

# MEASURING OUTCOMES OF NEURO-OPTOMETRIC CARE IN TRAUMATIC BRAIN INJURY

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## Abstract

*This paper discusses the use of “patient centered” outcome measures, particularly those questionnaires that assess health-related quality of life (QOL). More specifically, it goes on to review two questionnaires that relate to vision and brain injury. One of these is used to assess pre and post vision therapy reading abilities, while the other assesses pre and post accident vision symptoms.*

*The author recommends that two other questionnaires have the potential to assess the effect of optometric therapy on brain injured individuals. Thus, The National Eye Institute Visual Functioning Questionnaire (NEI VFQ-25) and the Veterans Affairs Visual Functioning Questionnaire (VA LV VFQ-48) are reviewed. Neither instrument has been used to measure outcomes of neuro-optometric treatment and vision-specific health related quality of life (HRQoL) of patients with traumatic brain injury (TBI.). The NEI VFQ-25 may be useful to compare the vision-specific HRQoL of patients with TBI to measurements of vision-specific HRQoL of patients with eye diseases. The VA LV VFQ-48 could be shortened to target items pertinent to neuro-optometric rehabilitation and to reduce respondent burden.*

*There are many challenges to the use of “patient centered” outcome measures in neuro-optometric care following adult TBI. These include: the variability in severity of TBI, overlaying behavioral and functional consequences of TBI that may confound the measurement, difficulty distinguishing treatment outcomes from natural recovery during the first seven to*

*nine months following brain injury, and concerns of respondent burden from use of multiple outcomes measures administered to patients and family members during recovery.*

## Key Words

*cerebral vascular accident, National Eye Institute Visual Functioning Questionnaire, patient centered outcome measures, Post Trauma Vision Symptom Questionnaire, quality of life, rehabilitation, Reading Rating Questionnaire, Veterans Affairs Visual Functioning Questionnaire, vision, visual function questionnaires, traumatic brain injury,*

## INTRODUCTION

One modern initiative in health care research has been to conduct holistic measurement of outcomes from the patient’s point of view.<sup>1</sup> These “patient centered outcomes” are what patients care about, such as their quality of life and ability to function. Quality of life related to health care, referred to as health-related quality of life (HRQoL), is difficult to define and even more difficult to measure.<sup>2</sup> However, many researchers and clinicians would agree that there are multiple dimensions that should be included. Most frequently described are: a *functional dimension* that includes the ability to carry out activities related to work, school, household and self care; a *psychological dimension* that includes cognitive functioning, emotional status, life satisfaction and happiness; a *social dimension* that involves social contact and interpersonal relationships; and, a *physical dimension* that relates to symptoms associated with disease treatment.<sup>3</sup>

## QUALITY OF LIFE QUESTIONNAIRES

Quality of life (QOL) is usually measured with questionnaires that are referred to as instruments.<sup>4,6</sup> Researchers begin instrument development by conducting focus groups or in-depth interviews with patients who have a disease(s) to determine the impact of these diseases and treatments on their daily lives. Subject matter experts are also interviewed, and literature searches are performed. Individual questions, referred to as items, are written from the item content identified by the interviews and focus groups. Responses to questions may be dichotomous, thus having two response choices, or polytomous, thus having multiple response choices. Examples of dichotomous response choices include true or false, yes or no, and agree or disagree. Polytomous response choices may include responses from a list of ordered response categories, such as difficulty levels or a frequency scale rating from 1-5. Short versions of the questionnaires are tested to finalize wording and item content prior to large-scale field testing. Items are eliminated during the process to leave a set of those that should discriminate among patients with mild to severe impairment. Items that are related and assess the same variable are grouped together in domains or subscales. It can be assumed that different domains represent different variables.

## Quality of Life Questionnaires’ Sensitivity, Reliability and Validity

To measure outcomes of disease treatment, questionnaires must demonstrate sensitivity to the clinical changes that occur with treatment or the disease process.<sup>5</sup> They must also be reliable and valid.<sup>4,6</sup> Reliability refers to an instrument’s ability to provide reproducible measurements.

