Development of Item Banks to Measure the Impact of Amblyopia and Strabismus on Quality of Life

by

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ABSTRACT

Amblyopia (lazy eye) and strabismus (cross eyes or ocular misalignment) are common developmental disorders of childhood. When not diagnosed or treated successfully, these endure as chronic conditions into adulthood and are associated with a range of visual and motor deficits. However, it is not clear how these conditions impact Quality of life (QoL). Understanding the patient's perspectives of the QoL implications of these conditions is important to evaluate its burden and the effectiveness of interventions provided. But these evaluations are limited by the lack of valid and comprehensive patient reported outcome measures (PROMs). Moreover, the existing PROMs, being paper based are limited in content and fall short of desired psychometric qualities. Most of them have been developed for high income countries. Therefore, the aim of this doctoral research was to develop amblyopia and strabismus specific QoL item banks that can be implemented via a computer adaptive testing (CAT) system for adults in Australia and India. The study comprised of two phases and was carried out independently in Australia and India to enable development of country-specific measurement systems. This thesis encompasses complete phase 1 (content identification) and phase 2 (psychometric validation and calibration) of the Indian item bank construction and the phase 1 of the Australian item bank construction. Phase 2 Australia is work in progress beyond this doctoral study.

In phase 1, the content for the item banks were identified by a systematic review of the existing PROMs (n=22), published qualitative studies (n=5) and extensive qualitative studies in Australia (n=49) and India (n=30). The pool of items underwent a systematic process of binning and winnowing (item reduction and classification) and optimal sets of representative items addressing all important aspects of QoL such as activity limitations, emotional impact and social impact were devised. The pilot item banks for Australia and India had 386 and 341 items respectively.

In phase 2, the Indian item banks were administered to adults with amblyopia and strabismus in India (n=304). Rasch analysis, a modern psychometric method, was used to validate and optimise the psychometric properties (e.g. rating scale functioning, measurement precision) of the Indian item banks and establish item calibrations for the CAT simulation. Phase 2 in Australia is ongoing; an interim psychometric analysis with the data collected (n=55) was performed.

The psychometric analysis of the Indian data resulted in twelve valid amblyopia and

strabismus specific item banks: symptoms – frequency (n=32), symptoms - severity (n=32), symptoms - bothersome (n=32), activity limitations (n=43), driving (n=18), mobility (n=12), concerns (n=58), emotional impact (n=35), social impact (n=19), convenience (n=24), economic impact (n=13) and coping (n=20). The CAT simulations of these item banks indicated that an average of 7 and 15 items are required to measure these QoL constructs with moderate and high precision respectively.

The item banks developed in this doctoral research show promising ability to measure the QoL impacts of amblyopia and strabismus precisely. Implementing these item banks via a CAT system will greatly reduce the respondent burden of answering long paper-based questionnaires. Incorporating these in routine clinical settings would enable real time measurement and monitoring of QoL parameters. This would be useful to substantiate the effectiveness of novel amblyopia treatments and the benefits of strabismus correction for adults.

DECLARATION

I certify that this thesis

- does not incorporate without acknowledgment any material previously submitted for a degree or diploma in any university; and
- to the best of my knowledge and belief, does not contain any material previously published or written by another person except where due reference is made in the text.

Signed: Sheela Evangeline Kumaran

Date: 22.11.2019

PUBLICATIONS, CONFERENCE PRESENTATIONS AND AWARDS

Publications (Supplement 1)

1. **Kumaran SE**, Khadka J, Baker R and Pesudovs K, 'Patient reported outcome measures in amblyopia and strabismus – a systematic review'. Clin Exp Optom. 2018 Jul;101(4):460-484
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2. **Kumaran SE**, Khadka J, Baker R and Pesudovs K, 'Functional limitations recognised by adults with amblyopia and strabismus in daily life: a qualitative exploration.' Ophthalmic Physiol Opt. 2019 May; 39(3): 131-140.

Conference presentations – Oral (Supplement 2)

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2. **Kumaran SE**, Khadka J, Baker R and Pesudovs K, The Amblyopia and Strabismus Eye-tem (Item) Bank project - Results of Phase 1: Content identification, Rasch measurement theory conference, January 2018, Perth, Australia
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DISCLOSURE

There are no conflicts of interest or proprietary interest. I am entirely responsible for the content and writing of this thesis. No editor was deployed.

