Population size:** 235 Age (mean): 74 Sex: 65% female Eye dx: Not reported **AMD:** Not reported **AMD Type:** All forms of AMD **Laterality:** Bilateral **Objective Measure(s) of function (e.g., visual acuity):** Distance and near visual acuity, contrast sensitivity	**Instrument/Technique Name:** DLTV **Method of administration:** Questionnaire **By whom:** X Masked □ Unmasked □ Unknown **Mode of administration:** □ Phone interview X Face to face interview □ Mail questionnaire X In office questionnaire □ Observation □ Other (physical exam) **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of administration:** NA (cross sectional)	**Question 1C: psychometric properties (validity, reliability, responsiveness)** Internal Consistency: Domain-specific Cronbach's alpha coefficients ranged from .66 to .96 Scaling Consistency: The application of item response theory (IRT) provided general, albeit not definitive, support for the subdivision of items into 4 sub-scales	**Quality assessment:** Meaningfully defined study population: + Protection from bias: + Consideration of statistical power: + **This article is relevant to:** □ Question 1A □ Question 1B X Question 1C □ Question 2 □ Question 3

Evidence Table 2: Daily Living Tasks Dependent on Vision (DLTV) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
McClure 2000 #8190	**Geographical location:** Belfast, Ireland **Dates:** 2/96-12/97 **Context:** □ Clinical trial □ Cohort X Cross sectional □ Longitudinal **Inclusion/Exclusion criteria:** AMD patients	**Population size: 100** Age (mean): 74 Sex: 67% female Eye dx: Not reported **AMD:** Not reported **AMD Type:** Unspecified **Laterality:** Bilateral **Objective Measure(s) of function (e.g., visual acuity)** Distance and near visual acuity, reading speed, contrast sensitivity, reading index (reading speed in wpm/text size in M)	**Instrument/Technique Name:** DLTV **Method of administration:** Questionnaire **By whom:** X Masked □ Unmasked □ Unknown **Mode of administration:** □ Phone interview X Face to face interview □ Mail questionnaire X In office questionnaire □ Observation □ Other **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of administration:** NA (cross sectional)	**Question 1A: Instrument scores in AMD patients** **Question 3: Relationship between QOL measures (s) and objective measure** Pearson's correlation coefficients between individual DLTV items and individual measures of vision in the better and worse eye *Distance visual acuity* / *Near visual acuity* / *Reading index* / *Reading speed* / *Contrast sensitivity* Read correspondence: 0.70 (0.22) / 0.58 (0.43) / 0.77 (0.46) / 0.69 (0.46) / 0.61 (0.43) Read newspaper print: 0.69 (0.25) / 0.51 (0.39) / 0.76 (0.44) / 0.67 (0.43) / 0.56 (0.36) Sign documents: 0.67 (0.23) / 0.58 (0.41) / 0.76 (0.42) / 0.69 (0.45) / 0.61 (0.44) Detect facial features across a room: 0.61 (0.24) / 0.50 (0.35) / 0.66 (0.37) / 0.57 (0.36) / 0.57 (0.37) Distinguish cash: 0.60 (0.10) / 0.52 (0.34) / 0.65 (0.36) / 0.58 (0.36) / 0.55 (0.41) Read newspaper headlines: 0.64 (0.23) / 0.60 (0.40) / 0.64 (0.35) / 0.59 (0.38) / 0.56 (0.41) Read street signs: 0.62 (0.08) / 0.49 (0.28) / 0.61 (0.28) / 0.55 (0.27) / 0.49 (0.29) Detect facial features across a road: 0.57 (0.29) / 0.47 (0.38) / 0.58 (0.36) / 0.53 (0.34) / 0.55 (0.41) Detect facial features at arm's length: 0.56 (0.08) / 0.47 (0.28) / 0.59 (0.32) / 0.56 (0.31) / 0.51 (0.25)	**Quality assessment:** Meaningfully defined study population: + Protection from bias: + Consideration of statistical power: +. **This article is relevant to:** X Question 1A □ Question 1B □ Question 1C □ Question 2 X Question 3

Evidence Table 2: Daily Living Tasks Dependent on Vision (DLTV) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results						Quality Scoring/Comments
				Detect seasonal changes	0.53 (0.10)	0.49 (0.10)	0.50 (0.28)	0.44 (0.27)	0.46 (0.32)	
				Use kitchen utensils	0.57 (0.12)	0.52 (0.37)	0.62 (0.35)	0.56 (0.36)	0.58 (0.41)	
				Watch television	0.54 (0.17)	0.55 (0.35)	0.56 (0.24)	0.55 (0.32)	0.55 (0.35)	
				Pour a drink	0.48 (0.11)	0.50 (0.40)	0.51 (0.31)	0.47 (0.37)	0.52 (0.47)	
				Confidence to walk around in a strange area	0.56 (0.23)	0.46 (0.38)	0.53 (0.35)	0.47 (0.31)	0.55 (0.47)	
				Ability to appreciate scenery	0.53 (0.04)	0.42 (0.18)	0.40 (0.23)	0.37 (0.21)	0.30 (0.20)	
				Confidence to walk around in own area	0.54 (0.19)	0.51 (0.30)	0.48 (0.25)	0.42 (0.24)	0.45 (0.35)	
				Cut finger nails	0.50 (0.14)	0.52 (0.45)	0.58 (0.39)	0.57 (0.45)	0.46 (0.39)	

* Correlations for the worse eye are represented in parentheses.

Evidence Table 2: Daily Living Tasks Dependent on Vision (DLTV) – continued

<table>
<tr><th>Study</th><th>Study Design</th><th>Study Population</th><th>Instrument Characteristics</th><th>Results</th><th>Quality Scoring/Comments</th></tr>
<tr>
<td>Stevenson 2004 #8500</td>
<td>Geographical location: Belfast, Ireland

Dates: 3/97-9/99

Context:
□ Clinical trial
□ Cohort
X Cross sectional
□ Longitudinal

Inclusion/Exclusion criteria: AMD patients</td>
<td>Population size: 199

Age (mean): 74

Sex: 63% female

Eye dx: Not reported

AMD: Not reported

AMD Type: Unspecified

Laterality: Bilateral

Objective Measure(s) of function (e.g., visual acuity):
Distance and near visual acuity, contrast sensitivity, ability to care for self or others</td>
<td>Instrument/Technique Name: DLTV

Method of administration:
Questionnaire

By whom:
X Masked
□ Unmasked
□ Unknown

Mode of administration:
□ Phone interview
X Face to face interview
□ Mail questionnaire
X In office questionnaire
□ Observation
□ Other

Respondent:
X Only patient
□ Patient or surrogate
□ Only surrogate
□ Unknown

Time points of administration: NA (cross sectional)</td>
<td>Question 1A: Instrument scores in AMD patients:

Question 3: Relationship between QOL measures (s) and objective measure

DLTV subscales and levels of care
<table>
<tr><th>DLTV sub-scale</th><th>Sub-scale 1 (reso-lution items)</th><th>Sub-scale 2 (compl ex visual tasks)</th><th>Sub-scale 3 (confide nce related items)</th><th>Sub-scale 4 (light and dark adapta-tion)</th></tr>
<tr><td>Level 1: Cannot care for self (27)</td><td>18 (22)</td><td>41 (24)</td><td>27 (15)</td><td>47 (31)</td></tr>
<tr><td>Level 2: Can look after self but not others (26)</td><td>27 (25)</td><td>60 (22)</td><td>37 (19)</td><td>64 (28)</td></tr>
<tr><td>Level 3: Can care for self and others (146)</td><td>61 (32)</td><td>82 (22)</td><td>58 (22)</td><td>68 (26)</td></tr>
<tr><td>One way ANOVA</td><td>P < 0.001</td><td>P < 0.001</td><td>P < 0.001</td><td>P < 0.01</td></tr>
</table>
DLTV = daily living tasks dependent on vision. Marked differences in mean subscale scores are seen between the care levels in subscales 1 and 2.</td>
<td>Quality assessment:
Meaningfully defined study population: +
Protection from bias: +
Consideration of statistical power: +

This article is relevant to:
X Question 1A
□ Question 1B
□ Question 1C
□ Question 2
X Question 3</td>
</tr>
</table>

Evidence Table 2: Daily Living Tasks Dependent on Vision (DLTV) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Stevenson 2005 #8490	**Geographical location:** Belfast, London, and Southampton, UK **Dates:** 12/95-9/98 **Context:** X Clinical trial □ Cohort □ Cross sectional □ Longitudinal **Inclusion/Exclusion criteria:** Wet AMD patients	**Population size:** 199 Age (mean): 74 Sex: 57% female Eye dx: Not reported **AMD:** Not reported **AMD Type:** 100% Wet **Laterality: B**ilateral **Objective Measure(s) of function (e.g., visual acuity):** Distance and near visual acuity, contrast sensitivity, reading speed	**Instrument/Technique Name:** DLTV **Method of administration:** Questionnaire **By whom:** X Masked □ Unmasked □ Unknown **Mode of administration:** □ Phone interview X Face to face interview □ Mail questionnaire X In office questionnaire □ Observation □ Other **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of administration:** Baseline, 12, 24 months	**Question 1A: Instrument scores in AMD patients:** DLTV scores at baseline DLTV score by dimension / Treat-ment / Control / P-value 1 / 50.4 / 54.9 / 0.33 2 / 80.9 / 80.1 / 0.81 3 / 82.2 / 83.1 / 0.77 4 / 66.5 / 70.0 / 0.41 **Question 3: Relationship between QOL measures (s) and objective measure** Relation between change in DLTV dimension score and change in visual acuity in better eye Change in DLTV score by dimension / Change in score / SE / P-value 1 / -38.67 / 6.35 / < 0.001 2 / -35.59 / 4.79 / < 0.001 3 / -28.39 / 4.06 / < 0.001 4 / -10.11 / 6.07 / 0.09	**Quality assessment:** Meaningfully defined study population: + Protection from bias: + Consideration of statistical power: + **This article is relevant to:** X Question 1A □ Question 1B □ Question 1C □ Question 2 X Question 3

Evidence Table 3: Quality of Well-Being Scale (QWB)

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Williams 1998 #2160	**Geographical location:** San Diego, CA **Dates:** 1/94-5/96 **Context:** □ Clinical trial □ Cohort X Cross sectional □ Longitudinal **Inclusion/Exclusion criteria:** AMD patients Vision ≤ 20/200 in one eye Vision ≤ 20/60 in better eye Age > 60 No overt cognitive or psychiatric conditions Able to respond to interview	**Population size (n):** 86 Age (mean): 79 Sex: 51% female Eye dx: Not reported **AMD %:** Not reported **AMD Type:** Mixed **Laterality:** □ Unilateral X Bilateral **Objective Measure(s) of function (e.g., visual acuity)** logMAR vision in better eye: 1.2 ± 0.5	**Instrument/Technique Name:** QWBS **Method of administration:** **By whom:** □ Masked X Unmasked □ Unknown **Mode of administration:** □ Phone interview X Face to face interview □ Mail questionnaire □ In office questionnaire □ Observation X Other (physical exam) **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of administration:** NA (cross sectional)	**Question 3: Relationship between QOL measures (s) and objective measure** QWB Scale: — Legally blind one eye: 0.584±0.08 Legally blind both eyes: 0.580±0.07	**Quality assessment:** Meaningfully defined study population: + Protection from bias: + Consideration of statistical power: + **This article is relevant to:** □ Question 1A □ Question 1B □ Question 1C □ Question 2 X Question 3

Evidence Table 4: Vision Quality of Life Core Measure (VCM-1)

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Frost 1998 #2060	**Geographical location:** Bristol, UK **Dates:** 1998 **Context:** □ Clinical trial □ Cohort X Cross sectional □ Longitudinal **Inclusion/Exclusion criteria:** Convenience sample	**Population size (n):** 92 (pilot phase) Age Mean (range): 72 (41-91) % female: 52/92 Eye dx: Not reported **AMD:** 5/38 (13%) Other central vision loss (by type): Cataract: 50% Unilateral cataract with prior extraction: 8% Glaucoma: 9% Other: 24% None: 19% **AMD Type:** Not reported **Laterality:** Not reported **Objective Measure(s) of function (e.g., visual acuity):** Not reported	**Instrument/Technique Name:** ADVS **Method of administration:** **By whom:** X Masked □ Unmasked □ Unknown **Mode of administration:** □ Phone interview X Face to face interview □ Mail questionnaire □ In office questionnaire □ Observation X Other (physical exam) **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of administration:** NA (cross sectional)	**Question 1C: psychometric properties (validity, reliability, responsiveness)** Validity: Extensive pretesting interviews Correlation of overall score with: Binocular far acuity: 0.54 Binocular near acuity: 0.48 Binocular contrast sensitivity: -0.54 VF-14: -0.80 SF-36 general health: -0.4 Reliability: Cronbach alpha coefficient = 0.93 Responsiveness not tested	**General comments:** Apparently a convenience sample **Quality assessment:** Meaningfully defined study population: - Protection from bias: + Consideration of statistical power: - **This article is relevant to:** □ Question 1A □ Question 1B X Question 1C □ Question 2 □ Question 3

Evidence Table 4: Vision Quality of Life Core Measure (VCM-1) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Reeves 2004 #400	**Geographical location:** Manchester, UK **Dates:** Not specified **Context:** X Clinical trial □ Cohort □ Cross sectional □ Other **Inclusion/Exclusion criteria:** AMD patients referred for low vision care Vision worse than 6/18 (>0.5 logMAR) in both eyes and ≥ 1/60 (≤1.8 logMAR in better eye Ineligible if living in residential or nursing home/mental illness/dementia	**Population size (n):** 92 Gp 1: Conv Low Vision Rehab Gp 2: Enhanced Low Vision Rehab Gp 3: Controlled for additional contact time in Enhanced Low Vision Rehab Age: Gp 1: 81 Gp 2: 80 Gp 3: 83 Eye dx: Not reported **AMD:** 100% **AMD Type:** Not reported **Laterality:** □ Unilateral X Bilateral **Objective Measure(s) of function (e.g., visual acuity):** Legally blind: Gp 1: 20% Gp 2: 12% Gp 3: 7%	**Instrument/Technique Name:** VCM-1 SF-36 **Method of administration:** **By whom:** □ Masked X Unmasked □ Unknown **Mode of administration:** □ Phone interview X Face to face interview □ Mail questionnaire □ In office questionnaire □ Observation □ Other **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate **Time points of administration):** At enrollment and 12 months	**Question 1A: Instrument scores in AMD patients:** Instrument / CLVR 0/12 mos / ELVR 0/12 mos / CELVR 0/12 mos VCM-1: 2.1/2.4 / 2.2/2.5 / 2.2/2.3 SF-36 Physical Health Component: 36/38 / 33/26 / 31/28 SF-36 Mental Health Component: 52/52 / 56/53 / 53/53 **Question 3: Relationship between QOL measures (s) and objective measures** Acuity < 20/25 in both eyes associated with difficulty on all ADVS subscales (see table above) Poor scotopic sensitivity associated with difficulty on night driving subscale (OR 6.6) but not other subscales	**Quality assessment:** Meaningfully defined study population:+ Protection from bias:+ Consideration of statistical power:- **This article is relevant to:** X Question 1A □ Question 1B □ Question 1C □ Question 2 X Question 3

Evidence Table 5: Visual Function Index (VF-14)

<table>
<tr><th>Study</th><th>Study Design</th><th>Study Population</th><th>Instrument Characteristics</th><th>Results</th><th>Quality Scoring/ Comments</th></tr>
<tr>
<td>Alonso 1997 #8250</td>
<td>Geographical location:
Four international sites: Manitoba, Denmark, Barcelona, and U.S.

Dates: Not specified

Context:
□ Clinical trial
□ Cohort
□ Cross sectional
X Longitudinal

Inclusion/ Exclusion criteria:
Patients were eligible if they were seen by an Ophthalmologist participating in the PORT study, ≥ 50 yrs. of age, and scheduled for a first eye cataract surgery that did not involve a combined procedure.</td>
<td>Population size (n): 1407

<table>
<tr><th></th><th>Manit.</th><th>Denk.</th><th>Barc.</th><th>U.S.</th></tr>
<tr><td>n</td><td>152</td><td>291</td><td>198</td><td>766</td></tr>
<tr><td>Mean age</td><td>71.7</td><td>73.5</td><td>70.1</td><td>72.5</td></tr>
<tr><td>% female</td><td>67.1</td><td>67</td><td>60.6</td><td>62.8</td></tr>
<tr><td>% married</td><td>62.5</td><td>46.4</td><td>62.6</td><td>56.4</td></tr>
<tr><td>Ed ≥ 8 yrs.</td><td>86.8</td><td>54.8</td><td>13.8</td><td>92.3</td></tr>
<tr><td>% working</td><td>21.1</td><td>19</td><td>7.7</td><td>18.9</td></tr>
</table>
Eye dx: Not reported

AMD: Not reported

AMD Type: Not reported

Laterality: Not reported

Objective Measure(s) of function (e.g., visual acuity):</td>
<td>Instrument/ Technique Name:
VF-14

Method of administration:

By whom:
□ Masked
□ Unmasked
□ Unknown

Mode of administration:
X Phone interview
□ Face to face interview
□ Mail questionnaire
□ In office questionnaire
□ Observation
X Other (physical exam)

Respondent:
□ Only patient
□ Patient or surrogate
□ Only surrogate
X Unknown

Time points of administration:
Pre surgery and 1year post surgery</td>
<td>Question 1C: psychometric properties (validity, reliability, responsiveness)
Internal consistency: 0% of patients with floor effects and 3.4% of patients with ceiling effects. Cronbach's alpha .87. Item-total correlations ranged from .29 to .72. The number of patients with all items applicable was 116/766.

Construct validity: VF-14 with visual acuity in operative eye .04, visual acuity in better eye .27, cataract symptom score .51, trouble with vision .45, satisfaction with vision .45, VR-SIP .57.

Responsiveness: For all cataract patients, the effect size was 1.01.

Note: This study, among first-eye cataract surgery patients, was mostly encouraging, although the item-total correlations were unexceptional and the correlations with visual acuity low.</td>
<td>Quality assessment:
Meaningfully defined study population: -
Protection from bias: 0
Consideration of statistical power: +

This article is relevant to:
□ Question 1A
□ Question 1B
X Question 1C
□ Question 2
□ Question 3</td>
</tr>
</table>

Evidence Table 5: Visual Function Index (VF-14) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/ Comments
Arm-brecht 2003 #850	**Geographical location:** Edinburgh, UK **Dates:** 1/98-12/99 **Context:** □ Clinical trial X Cohort □ Cross sectional □ Longitudinal **Inclusion/ Exclusion criteria:** Study group was comprised of 40 patients who were scheduled for cataract surgery and had documented in their records presence of ARMD in the eye to be operated on. The control group comprised 43 patients who were diagnosed with ARMD at the clinic or by fluororescein angiography. This group could have	**Population size (n):** 83 Eye dx: Not reported **AMD:** **AMD Type:** 100% dry **Laterality:** □ Unilateral X Bilateral **Objective Measure(s) of function (e.g., visual acuity):**	**Instrument/ Technique Name:** VF-14 **Method of administration:** **By whom:** X Masked □ Unmasked □ Unknown **Mode of administration:** X Phone interview X Face to face interview □ Mail questionnaire □ In office questionnaire □ Observation □ Other **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of administration:** Pre-op, 4 mo, and 12 mo	**Question 1C: psychometric properties (validity, reliability, responsiveness)** Internal consistency: Cronbach's alpha .90 Reproducibility: test-retest Spearman correlation .77 Responsiveness: The overall VF-14, as well as most items, improved from baseline to 4 months in the surgery groups, whereas controls did not show similar improvement. No change was observed in either group between months 4 and 12. Notes: This poorly-powered study of patients with cataract surgery provides some evidence in favor of the responsiveness of the VF-14.	**Quality assessment:** Meaningfully defined study population: + Protection from bias: + Consideration of statistical power: - **This article is relevant to:** □ Question 1A □ Question 1B X Question 1C □ Question 2 □ Question 3

	Control	Study
Mean age	75	80
% female	660	67
% white	100	100

Evidence Table 5: Visual Function Index (VF-14) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/ Comments
	cataract but their fundus photographs or fundal view were clear enough to allow grading of underlying maculopathy.				

