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Timing and directions for administration of questionnaires affect outcomes measurement

Joan A. Stelmack, OD, MPH;[1–3*] Judith L. Babcock-Parziale, PhD;[4] Daniel N. Head, EdD;[4] Gregory S. Wolfe, OD;[3] Nader E. Fakhoury, OD;[5] Shelley M. Wu, OD;[1] Robert W. Massof, PhD[5]

[1]Blind Rehabilitation Center, Edward Hines Jr. Department of Veterans Affairs (VA) Hospital, Hines, IL; [2]Illinois College of Optometry, Chicago, IL; [3]Department of Ophthalmology and Visual Science, University of Illinois at Chicago, School of Medicine, Chicago, IL; [4]Southern Arizona VA Health Care System, Southwestern Blind Rehabilitation Center, Tucson, AZ; [5]Wilmer Eye Institute, Johns Hopkins University, Baltimore, MD

Abstract—We used data from two pilot studies to compare the change in patients' self-reported health-related quality of life after participation in two nearly identical Department of Veterans Affairs (VA) Blind Rehabilitation Center (BRC) programs, the Southwestern BRC in Tucson, Arizona, and the BRC at the VA hospital in Hines, Illinois. Researchers at the Southwestern BRC administered the National Eye Institute Visual Functioning Questionnaire as directed by the developer. Researchers at the Hines BRC modified the directions to consider use of low-vision devices. Interval person-ability and item-difficulty measures estimated from patient responses pre- and postrehabilitation were compared with these same measures obtained at follow-up. At the Southwestern BRC, no change was reported in either person or item measures 3 months after rehabilitation. At the Hines BRC, improvement was seen in both the person and item measures when measurements were made immediately following rehabilitation. Because a temporary halo effect may explain the higher ratings at discharge, veterans from the Hines cohort were contacted by telephone and administered the same instrument 3 years later. For these subjects, the improvement noted in the person measure disappeared at follow-up, while the improvement in the item measure was maintained.

Key words: blind rehabilitation, health-related quality of life, low vision, low-vision rehabilitation, NEI VFQ-25, outcomes, outcomes measures, rehabilitation, vision rehabilitation, visual function.

INTRODUCTION

Quality of life is considered an important healthcare outcome measure. As early as the 1980s, the vision research community and the National Eye Institute (NEI) formally acknowledged that an instrument was needed to measure changes in health-related quality of life (HRQOL) caused by eye diseases and their treatment [1]. The NEI contracted RAND Corporation (Santa Monica, California), a firm known for its expertise in health-services research, to develop a vision-specific HRQOL instrument to measure eye disease clinical trial outcomes [2–4]. The NEI 52-item Visual Functioning Questionnaire (VFQ-52) content was developed from focus groups that identified the problems with vision-related function that are experienced by visually impaired persons [3]. The list of problems was divided

Abbreviations: BRC = Blind Rehabilitation Center, CI = confidence interval, HRQOL = health-related quality of life, logMAR = logarithm of minimum angle of resolution, NEI = National Eye Institute, SD = standard deviation, VA = Department of Veterans Affairs, VFQ = Visual Functioning Questionnaire.

***Address all correspondence to Joan A. Stelmack, OD, MPH; Blind Rehabilitation Center (124), Edward Hines Jr. VA Hospital, Hines, IL 60141; 708-202-2124; fax: 708-202-7949. Email: Joan.Stelmack@med.va.gov**

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into 12 categories: general health, general vision, ocular pain, near-vision activities, distance-vision activities, vision-specific social functioning, mental health, role difficulties, dependency, driving, color vision, and peripheral vision. The NEI 25-item VFQ (VFQ-25) includes several questions with response choices that reflect the level of agreement with statements about vision loss as well as questions that require patients to rate their health status and difficulty performing activities and role limitations associated with vision loss [2].

The NEI VFQ-52 and VFQ-25 have been used to assess HRQOL in studies on a wide range of clinical interventions, varying from surgical treatments and pharmaceutical therapies, in addition to driving habits and self-management of patients with age-related macular degeneration [5–19]. In studies where surgical treatments are performed successfully, a patient's visual ability is expected to improve. Cataract extraction is a good example. If a dense cataract is blurring vision and is removed from the better eye, restoring vision to 20/20, overall visual ability to perform many daily living tasks would improve. Similarly, correction of a large refractive error would also be expected to improve performance of almost all daily living tasks included on a visual function questionnaire, but only when glasses or contact lenses are worn.