Validity refers to the ability of a questionnaire to measure what it is supposed to measure in terms of content, criterion, and construct. Content validity is the degree to which items represent the information tested. Criterion validity tells how well the measurement predicts the characteristics associated with the measure. Lastly, construct validity is the degree to which the measure is related to similar measures of the same characteristic.

### **Generic And Disease-Specific Questionnaires**

QOL questionnaires are categorized as either generic or disease-specific.<sup>4</sup> Generic measures may be used to assess the impact of any treatment or disease process. They address different populations and many health issues. A good example is the Short Form-36 (SF-36) that was developed by Ware for the medical outcomes study.<sup>7</sup> The SF-36 includes one multi-item scale that assesses eight health concepts: 1) limitations in physical activities because of health problems; 2) limitations in social activities because of physical or emotional problems; 3) limitations in usual role activities because of physical health problems; 4) bodily pain; 5) general mental health (psychological distress and well-being); 6) limitations in usual role activities because of emotional problems; 7) vitality (energy and fatigue); and 8) general health perceptions. Instruments like the SF-36 are used either to measure co-morbidities or to compare the burden of different diseases (e.g., breast cancer and congestive heart failure). Because these instruments are too insensitive to show changes in disease-specific HRQoL, they usually lack the precision needed to assess outcomes of specific rehabilitation strategies.<sup>5</sup>

Disease-specific QOL questionnaires are developed to measure one or more dimensions of HRQoL.<sup>5</sup> They are used to assess specific treatments and disease processes; but they can not be used for comparisons with other conditions and populations. Vision function questionnaires are disease-specific measures for vision disorders and eye diseases.<sup>4,6</sup> Vision function questionnaires measure vision-specific functional limitations, QOL, or other traits. They are often better than traditional clinical measures of visual impairment in providing an overall assessment of a patient's ability to function in life.

### **VISION FUNCTIONING QOL QUESTIONNAIRES FOR THE BRAIN INJURED**

Outcomes researchers are provided with many different published questionnaires from which to choose. In terms of vision functioning, there are at least 29 different rating-scale questionnaires.<sup>8</sup> A review of the ophthalmic literature from 1996-2006 indicates that vision-specific HRQoL of patients with traumatic brain injury (TBI) has not been compared to vision-specific HRQoL of patients with eye diseases. Questionnaires that were developed to assess identified vision symptoms after brain injury included a reading rating scale<sup>9</sup> and a post-trauma vision symptom questionnaire.<sup>10</sup>

#### **Reading Rating Questionnaire**

Han et al developed the Reading Rating Scale Questionnaire to evaluate subjectively symptoms associated with TBI and cerebrovascular accident (CVA).<sup>9</sup> The instrument includes five questions that measure: the length of time patients are able to read comfortably; the ability to comprehend what was read; the ability to attend when in a quiet or noisy room; and the reading strategies used. The reading strategies are described using ratings of impulsive and inaccurate; impulsive and accurate; deliberate and inaccurate; or deliberate and accurate. Reading comfortably was rated on a scale from 1-5. Higher scores reflect longer reading time. Response choices are: 0-5 minutes, 5-10 minutes, 10-15 minutes, 15-30 minutes, and >30 minutes. The remaining questions used a rating scale from 1-5, corresponding to poor, fair, good, very good, and excellent. The Reading Rating Scale Questionnaire was used in a case series of subjects with either TBI or CVA to evaluate training paradigms including auditory-oculomotor and normal visual feedback during eye movements.<sup>9,11</sup>

#### **The Post-Trauma Vision Symptom Questionnaire (PTVSQ)**

The instrument was developed by May and Smith as a screening procedure for post-trauma vision syndrome.<sup>10</sup> This syndrome is a term used in neuro-optometric rehabilitation to describe a group of vision symptoms that are frequently manifest after brain injury.<sup>12,13</sup> Patients respond yes or no to 66 statements on the PTVSQ that describe their vision before and after the accident or illness. The Post-Trauma Vision Questionnaire for Youth and the

Post-Trauma Vision Interview for Children were developed as a modification to the original version of the questionnaire that was developed for adults. The investigators worked closely with behavioral optometrists in development of the instrument. A shorter version of the PTVSQ was recommended by the Department of Veterans Affairs Optometry Polytrauma Workgroup to evaluate vision symptoms of veterans experiencing TBI during the Iraq War.