Evidence Table 5: Visual Function Index (VF-14) – continued

<table>
<tr><th>Study</th><th>Study Design</th><th>Study Population</th><th>Instrument Characteristics</th><th>Results</th><th>Quality Scoring/ Comments</th></tr>
<tr>
<td>Arm-brecht 2005 3330</td>
<td>Geographical location:
Edinburgh, UK

Dates: 10/00-4/02

Context:
□ Clinical trial
X Cohort
□ Cross sectional
□ Other

Inclusion/ Exclusion criteria:
Inclusion: Predominantly classic CNV < 5400 microns, AMD, vision >6/36 In study eye

Exclusion: other ocular dz (not CNV) from AMD, inability to photograph/ FA, inability to give informed consent, PDT exclusion criteria</td>
<td>Population size (n): 51

Age: Mean 72 (range, 51-87)

Sex: 48% male

Eye dx: Not reported

AMD: 100%

AMD Type: 100% wet

Laterality: 40% unilateral

Objective Measure(s) of function (e.g., visual acuity):
Distance VA @ 1 yr
23% better ≥ 1 line
71% lost ≤ 3 lines
29% lost > 3 lines

AVG: lost 2 lines of vision

<table>
<tr><th>Visual function tests</th><th>Base-line Mean (SD)</th><th>1 yr Mean (SD)</th><th>P value</th></tr>
<tr><td>Distance VA</td><td>0.61 (0.19)</td><td>0.80 (1.6)</td><td><0.01</td></tr>
<tr><td>Near VA</td><td>0.92 (0.28)</td><td>1.1 (0.35)</td><td><0.02</td></tr>
<tr><td>Contrast sensitivity</td><td>1.14 (0.25)</td><td>1.11 (0.35)</td><td>0.31</td></tr>
<tr><td>CNV (largest linear diam)</td><td>3094 (1201)</td><td>4088 (1532)</td><td><0.01</td></tr>
</table>
</td>
<td>Instrument/ Technique Name:
VF-14

Method of administration:

By whom:
□ Masked
□ Unmasked
X Unknown

Mode of administration:
□ Phone interview
X Face to face interview
□ Mail questionnaire
X In office questionnaire
□ Observation
□ Other

Respondent:
X Only patient
□ Patient or surrogate
□ Only surrogate

Time points of administration:
Baseline and every 3 months x 1 yr</td>
<td>Question 1A: Instrument scores in AMD patients

<table>
<tr><th>VF-14</th><th>Base-line Mean</th><th>SD</th><th>1 yr Mean</th><th>SD</th><th>P value</th></tr>
<tr><td>Read small print</td><td>1.4</td><td>1.7</td><td>1.2</td><td>1.6</td><td>0.79</td></tr>
<tr><td>Read newspaper/ book</td><td>1.7</td><td>1.7</td><td>1.5</td><td>1.7</td><td>0.38</td></tr>
<tr><td>Large print books</td><td>1.8</td><td>1.7</td><td>1.3</td><td>1.7</td><td>0.53</td></tr>
<tr><td>Recognize people close</td><td>3.5</td><td>0.97</td><td>3.3</td><td>1.1</td><td>0.02</td></tr>
<tr><td>See steps/ curb</td><td>3.4</td><td>0.74</td><td>3.3</td><td>0.90</td><td>0.79</td></tr>
<tr><td>Read street signs</td><td>3.0</td><td>1.4</td><td>2.1</td><td>1.7</td><td><.001</td></tr>
<tr><td>Do fine hand-work</td><td>1.5</td><td>1.6</td><td>0.89</td><td>1.4</td><td>0.24</td></tr>
<tr><td>Fill forms or checks</td><td>2.5</td><td>1.5</td><td>1.9</td><td>1.6</td><td><.001</td></tr>
<tr><td>Cook</td><td>3.2</td><td>1.2</td><td>3.3</td><td>0.97</td><td>0.85</td></tr>
<tr><td>Watch TV</td><td>2.4</td><td>1.1</td><td>2.5</td><td>1.3</td><td>0.97</td></tr>
<tr><td>Cross roads</td><td>3.0</td><td>1.2</td><td>2.3</td><td>1.4</td><td><0.01</td></tr>
<tr><td>Recognize faces across street</td><td>1.9</td><td>1.7</td><td>1.2</td><td>1.6</td><td><0.01</td></tr>
<tr><td>Read bus numbers</td><td>2.6</td><td>1.5</td><td>1.9</td><td>1.7</td><td>0.02</td></tr>
<tr><td>Social activities</td><td>3.1</td><td>1.4</td><td>3.1</td><td>1.2</td><td>0.17</td></tr>
<tr><td>Getting about indoors</td><td>3.8</td><td>0.39</td><td>3.8</td><td>0.41</td><td>0.71</td></tr>
<tr><td>Hobbies</td><td>2</td><td>1.7</td><td>2.1</td><td>1.7</td><td>0.38</td></tr>
<tr><td>Total VF-14 score</td><td>68</td><td>26</td><td>63</td><td>25</td><td>0.11</td></tr>
</table>

Question 3: Relationship between QOL measures (s) and objective measures</td>
<td>Quality assessment:
Meaningfully defined study population: +
Protection from bias: 0
Consideration of statistical power: -

This article is relevant to:
X Question 1A
□ Question 1B
□ Question 1C
□ Question 2
X Question 3</td>
</tr>
</table>

Evidence Table 5: Visual Function Index (VF-14) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/ Comments
Cassard 1995 #8160	**Geographical location:** Columbus, OH; St. Louis, MO; Houston, TX **Dates:** 7/15/91-12/15/91 **Context:** □ Clinical trial □ Cohort □ Cross sectional X Longitudinal **Inclusion/ Exclusion criteria:** 1) patient was seen by ophthalmologist on 7/15/91 or later; 2) patient was scheduled to undergo cataract surgery within 3 mos. following initial visit; 3) patient had not undergone previous cataract surgery; 4) patient was ≥ 50 yrs. 5) planned cataract surgery did not involve any	**Population size (n):** 552 Mean age 72 White % 94 Female % 63 GT H.S. education 29 Married % 58 Living alone % 32 Eye dx: Not reported **AMD:** Not reported **AMD Type:** Not reported **Laterality:** Not reported **Objective Measure(s) of function (e.g., visual acuity):**	**Instrument/ Technique Name:** VF-14 **Method of administration:** **By whom:** □ Masked □ Unmasked X Unknown **Mode of administration:** X Phone interview □ Face to face interview □ Mail questionnaire □ In office questionnaire □ Observation X Other (physical exam) **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of administration:** Pre-op, and 4 and 12 mo post-surgery	**Question 1C: psychometric properties (validity, reliability, responsiveness)** Reproducibility: ICC was .57 to .79 among patients without change in visual acuity. Mean scores dropped by 0.4 to 1.7 units in this subgroup, depending upon how change in visual acuity was measured. Responsiveness: Among patients with notable changes in visual acuity the effect size was 1.07, much larger than the effect size for the SIP. Effect sizes were highest for patients with a great deal of trouble at baseline (1.49) in comparison with patients with a little trouble at baseline (.87), but all were high. Notes: This well-designed study among patients with first-eye cataract surgery provides good support for the reproducibility and responsiveness of the instrument.	**Quality assessment:** Meaningfully defined study population: - Protection from bias: 0 Consideration of statistical power: + **This article is relevant to:** □ Question 1A □ Question 1B X Question 1C □ Question 2 □ Question 3

Evidence Table 5: Visual Function Index (VF-14) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/ Comments
	other surgical proc.; 6) English speaking; 7) lived within a 50-mile radius of office; 8) lived within 50 miles of interviewer.				

Evidence Table 5: Visual Function Index (VF-14) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/ Comments
Cas-tells 1998 #8140	**Geographical location:** 3 public hospitals in Barcelona, Spain, where cataract surgery represented 90% of ophthalmology activity **Dates:** 4/93-1/94 **Context:** □ Clinical trial □ Cohort □ Cross sectional □ Longitudinal X Case series **Inclusion/ Exclusion criteria:** Patients were eligible for the study if they were scheduled for cataract surgery that did not involve a combined procedure and they met the inclusion criteria for outpatient surgery: 10 sufficient social and family support	**Population size (n):** 403 1st eye: Mean age 69.8; % male 47 2nd eye: Mean age 70.1; % male 37.9 p: Mean age .23; % male .21 Eye dx: Not reported **AMD:** Not reported **AMD Type:** Not reported **Laterality:** Not reported **Objective Measure(s) of function (e.g., visual acuity):** The total number of AMD Patients = 30.	**Instrument/ Technique Name:** VF-14 **Method of administration:** **By whom:** □ Masked □ Unmasked □ Unknown **Mode of administration:** X Phone interview □ Face to face interview □ Mail questionnaire □ In office questionnaire □ Observation □ Other clinical exam **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of administration:** Pre-op and 4 mo post-op	**Question 1C: psychometric properties (validity, reliability, responsiveness)** Responsiveness: Effect sizes for post-surgical improvement (.8 to 1.0) were greater than those for the SIP. Notes: This analysis, part of a randomized trial of cataract surgery, supports the responsiveness of the Spanish version of this instrument.	**Quality assessment:** Meaningfully defined study population: + Protection from bias: 0 Consideration of statistical power: + **This article is relevant to:** □ Question 1A □ Question 1B X Question 1C □ Question 2 □ Question 3

Evidence Table 5: Visual Function Index (VF-14) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/ Comments
	in postoperative period; 2) distance between the hospital and home was less than 1 hour; 3) no medical comorbidity requiring admission; 4) absence of severe ocular comorbidities or background of intraocular surgery.				

Evidence Table 5: Visual Function Index (VF-14) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/ Comments
Desai 1993-1994 #7240	**Geographical location:** 3 district general hospitals in London, UK **Dates:** 5/93-8/94 **Context:** □ Clinical trial □ Cohort □ Cross sectional X Longitudinal **Inclusion/ Exclusion criteria:** Patients admitted for surgery for age-related cataract, for first eye, and subsequently for second eye. Patients having combined procedures or surgery for other types of cataract were excluded.	**Population size (n):** 337 % ≥ 75 yrs: 59.3 % male: 38.9 Eye dx: Not reported **AMD:** Not reported **AMD Type:** Not reported **Laterality:** Not reported **Objective Measure(s) of function (e.g., visual acuity):**	**Instrument/ Technique Name:** VF-14 **Method of administration:** **By whom:** □ Masked X Unmasked □ Unknown **Mode of administration:** □ Phone interview X Face to face interview (at home) □ Mail questionnaire □ In office questionnaire □ Observation □ Other **Respondent:** □ Only patient □ Patient or surrogate □ Only surrogate X Unknown **Time points of administration:** Pre-op, and 4 and 12 mo post surgery	**Question 1C: psychometric properties (validity, reliability, responsiveness)** Internal consistency: Cronbach's alpha .74 Construct validity: VF-14 was significantly correlated with both visual acuity (.48) and the VR-SIP (.70) Responsiveness: Significant improvement was observed at both 4 and 12-months post cataract surgery. However, the VF-14 did not significantly distinguish between those with different magnitude of gains in visual acuity. Notes: A solid study of responsiveness in patients with cataract surgery.	**Quality assessment:** Meaningfully defined study population: - Protection from bias: 0 Consideration of statistical power: + **This article is relevant to:** □ Question 1A □ Question 1B X Question 1C □ Question 2 □ Question 3

Evidence Table 5: Visual Function Index (VF-14) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/ Comments
Gresset 1997 #8260	**Geographical location:** Ophthalmology Clinic of Maisonneuve-Rosemont Hospital at University of Montreal, Canada **Dates:** 5/95-6/95 **Context:** □ Clinical trial □ Cohort X Cross sectional □ Longitudinal **Inclusion/ Exclusion criteria:** Consecutive patients with ocular media opacities, such as cataracts and corneal opacities were recruited. Only subjects with-out cognitive or hearing impairments who spoke French or both French and English were included. Patients with visual field defects were excluded.	**Population size (n):** 66 Mean age 69.7 % female 43.9 % married 57.6 % living alone 25.8 Eye dx: Not reported **AMD:** Not reported **AMD Type:** Not reported **Laterality:** Not reported **Objective Measure(s) of function (e.g., visual acuity):** Not reported	**Instrument/ Technique Name:** VF-14 **Method of administration:** **By whom:** □ Masked □ Unmasked X Unknown **Mode of administration:** X Phone interview □ Face to face interview □ Mail questionnaire □ In office questionnaire □ Observation □ Other **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of administration:** NA (cross sectional)	**Question 1C: psychometric properties (validity, reliability, responsiveness)** Internal consistency: 17 of 66 patients considered all 14 items to be applicable. Cronbach's alpha was .96, item-total correlations ranged from .51 to .93. Reproducibility: The ICC was .88. Construct validity: Correlations were high with the cataract symptom score (.73), a global measure of trouble with vision (.69), and a global measure of satisfaction with vision (.77), these correlations exceeding the correlations between SF-36 subscales and these same measures. Correlations with the SF-36 subscales were moderate (.19 to .38). Notes: This small cross-sectional study among a cohort of patients within an ophthalmology clinic provides relatively little evidence in support of a foreign-language version of the instrument.	**Quality assessment:** Meaningfully defined study population: Protection from bias: 0 Consideration of statistical power: + but low power **This article is relevant to:** □ Question 1A □ Question 1B X Question 1C □ Question 2 □ Question 3

Evidence Table 5: Visual Function Index (VF-14) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/ Comments
Javitt 1995 #5450	**Geographical location:** Columbus, OH; St. Louis, MO; Houston, TX **Dates:** 7/15/91-12/15/91 **Context:** □ Clinical trial □ Cohort □ Cross sectional X Longitudinal **Inclusion/ Exclusion criteria:** Patients ≥ 50 yrs. of age; have no planned simultaneous surgery for glaucoma, corneal or vitreoretinal disorders; speak English; live within 50 miles of office.	**Population size (n): 669** Eye dx: Not reported **AMD:** Not reported **AMD Type:** Not reported **Laterality:** Not reported **Objective Measure(s) of function (e.g., visual acuity):**	**Instrument/ Technique Name:** VF-14 **Method of administration:** **By whom:** □ Masked □ Unmasked X Unknown **Mode of administration:** X Phone interview □ Face to face interview □ Mail questionnaire □ In office questionnaire □ Observation X Other (physical exam) **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of administration:** At enrollment, 4 mos. after first surgery; and 12 mos. After first eye surgery.	**Question 1C: psychometric properties (validity, reliability, responsiveness)** Responsiveness: As expected, patients with surgery in 2 eyes had greater improvement in the VF-14 than patients with surgery in a single eye. Notes: A solid study of responsiveness in patients with cataract surgery.	**Quality assessment: -** Meaningfully defined study population: Protection from bias: 0 Consideration of statistical power: + **This article is relevant to:** □ Question 1A □ Question 1B X Question 1C □ Question 2 □ Question 3

	Eye -1	Eye -2	p
Mean age	71.8	73.0	NS
Male %	38	35.4	NS
Married %	58.5	54.3	NS
Living alone %	30.8	36.2	NS
White %	94.3	94.7	NS

Evidence Table 5: Visual Function Index (VF-14) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/ Comments
Linder 1999 #1940	**Geographical location:** Vancouver, BC **Dates:** 5/1-8/15/98 **Context:** □ Clinical trial □ Cohort X Cross sectional □ Longitudinal **Inclusion/ Exclusion criteria:** Patients attending the Vancouver General Hospital Eye Care Centre retina clinic consecutively between study dates. Age 16 and older who speak English.	**Population size (n):** 546 Mean age: 55 Female %: 48 White %: 74 Eye dx: Not reported **AMD:** 13% **AMD Type:** Not reported **Laterality:** Not reported **Objective Measure(s) of function (e.g., visual acuity):** 71 Patients with AMD included	**Instrument/ Technique Name:** VF-14 **Method of administration:** **By whom:** □ Masked X Unmasked □ Unknown **Mode of administration:** □ Phone interview X Face to face interview □ Mail questionnaire X In office questionnaire □ Observation X Other (physical exam) **Respondent:** □ Only patient X Patient or surrogate (90% self and 10% assisted) □ Only surrogate □ Unknown **Time points of administration:** NA (cross sectional)	**Question 1C: psychometric properties (validity, reliability, responsiveness)** Internal consistency: Cronbach's alpha .91 Construct validity: Significant correlations in the expected direction with Snellen WMAR (.45), quality of vision scales (.50), satisfaction with vision scale (.43) and trouble with vision scale (.63) Scores on the VF-14 decreased with decreasing visual acuity. Notes: Overall, a high-quality validation study among a population of patients with a diverse set of visual problems.	**Quality assessment:** Meaningfully defined study population: + Protection from bias: 0 Consideration of statistical power: + **This article is relevant to:** □ Question 1A □ Question 1B X Question 1C □ Question 2 □ Question 3

Evidence Table 5: Visual Function Index (VF-14) – continued

<table>
<tr><th>Study</th><th>Study Design</th><th>Study Population</th><th>Instrument Characteristics</th><th>Results</th><th>Quality Scoring/ Comments</th></tr>
<tr>
<td>Mac-Kenzie 2002 #1130</td>
<td>Geographical location:
Vancouver, BC, retina-only clinic

Dates: 5/98-8/98 and 5/99-8/99

Context:
□ Clinical trial
□ Cohort
□ Cross sectional
□ Longitudinal
X Case series

Inclusion/ Exclusion criteria:
Consecutive patients with AMD who could communicate in English and provide informed consent were considered eligible for the study. Patients with multiple retinal conditions and patients with branch retinal vein occlusions and diabetic retinopathy in the absence of AMD were excluded from</td>
<td>Population size (n): 159

<table><tr><td>Mean age</td><td>75</td></tr><tr><td>% female</td><td>62</td></tr><tr><td>% White</td><td>83</td></tr></table>
Eye dx: Not reported

AMD: 100%

AMD Type:
84% wet only
11% dry only
8% wet and dry

Laterality:
□ Unilateral
X Bilateral

Objective Measure(s) of function (e.g., visual acuity):
Corrected visual acuity:
Better eye: 20/30 (20/20 – LP)
Worse eye: 20/200 (20/20 – NLP)
Weighted logMAR: 0.34</td>
<td>Instrument/ Technique Name:
VF-14

Method of administration:

By whom:
□ Masked
□ Unmasked
X Unknown

Mode of administration:
□ Phone interview
□ Face to face interview
□ Mail questionnaire
X In office questionnaire
□ Observation
□ Other

Respondent:
X Only patient
□ Patient or surrogate
□ Only surrogate
□ Unknown

Time points of administration:
Enrollment</td>
<td>Question 1A: Instrument scores in AMD patients:
<table><tr><th>VF-14</th><th>No diff (%)</th><th>Little dif (%)</th><th>Mod diff (%)</th><th>Great deal (%)</th><th>Unable to do (%)</th></tr><tr><td>Read small print</td><td>20</td><td>23</td><td>17</td><td>23</td><td>17</td></tr><tr><td>Read newspaper/ book</td><td>30</td><td>19</td><td>16</td><td>22</td><td>13</td></tr><tr><td>Large print books</td><td>60</td><td>15</td><td>12</td><td>8</td><td>6</td></tr><tr><td>Recognize people close</td><td>72</td><td>12</td><td>7</td><td>8</td><td>1</td></tr><tr><td>See steps/curb</td><td>56</td><td>26</td><td>8</td><td>9</td><td>0</td></tr><tr><td>Read street signs</td><td>44</td><td>29</td><td>12</td><td>10</td><td>6</td></tr><tr><td>Do fine handwork</td><td>30</td><td>26</td><td>15</td><td>15</td><td>15</td></tr><tr><td>Fill forms or checks</td><td>49</td><td>20</td><td>11</td><td>12</td><td>9</td></tr><tr><td>Cooking</td><td>64</td><td>16</td><td>13</td><td>6</td><td>1</td></tr><tr><td>Watch TV</td><td>50</td><td>23</td><td>14</td><td>12</td><td>1</td></tr></table>
<table><tr><th>SF-36</th><th>Mild (128)</th><th>Moderate (62)</th><th>Severe (11)</th><th>P value</th></tr><tr><td>Physical functioning</td><td>79</td><td>80</td><td>79</td><td></td></tr><tr><td>Role-physical</td><td>67</td><td>76</td><td>77</td><td></td></tr><tr><td>Bodily pain</td><td>73</td><td>75</td><td>82</td><td></td></tr><tr><td>General Health</td><td>68</td><td>68</td><td>63</td><td></td></tr><tr><td>Vitality</td><td>61</td><td>59</td><td>66</td><td></td></tr><tr><td>Social functioning</td><td>92</td><td>92</td><td>99</td><td></td></tr><tr><td>Role-emotional</td><td>82</td><td>87</td><td>88</td><td></td></tr><tr><td>Mental Health</td><td>75</td><td>74</td><td>73</td><td></td></tr></table></td>
<td>Quality assessment:
Meaningfully defined study population: +
Protection from bias: 0
Consideration of statistical power: -

This article is relevant to:
X Question 1A
□ Question 1B
X Question 1C
□ Question 2
X Question 3</td>
</tr>
</table>

Evidence Table 5: Visual Function Index (VF-14) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/ Comments

the study.

Physical Component	-0.35	-0.23	-0.19	
Mental Component	-0.22	0.18	0.32	

Question 1C: psychometric properties (validity, reliability, responsiveness)
Internal consistency: Cronbach's alpha .95 (in the subset of patients that rated all 14 items as applicable)

Construct validity: VF-14 total score was most strongly correlated (.62 to .67) with 3 global items (trouble with vision, satisfaction with vision, and overall quality of vision), well-correlated with visual acuity (.49) and also strongly correlated with weighted visual acuity (.69). The correlations were notably higher than those between SF-36 subscales and other vision scores. There was a strong bivariate relationship between AMD severity and VF-14 total score [manuscript table 6]. It was not possibly to definitively disentangle the effects of AMD severity from those of visual acuity.