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Inclusion of co-authored publications in this thesis

Two multi-authored manuscripts have been published from this thesis, on which I am the first author.

Paper 1 was a systematic review of patient reported outcome measures developed for amblyopia and strabismus. This publication established the rationale of this thesis and has been included as Chapter 2. The content of this chapter is mostly similar to Paper 1, formatted in slightly different fashion.

A part of the results from Chapter 3 was published as Paper 2. Paper 2 specifically focussed on one major quality of life theme that emerged from the qualitative study conducted in Australia. The published text has been incorporated in Chapter 3, particularly in sections 3.6.2 and 3.9.

My contribution: I designed both the studies, collected data, performed analysis, drafted the manuscripts and revised them based on the comments from the co-authors and the journal editors and reviewers. The co-authorship approval form attached as a supplement supports my contribution statement. The contributions of the co-authors in each publication is given below.

Paper 1: Kumaran SE, Khadka J, Baker R and Pesudovs K, 'Patient reported outcome measures in amblyopia and strabismus – a systematic review'. Clin Exp Optom. 2018 Jul;101(4):460-484

Co-author contributions:
Khadka J: Study design, Supervision, Critical revision of the manuscript
Baker R: Critical revision of the manuscript
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Above all, I praise and thank God for His marvellous grace. I can do nothing without Him. I dedicate this thesis to my Lord and Saviour Jesus Christ.

"Praise the Lord. Give thanks to the Lord, for he is good; his love endures forever."
Psalms 106:1

GLOSSARY OF ABBREVIATIONS

A&SQ	Amblyopia and Strabismus Questionnaire
ADL	Activities of Daily Living
AS-20	Adult Strabismus questionnaire
ATI	Amblyopia Treatment Index
B&A	Bland and Altman
CAT	Computer Adaptive Testing
cATI	Child Amblyopia Treatment Index
CATQoL	Child amblyopia treatment questionnaire
COSMIN	Consensus-based Standards for the selection of health Measurement Instruments
CPC	Category Probability Curves
CTT	Classical Test Theory
CVLS	Children's Vision for Living Scale
DIF	Differential Item Functioning
EAP	Expected A Posteriori Estimator
EDQ	Effect of Diplopia Questionnaire
EMA	European Medicines Agency
ERIQA	European Regulatory Issues and Quality of life Assessment
ESSQ	Expectations of Strabismus Surgery Questionnaire
FDA	Food and Drug Administration
GPCM	Generalised Partial Credit Model
HADS	Hospital Anxiety and Depression Scale
HRQoL	Health Related Quality of Life
ISI	Item Separation Index
ISPOR	International Society for Pharmacoeconomics and Outcomes Research
IVI	Impact of Visual Impairment questionnaire
IXTQ	Intermittent Exotropia Questionnaire
LID	Local item dependency
LOA	Limits of Agreement
MID	Minimally Important Difference
MNSQ	Mean-Square Fit Statistics
MPWI	Maximum Posterior Weighted Information
NEIVFQ-25	National Eye Institute Visual Function Questionnaire
OCQ	Occlusion patch Comfort Questionnaire
PCA	Principal Component Analysis
PedsQL	Paediatric Quality of Life Inventory
PEQ	Psychosocial Experience Questionnaire

PIQ	Psychological Impact Questionnaire
PPQ	Perceived Psychosocial Questionnaire
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-analyses
PROM	Patient Reported Outcome Measure
PROMIS	Patient Reported Outcomes Measurement Information System
PSI	Person Separation Index
PSQ	Patching Success Questionnaire
QF	Question format
QoL	Quality of Life
QSR	Qualitative Research Software
RC	Response categories
RMT	Rasch Measurement Theory
SE	Standard Error
SF-36	Short Form Health Survey
VF-14	Visual Function questionnaire
VRAL	Vision Related Activity Limitations
VRQoL	Vision-Related Quality of Life
WHO	World Health Organisation
WHOQOL-BREF	World Health Organisation Quality of Life Instrument (short version)
ZSTD	z-standardized

