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Original article

# Validity and reliability of the NEI VFQ-25 questionnaire in Indonesian leprosy patients

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ABSTRACT

*Background:* The National Eye Institute Visual Functioning Questionnaire (NEI VFQ-25) is one of the most frequently used questionnaires to assess visual function. However, its validity and reliability have not been documented in specific context of use in leprosy patients.
*Objectives:* To provide additional support to the reliability and validity of the NEI VFQ-25 in leprosy patients.
*Methods:* The reliability was assessed using internal consistency analysis (Cronbach's α formula). For validity assessment, item analysis was conducted by calculating the coefficient of corrected item-total correlation.
*Results:* The result showed all items included in the analysis were considered valid, as the coefficient was >0.3. Internal consistency reliability (calculation of all the questions taken together), the Cronbach's α of the instrument was 0.934 and 0.937. Due to low socioeconomic and low educational status, the majority of the patients have no vehicles nor can drive, therefore, there is a high missing rate of 'Driving' subscale.
*Conclusion:* The NEI VFQ-25 is a reliable and valid instrument, and can be used to assess vision-related quality of life in Indonesian leprosy patients.

## 1. Introduction

Leprosy is a chronic infectious disease with high incidence of physical deformity, including ocular involvement.[1,2] Globally, out of 70–75% cases with ocular involvement, 10–15% suffered severe visual impairment and 5% blindness.[1,2] Indonesia is the third-highest of leprosy new cases annually, after India and Brazil. World Health Organization (WHO) reported 17.439 new cases of leprosy in Indonesia, among them were 1.121 new leprosy cases with grade 2 disability.[3] A study in Bangladesh reported 7 out of 670 patients had ocular complications, among them were keratitis and dimness of vision (0.30%, respectively), followed by lagophthalmos, photophobia, and pain or discomfort[4] Another study conducted in India showed a high incidence of ocular lesions related to leprosy (60.3% of 1004 patients), with corneal lesions being the most frequent causes, followed by eyelid changes, lagophthalmos, corneal anesthesia, iridocyclitis, and cataract.[5] A study conducted in Sitanala, Indonesia in 2018 by Irawati et al. reported ocular manifestations found in leprosy patients were madarosis, cataract, corneal hypoesthesia, trichiasis, entropion, ectropion, punctate keratitis, epiphora, dacryocystitis, iritis, and iris pearls.[6] A study conducted in the United Kingdom found diminished lid closure and mild corneal opacity as the most frequent ocular complications.[7]

Leprosy patients who rely on their vision to protect their limbs may have devastating complications.[4,7] Vision impairment can further worsen a patient's quality of life. The decrease of vision may cause deterioration in physical function and mental health.[4,8,9] To provide a more comprehensive eye health assessment, subjective assessments by questionnaires are required in addition to objective assessments as they give more insight into the impact of vision loss and impairment.[10,11]

The National Eye Institute Visual Functioning Questionnaire (NEI VFQ-25) is one of the most frequently used questionnaires to assess visual function. It was designed to measure vision-related functioning and the influence of vision problems on health-related quality of life in persons with a variety of chronic eye diseases, such as glaucoma, diabetic retinopathy, age-related cataract, age-related macular degeneration, and low vision.[9–11] Notwithstanding the above facts, its validity

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and reliability have not been documented in specific context of use in leprosy patients. This study aimed to provide additional support to the reliability and validity of the NEI VFQ-25 in leprosy patients.

## 2. Methods

This study is part of a larger study entitled "*Manifestasi Kulit, Okular, dan Ekstremitas Pada Penderita Lepra*" ("Dermatologic, Ocular and Extremities Manifestations in Leprosy Patients"). The study was approved by the Ethics Committee of Faculty of Medicine, Universitas Indonesia, No. 0310/UN2.F1/ETIK/2018 (for study in Tangerang, year 2018) and No. 698/UN2.F1/ETIK/PPM.00.02/2019 (for study in Singkawang, year 2019), and consideration of the principles was proposed by Helsinki Declaration.

This cross-sectional study was conducted in a population of leprosy patients who resided at a leprosy settlement village in Tangerang, Banten, Indonesia in April 2018 and Alverno leprosy hospital, Singkawang, West Kalimantan, Indonesia in July 2019. During the program, eye examination was performed by ophthalmologists, as well as skin by dermatovenereologists, and extremity examination to detect abnormalities and deformities by physical medicine and rehabilitation physicians. Patients were also evaluated for sociodemographic characteristics and vision-related quality of life (VRQoL) using the NEI VFQ-25 translated in Indonesia, that has been validated and used in a previous study.[10] All patients were informed about the objectives of the study and signed an informed consent form prior to participation in this study.

The NEI VFQ-25 questionnaire comprises 25 questions which are classified into 12 subscales: general vision, difficulty with near vision activities, difficulty with distance vision activities, driving difficulties, ocular pain, color vision, peripheral vision, general health, vision-specific role difficulties, dependency, social function, and mental health. Subscale scores are an average of the relevant items in the subscale transformed to a 0 to 100 scale, with higher scores indicating better function. Composite score is an average of vision-targeted subscale scores, excluding general health subscale.[12] In this study, most of the subjects were uneducated and illiterate, hence the questionnaire was administered to the participants by trained interviewers. Interviewers were given training beforehand to prevent bias.