Notes:This study of clinic patients, including those with AMD, provides moderate support for the cross-sectional validity of the VF-14, and continued support for the notion that condition-specific measures are preferable to general measures among patients with AMD.

Question 3: Relationship between QOL measures (s) and objective measure

	Mild AMD (#54) Gps 1/2	Moderate AMD (#62) Gps3/4	Severe (#43) Gps 5/6/7	P value (adjusted for visual acuity)
VF-14 mean	86/81	74/71	71/62/45	0.54
Weighted Visual Acuity, mean	0.12/0.26	0.43/0.41	0.52/0.70/ 1.09	-----
SF-36, mean				
Physical functioning	80/71	76/74	57/66/59	0.28
Role-physical	67/70	71/65	45/44/51	0.34

Evidence Table 5: Visual Function Index (VF-14) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results					Quality Scoring/ Comments
				Bodily pain	69/74	70/80	72/61/81	0.12	
				General Health	64/73	65/69	55/69/68	0.18	
				Vitality	57/57	58/61	56/58/52	0.41	
				Social functioning	81/85	82/90	60/79/71	0.26	
				Role-emotional	75/86	74/80	40/63/76	0.44	
				Mental Health	21/22	21/15	22/16/18	0.44	
				Physical Component	47/46	46/47	44/41/42	0.84	
				Mental Component	49/53	50/52	38/52/51	0.70	

Evidence Table 5: Visual Function Index (VF-14) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/ Comments
Nij-kamp 2000 #4470	**Geographical location:** The Netherlands Inpatient, outpatient facilities **Dates:** 1/98 **Context:** □ Clinical trial □ Cohort □ Cross sectional X Longitudinal **Inclusion/ Exclusion criteria:** Patients consisted of 3 subgroups based on the institution (inpatient and outpatient) at which the cataract surgery was performed. Inclusion criteria were first-eye cataract surgery to prevent bias from earlier experiences and age older than 50 years.	**Population size (n):** 150 UHM=University Hospital Maastricht AMCH=Atrium Medical Center Heerlen MCMA=Medical Center Maastricht Annadal Eye dx: Not reported **AMD:** 6% Glaucoma: 9% Diabetic retinopathy: 4% Corneal disease: 8% Other 2% Other central vision loss (by type): Cataract 100% **AMD Type:** Not reported **Laterality:** X Unilateral □ Bilateral **Objective Measure(s) of function (e.g., visual acuity):** 41/150=27.3% 58/150=39% 51/150=34% Mean postoperative logMAR 0.16±26	**Instrument/ Technique Name:** VF-14, Dutch **Method of administration:** **By whom:** □ Masked □ Unmasked X Unknown **Mode of administration:** □ Phone interview □ Face to face interview X Mail questionnaire □ In office questionnaire □ Observation □ Other **Respondent:** □ Only patient □ Patient or surrogate X Only surrogate □ Unknown **Time points of administration:** 6 mos post surgery	**Question 1C: psychometric properties (validity, reliability, responsiveness)** Construct validity: **Question 3: Relationship between QOL measures (s) and objective measure** Reliability: Cronbach's alpha for 3 factor solution were 0.84, 0.88, 0.59. Validity score correlate with visual function (r=-0.283) Responsiveness: not evaluated	**Quality assessment:** Meaningfully defined study population: Protection from bias: + Consideration of statistical power: + **This article is relevant to:** □ Question 1A □ Question 1B X Question 1C □ Question 2 X Question 3

	UHM	MCMA	AMCH
Mean age	77.4	74.6	72.3
% male	41.2	46.6	39
Education (primary)	37.3	44.8	48.8
Lives alone	39.2	48.3	51.2

Evidence Table 5: Visual Function Index (VF-14) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/ Comments
Riusala 2003 #940	**Geographical location:** Finland **Dates:** 6/90-12/94 **Context:** □ Clinical trial □ Cohort □ Cross sectional □ Longitudinal X Case series **Inclusion/ Exclusion criteria:** Consecutive patients with recent neovascular AMD.	**Population size (n):** 62 Mean age: 76 % female: 65 Eye dx: Not reported **AMD: 100%** **AMD Type:** 100% wet **Laterality:** X Unilateral □ Bilateral **Objective Measure(s) of function (e.g., visual acuity):** Corrected visual acuity: Better eye: 0.3 logMAR Worse eye: 0.04 logMAR	**Instrument/ Technique Name:** VF-14 **Method of administration:** **By whom:** □ Masked □ Unmasked X Unknown **Mode of administration:** □ pphone interview X Face to face interview □ Mail questionnaire □ In office questionnaire □ Observation □ Other **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of administration:** At enrollment	**Question 1A: Instrument scores in AMD patients** VF-14 Wet AMD in better eye: No diff (%) / Little dif (%) / Mod diff (%) / Great deal (%) / Unable to do (%) Read small print: 0 / 4 / 7 / 0 / 89 Read newspaper/ book: 4 / 12 / 8 / 0 / 77 Large print books: 21 / 4 / 11 / 18 / 46 Recognize people close: 43 / 7 / 14 / 21 / 14 See steps/curb: 46 / 7 / 14 / 25 / 7 Read street signs: 18 / 13 / 7 / 14 / 54 Do fine handwork: 4 / 0 / 15 / 12 / 69 Fill forms or checks: 14 / 0 / 0 / 11 / 75 Cooking: 33 / 8 / 29 / 20 / 8 Watch TV: 18 / 11 / 11 / 40 / 21 Playing table games: 20 / 7 / 7 / 13 / 53 Sports involvement: 0 / 20 / 20 / 0 / 60 Driving Daytime: 0 / 0 / 0 / 0 / 0 Driving Nighttime: 0 / 0 / 0 / 0 / 0 VF-14 Wet AMD in worse eye: No diff (%) / Little dif (%) / Mod diff (%) / Great deal (%) / Unable to do (%) Read small print: 27 / 24 / 24 / 12 / 15 Read newspaper/ book: 74 / 6 / 12 / 3 / 6 Large print: 94 / 3 / 0 / 3 / 0	**Quality assessment:** Meaningfully defined study population:+ Protection from bias: 0 Consideration of statistical power: - **This article is relevant to:** X Question 1A □ Question 1B □Question 1C □ Question 2 X Question 3

Evidence Table 5: Visual Function Index (VF-14) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/ Comments

books					
Recognize people close	100	0	0	0	0
See steps/curb	65	18	12	6	0
Read street signs	71	15	3	9	3
Do fine handwork	40	10	27	10	13
Fill forms or checks	73	15	0	3	9
Cooking	77	10	7	7	0
Watch TV	71	9	15	6	0
Playing table games	89	6	6	0	0
Sports involvement	78	11	0	11	0
Driving Daytime	100	0	0	0	0
Driving Nighttime	27	46	9	18	0

Question 3: Relationship between QOL measures (s) and objective measure

Correlation between VF-14 and visual acuity (p<.05 = +)	Wet AMD better eye Best eye	Wet AMD in better eye (worse eye)	Wet AMD in worse eye (better eye)	Wet AMD in worse eye (worse eye)
Read small print	+		+	
Read newspaper /book	+		+	
Large print books	+		+	
Recognize people close	+			
See steps/curb	+	+		

Evidence Table 5: Visual Function Index (VF-14) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results					Quality Scoring/ Comments
				Read street signs	+		+	+	
				Do fine handwork			+		
				Fill forms or checks	+	+	+	+	
				Cooking	+	+			
				Watch TV	+		+	+	
				Playing table games		+	+		
				Sports involve-ment					
				Driving Daytime					
				Driving Nighttime					

Evidence Table 5: Visual Function Index (VF-14) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/ Comments
Sharma 2002 #1110	**Geographical location:** Philadelphia, PA, retina clinic **Dates:** 2001 **Context:** □ Clinical trial □ Cohort X Cross sectional □ Longitudinal **Inclusion/ Exclusion criteria:** Patients were eligible if they had 20/40 vision or worse in at lest one eye and were deemed competent to answer the required questions. Patients were excluded for communication barriers, developmental disability and psychiatric illness.	**Population size (n):** 323 61-70 yrs. 29.1 71-80 yrs. 36.2 ≥ 80 yrs age 10.5 % female 63.5 % white 96.3 > H.S educ. 42.2 Retired % 50.8 Employed % 39.6 Eye dx: Not reported **AMD:** Not reported **AMD Type:** Not reported **Laterality:** □ Unilateral X Bilateral **Objective Measure(s) of function (e.g., visual acuity):** Vision in better seeing eye 20/25 or better: 23% 20/30-20/50: 42% 20/60-20/100: 18% 20/200-20/400: 11% CF to NLP: 5%	**Instrument/ Technique Name:** VF-14 **Method of administration:** **By whom:** X Masked □ Unmasked □ Unknown **Mode of administration:** □ Phone interview X Face to face interview □ Mail questionnaire □ In office questionnaire □ Observation □ Other **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of administration:** NA (cross sectional)	**Question 1C: psychometric properties (validity, reliability, responsiveness)** Construct validity: The VF-14 was correlated with vision in the better eye. Vision in better seeing eye / VF – 14 score 20/25: 90.7 (88.3-93.1) 20/30-20/50: 79.28 (76.14-82.41) 20/60-20/100: 51.01 (45.55-56.48) 20/200-20/400: 34.03 (27.44-40.62) CF to NLP: 18.25 (5.49-31.02) Notes: This study of a diverse cohort of patients including those with AMD supports the construct validity of the VF-14, as well as the time trade-off and standard gamble.	**Quality assessment:** Meaningfully defined study population: Protection from bias: + Consideration of statistical power: + **This article is relevant to:** □ Question 1A □ Question 1B X Question 1C □ Question 2 □ Question 3

Evidence Table 5: Visual Function Index (VF-14) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/ Comments
Stein-berg 1994 #8240	**Geographical location:** Columbus, OH; St. Louis, MO; Houston, TX **Dates:** 7/15/91-12/15/91 **Context:** □ Clinical trial □ Cohort X Cross sectional □ Longitudinal **Inclusion/ Exclusion criteria:** Medicare beneficiaries and met the following: 1) patient was seen by ophthalmologist on 7/15/91 or later; 2) patient was scheduled to undergo cataract surgery within 3 mos. following initial visit; 3) patient had not undergone previous cataract surgery; 4) patient was ≥ 50 yrs.	**Population size (n):** 772 Mean age: 72 Range: 50-95 Female %: 63 White %: 94 Education > H.S. %: 28 Married %: 56 Living alone %: 33 Eye dx: Not reported **AMD:** Not reported **AMD Type:** Not reported **Laterality:** Not reported **Objective Measure(s) of function (e.g., visual acuity):** Pre-operative best corrected visual acuity in each eye	**Instrument/ Technique Name:** VF-14 **Method of administration:** **By whom:** □ Masked □ Unmasked X Unknown **Mode of administration:** X Phone interview X Face to face interview □ Mail questionnaire □ In office questionnaire □ Observation X Other (physical exam) **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of administration:** NA (cross sectional)	**Question 1C: psychometric properties (validity, reliability, responsiveness)** Internal consistency: Median number of applicable items 12 of 14. Factor analysis supported a single scale. Cronbach's alpha was .85, item-total correlations ranged from .32 to .61. Construct validity: Correlations with visual acuity were modest (.03 to .27); correlations with self-reported global items were moderate (.39 for satisfaction with vision, .45 for trouble with vision), correlation with VR-SIP was .57. The VF-14 had higher correlations with the global items than did the VR-SIP. Notes: This study provides a moderate level of support from the cross-sectional validity of the instrument.	**Quality assessment:** Meaningfully defined study population: + Protection from bias: 0 Consideration of statistical power: + **This article is relevant to:** □ Question 1A □ Question 1B X Question 1C □ Question 2 □ Question 3

Evidence Table 5: Visual Function Index (VF-14) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/ Comments
	5) planned cataract surgery did not involve any other surgical proc.; 6) English speaking; 7) lived within a 50-mile radius of office; 8) lived within 50 miles of interviewer.				

Evidence Table 5: Visual Function Index (VF-14) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/ Comments
Tielsch 1995 #8120	**Geographical location:** Columbus, OH; St. Louis, MO; Houston, TX **Dates:** 7/15/91-12/15/91 **Context:** □ Clinical trial □ Cohort □ Cross sectional X Longitudinal **Inclusion/ Exclusion criteria:** 1) patient was seen by ophthalmologist on 7/15/91 or later; 2) patient was scheduled to undergo cataract surgery within 3 mos. following initial visit; 3) patient had not undergone previous cataract surgery; 4) patient was ≥ 50 yrs. 5) planned cataract surgery did not involve any	**Population size (n):** 552 Mean age: 72 Male %: 37.1 White %: 94.4 > H.S. educ.: 29.5 Eye dx: Not reported **AMD:** Not reported **AMD Type:** Not reported **Laterality:** Not reported **Objective Measure(s) of function (e.g., visual acuity):** Included 55 Patients with AMD	**Instrument/ Technique Name:** VF-14 **Method of administration:** **By whom:** □ Masked □ Unmasked X Unknown **Mode of administration:** X Phone interview □ Face to face interview □ Mail questionnaire □ In office questionnaire □ Observation X Other (physical exam) **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of administration:** Pre-operatively; at 4 mos.	**Question 1C: psychometric properties (validity, reliability, responsiveness)** Construct validity: At baseline, patients with good vision in their better eye had better scores than others. No such trend was observed in the operated eye. At baseline, the VF-12 was correlated with global items on trouble with vision (.43) and satisfaction with vision (.31). Notes: Most of this article, taken from the patient population in a study of cataract surgery, is focused on patient expectations for improved quality of life, which are outside the scope of this review.	**Quality assessment:** Meaningfully defined study population: - Protection from bias: 0 Consideration of statistical power: + **This article is relevant to:** □ Question 1A □ Question 1B X Question 1C □ Question 2 □ Question 3

Evidence Table 5: Visual Function Index (VF-14) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/ Comments
	other surgical proc.; 6) English speaking; 7) lived within a 50-mile radius of office; 8) lived within 50 miles of interviewer.				

Evidence Table 5: Visual Function Index (VF-14) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/ Comments
Velozo 2000 #8440	**Geographical location:** Two surgical centers **Dates:** 2000 **Context:** □ Clinical trial X Cohort □ Cross sectional □ Longitudinal **Inclusion/ Exclusion criteria:** Patients who were about to undergo extracapsular cataract removal at one of two surgical centers.	**Population size (n):** 61 Mean age: 73.7 % male: 31 First eye surgery: 51 Second eye sugery: 28 Eye dx: Not reported **AMD:** Not reported **AMD Type:** Not reported **Laterality:** Not reported **Objective Measure(s) of function (e.g., visual acuity):** Not reported	**Instrument/ Technique Name:** VF-14 +10 items or VF-24 **Method of administration:** **By whom:** □ Masked □ Unmasked X Unknown **Mode of administration:** □ Phone interview □ Face to face interview □ Mail questionnaire □ In office questionnaire □ Observation X Other administered in clinic, method not specified **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of administration:** Prior to surgery	**Question 1C: psychometric properties (validity, reliability, responsiveness)** Internal consistency: Cronbach's alpha ranged from .83 to .91. Scaling consistency: A Rasch analysis of the VF-14 suggested that a number of potential limitations, including too many response categories, ceiling effects, redundant items and missing items. A 10-item version of the instrument exhibited better scaling properties.	**Quality assessment:** Meaningfully defined study population: + Protection from bias: 0 Consideration of statistical power:+ but low power **This article is relevant to:** □ Question 1A □ Question 1B X Question 1C □ Question 2 □ Question 3

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ)

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Brody 2005 #260	**Geographical location:** San Diego, CA **Dates:** 1/98 – 9/00 **Context:** X Clinical trial □ Cohort □ Cross sectional □ Other **Inclusion/Exclusion criteria:** AMD, vision ≤ 20/60 in better eye, ≤20/100 in worse eye, no other reason for decreased vision, age>60, no cognitive impairment	**Population size (n):** 232 Group 1: Self management Group 2: Tape-recording Group 3: Waiting list Age: Mean: Group 1 - 80.5 Group 2 - 81.3 Group 3 - 80.3 Eye dx: Not reported **AMD:** 100% **AMD Type:** Mix **Laterality:** □ Unilateral 40% X Bilateral **Objective Measure(s) of function (e.g., visual acuity):** Log visual acuity of best eye Group 1: 1.09 Group 2: 1.14 Group 3: 1.11	**Instrument/Technique Name:** NEI-VFQ **Method of administration:** **By whom:** □ Masked □ Unmasked X Unknown **Mode of administration:** □ Phone interview X Face to face interview □ Mail questionnaire X In office questionnaire □ Observation □ Other **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of administration:** Baseline and every 3 months x 1 yr	**Question 1A: Instrument scores in AMD patients** NEI-VFQ Score / No / Baseline / 6 mos Self-mngmt / 82 / / Depressed / 18 / 49 / 56 Nondepr / 62 / 63 / 62 / / / / Control / 131 / / Depressed / 32 / 49 / 49 Nondepr / 99 / 61 / 60	**Quality assessment:** Meaningfully defined study population: + Protection from bias: 0 Consideration of statistical power: - **This article is relevant to:** X Question 1A □ Question 1B □ Question 1C □ Question 2 □ Question 3

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

<table>
<tr><th>Study</th><th>Study Design</th><th>Study Population</th><th>Instrument Characteristics</th><th>Results</th><th>Quality Scoring/Comments</th></tr>
<tr>
<td>Cahill 2005 #120</td>
<td>Geographical location:
Durham, NC

Dates: 2/99-8/02

Context:
□ Clinical trial
□ Cohort
X Cross sectional
□ Other

Inclusion/Exclusion criteria:
Patients with bilateral severe neovascular MD scheduled to undergo MT360.

Inclusion criteria:
Age ≥ 50 yrs.
AMD with subfoveal CNV

Best-corrected Snellen visual acuity between 20/50 and 20/400 in the operative eye;
Maximum 6 mos. Central vision loss reported by patient;
No light perception in either eye;
Visual acuity of 20/50 or better in the fellow eye;
Previous laser treatment of the center of the fovea in the operative eye;
Previous submacular surgery in the treated eye;</td>
<td>Population size (n): 70

Age: Mean age 76.4 yrs
38.6% male

Eye dx: Not reported

AMD: 100%

AMD Type: 100% wet

Laterality:
□ Unilateral
X Bilateral

Objective Measure(s) of function (e.g., visual acuity):
Mean VA 62.4 letters (SD 16.7); mean fellow eye VA 33.1 letters (SD 23.6)
Mean near VA .81 log MAR (SD .37)
Mean reading speed 74.9 WPM (SD 41.3)
Mean Lesion size 10.0 MPS disc areas (SD, 5.5); all lesions were ≥ 3 MPS disc areas in size.
Duration of vision loss in second eye 13.5 weeks (SD, 11.2)

<table>
<tr><td>Mean VA</td><td>62.4</td></tr>
<tr><td>Fellow eye VA</td><td>33.1</td></tr>
<tr><td>Mean near VA</td><td>.81 log MAR</td></tr>
<tr><td>Mean reading speed</td><td>74.9</td></tr>
<tr><td>Mean lesion size</td><td>10.0 MPS</td></tr>
<tr><td>All lesions</td><td>≥ 3</td></tr>
</table>
</td>
<td>Instrument/Technique Name:
VQF-25
SF-12

Method of administration:

By whom:
X Masked
□ Unmasked
□ Unknown

Mode of administration:
□ Phone interview
X Face to face interview
□ Mail questionnaire
□ In office questionnaire
□ Observation
□ Other

Respondent:
□ Only patient
□ Patient or surrogate
□ Only surrogate
X Unknown

Time points of administration: NA (cross sectional)</td>
<td>Question 1A: Instrument scores in AMD patients

<table>
<tr><th>NEI VQF - 25</th><th>Study</th><th>Low Vis. (P value)</th><th>AMD (P value)</th><th>Ref (P value)</th></tr>
<tr><td>General vision</td><td>31.4</td><td>38 (.015)</td><td>53 (<.001)</td><td>83 (<.001)</td></tr>
<tr><td>Distance tasks</td><td>38.8</td><td>38 (.843)</td><td>56 (<.001)</td><td>93 (<.001)</td></tr>
<tr><td>Near tasks</td><td>29.4</td><td>36 (.047)</td><td>54 (<.001)</td><td>9 (<.001)</td></tr>
<tr><td>Peripheral vision</td><td>66.8</td><td>59 (.086)</td><td>77 (.011)</td><td>97 (<.001)</td></tr>
<tr><td>Color vision</td><td>67.5</td><td>71 (.453)</td><td>85 (<.001)</td><td>98 (<.001)</td></tr>
<tr><td>Dependency</td><td>42.7</td><td>51 (.087)</td><td>72 (<.001)</td><td>99 (<.001)</td></tr>
<tr><td>Role difficulties</td><td>38.2</td><td>44 (.195)</td><td>61 (<.001)</td><td>93 (<.001)</td></tr>
<tr><td>Mental health</td><td>34.1</td><td>46 (.005)</td><td>58 (<.001)</td><td>92 (<.001)</td></tr>
<tr><td>Social function</td><td>58.4</td><td>50 (.075)</td><td>73 (.001)</td><td>99 (<.001)</td></tr>
<tr><td>Driving</td><td>16.1</td><td>10 (.174)</td><td>39 (<.001)</td><td>87 (<.001)</td></tr>
<tr><td>Ocular pain</td><td>81.8</td><td>85 (.321)</td><td>87 (.073)</td><td>90 (.004)</td></tr>
<tr><td>SF-12</td><td></td><td></td><td></td><td></td></tr>
<tr><td>Phys. Comp.</td><td>45.1</td><td>35.8 (<.001)</td><td>46 (.532)</td><td>38.7 (<.001)</td></tr>
<tr><td>Ment. Comp.</td><td>48.4</td><td>49 (.636)</td><td>50 (.328)</td><td>50.1 (.239)</td></tr>
</table>

Question 2: Results of above, by major subgroup(s) and/or in a multivariate analysis (e.g., QOL measure = f(objective measure, clinical features))

Question 3: Relationship between QOL measures (s) and objective measure

VQF 25 subscales</td>
<td>Quality assessment:
Meaningfully defined study population: +
Protection from bias: +
Consideration of statistical power: -

This article is relevant to:
X Question 1A
□ Question 1B
□ Question 1C
X Question 2
X Question 3</td>
</tr>
</table>

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments

Severe diabetic retinopathy or previous lazer treatment for diabetic macular edema or proliferative diabetic retinopathy in the operative eye; Intraocular pressure of ≥ 30 mm-Hg in the operative eye; Ocular disease other than macular degeneration that would prevent the recovery of visual acuity after surgery (e.g., amblyopia, vascular occlusion); ocular disease causing severe peripheral visual field loss in the fellow eye 9e.g., severe glaucoma).