CHAPTER 1 INTRODUCTION

Measuring patient reported outcomes such as Quality of Life (QoL) using modern psychometric methods such as Rasch analysis has gained much momentum in health sciences, particularly in the optometry and ophthalmology disciplines.[1] The 'Eye-tem bank project' is a novel initiative aimed at creating scientifically sound and technologically advanced item banks to measure the QoL impacts of various eye diseases on adults.[2, 3] This doctoral research was part of the Eye-tem bank project, the aim of which was to develop amblyopia and strabismus specific item banks that can be administered using a Computer Adaptive Testing (CAT) system.[2] The study comprised of two phases and was carried out independently in Australia and India. This thesis encompasses complete phase 1 (content identification) and phase 2 (psychometric validation and calibration) of the Indian item bank construction and the phase 1 of the Australian item bank construction. Phase 2 Australia is work in progress beyond this doctoral study. This chapter presents an overview of the project and places the thesis in context.

1.1 Background: Amblyopia and strabismus

Amblyopia (commonly called 'lazy eye') is a neurodevelopmental disorder, in which vision in one or both eyes is reduced due to poor visual stimulation in childhood.[4] It is the second most common cause of vision impairment in children and young adults.[4, 5] Clinically, amblyopia is defined as 'best corrected visual acuity of 6/9 or worse in at least one eye without any underlying organic cause'.[6] Common amblyogenic factors are refractive errors, particularly anisometropia (difference in refractive error magnitude of 1 dioptre between the eyes) and strabismus (commonly referred as 'crossed eyes') which causes disruption in binocular fusion.[7-10] Amblyopia can also be caused by conditions such as congenital cataract (opacity of the ocular lens), which reduces the quality of the retinal image.[5] Although amblyopia can be bilateral (affecting two eyes), it mostly presents as a unilateral condition.[11]

Amblyopia is conventionally treated by depriving the better eye and forcing the usage of the amblyopic eye.[12] The underlying principle is that visual deprivation of the better eye would eliminate suppression of the amblyopic eye and promote its development and visual acuity improvement.[13] Common techniques followed to deprive the better eye are patching therapy (also called 'occlusion therapy') and pharmacological penalisation using atropine eye drops.[14] These techniques are used in conjunction with

treatment of the predisposing factors of amblyopia (e.g. refractive correction and strabismus surgery).[15]

Amblyopia treatment is considered most effective in childhood, during the critical period of visual development.[16] However, amblyopia is not always diagnosed early or treated appropriately.[13, 17] Compliance to treatment is affected by inconveniences and psychosocial burdens associated with patching therapy.[18] This is particularly significant in cases of severe amblyopia which is treated by longer hours of patching (6 hours) compared to moderate amblyopia which can be treated with considerably lesser amount of patching time (2 hours).[19] In addition, not all who undergo treatment achieve normal visual functioning.[13] In such cases, amblyopia endures as a chronic problem into adulthood.[20] The prevalence of amblyopia among adults range from 0.35% to 3.2% across the world.[7, 21-24] Novel interventions to treat amblyopia in older children and adults have recently been pioneered and evaluated.[25, 26] Examples are perceptual learning,[12, 27] dichoptic training,[28, 29] videogame training[30, 31] and pharmacological therapies using drugs such as dopamine and citicoline.[16, 25] The efficacy of these interventions are yet to be fully understood from patient's perspectives.

The prevalence of childhood strabismus among those with amblyopia range from 6% to 50%.[7, 10, 22, 24, 32-35] Strabismus can also be acquired in adulthood due to cranial nerve palsies or longstanding phorias.[36, 37] The prevalence of strabismus among adults is 4%.[36] Negative attitudes against strabismus emerge in children as young as 6 years.[38-40] Children with strabismus face maternal rejection[41] and social alienation.[38, 42-44] The problem continues in adulthood; negative social bias against adults with strabismus affects interpersonal relationships[45, 46] and limit employment opportunities.[45, 47-50] These issues may significantly impact one's QoL. As a result, those with strabismus express willingness to trade a portion of their life expectancy (time trade off utility evaluation) and accept death risk (standard gamble method) to get rid of strabismus.[51-53]

