# Developing a vision-related quality of life measure for persons with severe vision loss; The Impact of Vision Impairment – Very Low Vision (IVI-VLV) Questionnaire as part of the LoVADA protocol

**Robert P. Finger[1], Lauren N. Ayton[1], Betty Tellis[1], Julie Crewe[2], Jill E. Keeffe[1], Robyn H. Guymer[1]**

[1]Centre for Eye Research Australia, University of Melbourne, Royal Victorian Eye and Ear Hospital, Melbourne, Australia

[2]School of Public Health, Faculty of Health Sciences, Curtin University, Perth, Australia

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**Corresponding author:**

Robert P. Finger

Centre for Eye Research Australia, Department of Ophthalmology

University of Melbourne, Royal Victorian Eye and Ear Hospital

Level 1, 32 Gisborne St, East Melbourne, Victoria 3002, Australia

Email: robertfinger@gmx.net

(W) +61 3 9929 8381 (F) +61 3 9662 3859

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**Abstract:**

***Purpose*:** To design a measure appropriate for capturing vision-related quality of life in persons with severe vision loss.

***Design:*** Instrument development/ Cross-sectional study

***Participants:*** 603 legally blind persons (better eye with acuity of ≤20/200)

***Methods*:** Participants were interviewed using an item pool based on the original Impact of Vision Impairment (IVI) questionnaire, augmented by items appropriate for persons with severe vision loss. The item pool was refined and condensed in three steps using factor and Rasch analysis to assess psychometric properties, exploring key indices such as response category functioning (floor and ceiling effects), instrument unidimensionality, discriminant ability and targeting of item difficulty to patient ability.

***Main outcome measure:*** Measurement characteristics of the IVI-VLV

***Results:*** Over the three phases of instrument development a final pool of 28 items was selected which grouped into two subscales of the IVI-VLV – activities of daily living, mobility & safety (ADLMS; 16 items) and emotional well-being (EWB; 12 items). Both subscales are unidimensional, able to differentiate reliably between at least three different levels of VRQoL, and item difficulty was adequate for the assessed sample. In generalized linear models, controlling for age, only experiencing a lot of interference from other health problems in one's life ($p=0.005$ and $p=0.007$) as well as suffering from both depression and anxiety ($p=0.019$ and $p<0.001$) were associated with a lower ADLMS and EWB subscale score, respectively.

***Conclusions*:** The IVI-VLV is a valid and reliable VRQoL measure in persons with severe vision loss, and its measurement is almost unaffected by participants' self-perceived general or mental health status. The IVI-VLV captures VRQoL at the very low end of visual function, and can be used as an outcome measure in trials attempting sight restoration.

**Key Words:** quality of life, severe vision impairment, psychometric measurement, questionnaire development

**Precis:** The Impact of Vision Impairment – Very Low Vision (IVI-VLV) is a valid and reliable VRQoL measure in persons with severe vision loss, and its measurement is almost unaffected by self-perceived general or mental health status.

## INTRODUCTION

Visual impairment has a significant negative impact on quality of life. Using various vision-related quality of life measures, this has been demonstrated for a variety of conditions and levels of visual impairment.[1-6] However, to date most vision-related quality of life instruments have been developed for people with mild to moderate vision loss, and are not specific for severe impairment.

Measurement of quality of life involves a person self-rating the impact of their vision impairment (if any) or ocular condition on various underlying traits such as mobility, activity limitation, reading and accessing information or emotional well-being, using a set of relevant and validated items (questions).[7] Instruments are commonly developed to capture vision-related quality of life across various facets of visual function such as distance visual impairment, problems with near vision or loss of visual field. Thus, visual function at either end of the spectrum – very good or very poor – is commonly not well captured by most instruments due to floor and ceiling effects. To ensure high quality assessments and correct assumptions based on gathered data, psychometrically valid instruments are required.[8] With the promise of sight restoring treatments such as retinal prostheses, stem cell or gene therapy on the horizon, it is important to develop outcome measures applicable to persons with very poor vision, as neither visual acuity measurement nor measurement of vision-related quality of life using currently available instruments is meaningful in this group of patients.

Therefore we developed a vision-related quality of life measure, the Impact of Vision Impairment – Very Low Vision (IVI-VLV) questionnaire, appropriate for persons with severe vision loss. The IVI-VLV is based on the existing IVI questionnaire, and we have determined its validity, reliability and measurement characteristics using factor and Rasch analysis. This instrument development is part of the Low Vision Assessment of Daily Activities Protocol (LoVADA), developed as part of the Bionic Vision Australia retinal prosthesis project.