	MPS
Duration vision loss second eye	13.5 weeks

	Gen vision	Diff dist. task	Diff near task	Periph vision	Color vision
Age	.12	-.15	-.24	-.12	-.07
Dur. visionLoss	-.32	-.14	-.23	-.14	-.02
Lesion size	-.18	-.18	-.14	-.19	-.26
Near VA	-.34	-.21	-.34	-.17	-.26
Distant VA	.42	.31	.33	.23	.17
Read speed	.29	.23	.23	.18	.27

VQF 25 subscales

	Depen-dency	Role limits	Ment. Hlth.	Soc. Funct. Limits	Driving diff.	Ocular pain
Age	-.26	-.23	-.3	-.06	-.15	-.13
Dur. Vision loss	-.32	-.3	-.27	-.27	-.24	.01
Lesion size	-.2	-.2	-.12	-.13	-.19	-.05
Near VA	-.36	-.31	-.4	-.26	-.31	-.32
Distant VA	.39	.29	.38	.32	.2	.19
Read speed	.44	.3	.33	.34	.25	.12

SF-12

	Phys comp.	Mental comp.
Age	-.31	-.49
Dur. Vision Loss	.01	-.09
Lesion size	.15	-.08
Near VA	-.05	-.15
Distant VA	.08	.1
Read speed	<.01	.24

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

<table>
<tr><th>Study</th><th>Study Design</th><th>Study Population</th><th>Instrument Characteristics</th><th>Results</th><th>Quality Scoring/Comments</th></tr>
<tr>
<td>Cahill 2005 #130</td>
<td>Geographical location:
Durham, NC

Dates: 2/99-8/02

Context:
□ Clinical trial
□ Cohort
X Cross sectional
□ Other

Inclusion/Exclusion criteria:
Patients who met the inclusion criteria below and who underwent MT 360 with either silicone oil or gas tamponade.

Patients with bilateral severe neo-vascular MD scheduled to undergo MT360.
Inclusion criteria:
Age ≥ 50 yrs.

AMD with subfoveal CNV
Best-corrected Snellen visual acuity between 20/50 and 20/400 in the operative eye;

Maximum 6 mos.
Central vision loss reported by patient;
No light perception in either eye;
Visual acuity of 20/50 or better in the fellow eye;
Previous laser treatment of the center</td>
<td>Population size (n): 50

Age: Mean age 76.9 yrs
32% male

Eye dx: Not reported

AMD: 100%

AMD Type: 100% wet

Laterality:
□ Unilateral
X Bilateral

Objective Measure(s) of function (e.g., visual acuity):
<table>
<tr><th></th><th>Pre-op</th><th>Post-op</th><th>P value</th></tr>
<tr><td>Dist. VA</td><td>60.9</td><td>63</td><td>.278</td></tr>
<tr><td>Mean near VA</td><td>.84</td><td>.61</td><td><.001</td></tr>
<tr><td>Mean reading speed</td><td>74.5</td><td>89.3</td><td>.045</td></tr>
</table>
</td>
<td>Instrument/Technique Name:
VQF-25
SF-12

Method of administration:

By whom:
X Masked
□ Unmasked
□ Unknown

Mode of administration:
□ Phone interview
X Face to face interview
□ Mail questionnaire
□ In office questionnaire
□ Observation
□ Other

Respondent:
□ Only patient
□ Patient or surrogate
□ Only surrogate
X Unknown

Time points of administrationn: NA</td>
<td>Question 1A: Instrument scores in AMD patients
<table>
<tr><th>NEI VQF -25</th><th>Pre-op</th><th>Post-op</th><th>P value</th></tr>
<tr><td>Genl vision</td><td>30</td><td>53.7</td><td><.001</td></tr>
<tr><td>Near tasks</td><td>28</td><td>45.5</td><td><.001</td></tr>
<tr><td>Distance tasks</td><td>34.8</td><td>46.5</td><td>.004</td></tr>
<tr><td>Peripheral vision</td><td>66.5</td><td>66.5</td><td>.98</td></tr>
<tr><td>Color vision</td><td>64.5</td><td>67.5</td><td>.543</td></tr>
<tr><td>Dependency</td><td>38.2</td><td>50.3</td><td>.026</td></tr>
<tr><td>Role difficulties</td><td>38.1</td><td>46.6</td><td>.115</td></tr>
<tr><td>Mental health</td><td>33.9</td><td>50.2</td><td><.001</td></tr>
<tr><td>Social function</td><td>55.7</td><td>67</td><td>.011</td></tr>
<tr><td>Driving</td><td>12.7</td><td>20.1</td><td>.162</td></tr>
<tr><td>Ocular pain</td><td>79.6</td><td>84.4</td><td>.179</td></tr>
<tr><td>Comp. VQF 25</td><td>43.8</td><td>54.4</td><td><.001</td></tr>
<tr><td>SF-12</td><td></td><td></td><td></td></tr>
<tr><td>Phys. Comp.</td><td>44.8</td><td>44.2</td><td>.406</td></tr>
<tr><td>Ment. Comp.</td><td>49.3</td><td>50.8</td><td>.435</td></tr>
</table>
Question 2: Results of above, by major subgroup(s) and/or in a multivariate analysis (e.g., QOL measure = f(objective measure, clinical features))
<table>
<tr><th></th><th>n</th><th>Mean Comp. VFG-25</th><th>P value</th></tr>
<tr><td>Post-op near vision improvement</td><td>33</td><td>16.4</td><td></td></tr>
<tr><td>W/out post-op near vision improvement</td><td>17</td><td>-.79</td><td>.005</td></tr>
<tr><td>Post-op near vision ≥ 20/70</td><td>28</td><td>63.4</td><td></td></tr>
<tr><td>Post-op near vision < 20/70</td><td>22</td><td>43</td><td><.001</td></tr>
<tr><td>Post-op distance improvement</td><td>28</td><td>18.4</td><td></td></tr>
</table>
</td>
<td>Quality assessment:
Meaningfully defined study population: +
Protection from bias: +
Consideration of statistical power: -

This article is relevant to:
X Question 1A
□ Question 1B
□ Question 1C
X Question 2
X Question 3</td>
</tr>
</table>

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments

of the fovea in the operative eye;
Previous submacular surgery in the treated eye;
Severe diabetic retinopathy or previous lazer treatment for diabetic macular edema or proliferative diabetic retinopathy in the operative eye;
Intraocular pressure of ≥ 30 mm-Hg in the operative eye;
Ocular disease other than macular degeneration that would prevent the recovery of visual acuity after surgery (e.g., amblyopia, vascular occlusion); ocular disease causing severe peripheral visual field loss in the fellow eye (e.g., severe glaucoma).

w/out post-op distance improvemnt	22	.55	.002
Post-op distance vision ≥ 69 ETDRS	23	64.4	
Post-op distance vision ≥ 69 ETDRS	27	45.8	<.001
Post-op near vision improvement	29	22	
w/out post-op improvement in reading speed	21	-.28	.005
Post-op reading speed ≥ 90 wwpm	30	62	
Post-op reading speed <90 wpm	20	42.9	<.001

Question 3: Relationship between QOL measures (s) and objective measure

	Chg. QOL (genl. dist. and near vision)	Chg QOL (dep., role limits, MH, social function limits)	Chg QOL (dep., role limits, MH, social function limits0
Chg in VA dist. By 1 ETDRS letter			
Intercept	16.91	11.23	9.9
Slope	.31	.36	.29
P value	.017	.032	.017
Chg in near VA by .1 logMAR unit			
Intercept	14.52	8.44	7.42
Slope	-1.37	-1.59	-1.39
P value	.038	.057	.024
Chg in reading			

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results				Quality Scoring/Comments
				speed by 1 wpm				
				Intercept	15.91	9.82	8.52	
				Slope	.12	.14	.14	
				P value	.055	.048	.013	

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Complications of Age-Related Macular Degeneration Prevention Trial Research Group Maguire 2004 #470	**Geographical location:** Multicenter U.S. **Dates:** 5/99-3/01 **Context:** X Clinical trial □ Cohort □ Cross sectional □ Other **Inclusion/Exclusion criteria:** Inclusion: ≥ 10 drusen at least 125 micron diam Vision ≥ 20/40 Exclusion: CNV, serous RPED, geographic atrophy ≤ 500 microns of foveal center or > 1 MPS disc area, or other conditions that compromise vision/preclude laser	**Population size (n):** 1052 Age: Mean 71 (50-89) 39% male 99% white Eye dx: Not Reported **AMD:** 100% **AMD Type:** 0% wet 100% dry (severe early ARMD) **Laterality:** □ Unilateral X Bilateral **Objective Measure(s) of function (e.g., visual acuity):** Visual acuity ≥ 20/20: 65% Contrast threshold ≤ 2%: 47%	**Instrument/Technique Name:** NEI-VFQ **Method of administration:** **By whom:** X Masked □ Unmasked □ Unknown **Mode of administration:** □ Phone interview X Face to face interview □ Mail questionnaire X In office questionnaire □ Observation □ Other **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate **Time points of administration:** Baseline	**Question 1A: Instrument scores in AMD patients** NEI VQF -25 / Mean ± SD / Median / Stdz Cronbach's α Overall: 88 ± 10 / 91 / 0.92 Genl health: 71 ± 21 / 75 / NA Genl vision: 79 ± 14 / 80 / NA Ocular pain: 89 ± 15 / 88 / 0.69 Near vision: 85 ± 16 / 92 / 0.78 Distance vision: 86 ± 15 / 92 / 0.69 Vision specific: Role difficulties: 87 ± 19 / 100 / 0.81 Mental health: 85 ± 15 / 88 / 0.77 Social function: 97 ± 9 / 100 / 0.76 Dependency: 97 ± 10 / 100 / 0.78 Driving: 85 ± 15 / 88 / 0.47 Peripheral vision: 93 ± 15 / 100 / NA **Question 1C: psychometric properties (validity, reliability, responsiveness)** Subject to ceiling effects but not floor effects High internal consistency except driving See above for Cronbach's α **Question 3: Relationship between QOL measures (s) and objective measures** Visual function of better eye: For NEI VFQ overall, general health, general vision, near vision, distance vision, role difficulties, higher visual function (visual acuity,	**Quality assessment:** Meaningfully defined study population: + Protection from bias: + Consideration of statistical power: + **This article is relevant to:** X Question 1A □ Question 1B X Question 1C □ Question 2 X Question 3

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
				contrast sensitivity, critical print size) was associated with higher score on scale ** Subscales of general vision, near vision, and distance vision more than 5 units difference Fundus Features of better eye: For NEI VFQ overall, general health, general vision, near vision, distance vision, role difficulties, severity of fundus features (%area covered by drusen and focal hyperpigmentation) was not associated with higher score on scale	

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Mangione 2001 #6810	**Geographical location:** 11 university based ophthalmology practices and the NEI Clinical Center **Dates:** Unknown **Context:** □ Clinical trial □ Cohort X Cross sectional □ Longitudinal **Inclusion/Exclusion criteria:** Participants had to be 21 years of age and older, English speaking, pass a cognitive test, have one or more of the following: ARMD, diabetic retinopathy, primary open-angle glaucoma, or cytomegalovirus retinitis with one ocular condition only for the field test (pilot study participants could have multiple conditions).	**Population size (n):** 859 Field / Pilot Mean age: 64 / 61 % white: 63 / 81 % AA: 29 / 11 % female: 59 / 54 % employed: 36 / 40 Eye dx: Not reported **AMD:** 21 Other central vision loss (by type): Cataract: 31 Primary open angle glaucoma: 27 Diabetic retinopathy: 22 Cytomegalovirus retinitis: 8 **AMD Type:** Not reported **Laterality:** not reported **Objective Measure(s) of function (e.g., visual acuity):** Visual acuity: Better eye, median (range) 20/30 (20/15 – 20/400) Worse eye, median (range) 20/50 (20/20 – 20/500)	**Instrument/Technique Name:** VFQ-25 **Method of administration:** **By whom:** X Not relevant □ Masked □ Unmasked □ Unknown **Mode of administration:** □ Phone interview □ Face to face interview □ Mail questionnaire X In office questionnaire □ Observation X Other (physical exam) **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of administration:** NA	**Question 1C: psychometric properties (validity, reliability, responsiveness)** Internal consistency: Cronbach's alpha ranged from .71 to .85 (13 subscales) Construct validity: Correlations between VFQ-25 subscales and longer-form version of instrument (VFQ-51) exceeded .90. Correlations between VFQ-25 subscales and ETDRS visual acuity ranged from .65-.70. Notes: This study, derived from 2 field tests whose design details are described elsewhere, includes a diverse group of patients including 108 with AMD. Overall, a high-quality cross-sectional validation study. Except for reporting subscale means by condition (manuscript table 4), all analyses were performed on the combined set of patients.	**Quality assessment:** Meaningfully defined study population: + Protection from bias: + Consideration of statistical power: - **This article is relevant to:** □ Question 1A □ Question 1B X Question 1C □ Question 2 □ Question 3

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Massof 2001 #8450	**Geographical location:** Baltimore, MD **Dates:** NR **Context:** □ clinical trial □ cohort X cross sectional □ longitudinal **Inclusion/Exclusion criteria:** Diverse convenience sample for focus group	**Population size (n):** 246 Age Median (range): 79 (11 - 94) % female: NR Eye dx: **AMD:** 76% Other central vision loss (by type): Diabetic retinopathy: 9% Glaucoma: 5% Other: 10% **AMD Type:** Not reported **Laterality:** Not reported **Objective Measure(s) of function (e.g., visual acuity):** Not reported	**Instrument/Technique Name:** NEI-VFQ **Method of administration:** **By whom:** X Masked □ Unmasked □ Unknown **Mode of administration:** □ phone interview X face to face interview □ mail questionnaire □ in office questionnaire □ observation X other (physical exam) **Respondent:** X only patient □ patient or surrogate □ only surrogate □ unknown **Time points of administration:** NA (cross sectional)	**Question 1C: psychometric properties (validity, reliability, responsiveness)** Validity: not evaluated Reliability Rasch analysis indicated that 15 of the 22 items performed better than the others. Responsiveness not evaluated.	**General comments:** Apparently a convenience sample **Quality assessment:** Meaningfully defined study population: - Protection from bias: + Consideration of statistical power: - **This article is relevant to:** □ Question 1A □ Question 1B X Question 1C □ Question 2 □ Question 3

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Tranos 2004 #270	**Geographical location:** .London **Dates:** 1/03-8/03 **Context:** □ Clinical trial □ Cohort X Case series □ Cross sectional □ Longitudinal **Inclusion/Exclusion criteria:** Patients undergoing macular hole surgery that were a minimum of 17 yrs. old, and had evidence of stage II-IV full thickness macular hole by means of a slip lamp biomicroscopy, speak English, read fluently, and pass a mental health exam. Patients with a history of previous vitreoretinal intervention or those who underwent combined vitrectomy and cataract extraction were excluded. Also excluded were patients with clinically significant coexisting ocular pathology such as glaucoma and ARMD.	**Population size (n):** 30 Age (mean): 70 Sex: 63% male Eye dx:: Not reported **AMD:** 0 Other central vision loss (by type): Macular holes **AMD Type: NA** **Laterality:** X Unilateral □ Bilateral **Objective Measure(s) of function (e.g., visual acuity):**	**Instrument/Technique Name:** VFQ-25 **Method of administration:** **By whom:** □ Masked □ Unmasked X Unknown **Mode of administration:** □ Phone interview □ Face to face interview □ Mail questionnaire X In office questionnaire □ Observation X Other (physical exam) **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of administration:** pre operatively and 4 mos. Post.	**Question 1C: psychometric properties (validity, reliability, responsiveness)** Responsiveness: The VFQ-25 general vision subscale and composite score improved post-surgery. Note: This study, performed among patients with macular hole surgery, only provides weak evidence for the validity of the scale, both because of the small sample size and the single validation measure.	**Quality assessment:** Meaningfully defined study population: + Protection from bias: 0 Consideration of statistical power: - **This article is relevant to:** □ Question 1A □ Question 1B X Question 1C □ Question 2 □ Question 3

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Miskala 2005 #520	**Geographical location:** Multi center cites **Dates:** 1998-2000 **Context:** □ Clinical trial □ Cohort X Cross sectional □ Longitudinal **Inclusion/Exclusion criteria:** Two groups from the SST trials: persons with AMD who were 50 years or older, had subfoveal choroidal neovascularization and VA of 20/100 to 20/800; The subfoveal lesion could be large and well-demarcated or poorly demarcated with no lower limit size. The second group was also 50 and older, had AMD but had large hemorrhagic lesion with a VA of 20/100 or worse but at least light perception.	**Population size (n):** 120 Median age 77 % female 60 % white 98 % retired 78 % employed 12 Eye dx: Not reported **AMD:** 100% **AMD Type:** Not reported **Laterality:** Not reported **Objective Measure(s) of function (e.g., visual acuity):** Visual acuity, median (range) Better-seeing eye 20/100 (20/20 – 20/800) Worse-seeing eye 20/500 (20/50 – no light perception)	**Instrument/Technique Name:** VFQ-37 **Method of administration:** **By whom:** X Masked □ Unmasked □ Unknown **Mode of administration:** X Phone interview □ Face to face interview □ Mail questionnaire □ In office questionnaire □ Observation X Other (physical exam) **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of administration:** NA (cross sectional)	**Question 1C: psychometric properties (validity, reliability, responsiveness)** Construct validity: Ten of 12 VFQ-37 subscales were correlated with visual acuity in the better eye. Notes: This sample of AMD patients from the Submacular Surgery Trials Pilot Study provides a modest degree of support for the validity of the instrument.	**Quality assessment:** Meaningfully defined study population: + Protection from bias: + Consideration of statistical power: - **This article is relevant to:** □ Question 1A □ Question 1B X Question 1C □ Question 2 □ Question 3

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Miskala 2003 #820	**Geographical location:** Multi-center trials in US **Dates:** 1998-2000 **Context:** X Clinical trial □ Cohort □ Cross sectional □ Longitudinal **Inclusion/Exclusion criteria:** Patients receiving QoL and VA measurements at 12 and 24 mos. Of follow up by 12/2000 were included. Patients enrolled in the pilot trials beginning 12/93 and ending 12/97. Also included patients from 3 largest SST trials initiated in 4/97 and 7/98.Patients had large subfoveal hemorrhagic lesions secondary to AMD with VA from 20/100 to light perception in the study eye; A second group included patients with new subfoveal choroidal neovascular lesions secondary to AMD who had 20/100 to 20/800 Va in affected eye; had to be at least 50 yrs. old; and a third group had CNV due to OHS or	**Population size (n):** 218 Median age 73 % male 41 % white 97 % retired 56 % employed 32 Eye dx: Not Reported **AMD:** 100% **AMD Type:** Subfoveal choroidal neovascularization **Laterality:** □ Unilateral X Bilateral **Objective Measure(s) of function (e.g., visual acuity):** Median visual acuity at 12 months follow up (range) Better eye 20/25 (20/20 – 20/800) Worse eye 20/320 (20/20 – light perception)	**Instrument/Technique Name:** VFQ-37 **Method of administration:** **By whom:** X Masked □ Unmasked □ Unknown **Mode of administration:** X Phone interview □ Face to face interview □ Mail questionnaire □ In office questionnaire □ Observation X Other (physical exam) **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of administration:** 12 and 24 mos. after enrollment.	**Question 1C: psychometric properties (validity, reliability, responsiveness)** Responsiveness: In both bi-variate and multi-variate analyses, changes in visual acuity in the better eye were correlated with changes in the VFQ-37 subscale and overall scores. Notes: This sample of AMD patients from the Submacular Surgery Trials Pilot Study provides a modest degree of support for the validity of the instrument. Although focused on the 37-item version of the instrument, the authors also note that the dimension scores for the VFQ-25 were similar to those of the VFQ-37, and concluded that the shorter version of the instrument could be used as a replacement.	**Quality assessment:** Meaningfully defined study population: + Protection from bias: + Consideration of statistical power: + **This article is relevant to:** □ Question 1A □ Question 1B X Question 1C □ Question 2 □ Question 3

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
	idiopathic causes who were 18 or older with visual acuities between 20/50 and 20/800 in study eye.				