Unlike surgical procedures, low-vision devices do not restore vision or cause a permanent change in visual ability. Low-vision devices enhance a patient's remaining vision by making specific tasks or groups of tasks easier to perform [8]. For example, a hand-held magnifier will enlarge print and make it easier to read. We expect that specific activities where the magnifier can be used will be easier for the patient to perform. However, the performance of many activities at far and intermediate distances (e.g., those where hand-held magnifiers cannot be used) will not be changed and print will still be difficult or even impossible to read when the hand-held magnifier is not used.

The NEI VFQ-25 *Part 2—Difficulty with Activities* instructions state, "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" **(Figure 1)** [2]. The questions in this section assess the impact of vision loss on the patient's ability to perform activities. The questions, as written, do not ask the patient how difficult it is to perform these activities with low-vision devices. In low-vision care outcomes measurement, measuring the difficulty patients have performing tasks with their low-vision devices is important for assessing the benefits and use of these devices. Because the NEI VFQ-25 was developed to measure the benefits of treatments that restore visual ability—not changes in difficulty performing tasks when low-vision devices are used—the instrument may not be sensitive to the outcomes of low-vision rehabilitation.

Separate studies to test the sensitivity of the NEI VFQ-25 to change after low-vision rehabilitation were undertaken by Babcock-Parziale and Head at the Southwestern Blind Rehabilitation Center (BRC) [20] and by Stelmack et al. at the Hines BRC [8,10]. Babcock-Parziale and Head used the directions provided by the developer and Stelmack modified the directions to have

I'm going to read you some statements about problems that 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.

In *Part 2—Difficulty with Activities*, questions 5–14 begin with the qualification of:

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.

Figure 1.
Directions for administration of National Eye Institute 25-item Visual Functioning Questionnaire.

patients consider the use of low-vision devices when completing *Part 2—Difficulty with Activities* (questions 5–14). This article compares the findings from these pilot studies.

PRE- AND POSTREHABILITATION OUTCOMES AT SOUTHWESTERN AND HINES BLIND REHABILITATION CENTERS

Methods

Instruments

The NEI VFQ-25 plus *Appendix of Optional Additional Questions* was administered by personal interview at admission and discharge to 77 legally blind veterans at the Edward Hines Jr. Department of Veterans Affairs (VA) Hospital BRC in Hines, Illinois. Babcock-Parziale and Head at the Southwestern BRC in Tucson, Arizona, conducted separate outcomes study using the NEI VFQ-25. At the Southwestern BRC, trained interviewers conducted telephone interviews with 205 legally blind veterans and obtained prerehabilitation responses ~1 week prior to each veteran's arrival at the BRC. Postrehabilitation responses were collected by telephone interview 3 months postdischarge. Optometry residents and attending staff conducted the interviews at Hines BRC.

The only alteration to the telephone interview in the Southwestern BRC study was the omission of subscales that were not applicable to the veterans with severe visual impairments who attended the Southwestern BRC. The omitted subscales were ocular pain (items 4 and 19), driving (items 15a–d and 16), and responses to vision problems (items 20 and 21). At the Hines BRC, items from the *Appendix of Optional Additional Questions* subscales on near vision, distance vision, and social function were administered as recommended by the developer to enhance the reliability of these subscales [21]. The items on the questionnaire that pertained to driving (15a–d and 16) were not included in the analysis because few legally blind veterans were driving and driving training was not included in the blind rehabilitation program.

Department of Veterans Affairs Blind Rehabilitation Programs

The Southwestern and Hines BRCs offer nearly identical inpatient rehabilitation programs [22]. Both programs use an interdisciplinary team approach to rehabilitation that incorporates nurse practitioner, nursing, optometry, psychology, social work, and blind rehabilitation specialists. VA blind rehabilitation programs are designed for veterans to achieve maximum adjustment to their disability, reorganize their lives, and return to a contributing place in the family and community. Courses in visual skills, living skills, orientation and mobility, and manual skills are offered in conjunction with psychosocial interventions and recreational activities that assist veterans in development of a positive attitude toward themselves, their blindness, and their future.