## METHODS

### *Participants*

All participants were adults (≥ 18 years) and legally blind according to the Australian definition, which is based on either distance visual acuity or a visual field restriction (distance visual acuity impairment of equal to or less than 6/60 (20/200) in the better eye, or a binocular visual field restriction to no more than the central 10 degrees, or both).

The study was conducted between September 2012 and December 2013 at the Centre for Eye Research Australia, Royal Victorian Eye and Ear Hospital (RVEEH). Ethical approval was obtained from the Human Research and Ethics Committee at the RVEEH. All patients gave informed consent for study participation. The study adhered to the tenets of the Declaration of Helsinki.

### *Psychometric Evaluation*

Rasch analysis is a modern psychometric method that mathematically describes the interaction between respondents and test items and applies a strict model which the pattern of participants' responses should satisfy.[9-12] Rasch analysis provides greater insight into the psychometric properties of the instrument compared to traditional methods. Several techniques are available to determine how well items fit the latent trait being measured, i.e. vision-related quality of life; how well the items discriminate between the respondents; and how well item difficulty targets person ability, i.e. level of vision.[8] During Rasch analysis, scores that approximate interval-level measurement (person measures, expressed in log of the odds units, or logits) are estimated from raw ordinal data. We used the following criteria to assess the psychometric properties of the IVI-VLV.

Threshold ordering

To determine whether the categories used to rate the IVI-VLV items are valid, we assessed the response category threshold ordering. First, over- or underutilization of response categories, as well as ability of respondents to discriminate between response categories, was assessed. Disordered thresholds, if evident, were addressed by collapsing categories. In addition, the number of responses, average measure per response category

and category thresholds were assessed in detail. While the Rasch model is based on a strict pattern of expected responses, some random variation is always assumed. This amount is represented by the mean square (MnSq) statistic. An infit MnSq value of 1 is ideal, and up to 1.3 is acceptable. Anything above that indicates an excess amount of 'noise' in the data. Similarly, a value below 0.7 indicates an unacceptably high degree of uniformity in the responses.

Precision of the instrument

The ability of the scale to discriminate between different levels of person ability is assessed using person separation index (PSI) and person reliability (PR) scores. Values of >2.0 and >0.8, respectively, are considered adequate and represent the capacity of the scale to distinguish at least three levels of person ability i.e. visual functioning.

Unidimensionality

Whether the scale measured a single latent trait was assessed in two ways. First, by testing how well each item 'fits' or 'misfits' the underlying trait through an 'infit' mean square standardised residuals (MNSQ) statistic.[7] A value of 0.7-1.3 is considered acceptable, while lower or higher values may indicate redundancy or unacceptable variation in the responses, respectively. Second, the items were tested for local independence using Principal Components Analysis (PCA), which means that they are not related except for the fact that they measure the same trait, with as little overlap between items as possible. The PCA of residuals for the first factor should exceed 50% and the first contrast of residuals should be <2.5 eigenvalues.[7]

Targeting

The targeting of the instrument was determined by visual inspection of the person-item map and calculation of the difference between item and person means. A difference of >1.0 logits suggests that the difficulty of the items does not adequately target the ability of the sample participants.

Differential Item Functioning (DIF)

Each item was assessed for DIF, which is a statistical method for detecting whether sample subgroups (e.g. gender, age groups) systematically respond differently to certain items, despite having similar underlying ability. A DIF contrast of >1.0 logits for an item indicates that interpretation of the item may be biased for some participant subgroups.

We performed Rasch analysis on the IVI-VLV using Winsteps software (version 3.68, Chicago, Illinois, USA) and the Andrich single rating scale model was used.

***Statistical Analyses***

Data analysis was carried out with the SPSS statistical software (Version 19.0, SPSS Science, Chicago, IL). We used factor analysis in addition to the above described principal components analysis to explore the subscales of the IVI-VLV. Descriptive statistical analyses were performed to characterize the participants' sociodemographic, clinical, and vision-related quality of life (VRQoL) data. The association between VRQoL scores and participant characteristics were explored using bivariate correlations and Chi-Square tests. Factors found to be associated in univariate analyses were subsequently entered into a generalized linear model. All tests were considered to be statistically significant at a level of $p<0.05$.