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

<table>
<tr><th>Study</th><th>Study Design</th><th>Study Population</th><th>Instrument Characteristics</th><th>Results</th><th>Quality Scoring/Comments</th></tr>
<tr>
<td>AREDS Research Group 2005 Lindblad #7290</td>
<td>Geographical location:
11 clinical sites in US

Dates: 11/92-1/98

Context:
X Clinical trial
□ Cohort
□ Ccross sectional
□ Longitudinal

Inclusion/Exclusion criteria:
Except for the requirement that all participants have at least one eye with a visual acuity of 20/32 or better and that the media be sufficiently clear for reasonable quality fundus photography, lens opacity status was not considered. Additional exclusions were persons with more than minimal diabetic retinopathy, previous ocular surgery (except for cataract surgery and unilateral photocoagulation for AMD)
or presence of any other eye disease that could complicate assessing the progression of lens opacities or AMD or that could affect visual acuity. Finally persons with illnesses that made long term follow</td>
<td>Population size (n): 4119

Mean age 72
% female 57
% white 96

Eye dx: Not reported

AMD: 100%

AMD Type:
25% wet
75% dry

Laterality:
□ Unilateral
X Bilateral

Objective Measure(s) of function (e.g., visual acuity):
AMD cat 1: 24%
AMD cat 2: 23%
AMD cat 3: 34%
AMD cat 4: 19%</td>
<td>Instrument/Technique Name: NEI-VFQ

Method of administration:

By whom:
X Masked
□ Unmasked
□ Unknown

Mode of administration:
X Phone interview
X Face to face interview
□ Mail questionnaire
□ In office questionnaire
□ Observation
X Other (physical exam)

Respondent:
X Only patient
□ Patient or surrogate
□ Only surrogate
□ Unknown

Time points of administration:
enrollment</td>
<td>Question 1A: Instrument scores in AMD patients:

Question 3: Relationship between QOL measures (s) and objective measure
<table><tr><th>NEI VQF Domains And Progression to Advanced AMD</th><th>Difference</th><th>p</th></tr><tr><td>Genl health</td><td>4.5</td><td><.001</td></tr><tr><td>Genl vision</td><td>11</td><td><.001</td></tr><tr><td>Ocular Pain</td><td>-1.4</td><td>Not sign</td></tr><tr><td>Near Activities</td><td>16</td><td><.001</td></tr><tr><td>Distance Activities</td><td>15</td><td><.001</td></tr><tr><td>Social Functioning</td><td>12</td><td><.001</td></tr><tr><td>Mental Health</td><td>12</td><td><.001</td></tr><tr><td>Role Difficulties</td><td>15</td><td><.001</td></tr><tr><td>Dependency</td><td>15</td><td><.001</td></tr><tr><td>Driving</td><td>25</td><td><.001</td></tr><tr><td>Color Vision</td><td>9</td><td><.001</td></tr><tr><td>Peripheral Vision</td><td>7</td><td><.001</td></tr><tr><td>Global Score</td><td>12</td><td><.001</td></tr></table>
<table><tr><th>NEI VQF Domains And Progression to Signif Vision Loss</th><th>Difference</th><th>p</th></tr><tr><td>Genl health</td><td>6</td><td><.001</td></tr><tr><td>Genl vision</td><td>13</td><td><.001</td></tr><tr><td>Ocular Pain</td><td>-0.1</td><td>Not sign</td></tr><tr><td>Near Activities</td><td>16</td><td><.001</td></tr><tr><td>Distance Activities</td><td>15</td><td><.001</td></tr><tr><td>Social</td><td>11</td><td><.001</td></tr></table></td>
<td>Quality assessment:
Meaningfully defined study population: +
Protection from bias: +
Consideration of statistical power: +

This article is relevant to:
X Question 1A
□ Question 1B
□ Question 1C
□ Question 2
X Question 3</td>
</tr>
</table>

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results			Quality Scoring/Comments
	up unlikely were ineligible.			Functioning			
				Mental Health	11	<.001	
				Role Difficulties	15	<.001	
				Dependency	14	<.001	
				Driving	22	<.001	
				Color Vision	8	<.001	
				Peripheral Vision	6	<.001	
				Global Score	11	<.001	

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Berdeaux 2005 #190	**Geographical location:** 11 centers internationally **Dates:** 5/2000-7/2001 **Context:** X Clinical trial □ Cohort □ Cross sectional □ Longitudinal **Inclusion/Exclusion criteria:** 1) willing to give informed consent, able to make required study visits and follow instructions; 2) at least 50 years of age; 3) any race or gender; 4) clinical diagnosis of exudative AMD and primary or recurrent subbfoveal neovascular membrane with lesion area with greatest linear dimenion of ≤ 5400 um, at least 50% total lesion was choroidal neovascularization, best corrected ETDRS VA between 20/40 and 20/400 in studied eye at eligiblity visit and best corrected ETDRS VA in contralateral eye to be 20/800 or best with clinical evidence of macular degeneration;	**Population size (n):** 114 Age: 76.5 (58-91) Eye dx: Not reported **AMD:** 100% **AMD Type:** 100% wet **Laterality:** □ Unilateral X Bilateral **Objective Measure(s) of function (e.g., visual acuity):** Best Eye VA: 0.34 Worst Eye VA: 0.85 AMD affected eye VA: 0.72 Fellow Eye VA: 0.47	**Instrument/Technique Name:** VFQ-39 **Method of administration:** **By whom:** X Masked □ Unmasked □ Unknown **Mode of administration:** X Phone interview □ Face to face interview □ Mail questionnaire □ In office questionnaire □ Observation X Other (physical exam) **Respondent:** □ Only patient □ Patient or surrogate □ Only surrogate X Unknown **Time points of administration:** Not reported	**Question 1A: Instrument scores in AMD patients:** NEI VQF -39 Domains / Mean / SD Genl health: 72.9 / 18.6 Genl vision: 59.4 / 16.9 Ocular Pain: 87.5 / 14.5 Near Activities: 57.3 / 24.8 Distance Activities: 66.6 / 22.1 Social Functioning: 85.9 / 21.4 Mental Health: 61.1 / 25.4 Role Difficulties: 65.8 / 23.2 Dependency: 75.5 / 27.0 Driving: 53.4 / 34.0 Color Vision: 85.9 / 21.1 Peripheral Vision: 75.9 / 23.0 Global Score: 67.8 / 18.6 **Question 1C: psychometric properties (validity, reliability, responsiveness)** Internal consistency: Cronbach's alpha for most domains exceeded .70. Construct validity: Most VFQ-39 subscales, as well as the global score, were correlated with visual activity. Notes: This study, using baseline data from a clinical trial of patients with AMD, provides a modest degree of additional support to the validity of the instrument. **Question 3: Relationship between QOL measures (s) and objective measure** NEI VQF -39 Domains / R-square / P signif in Best Eye / P signif in Worst Eye Genl health: 0.01 / .8468 / .3416	**Quality assessment:** Meaningfully defined study population: + Protection from bias: 0 Consideration of statistical power: +. **This article is relevant to:** X Question 1A □ Question 1B X Question 1C □ Question 2 X Question 3

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results				Quality Scoring/Comments
	6) aphakic or pseudophakic eyes could be treated if axial length of eye was 26 mm or less. Patients with history of any medical condition which would preclude scheduled study visits or completion of study,; history of chronic hepatitis; history of ophthalmic disease in the study eye that might compromise its VA during study; angiographic evidence of well defined classical subfoveal < 10%; clinical signs of myopic retinopathy or refraction > -8 diopter in current prescription; clinical evidence of scleral thinning; previous treatment of AMD.			Genl vision	0.31	<.0001	.0123	
				Ocular Pain	0.00	.8887	.7136	
				Near Activities	0.61	<.0001	.0006	
				Distance Activities	0.47	<.0001	.0006	
				Social Functioning	0.36	<.0001	.0108	
				Mental Health	0.27	.0004	.0015	
				Role Difficulties	0.35	<.0001	.1014	
				Dependency	0.36	<.0001	.0011	
				Driving	0.53	<.0001	.0388	
				Color Vision	0.17	.0046	.0254	
				Peripheral Vision	0.12	.0355	.0355	
				Global Score	0.48	<.0001	.0010	

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Clemons 2003 #920	**Geographical location:** 11 clinical sites in US **Dates:** 12/97-4/01 **Context:** □ Clinical trial □ Cohort □ Cross sectional X Longitudinal **Inclusion/Exclusion criteria:** Except for the requirement that all participants have at least one eye with a visual acuity of 20/32 or better and that the media be sufficiently clear for reasonable quality fundus photography, lens opacity status was not considered. Additional exclusions were persons with more than minimal diabetic retinopathy, previous ocular surgery (except for cataract surgery and unilateral photocoagulation for AMD) or presence of any other eye disease that could complicate assessing the progression of lens opacities or AMD or that could affect visual acuity. Finally persons with illnesses that made long term follow up unlikely were	**Population size (n):** 4077 Mean age: 74 % female: 57.2 % white: 96.7 Eye dx: Not reported **AMD:** Not reported **AMD Type:** 25% wet 75% dry **Laterality:** □ Unilateral X Bilateral **Objective Measure(s) of function (e.g., visual acuity):** IVisual acuity of worse eye; 69 letters Both eyes 20/20 or better: 28.1% One eye worse than 20/20: 27.2% Both eyes worse than 20/20: 44.7% AMD cat 1: 22.9% AMD cat 2: 23.9% AMD cat 3: 28.3% AMD cat 4: 24.9%	**Instrument/Technique Name:** VFQ-39 **Method of administration:** **By whom:** □ Masked X Unmasked □ Unknown **Mode of administration:** □ Phone interview X Face to face interview □ Mail questionnaire □ In office questionnaire □ Observation X Other (physical exam) **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of administration:** Enrollment	**Question 1A: Instrument scores in AMD patients:** NEI VQF Domains / Mean / SE Genl health: 72 / .27 Genl vision: 76 / .27 Ocular Pain: 90 / .22 Near Activities: 84 / .32 Distance Activities: 87 / .29 Social Functioning: 95 / .21 Mental Health: 87 / .31 Role Difficulties: 88 / .32 Dependency: 94 / .25 Driving: 77 / .45 Color Vision: 94 / .25 Peripheral Vision: 93 / .25 Global Score: 87 / .22 **Question 1C: psychometric properties (validity, reliability, responsiveness)** Internal consistency: Cronbach's alpha for subscales ranged from .58 to .91, .82 for total score. Although individual subscales had numerous patients with ceiling effects, for the overall score only 1% of patients had ceiling effects and 0% had floor effects. Construct validity: There were significant positive correlations between all subscales and visual acuity (in both better and worse eye). Subscale scores differed when patients were classified by AMD severity; a similar exercise was performed by classifying patients according to current nuclear opacity status, current cortical opacity status, current cataract status, and current visual acuity status. Notes: These data are derived from the AREDS, a cohort study with a randomized trial embedded within, following patients with AMD. This is a comprehensive cross-sectional validation of the VFQ-39.	**Quality assessment:** Meaningfully defined study population: + Protection from bias: + Consideration of statistical power: + **This article is relevant to:** X Question 1A □ Question 1B X Question 1C □ Question 2 X Question 3

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
	ineligible.				

Question 3: Relationship between QOL measures (s) and objective measure

Correlation between visual acuity and NEI-VFQ Domain	Visual acuity of better eye	Visual acuity of worse eye
Genl health	.24	.25
Genl vision	.56	.62
Ocular Pain	.07	.08
Near Activities	.46	.50
Distance Activities	.47	.51
Social Functioning	.39	.41
Mental Health	.40	.47
Role Difficulties	.42	.46
Dependency	.43	.44
Driving	.44	.47
Color Vision	.25	.27
Peripheral Vision	.25	.31

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Scilley 2004 #450	**Geographical location:** Birmingham, AL **Dates:** 7/98-6/99 **Context:** □ Clinical trial □ Cohort X Cross sectional □ Other **Inclusion/Exclusion criteria:** Age >55 AMD patients referred to university low-vision clinic AMD primary cause of vision impairment	**Population size (n):** Unknown **Age (mean):** 80 Eye dx: Not reported **AMD:** 100% **AMD Type:** 46% wet 54% dry **Laterality:** □ Unilateral X Bilateral **Objective Measure(s) of function (e.g., visual acuity):** Vision: Better eye: 20/175 Worse eye: 20/600	**Instrument/Technique Name:** NEI-VFQ **Method of administration:** **By whom:** □ Masked X Unmasked □ Unknown **Mode of administration:** □ Phone interview X Face to face interview □ Mail questionnaire □ In office questionnaire □ Observation □ Other **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate **Time points of administration:** NA	**Question 1A: Instrument scores in AMD patients:** NEI VQF Domains / Mean / SD / % Floor / % Ceiling Genl health: 50 / 26 / 6 / 11 Genl vision: 39 / 18 / 0 / 0 Ocular Pain: 94 / 16 / 0 / 81 Near Activities: 32 / 22 / 7 / 2 Distance Activities: 38 / 26 / 6 / 2 Social Functioning: 57 / 31 / 3 / 20 Mental Health: 47 / 29 / 9 / 3 Role Difficulties: 45 / 30 / 13 / 9 Dependency: 46 / 33 / 9 / 13 Driving: 11 / 21 / 65 / 1 Color Vision: 67 / 33 / 8 / 38 Peripheral Vision: 83 / 28 / 3 / 66 **Question 3: Relationship between QOL measures (s) and objective measures** NEI VQF Domains / 1 VA> 20/200 both eyes / 2 VA> 20/200 one eye / 3 VA < 20/200 both eyes / p-value Genl health: 37 / 51 / 51 / .676 Genl vision: 52 / 41 / 36 / .003 Ocular Pain: 97 / 93 / 94 / .520 Near Activities: 47 / 38 / 25 / <.001 Distance Activities: 57 / 41 / 32 / <.001 Social Functioning: 79 / 65 / 50 / <.001 Mental Health: 60 / 51 / 42 / .021 Role Difficulties: 32 / 49 / 40 / .005	[Quality assessment: Meaningfully defined study population: + Protection from bias: 0 Consideration of statistical power: - **This article is relevant to:** X Question 1A □ Question 1B □ Question 1C □ Question 2 X Question 3

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results					Quality Scoring/Comments
				Dependency	70	42	45	.004	
				Driving	31	16	5	<.001	
				Color Vision	79	71	62	.010	
				Peripheral Vision	90	82	83	.433	

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Submacular Surgery Trials Research Group Childs 2004 #140	**Geographical location:** Multicenter trial, US **Dates:** enrollment began 7/98 **Context:** X Clinical trial □ Cohort □ Cross sectional □ Longitudinal **Inclusion/Exclusion criteria:** >50 yo with subfoveal CNV from AMD Vision 20/100 20/1600 and at least LP in one eye Classic cnv >3.5 disk areas Blood > 50% of lesion	**Population size (n):** 336 Group B (subretinal hemorrhage) Mean age: 79 % female: 54 % white: 94 Eye dx: Not reported **AMD:** 100% **AMD Type:** 100% wet **Laterality:** 55% Unilateral 46% Bilateral **Objective Measure(s) of function (e.g., visual acuity):** Mean Visual Acuity: Unilateral: observation: 20/25 better, 20/250 worse eye Unilateral: surgery: 20/32 better, 20/320 worse Bilateral: observation: 20/160 better, 20/500 worse Bilateral: surgery: 20/125 better, 20/400 worse	**Instrument/Technique Name:** NEI-VFQ **Method of administration:** **By whom:** X Masked □ Unmasked □ Unknown **Mode of administration:** X Phone interview X Face to face interview □ Mail questionnaire □ In office questionnaire □ Observation X Other (physical exam) **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of administration:** Enrollment, 6 mos, 12 mos, 24 mos, 36 mos	Median Change in NEI VQF Domains at 24 mos: 20/100 - 20/160 Obser; 20/100 - 20/160 Surg; ≤20/200 Obser; ≤20/200 Surg All patients: -1.4; 3.5; 0.7; -1.7 Unilat: -2.5; 1.5; -1.5; -2.1 Bilat: 2.5; 3.5; 4.1; 0.8 3. Visual acuity outcomes (different report), not statistically significant difference	**Quality assessment:** Meaningfully defined study population: + Protection from bias: + Consideration of statistical power: +. **This article is relevant to:** X Question 1A □ Question 1B □ Question 1C □ Question 2 X Question 3

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Submacular Surgery Trials Research Group 2004 Dong #480	**Geographical location:** Multicenter trial, US **Dates:** enrollment began 7/98 – 9/01 **Context:** X Clinical trial □ Cohort □ Cross sectional □ Longitudinal **Inclusion/Exclusion criteria:** **Criteria** / **Group N** New CNV Age: ≥50 CNV cause: AMD Classic CNV: Required Occult CNV: Optional Foveal center: CNV Lesion size: ≤9 disc areas Area of blood: < 50% lesion Prior laser: Not allowed Best visual acuity, study eye: 20/100 Worst visual acuity, study eye: 20/800 CNV=choroidal	**Population size (n):** Group N=454 Group B (subretinal hemorrhage)=335 Mean age: 78 % female: 54 % white: 98 Eye dx: Not reported **AMD:** 100% **AMD Type:** 100% wet **Laterality:** 55% Unilateral 45% Bilateral **Objective Measure(s) of function (e.g., visual acuity):** Mean Visual Acuity: Unilateral: observation: 20/25 better, 20/250 worse eye Unilateral: surgery: 20/32 better, 20/320 worse Bilateral: observation: 20/160 better, 20/500 worse Bilateral: surgery: 20/125 better, 20/400 worse	**Instrument/Technique Name:** NEI-VFQ **Method of administration:** **By whom:** X Masked □ Unmasked □ Unknown **Mode of administration:** X Phone interview X Face to face interview □ Mail questionnaire □ In office questionnaire □ Observation X Other (physical exam) **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of administration:** Baseline	**3.** Correlation Between Scores on Health-related Quality-of-life Scales and Visual Acuity of Better-seeing Eye at Baseline, SST Group N and Group B Trials (Pearson correlation) Scale / Group N / Group B NEI-VFQ Overall: 0.66 / 0.66 General vision: 0.60 / 0.56 Driving: 0.74 / 0.67 Near activities: 0.69 / 0.69 Distance activities: 0.65 / 0.68 Role difficulties: 0.54 / 0.52 Mental health: 0.45 / 0.41 Dependency: 0.59 / 0.59 Social functioning: 0.57 / 0.51 Peripheral vision: 0.34 / 0.35 Color vision: 0.34 / 0.41 Ocular Pain: 0.09 / 0.12 SF-36 Physical component summary: 0.08 / 0.11 Mental component summary: 0.18 / 0.07 HADS Anxiety: -0.14 / -0.02 Depression: -0.29 / -0.25 HADS = Hospital Anxiety and Depression Scale. NEI–VFQ, National Eye Institute Visual Function Questionnaire. SF-36 = SF-36 Health Survey. Effects of Explanatory Variables on NEI-VFQ Scores: Estimated Coefficients from Multiple Linear Regression Models, SST Group N and Group B Trials **[See Sub-Table #1 on following page]** Comparisons of NEI-VFQ Scores of SST Group N and Group B Patients with Patients with Other Ocular Disorders **[See Sub-Table #2 on following page]**	**Quality assessment:** Meaningfully defined study population: + Protection from bias: + Consideration of statistical power: +. **This article is relevant to:** X Question 1A □ Question 1B □ Question 1C □ Question 2 X Question 3

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
	neovascularization **Criteria** / **Group B** (Blood) Age: ≥50 CNV cause: AMD Classic CNV: Optional Occult CNV: Optional Foveal Center: Blood or CNV Lesion size: >3.5 disc areas Area of blood: ≥50% lesion Prior laser: Optional Best visual acuity, study eye: 20/100 Worst visual acuity, study eye: Light per-ception				