Subjects

Subjects included 205 blind rehabilitation patients admitted consecutively to the Southwestern BRC and 77 low-vision patients admitted consecutively to the Hines BRC. Mean best-corrected visual acuity of patients participating at the Southwestern BRC was 1.3 logarithm of minimum angle of resolution (logMAR) (20/400), standard deviation (SD) = 0.27, and range 0.92 to 1.96. Mean age was 71 years (range 38 to 93). Diagnoses most frequently reported were age-related macular degeneration (50%), diabetic retinopathy (13%), and glaucoma (15%). Mean best-corrected visual acuity of patients participating at the Hines BRC was 1.0 logMAR (20/200), SD = 0.29, and range 0.40 to 1.82. Mean age of patients was 72 years (range 38 to 88). Diagnoses most frequently reported were age-related macular degeneration (66%), diabetic retinopathy (16%), and glaucoma (12%).

Directions Used for Administration of NEI VFQ-25

In the Hines BRC pilot study, the general directions for *Part 2—Difficulty with Activities* section of the NEI VFQ-25 **(Figure 1)** were modified from, "Please answer all questions as if you were wearing your glasses or contact lenses (if any)" to "The next questions are about how much difficulty, if any, you have doing certain activities wearing your glasses, contact lenses, or using low-vision devices if you have them for that activity." For both pre- and postrehabilitation interviews at the Southwestern BRC, the interviewer-administered format and instructions were followed exactly as written by the developer.

Analysis

The traditional scoring algorithm for the NEI VFQ-25 includes a Likert score for each subscale or dimension of HRQOL on a 0 to 100 possible range [22]. Higher scores indicate higher HRQOL. The ratings for the individual

items in each subscale are summed and then divided by the number of items answered. A composite score is obtained by averaging the subscale Likert scores. Because these ratings are ordinal and do not represent equal intervals between difficulty ratings and because Likert scores do not produce a valid measurement scale for the NEI VFQ-25 [23], both research groups used Rasch analysis with the BIGSTEPS software program (Winsteps, Chicago, Illinois) to estimate interval scales from the rating responses [24–25]. Rasch analysis uses a probability model to estimate the visual ability each person has for performing activities (person measure) and the visual ability required to perform each activity (item measure) from the pattern of responses across patients [23,26–28]. We compared person and item measures for the pre- and postrehabilitation administrations of the NEI VFQ-25 within and between sites to investigate the effects of changing the directions for administration of the instrument. We used the *t*-test to compare the means of the pre- and postrehabilitation person measures between (independent measures) and within sites (paired comparison) [29]. We used the Pearson's product moment correlation (*r*) to compare item measures between sites and pre- versus postrehabilitation item measures within sites [29]. Confidence intervals (CIs) were computed to show the precision of the correlations.

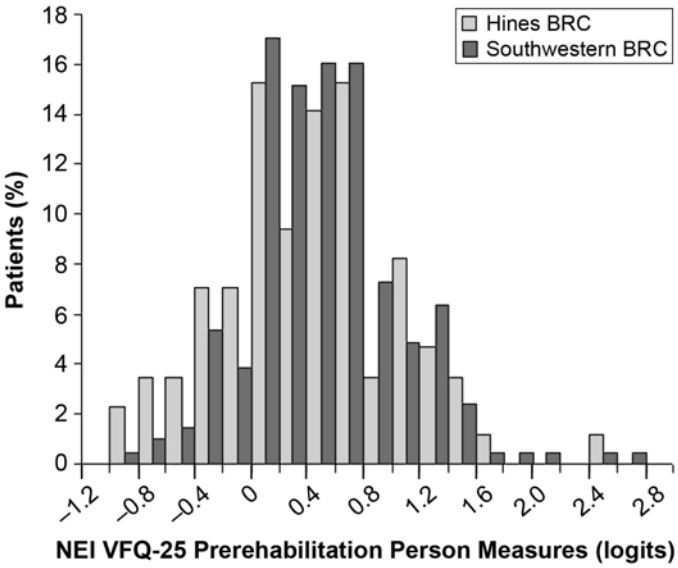

Figure 2.
Comparison of visual ability was calculated from rating responses on National Eye Institute 25-item Visual Functioning Questionnaire (NEI VFQ-25) for patients at Southwestern and Hines Blind Rehabilitation Centers (BRCs). Distribution of prerehabilitation visual ability measures for Hines (shaded bars) and Southwestern (filled bars) BRC patients were compared. Mean prerehabilitation visual ability measures for patients in two programs were not significantly different.