Similar to amblyopia treatment, the treatment for strabismus associated with amblyopia is considered most beneficial only during childhood.[54] Often treatment for adults with childhood onset of strabismus was neglected or denied presuming unsubstantial functional benefits.[36, 55] However, recent evidences suggest that in addition to psychosocial benefits, strabismus correction in adults improve visual functioning.[54, 56-58] These clinical findings need substantiation using patient reported

outcomes;[59, 60] the overall impact of strabismus on quality of life and subsequent improvement with treatment needs to be comprehensively evaluated.[61]

Both amblyopia and strabismus are associated with a range of lower and higher order visual and motor deficits.[5] These include impairments in contour, shape, motion and depth perception, contrast sensitivity, eye-hand coordination, prehension skills, visual search and positional uncertainty.[5, 62-67] Despite amblyopia treatment, which mainly focusses on the improvement of high contrast visual acuity, other visual functions such as perception of global form, vernier acuity and complex motor detection can remain deficient.[68] However, it is not clear how these deficits affect QoL.[5]

Understanding the long-term QoL impact of amblyopia is important to substantiate the importance of early diagnosis and cost-effectiveness of school vision screening programmes.[69-71] This understanding is also essential to determine the advantages and effectiveness of new interventions emerging for both childhood and adult amblyopia.[72] Similarly, understanding the impact of strabismus is important to substantiate the usefulness of strabismus correction, beyond psychosocial implications.[73, 74]

1.2 Approaches used to assess the impact of amblyopia and strabismus

Four common approaches have been adopted in literature to assess the impact of amblyopia, strabismus and their treatment on QoL.[75] First approach used empirical quantitative methods, in which the functional impairments associated with these conditions were assessed by evaluating the individuals' ability to perform real life tasks such as reading,[76, 77] grasping,[63, 64] perception of real-world images,[68] maintaining body balance or playing ball games.[78] The second approach studied outcomes (or achievements) such as socio-economic status, occupation and education in a cohort of amblyopes and compared them with non-amblyopic population.[6, 79, 80] The third approach used qualitative methodology to explore patients' perspectives of the impact of amblyopia,[81, 82] amblyopia treatment[18, 83, 84] and strabismus.[85, 86] The fourth approach used Patient Reported Outcome Measures (PROMs) in the form of structured questionnaires or surveys.

The first approach focussed on measuring functional abilities of individuals, for example, their ability to read.[76, 77] Although it might be true that reading skills are

impaired because of amblyopia,[5] this information does not translate into an understanding of whether the impairment affects an individual's QoL. For instance, an individual who is illiterate or who hardly read is not affected by this impairment in real life. The second approach looked at outcomes such as educational qualification. However, these studies recognises their limitation of not examining the impact of the disease at the level of the individual and suggests using qualitative methods for more specific investigation.[6, 80] Qualitative studies aims to explore the experiences, perceptions and beliefs of individuals experiencing a particular phenomenon or disease.[87] Although this approach offers an in-depth understanding of the impact of disease or treatment experience, unlike PROMs, it does not measure the impact and hence, cannot be used to quantify changes in the impact over time (e.g. post-treatment). Nevertheless, qualitative investigations involving patients provide useful insights and are highly recommended for developing PROMs with high content validity.[88]

1.3 Patient reported outcome measures (PROMs)

The Food and Drug administration (FDA) defines *patient reported outcomes* as *"Any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else."*[88] Patient reported outcomes are measured by administering paper-based or computer-based (electronic) structured questionnaires, called PROMs (also referred to as 'Instruments'). These are increasingly being used for psychometric measurement of latent (unobservable) traits (constructs) such as QoL and wellbeing.[89, 90]

The use of PROMs have recently gained much recognition in health research, especially in optometry and ophthalmology[1] and are being used to capture patient's perspectives about the effect of eye diseases such as cataract,[91] glaucoma,[92] diabetic retinopathy,[93] low vision[94] and convergence insufficiency[95] on daily functioning and QoL.[96] In relation to amblyopia and strabismus, PROMs have been used to understand the impact of the condition and treatment,[97, 98] evaluate treatment outcomes,[58, 99] compare different interventions,[98, 100] inform clinical decisions[101] and correlate with various clinical and demographic variables.[102, 103]

The importance of capturing patient's perspectives using PROMs can be realised by examining the following scenarios related to amblyopia and strabismus.