Sub-Table #1 Effects of Explanatory Variables on NEI-VFQ Scores

Scale	Better Eye VA (lines)	Bilateral CNV Cases	PCS	MCS	Age (Years)	Gender Male	Model R^2
Group N Trial							
Overall	1.9	-6.4	0.5	0.6	0.07	-1.1	0.62
General Vision	1.8	-5.5	0.4	0.2	0.13	-3.6	0.45
Driving	4.0	-14.2	0.5	0.4	-0.05	6.2	0.60
Near Activities	2.5	-9.4	0.5	0.5	0.20	0.3	0.59
Distance Activities	2.6	-6.8	0.6	0.5	-0.02	-0.2	0.54
Role difficulties	1.5	-10.5	0.8	0.6	-0.11	-5.0	0.49
Mental Health	1.6	-6.1	0.8	1.2	0.34	0.1	0.46
Dependency	1.9	-11.1	0.7	0.8	-0.13	0.7	0.52
Social functioning	2.0	-6.4	0.4	0.7	0.05	-2.0	0.47
Peripheral vision	1.4	-2.6	0.4	0.6	0.10	1.0	0.18
Color vision	1.5	-0.3	0.3	0.3	0.02	-5.2	0.17
Ocular pain	0.01	1.9	0.4	0.6	0.03	1.6	0.16
Group B Trial							
Overall	1.9	-9.9	0.7	0.4	0.41	-1.5	0.65
General Vision	1.7	-9.2	0.5	0.2	0.59	-2.9	0.44
Driving	2.8	-19.5	0.9	0.3	0.28	5.7	0.58
Near Activities	2.3	-16.0	0.7	0.4	0.34	0.7	0.61
Distance Activities	2.8	-11.7	0.7	0.3	0.44	0.2	0.59
Role difficulties	1.8	-9.7	1.0	0.5	0.42	-3.8	0.47
Mental Health	1.2	-13.4	0.8	1.0	0.50	0.01	0.44
Dependency	2.6	-10.5	1.0	0.7	0.24	-0.9	0.52
Social functioning	1.6	-8.4	0.6	0.4	0.48	-1.4	0.39
Peripheral vision	1.7	-3.5	0.6	0.2	0.21	0.3	0.18
Color vision	1.7	-7.3	0.7	0.3	0.51	-8.1	0.29
Ocular pain	-0.1	-1.4	0.6	0.4	0.07	0.6	0.15

All estimates have been adjusted for the reading speed in the better eye.
NEI-VFQ = National Eye Institute Visual Function Questionnaire
PCS = Physical component summary scale from the SF-36
MCS = Mental component summary scale from the SF-36
VA = visual acuity
CNV = choroidal neovascularization

Sub-Table #2 Comparisons of NEI-VFQ Scores of SST Group N and Group B Patients with Patients with Other Ocular Disorders

	SST Patients (means)		Other Ophthalmology Patients (means)		
Condition	**Group N Trial (n=454)**	**Group B Trial (n=335)**	**A (Ref) (n=122)**	**B (AMD) (n=108)**	**C (AMD) (n=151)**
NEI-VFQ					
Overall	65	63	-	-	57
General Vision	52	49	81	54	39
Driving	41	37	89	63	50
Near Activities	55	53	93	55	29
Distance Activities	61	59	95	63	39
Role Difficulties	62	58	96	64	44
Mental Health	59	58	91	63	58
Dependency	70	65	99	74	59
Social Functioning	78	77	99	78	64
Peripheral Vision	72	71	97	77	67
Color Vision	81	78	98	85	73
Ocular Pain	85	84	90	87	87
Mean Age, years (SD)	77 (6)	79 (7)	59 (14)	76 (10)	81 (6)
Women, %	53	54	62	63	68
Median better eye visual acuity	20/40	20/50	20/20	20/63	20/200

A, Mangione et al., 122 patients seen for screening eye examinations or correction of refractive errors.
B, Mangione et al., 108 patients with age-related macular degeneration.
C, Brody et al., 151 patients with age-related macular degeneration.
Best corrected visual acuity in the Submacular Surgery Trials, habitual correction in other three populations.
AMD = age-related macular degeneration

Evidence Table 6: National Eye Institute Visual Function Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Submacular Surgery Trials Research Group 2004 Miskala #150	**Geographical location:** Multicenter trial, US **Dates:** enrollment began 7/98 **Context:** X Clinical trial □ Cohort □ Cross sectional □ Longitudinal **Inclusion/Exclusion criteria:** >50 yo with subfoveal CNV from AMD Vision 20/100-20/800 Classic cnv ≤9 MPS disk areas Blood < 50% of lesion	**Population size (n):** 454 Group N (neovascular) Mean age: 77 % female: 53 % white: 98 Eye dx: Not reported **AMD:** 100% **AMD Type:** 100% wet **Laterality:** 55% Unilateral 45% Bilateral **Objective Measure(s) of function (e.g., visual acuity):** Mean Visual Acuity: Unilateral: observation: 20/25 better, 20/200 worse eye Unilateral: surgery: 20/25 better, 20/200 worse Bilateral: observation: 20/100 better, 20/400 worse Bilateral: surgery: 20/125 better, 20/320 worse	**Instrument/Technique Name:** NEI-VFQ **Method of administration:** **By whom:** X Masked □ Unmasked □ Unknown **Mode of administration:** X Phone interview X Face to face interview □ Mail questionnaire □ In office questionnaire □ Observation X Other (physical exam) **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of administration:** Enrollment, 6 mos, 12 mos, 24 mos, 36 mos, 48 mos	Median Change in NEI VQF Domains at 48 mos: Surg / Observ Genl vision: 0 / -5 Ocular Pain: 0 / 0 Near Activities: 0 / 4 Distance Activities: -4 / 0 Social Functioning: 0 / 0 Mental Health: 10 / 2 Role Difficulties: 0 / -9 Dependency: 0 / -3 Driving: 0 / 0 Peripheral Vision: 0 / 0 Global Score: 2 / 0 3. Visual acuity outcomes (different report), not statistically significant difference	**Quality assessment:** Meaningfully defined study population: + Protection from bias: + Consideration of statistical power: + **This article is relevant to:** X Question 1A □ Question 1B □ Question 1C □ Question 2 X Question 3

Evidence Table 6: National Eye Institute Visual Function Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Mangione 1998 #8170	**Geographical location:** Six ophthalmology practices, Bethesda MD **Dates:** 7/95-3/96 **Context:** □ Clinical trial X Cohort □ Cross sectional □ Longitudinal **Inclusion/Exclusion criteria:** Eligible participants had to have 1 of the following eye conditions: age-related cataracts, age related macular degeneration, diabetic retinopathy, primary open angle glaucoma, cytomegalovirus retinitis, or low vision from any cause. Participants with ARMD had to have evidence of retinal pigment epithelium changes, choroidal neovascular membrane, central foveal drusen 125 um or larger in diameter, or one of the following in each eye: disciform scar, past laser treatment within 500 um of the fovea, RPE detachment or geographic atrophy involving the fovea.	**Population size (n):** 583 (108 with AMD) **AMD** Mean age: 76 % female: 63 % retired: 75 Time since diagnosis > 2 yrs: 74 Eye dx: Not Reported **AMD:** 17 Other central vision loss (by type) Diabetic retinopathy: 19 Glaucoma: 12 Cataract: 14 CMV retinitis: 6 Low vision: 14 Reference: 19 **AMD Type:** Not reported **Laterality:** Not reported **Objective Measure(s) of function (e.g., visual acuity):** Snellen visual acuity equivalent, median (range) Better eye 20/63 (NLP – 20) Worse eye 20/252 (NLP – 20) Binocular 20/63 (NLP – 20)	**Instrument/Technique Name:** VFQ - 51 **Method of administration:** **By whom:** X Masked □ Unmasked □ Unknown **Mode of administration:** □ Phone interview X Face to face interview □ Mail questionnaire □ In office questionnaire □ Observation X Other (physical exam) **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of administration** Baseline and 2 weeks later for a convenience sample	**Question 1C: psychometric properties (validity, reliability, responsiveness)** Internal consistency: Cronbach's alphas for subscales ranged from .66 to .94. Between-scale correlations suggest that the subscales represent separate dimensions. Some subscales exhibited ceiling effects, especially for those dimensions that are expected to be unaffected by the condition in question. Reproducibility: Across subscales, test-retest ICCs ranged from .68 to .91. Construct validity: As expected, scales that are likely to be influenced by deficits in central acuity were lowest for those in the low vision group and for AMD. High correlations were observed between VFQ scales that are activity-oriented and other measures that assess vision-related activities (e.g., VF-14, ADVS). The correlations between the VFQ-51 subscales and objective measures of vision were positive, but more modest. Notes: This study, using a diverse sample of patients from tertiary care ophthalmology practices, provides strong evidence of reliability and construct validity.	**Quality assessment:** Meaningfully defined study population: + Protection from bias: + Consideration of statistical power: - **This article is relevant to:** □ Question 1A □ Question 1B X Question 1C □ Question 2 □ Question 3

Evidence Table 6: National Eye Institute Visual Function Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Tranos 2004 #370	**Geographical location:** Three hospitals in London, UK **Dates:** 2//01 – 8/02 **Context:** □ Clinical trial □ Cohort X Cross sectional □ Longitudinal **Inclusion/Exclusion criteria:** Participants had to be at least 17 yrs. old, English speaking, and have evidence of CSMO by means of slit lamp biomicroscopy using a 66 diopter lens requiring laser treatment accord-ing to the ETDRS guidelines. Individuals also had to pass an abbreviated version of the Folstein Mini Mental State exam. Patients with a history of laser photocoagulation for Proliferative Diabetic Retinopathy or CSMO and subjects with vitreous hemorrhage present at the time of recruitment or vitreous hemorrhage which developed after enroll-lment were excluded. Patients were also excluded if there was evidence of clinically significant coexisting	**Population size (n):** 55 Mean age 65.1 Duration of DM 11.6 % male 31 % white 55 Eye dx: Not reported **AMD:** Not reported Other central vision loss% by type Diabetic macular edema **AMD Type:** Not reported **Laterality:** □ Unilateral X Bilateral **Objective Measure(s) of function (e.g., visual** Baseline visual acuity < 45 letters – 26/55 (48%) > 45 letters 29/55 (51%)	**Instrument/Technique Name:** VFQ-51 **Method of administration: self-administration** **By whom:** □ Masked □ Unmasked X Unknown **Mode of administration:** □ Phone interview □ Face to face interview □ Mail questionnaire X In office questionnaire □ Observation X Other (physical exam) **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of dministration:** NA (cross sectional)	**Question 1C: psychometric properties (validity, reliability, responsiveness)** Reproducibility: Item-level test-retest correlations ranged from .44 to .96, although it is not clear whether this analysis was limited to those patients whose visual status remained essentially unchanged. Construct validity: Composite scores were higher for moderate-to-severe patients, in comparison with those having mild diabetic retinopathy. Strong associations were observed between VFQ-51 and visual acuity. Responsiveness: Most subscale scores improved with treatment. Notes: This very small study among patients with diabetic macular edema who underwent laser treatment provides little information about validation.	**Quality assessment:** Meaningfully defined study population: + Protection from bias: + Consideration of statistical power: - **This article is relevant to:** □ Question 1A □ Question 1B X Question 1C □ Question 2 □ Question 3

Evidence Table 6: National Eye Institute Visual Function Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
	ocular pathology such as glaucoma and AMD.				

Appendix C. Quality Criteria

1. Is the study population defined in a clinically meaningful way?

   Are **ALL** of the following clinical features quantified?

   - Code "+" when **ALL** the following are quantified;
     - age
     - percent AMD/central vision eye diseases
     - AMD type (wet/dry)
     - unilateral/bilateral
     - objective measure(s) of visual function, (e.g. visual acuity)
   - Code "-" when **NOT ALL** of the above are quantified

   Note: any exclusion criteria that potentially interferes with generalizability are to be noted in the "comments" section of the abstraction form.

2. Is the instrument administered with protection from bias?

   - Code "+" when instrument is administered by an individual who **IS** masked or otherwise **WITHOUT** a vested interest in outcome (e.g., not the surgeon or staff)
   - Code "0" when uncertain about masking or identity of person
   - Code "-" when instrument is administered by an individual who is **NOT** masked or by an individual **WITH** a vested interest.

3. Is the statistical power or sample size specified as it relates to analysis of interest?

   - Code "+" when power/sample size **IS** specified.
   - Code "-" when power/sample size is **NOT** specified.

Quality-of-Life Instruments

ADVS

DLTV

NEI-VFQ

VCM1

VF-14

Activities of Daily Vision Scale

The following activities include those that some patients with visual problems find difficult. For each activity we will ask you if you can do it, and then will ask you to rate the degree of visual difficulty you have. Think of how difficult each activity is with both eyes open and your glasses on if you wear them.

The following are related to ***driving:***

A) Have you ever driven a car?
1 ___ YES (go to 1a) 2 ___ NO (go to 3a)

1a) During the past 3 months, have you driven at night?
1 ___ YES (go to 1b) 2 ___ NO (go to 1c)

1b) Would you say that you drive at night with:
5 ___ No difficulty at all (go to 1d)
4 ___ A little difficulty (go to 1d)
3 ___ Moderate difficulty (go to 1d)
2 ___ Extreme difficulty (go to 1d)

1c) Is it because of your visual problems that you are unable to drive at night?
1 ___ YES (go to 2a) 2 ___ NO (go to 2a)

1d) How difficult does seeing moving objects such as people or other cars make driving at night for you:
5 ___ Not difficult at all
4 ___ A little difficult
3 ___ Moderately difficulty
2 ___ Extremely difficult
1 ___ So difficult, I no longer drive for this reason

1e) How difficult do oncoming headlights or street lights make driving at night for you:
5 ___ Not difficult at all
4 ___ A little difficult
3 ___ Moderately difficulty
2 ___ Extremely difficult
1 ___ So difficult, I no longer drive for this reason

2a) During the past 3 months, have you been able to drive a car during the day?
1 ___ YES (go to 2b) 2 ___ NO (go to 2c)

2b) Would you say that you drive during the day with:
5 ___ No visual difficulty at all
4 ___ A little difficulty because of vision

3 ___ Moderate difficulty because of vision
2 ___ Extreme difficulty because of vision

2c) Is it because of *visual problems* that you are unable to drive during the day?
1 ___ YES (go to 3a) 2 ___ NO (go to 3a)

2d) During the past 3 months, have you been able to drive a car in unfamiliar areas?
1 ___ YES (go to 2e) 2 ___ NO (go to 2f)

2e) Would you say that you drive in unfamiliar areas with:
5 ___ No difficulty at all
4 ___ A little difficulty
3 ___ Moderate difficulty
2 ___ Extreme difficulty

2f) Is it because of *visual problems* that you are unable to drive in unfamiliar areas?
1 ___ YES (go to 3a) 2 ___ NO (go to 3a)

The following activities require ***distance or far vision:***

3a) During the past 3 months, have you tried to read street signs at night either when driving or when you are a passenger in a car?
1 ___ YES (go to 3b) 2 ___ NO (go to 3c)

3b) Would you say that you read street signs at night with:
5 ___ No difficulty at all
4 ___ A little difficulty
3 ___ Moderate difficulty
2 ___ Extreme difficulty

3c) Is it because of *visual problems* that you do not read street signs at night?
1 ___ YES (go to 4a) 2 ___ NO (go to 4a)

4a) During the past 3 months, have you tried to read street signs in daylight?
1 ___ YES (go to 4b) 2 ___ NO (go to 4c)

4b) Would you say that you read street signs in daylight with:
5 ___ No difficulty at all
4 ___ A little difficulty
3 ___ Moderate difficulty
2 ___ Extreme difficulty

4c) Is it because of *visual problems* that you do not read street signs in daylight?
1 ___ YES (go to 5a) 2 ___ NO (go to 5a)

5a) During the past 3 months, have you used public transportation?
1 ___ YES (go to 5b) 2 ___ NO (go to 5c)

5b) Would you say that you use public transportation with:
5 ___ No visual difficulty at all
4 ___ A little difficulty because of vision
3 ___ Moderate difficulty because of vision
2 ___ Extreme difficulty because of vision

5c) Is it because of *visual problems* that you do not use public transportation?
1 ___ YES (go to 6a) 2 ___ NO (go to 6a)

6a) During the past 3 months, have you tried to walk down steps without handrails or help during the daylight?
1 ___ YES (go to 6b) 2 ___ NO (go to 6c)

6b) Would you say that you walk down steps with:
5 ___ No apprehension (or fear) at all
4 ___ A little apprehension (or fear)
3 ___ Moderate apprehension (or fear)
2 ___ Extreme apprehension (or fear)

6c) Is it because of *visual problems* that you are unable to walk down steps without handrails or help?
1 ___ YES (go to 7a) 2 ___ NO (go to 7a)

7a) During the past 3 months, have you tried to walk down steps without handrails or help in dim light (or at dusk)?
1 ___ YES (go to 7b) 2 ___ NO (go to 7c)

7b) Would you say that you walk down steps in dim light with:
5 ___ No apprehension (or fear) at all
4 ___ A little apprehension (or fear)
3 ___ Moderate apprehension (or fear)
2 ___ Extreme apprehension (or fear)

7c) Is it because of *visual problems* that you are unable to walk down steps in dim light without handrails or help?
1 ___ YES (go to 8a) 2 ___ NO (go to 8a)

8a) During the past 3 months, on a bright sunny day, can you see peoples' faces from across the street?
1 ___ YES (go to 8b) 2 ___ NO (go to 8c)

8b) Would you say that you see faces in bright sunlight with:

5 ___ No difficulty at all
4 ___ A little difficulty
3 ___ Moderate difficulty
2 ___ Extreme difficulty

8c) Is it because of *visual problems* that you are unable to see faces in bright sunlight?
1 ___ YES (go to 9a) 2 ___ NO (go to 9a)

The following activities require ***near vision:***

9a) During the past 3 months, have you watched television?
1 ___ YES (go to 9b) 2 ___ NO (go to 9c)

9b) Would you say that you are able to see television with:
5 ___ No difficulty at all (go to 10a)
4 ___ A little difficulty (go to 10a)
3 ___ Moderate difficulty (go to 10a)
2 ___ Extreme difficulty (go to 10a)

9c) Is it because of *visual problems* that you are unable to watch television?
1 ___ YES (go to 10a) 2 ___ NO (go to 10a)

10a) Can you read numbers on the television screen?
1 ___ YES (go to 10b) 2 ___ NO (go to 10c)

10b) Would you say that you are able to read numbers:
5 ___ No difficulty at all
4 ___ A little difficulty
3 ___ Moderate difficulty
2 ___ Extreme difficulty

10c) Is it because of *visual problems* that you are unable to read numbers?
1 ___ YES (go to 11a) 2 ___ NO (go to 11a)

11a) During the past 3 months, have you tried to read the ordinary print in newspapers?
1 ___ YES (go to 11b) 2 ___ NO (go to 11c)

11b) Would you say that you read the ordinary print in newspapers with:
5 ___ No difficulty at all
4 ___ A little difficulty
3 ___ Moderate difficulty
2 ___ Extreme difficulty

11c) Is it because of *visual problems* that you are unable to read the ordinary print in newspapers?
1 ___ YES (go to 12a) 2 ___ NO (go to 12a)

12a) During the past 3 months, have you tried to read the directions on medicine bottles?
1 ___ YES (go to 12b) 2 ___ NO (go to 12c)

12b) Would you say that you read the directions on medicine bottles with:
5 ___ No difficulty at all
4 ___ A little difficulty
3 ___ Moderate difficulty
2 ___ Extreme difficulty

12c) Is it because of *visual problems* that you are unable to read the directions on medicine bottles?
1 ___ YES (go to 13a) 2 ___ NO (go to 13a)

13a) During the past 3 months, have you tried to read the ingredients on cans of food?
1 ___ YES (go to 13b) 2 ___ NO (go to 13c)

13b) Would you say that you read the ingredients on cans of food with:
5 ___ No difficulty at all
4 ___ A little difficulty
3 ___ Moderate difficulty
2 ___ Extreme difficulty

13c) Is it because of *visual problems* that you are unable to read the ingredients on cans of food?
1 ___ YES (go to 14a) 2 ___ NO (go to 14a)

14a) During the past 3 months, have you been able to write checks without help?
1 ___ YES (go to 14b) 2 ___ NO (go to 14c)

14b) Would you say that you write checks with:
5 ___ No difficulty at all
4 ___ A little difficulty
3 ___ Moderate difficulty
2 ___ Extreme difficulty

14c) Is it because of *visual problems* that you are unable to write checks without help?
1 ___ YES (go to 15a) 2 ___ NO (go to 15a)

15a) During the past 3 months, have you tried to thread a needle without using a threading device (or help mate)?
1 ___ YES (go to 15b) 2 ___ NO (go to 15c)

15b) Would you say that you thread a needle with:
5 ___ No visual difficulty at all
4 ___ A little difficulty because of vision
3 ___ Moderate difficulty because of vision
2 ___ Extreme difficulty because of vision

15c) Is it because of *visual problems* that you are unable to thread a needle?
1 ___ YES (go to 16a) 2 ___ NO (go to 16a)

16a) During the past 3 months, have you tried to use rulers, yardsticks, or tape measures?
1 ___ YES (go to 16b) 2 ___ NO (go to 16c)

16b) Would you say that you use rulers, yardsticks, or tape measures with:
5 ___ No visual difficulty at all
4 ___ A little difficulty because of vision
3 ___ Moderate difficulty because of vision
2 ___ Extreme difficulty because of vision

16c) Is it because of *visual problems* that you do not use rulers, yardsticks, or tape measures?
1 ___ YES (go to 17a) 2 ___ NO (go to 17a)

17a) During the past 3 months, have you tried to use a screwdriver?
1 ___ YES (go to 17b) 2 ___ NO (go to 17c)