Results

Mean visual ability of the Hines BRC patients prerehabilitation (0.21 logits, SD = 0.63) was not significantly different from the mean visual ability of the Southwestern BRC patients prerehabilitation (0.31 logits, SD = 0.54) (two-tailed *t*-test for independent measures, $p = 0.15$) **(Figure 2)**. The prerehabilitation item measures for Hines and Southwestern BRCs were highly correlated ($r = 0.93$, $p < 0.01$, 95% CI = 0.82 to 0.97). No change was noted in the Southwestern BRC person measures 3 months after blind rehabilitation (two-tailed paired-comparison *t*-test, $p = 0.15$). The prerehabilitation item measures were highly correlated with the postrehabilitation item measures ($r = 0.96$, $p < 0.01$, 95% CI = 0.95 to 0.97).

For the Hines BRC data, 7 of the 34 items tested from the NEI VFQ-25 plus the *Appendix of Optional Additional Questions* were sensitive to change after rehabilitation. Consequently, the correlation between pre- and postrehabilitation item measures at the Hines BRC was weak ($r = 0.33$, $p = 0.03$, 95% CI = –0.01 to 0.67), which confirmed a change in the ordering of item difficulty. The items that showed significant change were from the near- and distance-vision subscales and included reading ordinary print in newspapers (item 5); going out to see movies, plays, or sports events (item 14); reading small print in a telephone book, on a medicine bottle, or a legal form (Appendix item 3); figuring out whether bills you receive are accurate (Appendix item 4); seeing well up close (item 6); reading street signs or the names of stores (item 8); and seeing and enjoying programs on television (Appendix item 8). The remaining items did not demonstrate a significant change in difficulty postrehabilitation (results described in detail elsewhere [8]).

An improvement in visual ability (person measures) that was independent of the change in the difficulty of targeted items was also observed in the Hines cohort data [8]. The changes noted were equivalent to a 0.425 logMAR improvement in visual acuity for the Hines BRC patients. Improvement in visual ability was significant (two-tailed paired-comparison *t*-test; $p < 0.001$).

Discussion

The Southwestern and Hines BRCs have nearly identical comprehensive inpatient blind rehabilitation programs. The distributions of visual ability among veterans were the same for the two programs. When NEI VFQ-25 items were administered with strict adherence to the instructions, patients were told to answer the questions considering only use of glasses or contact lenses, the use of low-vision devices was not considered, and the instrument proved to be insensitive to the effects of rehabilitation. When the NEI VFQ-25 instructions were modified to remind patients to consider use of low-vision devices in their responses, patients reported that the use of low-vision devices reduced the difficulty performing tasks, and the instrument then proved to be sensitive to the effects of low-vision rehabilitation. These observations illustrate why researchers measuring low-vision outcomes must explicitly remind patients about the use of low-vision devices when eliciting patients' self-reports of the difficulty they experience performing daily activities.

This retrospective comparison of two pilot studies that were designed and conducted independently has many limitations. Subtle program differences, characteristics of the veterans admitted to each BRC, and the research protocols used at the two sites may confound the results. Adjusting for all confounding factors is impossible. Additional studies are needed to further explore the effects of timing and directions for administration of questionnaires on outcomes.

The improvement in visual ability observed for Hines BRC patients when the self-report questionnaire was administered at discharge was unexpected because of the selective changes in item difficulty postrehabilitation. In other words, selected items became less difficult after rehabilitation, as opposed to a global improvement in patients' ability. The observed improvement in person measures could be a consequence of rehabilitation but could also be a halo effect [30]. That is, patients may overestimate their visual abilities at discharge before they have the opportunity to integrate the use of low-vision devices and adaptive techniques in daily living [8]. Bona fide changes in visual ability could conceivably result from refractive error correction, eccentric viewing training, or counseling. To explore this question further, we conducted a telephone follow-up interview of the original Hines BRC cohort 3 years later to determine if patient's self-reported HRQOL measured at discharge changed over time [31].

HINES BLIND REHABILITATION CENTER FOLLOW-UP STUDY

Methods

Subjects

Thirty-five veterans from the original cohort participated in the follow-up study. The mean visual acuity at baseline for these subjects was 1.1 logMAR (SD = 0.29, range 0.4 to 1.8). The mean visual acuity reported for the follow-up group is the prerehabilitation acuity, not the acuity at follow-up. Diagnoses most frequently reported were age-related macular degeneration (63%), diabetic retinopathy (17%), and glaucoma (6%). Patients were approximately 1 year older (mean age of 73 years, range 41 to 92) than the patients in the original cohort (mean age 72 years, range 38 to 88).