- *First, there are differences between the clinician and patient perspectives*; the perspectives of clinicians may not truly represent the experiences of a patient. For example, Beauchamp GR *et al,* 2005[104] assessed the severity of strabismus pre-and post-strabismus surgery from patients and clinicians' perspectives using a perspectives questionnaire. Although improvement in strabismus severity post-surgery was reported by both clinicians and patients, the improvement perceived by clinicians was greater than that perceived by the patients themselves.[104]
- *Second, clinical measures such as visual acuity which are important to clinicians may not represent the actual impact of the condition on a patient.*[105] As a result, two patients with similar clinical characteristics may perceive and report different levels of impact.[106] For example, one might expect poor psychological functioning and QoL in people with larger ocular deviation (magnitude of strabismus); however, studies have not found any such correlation.[102, 107] Therefore, clinical variables alone may be insufficient to explain the variance in patients' experience and QoL impacts.[108]
- *Third, improvement in clinical measures following treatment may not imply improved functioning and vice versa.* For instance, improvement in QoL scores (measured by PROMs) have been observed in strabismic patients who were classified as surgical failures by standard clinical criteria.[59] Thus, the inclusion of PROMs into assessment of treatment outcomes is important[59, 109] and is highly recommended by the FDA and the European Medicines Agency (EMA) to support labelling claims of novel drugs and medical products.[61, 110-112]
- *Finally, when different treatment results in the same objective outcome, PROMs provide guidance in making clinical decisions.*[113] For example, a randomised controlled trial comparing different treatment modalities for children with amblyopia found that both patching therapy and atropine produced comparable improvements in visual acuity.[14] However, evaluating the impact of amblyopia treatment using a PROM (amblyopia treatment index), revealed that atropine had better acceptance than patching therapy.[98] This indicates that one might miss out on things that are significant to the patient by limiting assessment to clinical outcomes.

To summarise, PROMs are crucial for measuring disease impact, to obtain reliable interpretation of treatment outcomes and for accurate evaluation of patient-centered care.[114] Over 160 PROMs have been developed in the field of optometry and

ophthalmology to measure QoL[2] and about thirty-two have been developed to assess the impact of amblyopia and strabismus on various aspects of QoL.[115]

1.4 Quality of life measurement

QoL is a diverse concept and its definition is constantly evolving. [116, 117] The World Health Organisation (WHO) defines QoL as *"Individuals' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships, personal beliefs and their relationship to salient features of their environment".* [118] From this definition, it is evident that QoL is 'subjective' and 'multidimensional'.[119, 120] An example of PROM developed to measure general QoL is the World Health Organisation Quality of Life Instrument – short version (WHOQOL-BREF).[121]

Increasing need for the assessment of disease impact and health outcomes led to the concept of Health Related Quality of Life (HRQoL) that narrowed down the focus from the broader QoL construct to *'QoL affected by health condition'*.[122] Like QoL, HRQoL is multidimensional; it encompasses domains of QoL such as daily life, physical functioning, emotional wellbeing and social relationships that are impacted by ill health or its treatment.[112, 117] The medical outcomes short form health survey (SF-36) is an example of PROM that measures HRQoL.[123, 124]

While HRQoL narrowed down the focus to health, it could not capture the QoL issues significant to those with ocular diseases and visual impairment.[125] This led to the emergence of Vision-Related Quality of Life (VRQoL) measurement. Assessment of VRQoL is often confused with Vision Related Activity Limitations (VRAL) which is limited to the assessment of functional limitations that are consequences of the visual impairment (e.g. limitations in performing activities of daily living). VRAL is a subset of VRQoL; ideally, VRQoL assessment should include all aspects of QoL affected by ocular health. The Visual Function questionnaire (VF-14) is an example of PROM measuring VRAL.[126] The National Eye Institute Visual Function Questionnaire (NEIVFQ-25) and the Impact of Visual Impairment questionnaire (IVI) are examples of PROMs measuring aspects of VRQoL.[127]

Recently, it has been recognised that even PROMs measuring VRQoL are inadequate

to capture all QoL issues that are specific to particular eye conditions.[128] For example, the NEIVFQ-25[129] do not address the psychosocial problems relevant to patients with strabismus.[130] Therefore, a more focussed approach in evaluating QoL evolved and paved way for the development of condition-specific or eye disease-specific PROMs.[131] Condition-specific PROMs address specific issues that are relevant to particular disease groups and hence offer more precise measurement of impacts.[132]