17b) Would you say that you use a screwdriver with:
5 ___ No visual difficulty at all
4 ___ A little difficulty because of vision
3 ___ Moderate difficulty because of vision
2 ___ Extreme difficulty because of vision

17c) Is it because of *visual problems* that you do not use a screwdriver?
1 ___ YES (go to 18a) 2 ___ NO (go to 18a)

18a) During the past 3 months, have you prepared meals?
1 ___ YES (go to 18b) 2 ___ NO (go to 18c)

18b) Would you say that you prepare meals with:
5 ___ No visual difficulty at all
4 ___ A little difficulty because of vision
3 ___ Moderate difficulty because of vision

2 ___ Extreme difficulty because of vision

18c) Is it because of *visual problems* that you do not prepare meals?
1 ___ YES (go to 19a) 2 ___ NO (go to 19a)

19a) During the past 3 months, have you tried to play cards?
1 ___ YES (go to 19b) 2 ___ NO (go to 19c)

19b) Would you say that you play cards with:
5 ___ No visual difficulty at all
4 ___ A little difficulty because of vision
3 ___ Moderate difficulty because of vision
2 ___ Extreme difficulty because of vision

19c) Is it because of *visual problems* that you do not play cards?
1 ___ YES 2 ___ NO

Subscale Contents:

Night Driving Score	Questions 1a-e and 3a-c
Day Driving Score	Questions 2a-f and 4a-c
Far Vision Score	Questions 3a-7c and 9a-c
Near Vision Score	Questions 11-19
Glare Disability Score	Questions 1e, 8a-c, 10a-c, and 19a-c
Overall ADVS Score	Questions 1-19

Table 1 The complete questionnaire and the scoring system for the DLTV (Daily Living Tasks Dependent on Vision)

How much difficulty do you have					
		No difficulty	*A little difficulty*	*A lot of difficulty*	*Cannot see to do*
1	Distinguishing a person's features across the room	4	3	2	1
2	Noticing objects off to either side	4	3	2	1
3	Watching TV programmes	4	3	2	1
4	Seeing steps and using them	4	3	2	1
5	Enjoying the scenery if out for a drive	4	3	2	1
6	Reading road signs/street names	4	3	2	1
7	Distinguishing a person's features across the street	4	3	2	1
8	Recognising seasonal changes in the garden	4	3	2	1
9	Distinguishing a person's features at arm's length	4	3	2	1
10	Pouring yourself a drink	4	3	2	1
11	Cutting up food on your plate	4	3	2	1
12	Cutting your finger nails	4	3	2	1
13	Using kitchen appliances	4	3	2	1
14	Adjusting to darkness after being in the light	4	3	2	1
15	Adjusting to the light after being in the dark	4	3	2	1
How confident do you feel in your ability to walk around					
		Extremely	*Somewhat*	*Barely*	*Not at all*
16	In your immediate neighbourhood	4	3	2	1
17	Outside your immediate neighbourhood	4	3	2	1
With your near glasses on how much difficulty do you have					
		No difficulty	*A little difficulty*	*A lot of difficulty*	*Cannot see to do*

18	Reading normal sized newspaper print	4	3	2	1
19	Reading newspaper headlines	4	3	2	1
20	Reading correspondence—eg, bills, letters, cards	4	3	2	1
21	Signing documents (cheques, pension book)	4	3	2	1
22	Identifying money from purse or wallet	4	3	2	1
How would you rate					
		Excellent	*Good*	*Fair*	*Poor*
23	Your overall distance vision	4	3	2	1
24	Your overall near vision (ie, for close work)	4	3	2	1

Note scores from 23 and 24 are not included in summary DLTV score.

PB/IA

National Eye Institute
Visual Functioning Questionnaire - 25
(VFQ-25)

version 2000

(INTERVIEWER ADMINISTERED FORMAT)

January 2000

Instructions:

I'm going to read you some statements about problems which involve your vision or feelings that you have about your vision condition. After each question I will read you a list of possible answers. Please choose the response that best describes your situation.

Please answer all the questions as if you were wearing your glasses or contact lenses (if any).

Please take as much time as you need to answer each question. All your answers are confidential. In order for this survey to improve our knowledge about vision problems and how they affect your quality of life, your answers must be as accurate as possible. Remember, if you wear glasses or contact lenses for a particular activity, please answer all of the following questions as though you were wearing them.

Visual Functioning Questionnaire - 25

PART 1 - GENERAL HEALTH AND VISION

1. In general, would you say your overall health is*:

(Circle One)

READ CATEGORIES:

Excellent	**1**
Very Good	**2**
Good	**3**
Fair	**4**
Poor	**5**

2. At the present time, would you say your eyesight using both eyes (with glasses or contact lenses, if you wear them) is excellent, good, fair, poor, or very poor or are you completely blind?

(Circle One)

READ CATEGORIES:

Excellent	**1**
Good	**2**
Fair	**3**
Poor	**4**
Very Poor	**5**
Completely Blind	**6**

*** Skip Question 1 when the VFQ-25 is administered at the same time as the SF-36 or RAND 36-Item Health Survey 1.0**

3. How much of the time do you worry about your eyesight?

(Circle One)

READ CATEGORIES:

None of the time	**1**
A little of the time	**2**
Some of the time	**3**
Most of the time	**4**
All of the time?	**5**

4. How much pain or discomfort have you had in and around your eyes (for example, burning, itching, or aching)? Would you say it is:

(Circle One)

READ CATEGORIES:

None	**1**
Mild	**2**
Moderate	**3**
Severe, or	**4**
Very severe?	**5**

PART 2 - DIFFICULTY WITH ACTIVITIES

The next questions are about how much difficulty, if any, you have doing certain activities wearing your glasses or contact lenses if you use them for that activity.

5. How much difficulty do you have reading ordinary print in newspapers? Would you say you have:
(READ CATEGORIES AS NEEDED)

(Circle One)

No difficulty at all	**1**
A little difficulty	**2**
Moderate difficulty	**3**
Extreme difficulty	**4**
Stopped doing this because of your eyesight	**5**
Stopped doing this for other reasons or not interested in doing this	**6**

6. How much difficulty do you have doing work or hobbies that require you to <u>see well up close</u>, such as cooking, sewing, fixing things around the house, or using hand tools? Would you say:
(READ CATEGORIES AS NEEDED)

(Circle One)

No difficulty at all	**1**
A little difficulty	**2**
Moderate difficulty	**3**
Extreme difficulty	**4**
Stopped doing this because of your eyesight	**5**
Stopped doing this for other reasons or not interested in doing this	**6**

7. Because of your eyesight, how much difficulty do you have <u>finding something on a crowded shelf</u>?
(READ CATEGORIES AS NEEDED)

(Circle One)

No difficulty at all	**1**
A little difficulty	**2**
Moderate difficulty	**3**
Extreme difficulty	**4**
Stopped doing this because of your eyesight	**5**
Stopped doing this for other reasons or not interested in doing this	**6**

8. How much difficulty do you have <u>reading street signs or the names of stores</u>?
(READ CATEGORIES AS NEEDED)

(Circle One)

No difficulty at all	**1**
A little difficulty	**2**
Moderate difficulty	**3**
Extreme difficulty	**4**
Stopped doing this because of your eyesight	**5**
Stopped doing this for other reasons or not interested in doing this	**6**

9. Because of your eyesight, how much difficulty do you have <u>going down steps, stairs, or curbs in dim light or at night</u>?

(READ CATEGORIES AS NEEDED)

(Circle One)

No difficulty at all 1
A little difficulty..... 2
Moderate difficulty 3
Extreme difficulty 4
Stopped doing this because of your eyesight 5
Stopped doing this for other reasons or not interested in doing this 6

10. Because of your eyesight, how much difficulty do you have <u>noticing objects off to the side while you are walking along</u>?
(READ CATEGORIES AS NEEDED)

(Circle One)

No difficulty at all 1
A little difficulty..... 2
Moderate difficulty 3
Extreme difficulty 4
Stopped doing this because of your eyesight 5
Stopped doing this for other reasons or not interested in doing this 6

11. Because of your eyesight, how much difficulty do you have <u>seeing how people react to things</u> you say?
(READ CATEGORIES AS NEEDED)

(Circle One)

No difficulty at all 1
A little difficulty..... 2
Moderate difficulty 3
Extreme difficulty 4
Stopped doing this because of your eyesight 5
Stopped doing this for other reasons or not interested in doing this 6

12. Because of your eyesight, how much difficulty do you have <u>picking out and matching your own clothes</u>?
(READ CATEGORIES AS NEEDED)

(Circle One)

No difficulty at all 1
A little difficulty 2
Moderate difficulty 3
Extreme difficulty 4
Stopped doing this because of your eyesight 5
Stopped doing this for other reasons or not interested in doing this 6

13. Because of your eyesight, how much difficulty do you have <u>visiting with people in their homes, at parties, or in restaurants</u> ?
(READ CATEGORIES AS NEEDED)

(Circle One)

No difficulty at all 1
A little difficulty 2
Moderate difficulty 3
Extreme difficulty 4
Stopped doing this because of your eyesight 5
Stopped doing this for other reasons or not interested in doing this 6

14. Because of your eyesight, how much difficulty do you have <u>going out to see movies, plays, or sports events</u>?
(READ CATEGORIES AS NEEDED)

(Circle One)

No difficulty at all 1
A little difficulty 2
Moderate difficulty 3
Extreme difficulty 4
Stopped doing this because of your eyesight 5
Stopped doing this for other reasons or not interested in doing this 6

15. Now, I'd like to ask about driving a car. Are you currently driving, at least once in a while?

(Circle One)

Yes..... 1 *Skip To Q 15c*

No 2

15a. IF NO, ASK: Have you never driven a car or have you given up driving?

(Circle One)

Never drove..... 1 *Skip To Part 3, Q 17*

Gave up..... 2

15b. IF GAVE UP DRIVING: Was that mainly because of your eyesight, mainly for some other reason, or because of both your eyesight and other reasons?

(Circle One)

Mainly eyesight..... 1 *Skip To Part 3, Q 17*

Mainly other reasons..... 2 *Skip To Part 3, Q 17*

Both eyesight and other reasons .... 3 *Skip To Part 3, Q 17*

15c. IF CURRENTLY DRIVING: How much difficulty do you have driving during the daytime in familiar places? Would you say you have:

(Circle One)

No difficulty at all 1
A little difficulty..... 2
Moderate difficulty 3
Extreme difficulty 4

16. How much difficulty do you have <u>driving at night</u>? Would you say you have: (READ CATEGORIES AS NEEDED)

(Circle One)

No difficulty at all	**1**
A little difficulty	**2**
Moderate difficulty	**3**
Extreme difficulty	**4**
Have you stopped doing this because of your eyesight	**5**
Have you stopped doing this for other reasons or are you not interested in doing this	**6**

16a. How much difficulty do you have <u>driving in difficult conditions, such as in bad weather, during rush hour, on the freeway, or in city traffic</u>? Would you say you have:
(READ CATEGORIES AS NEEDED)

(Circle One)

No difficulty at all	**1**
A little difficulty	**2**
Moderate difficulty	**3**
Extreme difficulty	**4**
Have you stopped doing this because of your eyesight	**5**
Have you stopped doing this for other reasons or are you not interested in doing this	**6**

PART 3: RESPONSES TO VISION PROBLEMS

The next questions are about how things you do may be affected by your vision. For each one, I'd like you to tell me if this is true for you <u>all</u>, <u>most</u>, <u>some</u>, <u>a little</u>, or <u>none</u> of the time.

(Circle One On Each Line)

READ CATEGORIES:	**All of the time**	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
17. <u>Do you accomplish less</u> than you would like because of your vision?	**1**	**2**	**3**	**4**	**5**
18. <u>Are you limited</u> in how long you can work or do other activities because of your vision?.....	**1**	**2**	**3**	**4**	**5**
19. How much does pain or discomfort <u>in or around your eyes</u>, for example, burning, itching, or aching, keep you from doing what you'd like to be doing? Would you say:	**1**	**2**	**3**	**4**	**5**

For each of the following statements, please tell me if it is definitely true, mostly true, mostly false, or definitely false for you or you are not sure.

(Circle One On Each Line)

	Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
20. I stay home most of the time because of my eyesight.	**1**	**2**	**3**	**4**	**5**
21. I feel frustrated a lot of the time because of my eyesight.	**1**	**2**	**3**	**4**	**5**
22. I have much less control over what I do, because of my eyesight.	**1**	**2**	**3**	**4**	**5**
23. Because of my eyesight, I have to rely too much on what other people tell me...	**1**	**2**	**3**	**4**	**5**
24. I need a lot of help from others because of my eyesight.	**1**	**2**	**3**	**4**	**5**
25. I worry about doing things that will embarrass myself or others, because of my eyesight.	**1**	**2**	**3**	**4**	**5**

That's the end of the interview. Thank you very much for your time and your help.

Appendix of Optional Additional Questions

SUBSCALE: GENERAL HEALTH

A1. How would you rate your <u>overall health</u>, on a scale where zero is <u>as bad as death</u> and 10 is <u>best</u> possible health?

(Circle One)

0	1	2	3	4	5	6	7	8	9	10
Worst										**Best**

SUBSCALE: GENERAL VISION

A2. How would you rate your eyesight now (with glasses or contact lens on, if you wear them), on a scale of from 0 to 10, where zero means the worst possible eyesight, as bad or worse than being blind, and 10 means the best possible eyesight?

(Circle One)

0	1	2	3	4	5	6	7	8	9	10
Worst										**Best**

SUBSCALE: NEAR VISION

A3. Wearing glasses, how much difficulty do you have <u>reading the small print in a telephone book, on a medicine bottle, or on legal forms</u>? Would you say:
(READ CATEGORIES AS NEEDED)

(Circle One)

No difficulty at all 1
A little difficulty 2
Moderate difficulty 3
Extreme difficulty 4
Stopped doing this because of your eyesight 5
Stopped doing this for other reasons or not interested in doing this 6

A4. Because of your eyesight, how much difficulty do you have <u>figuring out whether bills you receive are accurate</u>?
(READ CATEGORIES AS NEEDED)

(Circle One)

No difficulty at all 1
A little difficulty..... 2
Moderate difficulty 3
Extreme difficulty 4
Stopped doing this because of your eyesight 5
Stopped doing this for other reasons or not interested in doing this 6

A5. Because of your eyesight, how much difficulty do you have doing things like <u>shaving, styling your hair, or putting on makeup</u>?
(READ CATEGORIES AS NEEDED)

(Circle One)

No difficulty at all 1
A little difficulty..... 2
Moderate difficulty 3
Extreme difficulty 4
Stopped doing this because of your eyesight 5
Stopped doing this for other reasons or not interested in doing this 6

SUBSCALE: DISTANCE VISION

A6. Because of your eyesight, how much difficulty do you have <u>recognizing people you know from across a room</u>?
(READ CATEGORIES AS NEEDED)

(Circle One)

No difficulty at all 1
A little difficulty..... 2
Moderate difficulty 3
Extreme difficulty 4
Stopped doing this because of your eyesight 5
Stopped doing this for other reasons or not interested in doing this 6

A7. Because of your eyesight, how much difficulty do you have <u>taking part in active sports or other outdoor activities that you enjoy</u> (like golf, bowling, jogging, or walking)?
(READ CATEGORIES AS NEEDED)

(Circle One)

No difficulty at all	**1**
A little difficulty	**2**
Moderate difficulty	**3**
Extreme difficulty	**4**
Stopped doing this because of your eyesight	**5**
Stopped doing this for other reasons or not interested in doing this	**6**

A8. Because of your eyesight, how much difficulty do you have <u>seeing and enjoying programs on TV</u>?
(READ CATEGORIES AS NEEDED)

(Circle One)

No difficulty at all	**1**
A little difficulty	**2**
Moderate difficulty	**3**
Extreme difficulty	**4**
Stopped doing this because of your eyesight	**5**
Stopped doing this for other reasons or not interested in doing this	**6**

SUBSCALE: SOCIAL FUNCTION

A9. Because of your eyesight, how much difficulty do you have <u>entertaining friends and family in your home</u>?
(READ CATEGORIES AS NEEDED)

(Circle One)

No difficulty at all	**1**
A little difficulty	**2**
Moderate difficulty	**3**
Extreme difficulty	**4**
Stopped doing this because of your eyesight	**5**
Stopped doing this for other reasons or not interested in doing this	**6**

SUBSCALE: DRIVING

A10. [This items, "driving in difficult conditions", has been included as item 16a as part of the base set of 25 vision-targeted items.]

SUBSCALE: ROLE LIMITATIONS

A11. The next questions are about things you may do because of your vision. For each item, I'd like you to tell me if this is true for you <u>all</u>, <u>most</u>, <u>some</u>, <u>a little</u>, or <u>none</u> of the time.
(READ CATEGORIES AS NEEDED)

(Circle One On Each Line)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. <u>Do you have more help</u> from others because of your vision?.....	**1**	**2**	**3**	**4**	**5**
b. <u>Are you limited</u> in the kinds of things you can do because of your vision?.	**1**	**2**	**3**	**4**	**5**

SUBSCALES: WELL-BEING/DISTRESS (#A12) and DEPENDENCY (#A13)

The next questions are about how you deal with your vision. For each statement, please tell me if it is definitely true, mostly true, mostly false, or definitely false for you or you don't know.

(Circle One On Each Line)

	Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
A12. I am often irritable because of my eyesight.....	**1**	**2**	**3**	**4**	**5**
A13. I don't go out of my home alone, because of my eyesight.	**1**	**2**	**3**	**4**	**5**

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Referral criteria
Action on cataracts

ABDO has awarded this article 2 CET credits (LV).

The College of Optometrists has awarded this article 2 CET credits. There are 12 MCQs with a pass mark of 60%.

Age-related cataract constitutes the main surgical workload of eyecare services and the bulk of ophthalmic surgical waiting lists. Furthermore, national surveys have provided some limited evidence of unmet need for cataract surgery in the UK. In order to address these issues, the government has produced a document termed 'Action on Cataracts'[1].

The document provides guidance about how services are organised and identifies where services can be made more effective, and how access to services can be improved. Such changes will undoubtedly have a significant impact on the role of the optometrist. The document can be accessed via www.doh.gov.uk/cataracts/, and an information pack is available from the Association of Optometrists.

The Action on Cataracts document[1] is not intended to be prescriptive, but contains suggestions about how the organisation of cataract surgery services could be changed in order to increase cataract surgery rates and reduce waiting times. The document focuses on organisational aspects rather than the clinical aspects of care, although of course, these issues are not completely separate. Pertinent to optometrists are the sections relating to the detection of disease, referral criteria and the education and counselling of patients. The pre-operative evaluation of cataract patients, follow-up, audit and outcome assessments are also discussed.

Summary of changes recommended in Action on Cataracts

Table 1 outlines the key points raised in the 'Action on Cataracts' document.

Table 1: SUMMARY

• 'Action on Cataracts' is a government document aimed at improving the delivery of cataract surgery services[1]
• Optometrists are being encouraged to take a greater clinical role in cataract referral
• Referrals should not be based simply on the presence of a cataract
• The decision to refer should include: The effect of the cataract on Quality of Life (QOL) Thorough ocular examination The patient's willingness to have surgery
• Referral policies and the potential role(s) of optometrists will vary according to local arrangements

- ***"Streamline the pathway of diagnosis and treatment"***
  The document suggests that there should be a "uniform" pathway for patients with similar needs. Agreed guidelines for referral are proposed as a way of ensuring that patients are managed appropriately. In line with this, optometrists may be encouraged to refer patients directly to ophthalmologists. In addition, the number of visits to the hospital could be reduced by confirmation of the diagnosis and pre-operative assessment at the same visit, coupled with a reduction in the amount of post-operative follow-up.

- ***"Perform high volume high quality surgery"***
  It is suggested that high volume surgery might be achieved by eliminating the obstacles and constraints which slow down a theatre list, for example, eliminating delays in the preparation of sterile equipment.

- ***"Provide high quality patient information"***
  The document proposes that patients should be given information about the whole treatment pathway, not just individual steps and this should be given to them at the beginning of the pathway.

- ***"Audit outcomes"***
  In order to assess the quality of care provided to patients, it is advised that the outcomes of cataract surgery should be audited, including the feedback obtained from patients.

Cataract referral

It is clearly stated in the Action on Cataracts document that the guidance is not intended to be prescriptive. It is recommended that agreement on referral guidelines should be reached locally between the local ophthalmology service, GPs and optometrists.

Direct referral by optometrists

Some local policy committees, e.g. Primary Care Groups (PCGs), may decide that it is permissible for an optometrist to refer directly to an ophthalmologist according to locally agreed protocols (including which hospital to refer to) using a standardised referral form. It is believed that a majority of GPs will accept the optometrist's judgement and refer the patient straight on to the ophthalmologist, so an extra visit to the GP may not add any significant value as regards the patient's visual status. However, the GP has an overall responsibility for the patient's healthcare and many GPs would wish to maintain their important role in co-ordinating the patient's care. Direct referral by the optometrist will save time for both patient and GP but it is important that the GP is kept fully informed. Therefore, it is suggested that a copy of the referral is sent to the GP so that additional information (such as medical and social information) can be sent on to the hospital where necessary. The PCG may also want to be aware of the referral for organisational reasons.