The present paper introduces two visual function questionnaires, the National Eye Institute Visual Functioning Questionnaire-25 (NEI VFQ)<sup>14-17</sup> and the Veterans Affairs Low Vision Visual Functioning Questionnaire (VA LV VFQ).<sup>18-21</sup> They have the potential as instruments to measure the impact of TBI on vision function, and the outcomes of neuro-optometric treatment. These instruments would complement information obtained from the clinical assessments, the symptom checklists, and the reading scale that were previously discussed.

#### **National Eye Institute Visual Functioning Questionnaire (NEI VFQ-25)**

In 1988, the National Eye Institute conducted a workshop on QOL of persons with visual impairment.<sup>22</sup> The workshop participants identified the need for a vision-specific QOL measure. Subsequently, the National Eye Institute contracted the Rand Corporation to develop a questionnaire to measure the outcomes of eye disease treatment trials.

Mangione et al<sup>14</sup> conducted focus groups with 246 visually-impaired patients diagnosed with cataract, diabetes, glaucoma, macular degeneration and low vision from any cause. The objective was to identify item content for the 52-item version of the original National Eye Institute Visual Function Questionnaire (NEI VFQ). Although patients reported problems that were unique to their particular eye diseases, the problems reported were similar across conditions. Difficulty with reading and driving, general difficulty with seeing clearly, and mental health complaints caused by poor vision were frequently reported. The most common components of each problem were difficulty of performance, psychological stress associated with performance of the activity, and complete inability to participate in a visual activity.

**Table 1.**  
**The 12 National Eye Institute**  
**Visual Function Questionnaire**  
**(NEI VFQ-25) subscales**

1. General health status
2. Difficulty with general vision activities
3. Difficulty with activities at distance
4. Difficulty with activities at near
5. Role difficulty
6. Social functioning
7. Dependency on others
8. Mental health symptoms
9. Driving Difficulties
10. Limitations in peripheral vision
11. Color vision
12. Ocular pain

The resulting NEI VFQ-52 is a vision-specific measure of the functional, psychological, social, and physical domains of HRQoL.<sup>15</sup> The 52-item field test version of the NEI VFQ was developed using classical test theory.<sup>4,6,15</sup> Validation evidence consists of correlations of instrument scores with visual impairment measures and demonstrations of “acceptable” values of Cronbach’s alpha. It further requires demonstrations that instrument scores could be used to discriminate groups of respondents who were categorized by other criteria (e.g. normal and abnormal visual acuity).<sup>6</sup> The original 52-item NEI VFQ was later shortened to a 25 item (questions) version plus supplemental questions that can be added to expand some of the subscales.<sup>16</sup> The 12 NEI VFQ-25 subscales are presented in Table 1.

The NEI VFQ-25 has a simple scoring system. Patient responses are summarized by adding the average rank of the respondents’ answers across items in each of the 12 domains. The summary score is assumed to measure QOL.

The NEI VFQ-25 has been translated into several languages. It has been used to measure QOL of patients with many eye diseases (e.g. diabetes, glaucoma, macular degeneration, allergic conjunctivitis),<sup>23-26</sup> in population-based studies. These have included the Wisconsin Epidemiologic Study of Diabetic Retinopathy, the Los Angeles Latino Eye Study, and the Blue Mountains Eye Study.<sup>27-30</sup> It has also been used in eye disease treatment trials to

evaluate treatments including: blue light filtering intraocular lenses in cataract surgery, nutritional supplements in age related macular degeneration, and photocoagulation for diabetic macular edema,<sup>31-33</sup> and to measure outcomes of vision rehabilitation.<sup>34-39</sup>

Presently, it has not been determined whether the NEI VFQ-25 can capture the changes of QOL in patients who have experienced brain injuries. The focus groups conducted by Mangione et al,<sup>14</sup> prior to the development of the NEI VFQ-52, included low vision patients with visual acuity of 20/200 or poorer in their better eye, or visual field of 10 degrees or less. This group does not constitute a representative sample of patients with TBI. Patients with vision symptoms secondary to TBI may have normal visual acuities and visual fields, or have hemianopsias, or other visual field defects with more than 10 degrees of intact visual fields. Concurrent administration of the Post-Trauma Vision Symptom Questionnaire, the Reading Rating-Scale Questionnaire, and the NEI VFQ-25 would allow researchers to compare the NEI VFQ-25 ratings to those from the other instruments that are sensitive to visual functioning problems in TBI. If the NEI VFQ-25 captures changes in QOL associated with TBI, vision-specific HRQoL of patients with TBI could be compared to vision-specific HRQoL of patients with eye diseases.