***Phases of instrument development***

The instrument development was structured in three phases. In the first phase, we pooled data from previous studies which have used the IVI 28-items in persons who are legally blind and assessed its measurement properties.[13-17] Data for a total of 204 legally blind participants were collated and assessed using Rasch analysis. As expected, measurement properties were suboptimal for our desired target population of people with severe vision loss, and the majority of items had a ceiling effect (a lot of problems/too difficult). In addition some items were inapplicable to this group as they had either stopped doing this particular task or activity, or – rarely – had adapted to a degree that caused them to have no problems any longer. Thus, we decided to develop a new instrument with different, more appropriate items.

Thus, in the second phase, we went back to the original item pool used to develop the current IVI-28 items. In several focus group discussions with visually impaired patients,

healthy controls and professionals, an initial item pool of 76 items had been created and subsequently reduced to form the currently used IVI-28 which is a well validated VRQoL measure for persons with varying degrees of visual impairment.[15, 18-20] Using a number of items which had been eliminated based on mostly a floor effect (no problems/too easy) in the initial evaluations, a total of 52-items was taken forward for evaluation in phase two of this study. In this phase we conducted telephone interviews with 198 legally blind persons, collecting sociodemographic characteristics, VRQoL data and qualitative feedback.

Following the Rasch analysis of the 52-item version, a number of items were removed based on floor or ceiling effects, or misfit, and 34 items remained. These grouped into an emotional wellbeing, and a mobility & activities of daily living and safety subscale. However, based on qualitative feedback gathered after each interview, a number of items and response options were rephrased and new items added. A large number of participants highlighted a lack of items related to employment, financial issues and education. Discussions with low vision experts confirmed that these were frequently encountered issues. Based on this, three items were added and a 37-item version taken forward into phase three of the study.

In the third phase, 201 legally blind participants were interviewed by telephone, collecting sociodemographic data in addition to the IVI-VLV 37-item interview. The results of this final phase of the instrument development are presented in the results section. **Supplemental table 1** provides an overview of all items tested and the final items retained for the IVI-VLV.

## Results

*Participant characteristics*

Of the 201 participants, slightly over half were female (n=116, 58%), and the average age was 72 years (±16 years standard deviation (SD), **Table 1**). All participants were legally blind. The most common cause of vision loss was age-related macular degeneration (AMD, 50%), followed by retinitis pigmentosa (RP; 14%) and other retinal dystrophies (12%; **Table 1**). On average, participants had been legally blind for 18 years, and were using just under

eight different visual aids and devices. Most participants were married or had a defacto partner (54%) and lived with someone (62%). Younger participants (< 65 years) were less severely visually impaired (p=0.033), had been blind for longer (p<0.001), more often had a higher educational level (p=0.001), were less likely to be retired (p<0.001), reported fewer other health problems (p<0.001) and a better general health (p=0.015). Just under 30% of participants suffered from either anxiety, depression or both (**Table 1**).