Referral criteria

Unfortunately, there is insufficient evidence in the scientific literature on which to base a comprehensive set of referral criteria. Below is a summary of the evidence that should inform 'best practice' regarding cataract referral.

Modern surgical techniques mean that it is no longer necessary to wait until a cataract is 'ripe', i.e. fully opaque before referring for surgery. Over the last two decades, there has been an increase in cataract surgery rates in the UK, which has paralleled changes in other industrialised countries. The change has coincided with the adoption of extracapsular cataract extraction and intraocular lens implantation. As a result, there has been a change in the clinical thresholds for surgery, with an increasing tendency for surgeons to perform surgery on cases with relatively good visual acuity (VA),[2-7] with less self-reported limitation in abilities,[6] and at older ages.[2,4,8] Thresholds may reduce further as phacoemulsification becomes increasingly popular.

Role of vision tests

Certain surgeons in the UK are prepared to perform cataract extraction on patients with visual acuities as good as 6/6 Snellen[9-13] and do not use other tests of vision[13], suggesting that

vision tests have a limited role in deciding who should have surgery. The most recent guidelines from the Royal College of Ophthalmologists suggest that patients should be referred if they have sufficient cataract to limit their quality of life (QOL), irrespective of Snellen acuity[14]. Therefore, asking about symptoms and a thorough slit-lamp examination of the lens through a dilated pupil, together with fundus examination may provide adequate information in many cases.

Diagnosing cataract

Vision tests cannot easily be used to confirm or exclude the presence of cataract **(Table 2)**. Any disease which interferes with foveal or neural function, or with the normal transparency of ocular structures may cause a reduction in Snellen VA. Similarly, a wide variety of ocular disorders may also cause contrast sensitivity loss[15] which limits the value of contrast sensitivity tests as a screening tool for cataract.

Glare is a well recognised symptom in cataract, but glare may be caused by other pathological opacities of the ocular media, such as corneal oedema or conditions leading to reduced uveal pigment. In addition, the commonly used glare testers are each subtly different and there is a lack of standardisation across techniques. Furthermore, neural factors may affect the accuracy of glare measurements. The variety of ocular disorders which may cause glare limits the usefulness of glare-testing as a means of screening for cataract[16,17]. That said, tests such as contrast sensitivity and glare sensitivity can provide additional information about vision in cases where the patient's symptoms appear to be disproportional to the standard of vision measured using high contrast VA (see previous CPD article).

TABLE 2: KEY Points: VISION TESTING

- Many ophthalmologists are prepared to offer cataract extraction at good levels of VA and do not use other tests of vision, suggesting that vision tests have a limited role in deciding who should have surgery
- Vision tests cannot be used in isolation to diagnose cataract. Nor can it be assumed that visual impairment is due to the easily recognised cataract morphologies unless a very detailed and thorough ocular examination has been performed
- Information about symptoms and quality of life will be most reliably obtained from the patient themselves, their relatives or carers. Vision testing in people with communication difficulties or in whom the ophthalmic history is suspected to be unreliable provides valuable information. Vision tests confirming the patient's description of their vision strengthen the case for cataract extraction.
- It is uncertain whether useful predictions can be made about the success of surgery, based on vision test results

It is well established that visual impairment in cataract cannot be described in terms of a single visual loss function[18]. Cataract may affect VA, contrast sensitivity, glare sensitivity, refractive status, colour vision, visual field, binocular status and may also give rise to symptoms which are not well described by any of these functions, for example, monocular diplopia. Vision tests are, as a rule, carefully designed to measure discrete modalities of vision. The choice of test is therefore problematic. A single test will not give an overall measure of vision and to evaluate every aspect of vision, a large battery of tests would be required. Even with such a battery, the clinician would remain uncertain as to the relative importance of each test to the individual. The importance of a given test may vary within and between individuals, depending on environments and activities. Due to the discordance between the results of various vision tests, good visual performance on a single test cannot be used to rule out the presence of visually impairing cataract. The working ranges of some test charts also need to be considered. For example, if a Snellen chart is 'truncated' at the 6/6 level, deterioration from 6/3 to 6/6 (a doubling of the visual angle) may go undetected.

Evaluation of symptoms, 'disabilities and handicaps'

The relationship between glare tests and self-reported glare symptoms in cataract cases appears to be weak[16,19-23]. Other cataract symptoms include haloes or rings around lights[24,25], multiple images (polyopia)[26,27], 'star-burst' effects[26] and 'rainbow' effects[28]. The relationship between these symptoms and vision tests remains poorly defined.

The correlation between high contrast VA and self-reported impairment using a variety of measures has been generally poor[29-33]. In reality, it is likely that visually dependent tasks are dependent on combinations of several visual functions[29,34,35]. It is uncertain which test of vision gives the most useful information about overall quality of vision or the need for cataract surgery. 'Handicap' (as defined by the World Health Organisation) refers to the psycho-social disadvantage resulting from poor vision and therefore cannot, by definition, be measured by vision tests.

Prediction of the outcomes of cataract surgery

'Patient centred outcomes' are those outcomes that directly measure the perceived benefit for the patient, for example, satisfaction with vision or self-reported problems with everyday activities.

Several studies have investigated the value of pre-operative high contrast acuity testing in the prediction of patient centred outcomes of cataract surgery and the results have been conflicting[25,36-41]. Other studies have examined the relationship of pre-operative contrast sensitivity testing to patient-centred outcomes of cataract surgery. For example, Adamsons et al (1993) reported that pre-operative logMAR acuity and Pelli-Robson scores were both associated with post-operative improvements in patients' perception of their vision[39,40]. However, Bellucci et al. (1995) reported that pre-operative glare sensitivity and contrast sensitivity were not significantly associated with the degree of post-operative self-reported improvement[42].

Other studies have examined the relationship between pre-operative glare testing and post-operative patient-centred outcomes of cataract surgery and have found little or no association between the results of glare-tests and self-reported improvement in vision following surgery[39,40,42].

Several methods have been developed for the assessment of 'potential vision' behind cataract, including the Amsler grid, entoptic tests, interferometry, hyperacuity tests and electro-physiological tests[43]. The ability of potential vision tests to predict patient-centred outcomes of cataract surgery requires investigation.

Monitoring cataract progression

Vision tests cannot easily be used to monitor the progression of cataract because deterioration in test results may be due to causes other than cataract. Even if a particular test suggests stability, deterioration may still have occurred in some other unmeasured aspect(s) of visual function. Monitoring by vision testing does not reliably inform about new visual symptoms or quality of life.

The limitations of vision tests also extend to refractive errors. For example, although it is recognised that nuclear sclerosis is associated with myopia, a change in refractive error cannot easily be used to decide when to refer. Indeed, some hypermetropic patients may welcome the myopic shift and so ultimately it will be the patient's QOL, rather than their refractive error that determines the need for referral.

Quality of Life (QOL)

There is growing awareness of the importance of QOL in judging the need for cataract surgery **(Table 3)**. The concept of QOL has been incorporated into statements about the aims of cataract management by eyecare professionals and researchers[44-46], and has been included in clinical guidelines for cataract surgery[47,48].

QOL assessment is an integral part of clinical decision making but is usually performed on an individual basis in a casual manner. Such informal questioning may result in biased judgements. Therefore, it may

TABLE 3: KEY Points: QOL Assessment

- In ophthalmic needs-assessment there is growing awareness of the importance of QOL and the limitations of measures of visual function such as high contrast VA
- QOL assessment should include not only the assessment of physical health, but also social and psychological well-being
- It is not sufficient to simply ask about visual symptoms (e.g. glare) or visual functions (e.g. recognising a face across the street) because an individual with visual impairment may find the particular symptoms or activities covered irrelevant to their own situation or may not be concerned by their impairment
- General questions, such as "Does your eyesight stop you doing the activities that you want to do?" may be more informative and less prejudicial than specific ones, e.g. about driving or employment

become necessary in the future to make a more standardised assessment.

QOL is taken to encompass all aspects of life, of which health is one of many parts. The term has become popularised and clichéd, featuring in political speeches and articles in the popular media. QOL has been variously defined as the extent to which pleasure and satisfaction have been obtained, the degree of satisfaction of human needs, happiness, feelings of control and coping, life satisfaction, morale, the realisation of a life plan or the difference between desired and actual circumstances.

Subjective indicators based on self-ratings of QOL have become more popular due to the recognition of the importance of how individuals feel, rather than how professionals think they ought to feel on the basis of clinical measurements. As QOL is a personal concept there is strong argument that QOL assessment should be based on patient-defined issues, rather than those defined by eyecare professionals.

Vision-related QOL (VR-QOL)

VR-QOL is not the same as visual function. For example, a person who is completely blind may still have a good QOL. It is well recognised that poor vision is for some people much more unpleasant than for others. A group of individuals with the same level of visual impairment may have widely varying levels of physical, social and emotional disturbance because of varying needs, attitudes and environments. Variation due to these factors will never be predicted accurately by taking clinical measurements (e.g. vision testing) regardless of the number of tests employed.

Any self-reported problem with vision may be a QOL issue. The range of possible issues is wide and may include loss of self esteem, vulnerability, loss of confidence, embarrassment, anger, difficulties with social interaction, communication, and relationships, being treated badly by others, loss of independence, depression and anxiety.

QOL measurement is of particular value when there is a poorly defined relationship between clinical measures and the patient's perceptions. Such is the situation in optometry/ophthalmology. Pioneering work in this area of research was performed by Bernth-Petersen[49] and now there are numerous vision questionnaires available which are based on visual symptoms and physical function. However, it is clear that assessing a few selected physical activities gives a grossly inadequate description of VR-QOL impairment[50]. Although the person's report of functioning provides important information, more general questions provide information regarding QOL[51]. Indeed, researchers have concluded that it may not be appropriate to require specific functional limitations as a precondition for cataract surgery and have suggested the use of more general questions[52].

Recently, the National Eye Institute Visual Function Questionnaire (NEI-VFQ)[53,54] has become available in the USA and the VCM1 questionnaire has been introduced in the UK **(Table 4)**. These questionnaires aim to cover a broader range of issues and thus provide a more balanced assessment of vision-related QOL.

TABLE 4: THE VCM1 Questionnaire

- The VCM1 is based upon patients' own definitions of vision-related QOL[50] and contains 10 broad, general questions referring to physical, social and psychological (vision-related) problems:

Embarrassment
Anger
Loneliness /isolation
Depression
Fear of deterioration in vision
Safety at home
Safety outside the home
Coping with everyday life
Inability to do preferred activities
Overall life-interference

- The VCM1 score correlates strongly with answers to a wide range of other questions about QOL issues such as mobility, reading and leisure
- Data on the reliability of postal and telephone administration is available[65]
- Population data should soon be available from three sites in the UK: Bristol, Sheffield and Wiltshire including more than 10 000 people. The results should provide an insight into VR-QOL in the general population
- The VCM1 is already in use in a range of research studies, including the Investigation of VR-QOL in macular disease, cataract, amblyopia, uveitis, myopia, hypermetropia, low-vision and the outcomes of various treatments. The questionnaire is also being used to evaluate the need for cataract surgery

Examination of the lens

Examination of the human ocular lens is necessary to detect the presence of opacities and is essential to the diagnosis of cataract. However, lens examination has received relatively little attention by researchers[55]. Posterior subcapsular, cortical and nuclear cataracts may cause visual impairment but there is a variety of other opacities that occur in the ageing lens such as anterior subcapsular opacity, vacuoles, waterclefts, coronary flakes, focal dots, retrodots and fibre-folds[28,56] some of which may have little or no effect on vision. Therefore, a careful examination of the lens through a dilated pupil at the slit lamp is needed to help distinguish visually impairing cataract from other opacities such as fibre folds, vacuoles and coronary flakes that may not affect vision. For the same reason, it is important not to overlook other causes of visual impairment.

Suitability for surgery

As a result of the availability of both general and local anaesthesia for cataract surgery, there are very few anaesthetic contraindications to elective surgery for age-related cataract. The relative contraindications to individual techniques are listed in the Guidelines of the Royal College of Ophthalmologists[48].

Willingness to have surgery

Willingness to have surgery is included as a referral criterion in the Action on Cataracts document. It is clearly stated in the document that the patient should have all the necessary information well before surgery enabling them to make informed decisions about their care. This implies that the optometrist may be required to give the patient sufficient information regarding surgery at the first visit including the risks involved. A list of information sources is provided in the document.

Using pooled data, Powe et al (1994) estimated that approximately 95% of eyes without other pre-existing eye conditions and 90% of all eyes achieve a post-operative best-corrected VA of 6/12 or better[57]. In the recent UK national cataract surgery survey (1997-1998), 92% of patients without other eye conditions and 77% of patients with other co-existing eye conditions achieved a final refracted acuity of 6/12 or better[58].

Major sight-threatening complications are infrequent and may not always result in complete loss of vision. The following complication frequencies were reported from pooled data by Powe et al (1994): angiographic cystoid macular oedema 3.5%, clinical cystoid macular oedema 1.4%, malposition/dislocation of intraocular lenses 1.1%, retinal detachment 0.7% and

bullous keratopathy 0.3%, endophthalmitis 0.13%. Less serious complications also occur infrequently, with the exception of posterior capsular opacification which occurs in up to 19.7% cases[57]. Further details can be obtained from the report of the outcomes of the UK national cataract surgery survey[58].

In contrast to the claims of 90% to 95% success rates from those who quote high contrast VA results, the self-reported outcomes are poorer. Where validated vision-specific questionnaires have been employed, the percentage of cases who report improvement range from 80-89%[25,37,59]. Those who report no change comprise 5-10% of cases and those reporting a deterioration comprise 5-7%[25,37,59].

Presence or absence of ocular co-morbidity

The term 'ocular co-morbidity' refers to co-existing eye conditions which may either cause visual impairment or may increase the risks of surgery. In the UK national cataract surgery survey, 72% of patients with age-related macular degeneration, 77% of patients with glaucoma, 68% of patients with diabetic retinopathy and 67% of patients with amblyopia achieved a final refracted acuity of 6/12 or better. The adverse effect of ocular co-morbidity on patient-centred outcomes is well recognised[25,36,38,60], although existing studies have tended to group various co-morbidities together for analysis. Further research is needed to quantify the risks of poorer outcomes and the magnitudes of the shortfalls in QOL benefits for specific co-morbidities. Ocular co-morbidity tends to either increase the risk of complications or reduce the scope for visual improvement, and is thus a relative contraindication to cataract surgery. However, some patients may still benefit from surgery and even though the anticipated benefit of cataract extraction may be small in the presence of other pathology, the surgeon and patient may still wish to proceed. Furthermore, it may be necessary in some cases to remove the cataract in order to assess and treat other conditions such as diabetic retinopathy. Referral in the presence of ocular co-morbidity will depend on the specific aspects of the case.

Second-eye surgery

Several studies have reported benefits from second eye surgery using patient-centred outcome measures[32,61-64]. The need for second-eye surgery should be determined in the same manner as for the first. The patient should be able to make an informed decision based upon their QOL and the anticipated risks and benefits of surgery. This is a preferable strategy to automatic referral for the second eye.

Conclusion

Redesigning the care pathway from the patient's view point and implementing best practice may lead to a benificial improvement in patient satisfaction with the cataract service.

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About the author

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Multiple choice questions

Referral Criteria - Action on Cataracts MCQs

Please note there is only one correct answer

1. The Action on Cataracts document makes which one of the following recommendations about cataract referral?
a. Optometrists should be able to make referrals with complete clinical freedom
b. General practitioners should be removed from the referral process
c. Referrals should be made with the agreement of the primary care group
d. National guidelines should be imposed upon optometrists

2. Which one of the following observations about visual acuity (VA) is correct?
a. VA has been confirmed to be a good predictor of the outcome of surgery
b. VA testing is a rapid means of confirming the presence of cataract
c. VA testing gives a good impression of the patient's disabilities
d. VA is not always reduced when a visually impairing cataract is present

3. Which one of the following observations about contrast sensitivity (CS) is correct?
a. CS testing provides information about vision within the limits of spatial resolution
b. CS is a good predictor of the outcome of surgery
c. CS testing is a reliable means of screening for cataract
d. CS testing gives a good impression of the patient's degree of handicap

4. Which one of the following observations about glare testing is correct?
a. Glare tests correlate well with glare symptoms
b. Glare tests are uniformly standardised
c. Glare sensitivity is a poor predictor of the outcome of surgery
d. Glare sensitivity is a specific test for light scattered by the lens

5. Which one of the following observations about quality of life is correct?
a. The aim of cataract surgery is to improve quality of life
b. Quality of life can be judged only with a very large battery of vision tests
c. Eyecare professionals are usually able to make accurate judgements about the patient's quality of life
d. QOL assessments should concentrate only on aspects of physical health

6. Which one of the following gives the best impression of the patient's quality of life?
a. Glare
b. Reading
c. Driving
d. The patient's own concerns

An answer return form is included in this issue. It should be completed and returned to: CPD Initiatives (c2983g), OT, Victoria House, 178–180 Fleet Road, Fleet, Hampshire, GU51 4DA by July 25, 2001.

Continued

Multiple choice questions - Referral Criteria - Action on cataracts MCQs

7. Which one of the following is correct about ocular examination?
a. Non-visually impairing lens opacities may be present in the visual axis
b. It is not necessary to dilate the pupils if the patient is going to be referred anyway
c. Fundal examination is irrelevant in identifying the source of glare symptoms
d. The appearance of the fundus is not important when deciding who to refer

8. Cataractous changes in the lens can confidently be diagnosed when which of the following are present?
a. Coronary flakes
b. Nuclear opalescence
c. Fibre folds
d. Vacuoles

9. Which one of the following instruments is the most suitable for assessing cataract?
a. Direct ophthalmoscope
b. Retinoscope
c. Slit lamp
d. Indirect ophthalmoscope

10. Which one of the following is the most common sight threatening complication of cataract surgery?
a. Retinal detachment
b. Malposition/dislocation of intraocular lens
c. Endophthalmitis
d. Angiographic cystoid macular oedema

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11. In the recent UK national cataract surgery survey, approximately what proportion of cataract patients without any other eye conditions achieved a best corrected VA of 6/12 or better?
a. 90%
b. 100%
c. 80%
d. 70%

12. Which one of the following aspects of cataract assessment is least important when making the decision whether to perform cataract surgery?
a. Quality of life
b. High contrast VA
c. Ocular examination
d. Willingness to undergo surgery

Continued

Overview:

The Visual Function Index (VF-14) is a brief questionnaire designed to measure functional impairment on patients due to cataract. It consists of 18 questions covering 14 aspects of visual function affected by cataracts. The VF-14 shows high internal consistency and is a reliable, valid instrument providing information not conveyed by visual acuity or general health status measures.

General Functioning

(1) Do you have any difficulty, even with glasses, reading small print, such as labels on medicine bottles, a telephone book, food labels?

(2) Do you have any difficulty, even with glasses, reading a newspaper or a book?

(3) Do you have any difficulty, even with glasses, reading a large-print book or large-print newspaper or numbers on a telephone?

(4) Do you have any difficulty, even with glasses, recognizing people when they are close to you?

(5) Do you have any difficulty, even with glasses, seeing steps, stairs or curbs?

(6) Do you have any difficulty, even with glasses, reading traffic signs, street signs, or store signs?

(7) Do you have any difficulty, even with glasses, doing find handwork like sewing, knitting, crocheting, carpentry?

(8) Do you have any difficulty, even with glasses, writing checks or filling out forms?

(9) Do you have any difficulty, even with glasses, playing games such as bingo, dominos, card games, mahjong?

(10) Do you have any difficulty, even with glasses, taking part in sports like bowling, handball, tennis, golf?

(11) Do you have any difficulty, even with glasses, cooking?

(12) Do you have any difficulty, even with glasses, watching television?

Response	**Points**
not applicable	
no	4
yes, with a little difficulty	3
yes, with a moderate amount of difficulty	2
yes, with a great deal of difficulty	1
yes, and am unable to do the activty	0

Driving

(13) Do you currently drive a car?

if Yes, go to 14

if No, go to 16

(14) How much difficulty do you have driving during the day because of your vision?

no difficulty (4 points)

a little difficulty (3 points)

a moderate amount of difficulty (2 points)

a great deal of difficulty (1 point)

(15) How much difficulty do you have driving at night because of your vision?

no difficulty (4 points)

a little difficulty (3 points)

a moderate amount of difficulty (2 points)

a great deal of difficulty (1 point)

(16) Have you ever driven a car?

if Yes, go to 17

if No, stop

(17) When did you stop driving?

less than 6 months ago

6-12 months ago

more than 12 months ago

(18) Why did you stop driving?

vision

other illness

other reason

Scoring

An item is not included in scoring if the person does not do the activity for some reason other than their vision.

Scores on all activities that the person performed or did not perform because of vision were then averaged, yielding a value from 0 to 4.

This value was multiplied by 25, giving a final score from 0 to 100.

a score of 100 indicates able to do all applicable activities

a score of 0 indicates unable to do all applicable activities because of vision

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