There are some limitations to use of the NEI VFQ-25.<sup>36,37</sup> Stelmack et al reported that many low vision patients experienced difficulty completing the self-administered version of the questionnaire due to confusion with the multiple question formats and response choices used on the instrument.<sup>36</sup> For example, the questionnaire includes ratings of:

*General health* – Response choices are: excellent, very good, good, fair, poor and a rating scale of 0-10.

*Difficulty with activities* – The response choices are: no difficulty, a little difficulty, moderate difficulty, extreme difficulty, stopped because of eyesight, stopped for other reason.

*Vision problems* – The response choices are: all of the time, most of the time some of the time, a little of the time, and none of the time.

*Agreement statements regarding vision loss* – The response choices are: definitely true, mostly true, not sure, mostly false.

Although the NEI VFQ-25 can be administered in the personal interview or self administered format, this questionnaire might overwhelm patients with TBI, especially those with cognitive and attentional defects. An alternative could be to administer the instrument in multiple sessions prior to therapy to decrease the respondent burden.

Prior to planning a low vision clinical trial, Stelmack et al tested the sensitivity of the NEI VFQ-25 to the low vision intervention in two VA programs serving the blind and visually impaired.<sup>35</sup> The investigators found that only seven of 34 items (questions) on the NEI VFQ-25, plus the supplemental questions, demonstrated significant change after veterans completed a VA visual impairment center program to optimize remaining sight (VICTORS), or a VA blind rehabilitation center (BRC) program. Unfortunately, the NEI VFQ-25 exhibited poor measurement accuracy and was too unresponsive to the effects of low vision rehabilitation to be useful as an outcome measure in clinical trials.

### **Veterans Affairs Low Vision Visual Functioning Questionnaire (VA LV VFQ-48)**

This instrument was developed by Stelmack et al to measure outcomes of vision rehabilitation.<sup>18-21</sup> The VA LV VFQ-48 captures patient self-report of the difficulty modulated by visual impairment for 48 tasks involving reading, mobility, visually-guided motor behavior, and visual information processing. The primary measurement question, “Is it difficult to .....?” is asked about all 48 items that are noted in the Appendix.

Response choices include: not difficult, slightly/moderately difficult, extremely difficult, impossible, and do not do it for non-visual reasons (which is scored as missing data). If it is difficult to perform the activity, the second question is asked. “Is it because of your vision?” Response choices include yes or no. An optional question could be used to identify patient goals. “Is it important to ..... independently? If it is important to perform the activity independently, the patient is asked to rate the importance of achieving the goal. “How important?” Response choices include somewhat important or very important.

Prior to the development of the VA LV VFQ-48, structured interviews were conducted with 149 low vision patients and rehabilitation professionals in the VA and

private sector to identify item content for a questionnaire to measure low vision outcomes.<sup>40</sup> Vision Rehabilitation practice guidelines for optometry, ophthalmology, and occupational therapy were reviewed. The information gathered from multiple sources was collated using a modified Delphi method to generate the questionnaire.<sup>18-20</sup>

In addition to being a valid and reliable measure of visual ability, the VA LV VFQ-48 is a sensitive measure of changes that occur in visual ability as a result of rehabilitation.<sup>21</sup> Patients' self-reports of the difficulty they experience performing daily activities measured with this instrument can be used to compute a composite score. Changes in scores from pre- to post-rehabilitation serve as an outcome measure for low vision rehabilitation. The VA LV VFQ-48 can be used to compare programs that offer different levels of intervention and serve patients across the continuum of vision loss. The VA LV VFQ-48 was developed and validated using the Rasch Rating Scale Model to scale persons according to a series of responses to the items.<sup>18-21</sup> A Rasch scale conversion is available for scoring to obviate the need for questionnaire users to perform Rasch analysis.<sup>41</sup>