**Table 1.** Characteristics of the sample, as mean(±SD) or n(%)

| | | **Total sample** | **Age groups** | | **p*** |
|---|---|---|---|---|---|
| | | n=201 | <65 years n=64 | ≥65 years n=137 | |
| Age (years) | | 72±16 | 52±9 | 81±9 | <0.001 |
| Gender | Male | 85(42.3%) | 32(50.0%) | 53(38.7%) | 0.131 |
| | Female | 116(57.7%) | 32(50.0%) | 84(61.3%) | |
| Marital status | single/divorced/widowed | 92(45.8%) | 29(45.3%) | 63(46.0%) | 0.929 |
| | married/partner | 109(54.2%) | 35(54.7%) | 74(54.0%) | |
| Living situation | alone | 74(37.9%) | 19(32.8%) | 55(40.1%) | 0.332 |
| | with someone | 121(62.1%) | 39(67.2%) | 82(59.9%) | |
| Employment | full-time | 7(3.5%) | 7(11.3%) | 0(0%) | <0.001 |
| | part-time | 30(15.2%) | 25(40.3%) | 5(3.7%) | |
| | retired | 153(77.3%) | 23(37.1%) | 130(95.6%) | |
| | unemployed | 8(4.0%) | 7(11.3%) | 1(.7%) | |
| Education | primary/some secondary | 79(39.3%) | 15(23.4%) | 64(46.7%) | 0.001 |
| | secondary completed | 24(11.9%) | 11 (17.2%) | 13(9.5%) | |
| | Apprenticeship/TAFE | 56(27.9%) | 17(26.6%) | 39(28.5%) | |
| | University | 42(20.9%) | 21(32.8%) | 21(15.3%) | |
| General health | Excellent | 32(15.9%) | 12(18.8%) | 20(14.6%) | 0.015 |
| | very good | 59(29.4%) | 26(40.6%) | 33(24.1%) | |
| | good | 70(34.8%) | 18(28.1%) | 52(38.0%) | |
| | fair | 26(12.9%) | 4(6.3%) | 22(16.1%) | |
| | poor | 14(7.0%) | 4(6.3%) | 10(7.3%) | |
| Other health problems | yes | 156(77.6%) | 39(60.9%) | 117(85.4%) | <0.001 |
| | no | 45(22.4%) | 25(39.1%) | 20(14.6%) | |
| Do other health problems interfere? | not at all | 52(25.9%) | 13(20.3%) | 39(28.5%) | 0.005 |
| | a little | 50(24.9%) | 13(20.3%) | 37(27.0%) | |
| | a great deal | 57(28.4%) | 14(21.9%) | 43(31.4%) | |
| | not applicable | 42(20.9%) | 24(37.5%) | 18(13.1%) | |
| Anxiety & Depression | depression | 25(12.4%) | 5(7.8%) | 20(14.6%) | 0.245 |
| | anxiety | 17(8.5%) | 7(10.9%) | 10(7.3%) | |
| | both | 12(6.0%) | 6(9.4%) | 6(4.4%) | |
| | None | 147(73.1%) | 46(71.9%) | 101(73.7%) | |
| Eye condition | RP | 28(13.9%) | 21(32.8%) | 7(5.1%) | 0.223 |
| | AMD | 101(50.2%) | 6(9.4%) | 95(69.3%) | |
| | other retinal dystrophy | 25(12.4%) | 16(25.0%) | 9(6.6%) | |
| | glaucoma | 15(7.5%) | 2(3.1%) | 13(9.5%) | |

| | | | | | |
|---|---|---|---|---|---|
| | other | 32(15.9%) | 19(29.7%) | 13(9.5%) | |
| Level of visual impairment | 6/60 - > CF | 45 (22.4%) | 25(39.1%) | 20(14.6%) | 0.033 |
| | CF - > PL | 127 (63.2%) | 27(42.2%) | 100(73.0%) | |
| | PL and worse | 29 (14.4%) | 12(18.8%) | 17(12.4%) | |
| Duration of vision loss/legally blind (years) | | 18±18 | 24±17 | 15±18 | 0.001 |
| No of visual aids and devices used | | 7.73±3.58 | 7.41±3.44 | 7.88±3.65 | 0.388 |

SD= standard deviation; CF = Counting fingers, PL= Perception of Light, * two-samples t-tests or Mann-Whitney U-tests

*Psychometric Evaluation of the IVI-VLV*

All items of the IVI-VLV are preceded by “How much does your eyesight....” and use the same rating scale with the following four response options: Not at all, a little, some of the time, and a lot. In addition, all items have a “Don’t do this for other reasons” option. Response category thresholds were ordered, indicating that participants were able to differentiate sufficiently between them. Three items displayed misfit, and the PCA indicated multidimensionality (**Table 2**).

Based on the PCA, confirmed by a factor analysis, the scale was split into two subscales, the Emotional Wellbeing (EWB) subscale and a subscale which we termed Activities of Daily Living, Mobility and Safety (ADLMS), as it contains items related to these inter-related aspects of daily life. The remaining items did not group together in any particular way and we were unable to incorporate them into another subscale or add them to either of the other two. Against this background we dropped all items not contributing any measurement to the two identified subscales (in total nine items, related to operating household appliances, using a computer, social activities, colliding with an obstacle or a car, education and employment). The ADLMS subscale contains 16 items, and the EWB subscale 12 items.

Assessing the two identified subscales, none of the items were misfitting, and item reliability and separation were above 0.9 and 3.0 respectively for all subscales. This indicated that all thresholds were ordered and that the number and clarity of the response categories were appropriate. The PR above 0.8 indicated acceptable ability to differentiate reliably between at least three different levels of VRQoL for both subscales. The targeting of the instrument was

slightly suboptimal, with a difference between person and item means of -0.12 (*ADLMS*) and 0.28 (*EWB*) logits. This, however, is still well within acceptable levels and the person item maps for both subscales demonstrated a good spread of items across the spectrum of participants' VRQoL (**Figure 1**). There was no evidence of multidimensionality in either of the subscales. The raw variance explained by the PCA of the residuals was adequate for both the *ADLMS* and *EWB* subscales (50.6% and 54.1%). None of the items showed any DIF. Taking these parameters together, both IVI-VLV subscales satisfy all requirements of the Rasch model. A final version of the IVI-VLV questionnaire can be found in **supplemental document 1**.