The Eye-tem bank research group is thus developing eye disease specific QoL PROMs. Upon comprehensive consultation with patients experiencing a range of eye diseases, the research group identified nine important ophthalmic QoL domains (constructs) namely: symptoms, activity limitations, mobility, concerns, emotional well-being, social impact, convenience, economic impact and coping.[2, 133] These domains, despite being similar across eye conditions, constitute disease-specific items. For example, the symptoms domain in glaucoma-specific PROM contain symptoms such as 'decreased visual field' and the amblyopia and strabismus specific PROM (developed in current research) contain symptoms such as 'misalignment of eyes'.

Although HRQoL, VRQoL and condition specific QoL have different meanings and implications, these terms are used interchangeably with QoL.[134] For the purpose of this thesis, the term 'QoL' refers to condition specific QoL affected by amblyopia and strabismus.

1.5 Extant amblyopia and strabismus specific PROMs

As a first step towards this doctoral project, a systematic review was conducted to evaluate the content and measurement qualities of the extant amblyopia and strabismus specific PROMs used to measure QoL.[115] This is presented in Chapter 2 of this thesis.

The review identified 32 amblyopia and strabismus specific PROMs, out of which 18 were developed for adolescents and/or adults. Upon thorough evaluation, several limitations were evident.[115] Most of the extant PROMs specific to amblyopia and strabismus focus on few QoL constructs such as activity limitations and concerns.[115] They lack items (questions) to measure all the aspects of QoL comprehensively. Some focus solely on strabismus[135-137] or amblyopia[97, 138] and therefore lack items addressing the entire spectrum of the disease (e.g. strabismic amblyopia). Some were developed for assessing impacts caused by both conditions on a single scale.[139, 140] Yet, targeting

was sub-optimal when the PROM was applied to a sub-group (e.g. isolated amblyopia).[75] Moreover, several issues exist in their measurement properties, indicating the need for developing psychometrically robust PROM that offers holistic measurement of QoL.[115, 131]

Although amblyopia and strabismus are often associated, they are two separate conditions that can exist by themselves [e.g. anisometropic amblyopia (isolated amblyopia) and paralytic strabismus (isolated strabismus)]. Currently, there is a lack of evidence in the literature concerning the variance in QoL issues caused by these conditions and it is unclear whether a single PROM would suffice both these disease groups.[75] Moreover, 75% (24 out of 32) of the PROMs developed for amblyopia and strabismus are in English and about 97% (31 out of 32) have been developed in high or upper middle income country settings (Appendix 1). To the best of my knowledge, there are currently no amblyopia or strabismus specific PROMs developed for low income country settings and the only PROM developed for an Indian population is a non-validated proxy measure for children with strabismus.[106] Although a low middle income country, India stands second, next to China in population, contributing 17.74% to the world's total population in 2018.[141] Therefore, developing amblyopia and strabismus specific PROM for the Indian population was considered to be greatly beneficial.

In health outcomes research, it is a common practice to translate / adapt PROMs developed for different country settings or language for different populations.[142-144] However, in view of the differences in economy, culture and values, there remains uncertainty about the content appropriateness of the PROM across different populations. High ceiling effects observed in the translated (adapted) versions of amblyopia and strabismus specific PROMs suggests the need for developing country/ culture-specific PROMs. [145-149] While it may be laborious and expensive to create and calibrate several country-specific PROMs, it will also be difficult to compare the levels of latent traits or evaluate effects of treatment across population using PROMs calibrated on different scales. Calibrating a universal set of items (common items across population) on a single scale might be a reasonable solution. To explore this possibility, it was decided to carry out two independent studies in Australia (high income country) and India (low middle-income country) as part of this thesis.