The VA LV VFQ-48 was validated using a representative sample of low vision patients. Unfortunately, only 7% of the subjects in the VA LV VFQ-48 development studies had neurological disorders.<sup>20</sup> The VA LV VFQ-48 has not been used to measure outcomes of neuro-optometric rehabilitation of TBI. Further studies are needed to determine if the VA LV VFQ-48 is sensitive to neuro-optometric rehabilitation of TBI. A shorter version of the instrument could be constructed using the items appropriate to assessment of patients with TBI to reduce respondent burden.

## DISCUSSION

There are a number of challenges to the measurement of TBI outcomes. Severity ranges from mild TBI to life-threatening injury.<sup>42</sup> Many other conditions (cognitive deficits, behavioral disorders, emotional disorders, attentional and concentration deficits, communication disorders, medication side-effects, vestibular dysfunctions and auditory dysfunctions) often accompany the vision dysfunctions associated with TBI.<sup>42</sup> The overlaying conditions may confound measurement of outcomes from neuro-optometric rehabilitation, thus making it difficult to sepa-

rate the outcomes of the neuro-optometric rehabilitation from other treatments for TBI.

A further challenge relates to the difficulty in determining whether improvements that occur within the first seven to nine months after recovery were caused by optometric interventions or the natural course of recovery. Control subjects will be needed. Furthermore, data will have to be obtained from multiple sites to have sufficient numbers of treatment and control subjects for statistical analysis of the clinical trials, cohort, or case-control studies that are needed to develop an evidence base for the optometric treatment of TBI. Patients with TBI often experience frequent changes in functional status.<sup>42</sup> The time frame(s) for outcomes measurement during the stages of recovery must be consistent to compare outcomes across studies or across sites. Multiple administrations of questionnaires may be required to assess outcomes fully. Respondent burden must be considered when choosing instruments as multiple areas of impairment must be addressed. Use of family members as surrogates may reduce some of the respondent burden. Development and use of short-form questionnaires that employ the least number of items to measure a construct would also reduce administration time and respondent burden. Short-form instruments can improve sensitivity of questionnaires by eliminating questions that are irrelevant to the populations being studied.<sup>43,44</sup> This approach has been used with other vision function questionnaires such as the VF-14.<sup>44,45</sup>

In summary, we have discussed the NEI VFQ-25 and the VA LV VFQ-48, two vision function questionnaires that could be used in their current state or shortened to measure vision specific QOL aspects for patients with TBI. However, sensitivity of these instruments to neuro-optometric rehabilitation of TBI must be confirmed prior to their use in outcomes studies.

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## Appendix Items Included in the VA LV VFQ – 48

1. Physically Get Dressed
2. Keep Your Clothes Clean
3. Identify Medicine
4. Tell Time
5. Identify Money
6. Match Clothes
7. Groom Yourself
8. Identify Food on a Plate
9. Eat and Drink Neatly
10. Fix a Snack
11. Prepare Meals
12. Use Appliance Dials
13. Clean the House
14. Handle Finances
15. Make Out a Check
16. Take a Message
17. Find Something on a Crowded Shelf
18. Find Public Restrooms
19. Get Around Indoors in Places You Know
20. Get Around Outdoors in Places You Know
21. Get Around in Unfamiliar Places
22. Go Out At Night
23. Go Down Steps in Dim Light
24. Adjust to Bright Light
25. Cross Streets at Traffic Light
26. Use Public Transportation
27. Get Around in a Crowd
28. Avoid Bumping Into Things
29. Recognize Persons Up Close
30. Recognize Persons From Across the Room
31. Read Street Signs and Store Names
32. Read Headlines
33. Read Menus
34. Read Newspaper or Magazine Articles
35. Read Mail
36. Read Small Print on Package Labels
37. Read Print on TV
38. Keep Your Place While Reading
39. Watch TV
40. Play Table and Card Games
41. See Photos
42. Work on Your Favorite Hobby
43. Go to Movies
44. Go to Spectator Events
45. Play Sports
46. Do Yard Work
47. Sign Your Name
48. Read Signs