**Table 2. The fit parameters of the complete IVI-VLV and its subscales Activities of Daily Living, Mobility & Safety (ADL) and Emotional Wellbeing (EWB) compared to the Rasch model**

| Parameters | Rasch model | Complete IVI-VLV | ADL, M&S | EWB |
|---|---|---|---|---|
| Item No. | | 1-37 | 1,3,5,8-20 | 23—27, 29-31, 34-37 |
| Number of misfitting items | 0 | 3 | 0 | 0 |
| Person separation (PSI) | >2.0 | 3.39 | 2.34 | 2.24 |
| Person reliability (PR) | >0.8 | 0.92 | 0.85 | 0.83 |
| Person mean | 0 | 0.01 | -0.12 | 0.28 |
| Principal Components Analysis (PCA; Eigenvalue for first contrast) | <2.5 | 3.4 | 2.3 | 1.6 |
| Variance by the first factor | 50-60% | 44.9% | 50.6% | 54.1% |

*Association of the IVI-VLV scores with sample characteristics*

Rasch analysis was used to generate person measures for both subscales, with higher scores indicating better VRQoL. The mean ADLMS subscale score was -0.05 (±1.03 SD) and the mean EWB subscale score was 0.28 (±1.12 SD). The different eye conditions

causing visual impairment were associated with the ADLMS but not the EWB subscale scores (p=0.018 and p=0.685, respectively, **Table 3**). However, both subscale scores demonstrated changes over the three categories of visual impairment (**Table 3**). Both ADLMS and EWB scores decreased with worsening general health, the presence of other health problems, and with increasing interference of these health problems and with the presence of depression or anxiety (**Table 3**). In generalized linear models, controlling for age, only experiencing a lot of interference from other health problems in one's life as well as suffering from both depression and anxiety, were associated with a lower ADLMS and EWB subscale score (**Table 4**). Of the eye conditions, only AMD remained associated with both ADLMS and EWB subscale scores, and males were more likely to report a lower EWB score (**Table 4**). Categories of visual impairment were not associated with the ADLMS subscale score, and only the intermediate category (Count Fingers to better than Light Projection) was associated with the EWB subscale score.

**Table 3.** IVI-VLV subscale scores by sample characteristics, n=201

| | | **ADLMS** | | **EWB** | |
|---|---|---|---|---|---|
| | | Mean±SD | p* | Mean±SD | p* |
| Age | <65 | .01±.99 | 0.588 | .11±1.00 | 0.140 |
| | 65+ | -.08±1.06 | | .36±1.17 | |
| Gender | Male | -.01±1.15 | 0.627 | .21±1.12 | 0.465 |
| | female | -.08±.95 | | .33±1.12 | |
| Marital status | single/divorced/widowed | -.03±1.04 | 0.819 | .34±1.13 | 0.473 |
| | married/partner | -.07±1.03 | | .23±1.11 | |
| Living situation | alone | .01±1.08 | 0.518 | .36±1.16 | 0.453 |
| | with someone | -.09±1.01 | | .24±1.10 | |
| Employment | full-time | .46±.71 | 0.165 | .53±.93 | 0.726 |
| | part-time | .18±1.35 | | .43±1.30 | |
| | retired | -.14±1.00 | | .25±1.11 | |
| | unemployed | .29±.53 | | .05±1.02 | |
| Education | primary/some secondary | -.02±1.15 | 0.342 | .40±1.26 | 0.287 |
| | secondary completed | -.36±.80 | | -.11±.89 | |
| | Apprenticeship/TAFE | -.09±.93 | | .30±1.05 | |
| | University | .12±1.05 | | .27±1.03 | |
| General health | Excellent | .59±1.68 | <0.001 | .67±1.49 | 0.008 |
| | very good | .08±.84 | | .55±1.08 | |
| | good | -.23±.73 | | .06±.98 | |
| | fair | -.50±.76 | | .01±.90 | |
| | poor | -.38±.92 | | -.13±.89 | |
| Other health problems | yes | -.16±.95 | 0.005 | .19±1.00 | 0.026 |
| | no | .32±1.22 | | .61±1.42 | |