The data was analyzed using SPSS version 20.0 (IBM Corporation, Armonk, New York, USA). The reliability was assessed using internal consistency analysis (Cronbach's α formula). A Cronbach's α of $\geq$0.70 was indicated as acceptable.[13] For validity assessment, item analysis was tested. Item analysis was conducted by calculating the coefficient of corrected item-total correlation. It was considered acceptable if the value was >0.3.

## 3. Results

A total of 325 subjects completed the NEI VFQ-25 questionnaire (Table 1). The majority of the study subjects were males (63.4%). The mean age of subjects was 53.21 ± 12.32 years, ranging between 15 and 90 years old. Based on their educational background, most subjects in this study were uneducated (47.4%). Almost half of the subjects (49.8%) had non-fixed income (freelancer, taxi bike driver, construction worker, stall owner). The majority of the subjects were diagnosed with multibacillary (MB) type of leprosy (84.6%)

Composite score is an average of vision-targeted subscale scores, excluding general health subscale. The mean scores on the NEI VFQ-25 subscales and composite score are presented in Table 2. The lowest NEI VFQ-25 score was the General Health subscale, while the highest scores were for the Vision Specific Social Functioning and Color Vision subscales.

In this study, high missing rates was found in the 'Driving' subscale, with only 162 out of 325 subjects answered the subscale questions, thus we present two analyses: 1) with 'Driving' subscale, and 2) without 'Driving' subscale, as shown in Table 3. The validity of the questionnaire was done by calculating the coefficient of corrected item-total correlation. The result showed all items included in both analysis was considered valid, as the coefficient was >0.3. For internal consistency reliability (calculation of all the questions taken together), the Cronbach's α of the instrument was 0.934 and 0.937, thus it was considered

**Table 1**
Demographic characteristics of study participants.

| Variables | Total subjects (n = 325) n | % |
|---|---|---|
| **Age (Mean ± SD)**[a] | 53.21 ± 12.32 | |
| **Gender** | | |
| Male | 206 | 63.4 |
| Female | 119 | 36.6 |
| ****Occupation** | | |
| Fixed income | 10 | 3.1 |
| Non-fixed income | 162 | 49.8 |
| Unemployed | 83 | 25.5 |
| Unemployment | 70 | 21.5 |
| **Educational Background** | | |
| Undergraduate | 1 | 0.3 |
| Senior high school | 33 | 10.2 |
| Junior high school | 26 | 8.0 |
| Primary school | 111 | 34.2 |
| Uneducated | 154 | 47.4 |
| **Type of leprosy** | | |
| Paucibacillary (PB) | 50 | 15.4 |
| Multibacillary (MB) | 275 | 84.6 |

[a] n = 303 **Fixed income: factory worker, teacher, office employee; Non-fixed income: taxi bike driver, construction worker, stall owner, freelancer; Unemployed: student, housewife; Unemployment: not working nor studying.

**Table 2**
Descriptive statistics of the NEI VFQ-25 subscale and composite scores.

| VFQ-25 Subscale/Composite Score | n | Mean | SD | Median | Range |
|---|---|---|---|---|---|
| General health | 325 | 33.85 | 23.58 | 25.0 | 0–100 |
| General vision | 325 | 44.68 | 25.34 | 40.0 | 0–100 |
| Color vision | 325 | 84.92 | 24.12 | 100.0 | 0–100 |
| Peripheral vision | 325 | 79.62 | 24.09 | 100.0 | 0–100 |
| Ocular pain | 325 | 75.02 | 21.79 | 75.0 | 13–100 |
| Near vision | 325 | 71.42 | 22.08 | 75.0 | 0–100 |
| Distance vision | 325 | 78.32 | 20.96 | 83.0 | 25–100 |
| Vision-specific role difficulties | 325 | 69.28 | 28.59 | 75.0 | 0–100 |
| Vision-specific dependency | 325 | 78.12 | 26.78 | 92.0 | 0–100 |
| Vision-specific social functioning | 325 | 83.82 | 20.69 | 100.0 | 25–100 |
| Vision-specific mental health | 325 | 74.02 | 22.36 | 75.0 | 0–100 |
| Driving | 162 | 71.27 | 26.63 | 75.0 | 0–100 |
| Composite score[a] | 325 | 73.91 | 18.32 | 77.5 | 13.80–100 |

[a] Exclude 'Driving' subscale.

**Table 3**
Validity and reliability of NEI VFQ-25 subscales.

| VFQ-25 Subscale/Total Score | r* (n = 162) | r** (n = 325) |
|---|---|---|
| General vision | .504 | .528 |
| Color vision | .503 | .629 |
| Peripheral vision | .742 | .770 |
| Ocular pain | .678 | .555 |
| Near vision | .740 | .745 |
| Distance vision | .773 | .791 |
| Vision-specific role difficulties | .659 | .750 |
| Vision-specific dependency | .762 | .786 |
| Vision-specific social functioning | .778 | .810 |
| Vision-specific mental health | .841 | .850 |
| Driving | .738 | N/A |
| Composite score | 1.000 | 1.000 |
| Cronbach α | 0.934 | 0.937 |

r*: include 'Driving' subscale.
r**: exclude 'Driving' subscale.

reliable.