1.6 Item banking and computer adaptive testing

A significant drawback of all extant PROMs is that they are static-short forms. Being limited in content and fixed in length, these require all respondents to answer all items irrespective of whether the item provides information about the level of their latent trait or not, posing unnecessary respondent burden.[150] These PROMs cannot be customised to individual characteristics and there is limited scope for improving validity and reliability once they have been developed.[151] Furthermore, large-scale data collection and data management is challenging as they are labour-intensive (being paper and pencil based).[151]

The disadvantages of static PROMs are overcome by latest innovations - item banking and Computer Adaptive Testing (CAT).[152] These are technologically advanced and offer precise and quick measurement of latent traits.[153] An item bank consists of a large collection of items that are calibrated by modern psychometric methods.[3] The CAT system uses a computer algorithm that selects the best item matching the respondent's ability based on his/her response to the previous question.[154] For example, a CAT system measuring the level of difficulties one has in performing daily living activities will present difficult questions for individuals with high ability and easy questions for those with lower ability.[155] By tailoring items that are more appropriate to each individual,[156] the dynamic CAT system achieves reliable measurement using fewer number of questions.[2, 157]

1.7 Thesis overview

The overarching aim of this doctoral research was to develop amblyopia and strabismus specific QoL item banks that can be implemented via a CAT system, for adults in Australia and India.

The study was approved by the Southern Adelaide Clinical Human Research Ethics Committee, Australia (Approval number: 469.11, Appendix 2) and the Research cell committee, Vision Research Foundation, Sankara Nethralaya, India (Appendix 3). It adheres to the Tenets of declaration of Helsinki for human study.

The quality of the CAT system and its estimation of QoL constructs largely depends on the quality of the item bank from which it draws the items.[158] It is therefore crucial that the item bank is comprehensive and psychometrically robust. [154, 159, 160] The construction and validation of item banks comprises four phases[2] (Figure 1-1).