| | | | | | |
|---|---|---|---|---|---|
| Do other health problems interfere? | not at all | .17±1.20 | <0.001 | .44±1.06 | 0.002 |
| | a little | -.05±.77 | | .41±.88 | |
| | a great deal | -.53±.70 | | -.19±.95 | |
| | not applicable | .32±1.23 | | .57±1.46 | |
| Anxiety & Depression | depression | -.43±.88 | 0.008 | -.31±.80 | <0.001 |
| | anxiety | -.38±.78 | | -.40±1.04 | |
| | none | .10±1.06 | | .55±1.09 | |
| | both | -.62±.93 | | -.76±.65 | |
| Eye condition | RP | .15±.90 | 0.018 | .24±1.02 | 0.685 |
| | AMD | -.27±.80 | | .21±1.02 | |
| | other retinal dystrophy | .37±1.41 | | .45±1.14 | |
| | glaucoma | -.19±1.03 | | .11±1.21 | |
| | other | .19±1.32 | | .48±1.44 | |
| Level of visual impairment | 6/60 - > CF | .08±1.02 | 0.003 | .23±1.01 | 0.010 |
| | CF - > PL | -.22±.99 | | .17±1.12 | |
| | PL and worse | .47±1.09 | | .86±1.15 | |

SD= standard deviation; CF = Counting fingers, PL= Projection of light, * one-factorial ANOVA

**Table 4.** Factors associated with ADLMS and EWB subscale scores

| | ADLMS | | | | EWB | | | |
|---|---|---|---|---|---|---|---|---|
| **Factors** | | | 95% CI | | | | 95% CI | |
| | p | OR | Lower | Upper | p | OR | Lower | Upper |
| Eye Condition | | | | | | | | |
| • Retinitis pigmentosa | .884 | 1.04 | 0.64 | 1.68 | .854 | 0.95 | 0.58 | 1.58 |
| • AMD | .022 | 0.56 | 0.34 | 0.92 | .048 | 0.59 | 0.36 | 0.99 |
| • Retinal dystrophy | .501 | 1.19 | 0.72 | 1.98 | .856 | 0.95 | 0.56 | 1.62 |
| • Glaucoma | .107 | 0.61 | 0.34 | 1.11 | .073 | 0.57 | 0.30 | 1.05 |
| • Other (reference) | | 1.00 | | | | 1.00 | | |
| Level of visual impairment | | | | | | | | |
| • 6/60 - > CF | .325 | 0.80 | 0.51 | 1.25 | .110 | 0.69 | 0.43 | 1.09 |
| • CF - > PL | .095 | 0.69 | 0.45 | 1.07 | .027 | 0.60 | 0.38 | 0.94 |
| • PL and worse (reference) | | 1.00 | | | | 1.00 | | |
| Gender | | | | | | | | |
| • Male | .488 | 0.91 | 0.70 | 1.19 | .023 | 0.72 | 0.55 | 0.96 |
| • Female(reference) | | 1.00 | | | | 1.00 | | |
| General Health | | | | | | | | |
| • Excellent | .559 | 1.22 | 0.63 | 2.37 | .885 | 1.05 | 0.53 | 2.11 |
| • Very good | .429 | 0.78 | 0.43 | 1.43 | .962 | 0.98 | 0.52 | 1.85 |
| • Good | .420 | 0.80 | 0.46 | 1.38 | .305 | 0.74 | 0.42 | 1.31 |
| • Fair | .551 | 0.83 | 0.45 | 1.52 | .971 | 1.01 | 0.54 | 1.90 |
| • Poor (reference) | | 1.00 | | | | 1.00 | | |
| Do other health problems interfere? | | | | | | | | |
| • Not at all | .456 | 0.86 | 0.58 | 1.28 | .242 | 0.78 | 0.51 | 1.18 |
| • A little | .358 | 0.82 | 0.54 | 1.25 | .626 | 0.90 | 0.58 | 1.39 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| • A lot | .005 | 0.54 | 0.35 | 0.83 | .007 | 0.53 | 0.34 | 0.84 |
| • No other health problems (reference) | | 1.00 | | | | 1.00 | | |
| Anxiety or Depression | | | | | | | | |
| • Depression | .243 | 1.48 | 0.77 | 2.85 | .097 | 1.79 | 0.90 | 3.54 |
| • Anxiety | .678 | 1.16 | 0.58 | 2.34 | .290 | 1.48 | 0.71 | 3.08 |
| • Both | .019 | 2.00 | 1.12 | 3.56 | .000 | 3.51 | 1.92 | 6.42 |
| • None (reference) | | 1.00 | | | | 1.00 | | |

ADLMS= Activities of Daily Living, Mobility and Safety, EWB= Emotional wellbeing, OR= odds ratio, CI= confidence interval, CF = Counting fingers, PL= Projection of light; grey shaded areas indicate statistical significance.