Because the Hines VA BRC is a regional referral program, patients do not return to the BRC for follow-up appointments to assess change in visual status. A surrogate measure for visual status, the patients' self-report of his or her ability to continue to use the low-vision devices prescribed at the BRC, was used because current information on visual status was not available.

Excluded from participation were 6 patients with severe cognitive deficits or declining health status who were unable to participate in the interview, 1 patient who self-reported significant vision loss (could no longer see well enough to use prescribed devices), 3 patients who were deceased, and 32 patients who were lost to follow-up or could not be reached with repeated telephone calls.

NEI VFQ-25 Administration and Data Analysis

Veterans were administered the NEI VFQ-25 plus *Appendix of Optional Additional Questions* in a telephone interview with the instructions for administration modified, as in the original study, so that study participants answered all questions as if they were wearing their glasses, contact lenses, or using low-vision devices [32]. As before, the Hines BRC 3-year follow-up data were analyzed with BIGSTEPS [25].

Results

Long-term postrehabilitation item measures were well correlated with intermediate postrehabilitation item measures ($r = 0.61$, $p < 0.01$, 95% CI = 0.34 to 0.79). The postrehabilitation reduction in item difficulty for selected items that was observed at discharge per-

sisted in the 3-year follow-up measures. However, the small improvement in person measures seen at discharge was not observed in the 3-year follow-up data. In fact, the 3-year postrehabilitation person measures deceased by 0.25 logit. The follow-up postrehabilitation person measures were significantly different from prerehabilitation person measures (two-tailed paired-comparison *t*-test, $p < 0.01$), which suggested a further advancement of visual impairment or other causes of functional loss.

Discussion

Measurement of HRQOL 3 years after rehabilitation did not confirm an improvement in person measures from pre- to postrehabilitation, whereas measurement of HRQOL immediately after rehabilitation showed a positive effect. With longer follow-up, measurement of overall ability of a person would not be expected to change as a result of low-vision rehabilitation, because counseling, devices, and training make specific activities easier to perform. However, they do not alter the visual impairment, which remains the same. The improvement in the item measure was maintained at 3-year follow-up. The ordering of items according to difficulty would not be expected to change over time.

The changes found 3 years after veterans participated in the Hines BRC program may be explained by a more realistic estimation of the use of low-vision devices and techniques after the veterans had experience using the skills and devices acquired from the rehabilitation program as well as declining vision, health, or cognition. While low-vision outcomes are usually measured after patients have had time to evaluate the usefulness of low-vision devices, the time frame that has been used varies from assessment at discharge to assessment a year or longer after the low-vision programs are completed [8,32–36]. Residential programs of longer length and intensity may be more susceptible to halo effects and require a longer transition back to community living before outcomes are measured.

Many limitations to the 3-year follow-up study conducted at the Hines BRC exist. Although 77 veterans were included in the original cohort, only 35 veterans were in the follow-up study. Questionnaires that measure changes in cognitive status or screening tools that assess symptoms of depression were not used in the original cohort or in the follow-up study. We estimated health status of the Hines BRC cohort 3 years postdischarge by asking the veterans if they had experienced a serious decline in health and by using a surrogate measure of visual status, the patients' self-report of his or her ability to continue to use the low-vision devices that were prescribed at the BRC. Additional research is needed to fully explore the issues raised in comparison of these studies.

CONCLUSIONS

This comparison of two studies that used the NEI VFQ-25 to measure changes in HRQOL after participation in two nearly identical blind rehabilitation programs demonstrates the importance of the time interval from discharge to administration of follow-up questionnaires and the directions on responding to survey questions that are given to patients. If outcomes are measured before patients have time to use their low-vision devices and skills at home and in the community, halo effects may modify outcomes measurement. Because of the age of the veteran population and the typical clinical course of age-related eye diseases, a greater chance exists that disease progression and changes in health status will occur when outcomes measurement is delayed.

The pilot study conducted at the Southwestern BRC demonstrates that patients may not consider use of low-vision devices when reporting the difficulty they have performing daily tasks. Our recommendation is that researchers who are using the NEI VFQ-25 to measure low-vision outcomes modify the question on these activities to make the instrument more sensitive to the improvements that occur after treatment. Changing the question to, "The next questions are about how much difficulty, if any, you have doing certain activities wearing your glasses or contact lenses or using low-vision devices if you have them for that activity," would facilitate consistent administration of the questionnaire and more meaningful comparison of results across studies.

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