## 4. Discussion

Physical deformities and disabilities in leprosy may have an impact in Quality of Life (QoL). Several instruments have been widely used to assess quality of life in leprosy patients, including the World Health Organization Quality of Life Scale (WHOQoL-BREF); the Medical Outcomes Study 36-item short-form health survey (SF-36), a questionnaire that measure eight health concepts including physical functioning, role in physical health, bodily pain, general health, vitality, social functioning, role of emotional problems and mental health; and the Dermatology Life Quality Index (DLQI), a dermatology-specific QoL questionnaire.[14–17] As individuals with leprosy may experience the significant impact of visual impairment in their quality of life, assessment using a specific vision-related quality of life questionnaire is needed, but no studies have been conducted.

The NEI-VFQ was originally consisted of 51 items (13 subscales), but later the developers shortened it to a 25-item questionnaire (NEI VFQ-25) which was shown to provide valid data when used in several eye conditions in varying severity. The appendix of additional items from the 51-item version can be used to enhance the reliability and responsiveness that bring the total number to 39 (NEI VFQ-39), depending on the study. This questionnaire was originally written in English and has been translated and adapted to many languages.[12,18] Studies in various countries showed that the NEI VFQ-25 is a valid instrument in assessing vision-related quality of life in several chronic eye diseases. To our best knowledge, no studies have been conducted on measuring validity and reliability of this questionnaire in a leprosy population that may experience chronic visual impairment. In this study, the questionnaire had been translated to Bahasa Indonesia and had been validated in a previous study.[10] Interview-assisted questionnaire administration was done by trained interviewers since in this study 81.6% had low educational background (uneducated and primary school graduate). This mode of administration also allowed interviewers to deliver some phrases in local language so that the participants would understand the questions clearly. This questionnaire originally consisted of 12 subscales, with one general health subscale and eleven vision-targeted health-related QoL subscales. In this study, we excluded general health in the analysis as this subscale does not specifically measure the vision-related QoL.

In this study, 50.1% of the responses on the 'Driving' subscale was missing, with only 162 out of 325 subjects answered the 'Driving' subscale questions. One of the possible explanation of low driving rates in this study could be connected with low educational background and low socioeconomic status, where many subjects originally have no vehicles or could not drive, thus the questions regarding 'Driving' were skipped or unanswered. This was similar to other validation studies in other populations that encountered relatively high missing rates in 'Driving' subscale. A study by Kovac et al. in cataract, age-related macular degeneration, glaucoma, and diabetic retinopathy population in Serbia reported 73.3% missing values in 'Driving' subscale due to low economic status of the population.[19] A study in Taiwanese population identified high missing values in question number 15 and 16 regarding 'Driving', with missing percentages of 90.2% and 91.4%, respectively, in similar reason with our study.[20] Another study conducted in low vision patients with retinal diseases, glaucoma, and cataract as the main causes of vision loss showed more than 80% of the population did not drive, which resulted in high levels of missing data in the 'Driving' items.[18]

Due to the high missing rates of the 'Driving' subscale, to ensure the validity and reliability, we conduct two analyses to compare the results between with and without 'Driving' subscale. The validity evaluation was measured by the correlation coefficient of each subscales. Looking at the item-total correlation, all coefficient of the subscales and total score included in both analysis was >0.3. This showed that this questionnaire has good validity using the two analyses. This result is similar with another validation study. A study by Lin et al. showed a good result, with range of item-scale correlations value were >0.7.[20]

The Cronbach's α of this questionnaire was 0.934 and 0.937, which indicates excellent reliability because it was greater than the acceptable value of 0.7. Studies in age related macular degeneration population reported the reliability value of the NEI VFQ-25 total score was 0.91–0.96.[9,11,21] A study in glaucoma population reported the reliability value was 0.94.[22] A study in Chinese patients with cataracts reported the reliability value of 0.89.[23] Therefore, the reliability value of this study was similar to previous studies conducted in other chronic eye disease populations.

The limitation of this study is that there was a high missing rate of 'Driving' subscale that could be connected to the low socioeconomic and education status in our population study, therefore, we suggest the 'Driving' subscale in the NEI VFQ-25 questionnaire should not be compulsory or modified in the population where the majority have no vehicles or cannot drive.

## 5. Conclusion

This study showed that NEI VFQ-25 questionnaire is a valid and reliable instrument to assess vision-related quality of life in leprosy patients in Indonesia. We suggest that the 'Driving' subscale can be substituted or modified as reasons described in detail above.

## Declaration of patient consent

The author certify that they have obtained all appropriate patient consent.

## Declaration of competing interest

There are no conflicts of interest.

## Acknowledgement

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