## Discussion

Using a large item pool, participant and expert input and Rasch analysis, we designed a valid and reliable measure of VRQoL in persons with very poor vision, the IVI-VLV. It can differentiate between different levels of VRQOL in participants, with measurement only affected by other health problems if they interfere a lot with respondents lives, or when respondents suffer from both anxiety and depression. The questionnaire adds to the currently available pool of VRQoL instruments by allowing measurement in persons whose VRQoL is not captured by available instruments due to floor effects and inappropriate item content. The IVI-VLV meets all requirements of the Rasch model, and proposed quality criteria for health status questionnaires, such as content validity, internal consistency, reliability, no floor or ceiling effects and good interpretability.[21]

Self-perceived general and mental health is known to affect measurement of VRQoL.[22, 23] Our results indicate, however, that only health problems which interfere with respondents' lives a lot affected IVI-VLV measurement. Thus, contamination or distortion is unlikely to be significant. Similarly, severe visual impairment is often associated with higher rates of depression and anxiety which may distort measurement of VRQoL.[24, 25] Given that we found depression and anxiety only to be associated with measured VRQoL if occurring concurrently, the distortion of the IVI-VLV measurement is likely to be small.

Neither ocular conditions nor categories of visual impairment showed strong associations with measured VRQoL in this sample, which is not unexpected. VRQoL has been shown to be determined mostly by the extent of visual impairment as well as the type (central versus peripheral visual field loss, etc.) irrespective of the underlying condition.[3] In addition, the level of adaptation as well as certain personality traits (optimism, coping, etc.) further determine a person's reported VRQoL.[26] Given the very similar, and severe visual impairment across the whole sample, it is unlikely that very small differences in visual impairment levels outweigh differences in adaptation and personality traits in this seemingly well adjusted sample, who used an average of 8 visual aids/devices per person. Conversely, a lack of an association of measured VRQoL with levels of visual impairment may reflect differing levels of personal experience, coping strategies and adaptation in these patients with long-standing severe visual loss, which is well in keeping with the literature.[27, 28]

Strengths of our study include the use of a large item pool based on focus group discussions with affected persons and experts, ongoing participant and expert input into item selection, content and wording, and Rasch analysis to assess the psychometric function and measurement characteristics of the IVI-VLV. Using Rasch analysis as well as factor analysis, final items were selected and grouped into two subscales, which could be shown to satisfy all requirements of the Rasch model. In addition, Rasch analysis provides several useful indicators of scale category organization such as the validity and functioning of the rating scale, and the optimal number of response categories.[29, 30] A limitation of our study is the use of respondent-reported clinical characteristics (level of visual impairment and condition), and a lack of further functional data (visual field, etc.) which may have diminished our ability to reveal significant associations with these. Further studies will assess associations with functional clinical measures of vision. As AMD constitutes the largest single cause of blindness in all industrialized countries, our sample is fairly representative of a group of severely visually impaired persons. The Australian definition of blindness has previously been shown to better in identify persons with vision loss related morbidity compared to the

US American or World Health Organization's definition.[13] Thus, legally blind Australians constitute a valid group of respondents to develop the IVI-VLV.

In conclusion, the IVI-VLV is a valid VRQoL measure in persons with very poor vision, and its measurement is almost unaffected by participants' self-perceived general or mental health status. At this very low level of visual function, small differences in visual impairment do not seem to influence reported VRQoL which may rather be determined by someone's adaptation, coping and other personality traits. The IVI-VLV captures VRQoL at the very low end of visual function, and can be used as an outcome measure in trials attempting sight restoration.

***Figure legends:***

**Figure 1.** Person-Item Maps for the Activities of Daily Living, Mobility and Safety (ADLMS) and the Emotional Wellbeing (EWB) subscales of the IVI-VLV.

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