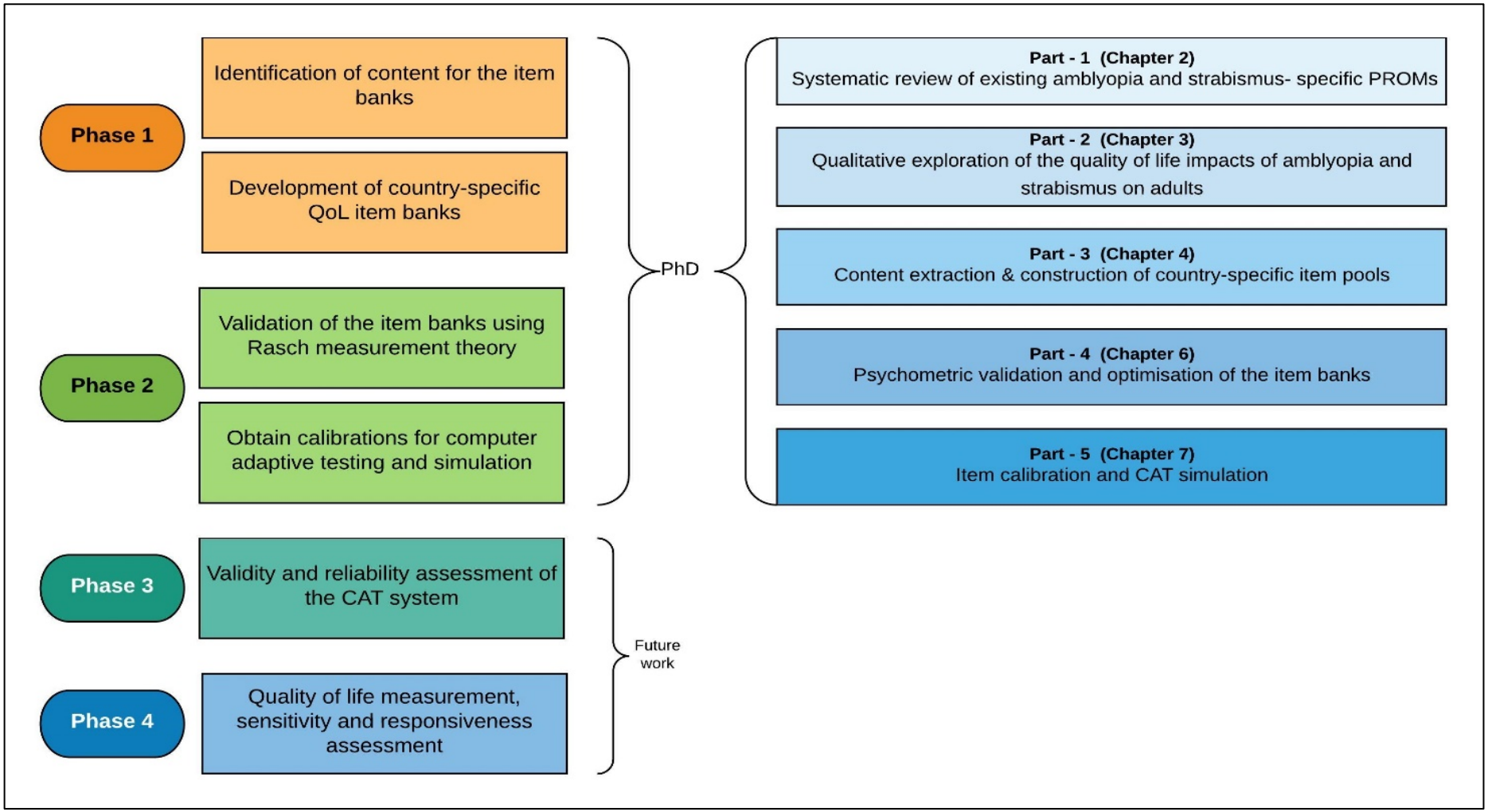


Figure 1-1 Phases in the development of item banks and overview of the thesis
Phases 1 (Australia and India) and Phase 2 (India) are part of this PhD thesis.
Phase 2 Australia is ongoing (post-PhD work), and its interim results are presented in this thesis.
Phases 3 and 4 are future scope of the Eye-tem bank project beyond PhD
*The figure doesn't include Chapter 5 which presents the epistemology of measurement, its theories and Rasch analysis used for psychometric evaluation in Chapter 6.

The first phase involves a qualitative process by which the content for the item banks are identified, evaluated and item pools (groups of items intending to measure specific constructs) are developed. The second phase involves a quantitative methodology, in which the item banks undergo psychometric validation and calibration.[161] This is accomplished by administering the item banks to a sample of participants (pilot testing). This doctoral research comprises of these two equally important phases (Phases 1 and 2) that were carried out to develop amblyopia and strabismus specific item banks for adults in Australia and India.

The next two phases are future directions post-PhD. Phase 3 would involve validation and reliability testing of the item banks implemented by a CAT system and Phase 4 would involve measurement of the amblyopia and strabismus specific QoL constructs, collection of normative data and determination of responsiveness and sensitivity of the system to detect clinically significant changes.

Phases 1 and 2 are complete in India and Phase 1 is complete in Australia. The complete results from these phases are included in this thesis. Phase 2 (Australia) is ongoing (future work post-PhD) and only its interim results are reported. The entire thesis comprises of five parts which are presented in individual chapters.

Part 1: Systematic review of existing amblyopia and strabismus- specific PROMs (Chapter 2)

The aim of Part 1 was to review the content and quality of all PROMs that were developed to study the QoL impacts caused by amblyopia and strabismus. The review addressed the following research objectives and in addition enabled identification of extant items to be incorporated in the item banks developed in this thesis.

The objectives were to

1) Identify all the extant PROMs used to study the impacts of amblyopia and strabismus
2) Examine the characteristics and content of the amblyopia and strabismus specific (disease-specific) PROMs to find those that provide comprehensive measurement of QoL
3) Evaluate the quality of content, psychometric properties, validity, reliability and responsiveness of the amblyopia and strabismus specific PROMs to find those with good measurement qualities

Part 2: Qualitative exploration of the quality of life impacts of amblyopia and strabismus on adults (Chapter 3)

The aim of Part 2 was to elicit concepts (identify content) for the development of the amblyopia and strabismus specific item banks for adults in Australia and India.

The objectives were to

1) Identify the QoL dimensions, important to adults with amblyopia and/or strabismus
2) Explore differences in perspectives and QoL experiences of adults in two economically and culturally different settings (Australia and India)
3) Compare the QoL issues faced by participants experiencing different amblyopia and strabismus diagnosis: isolated amblyopia, isolated strabismus and both amblyopia and strabismus

Part 3: Content extraction & construction of country-specific item pools (Chapter 4)

The aim of Part 3 was to obtain optimal sets of representative items addressing all important aspects of QoL (QoL domains) to enable comprehensive measurement of the impact of amblyopia and strabismus on adults.

The objectives were to

1) Develop QoL item pools in English for Australia and in three languages (English, Hindi and Tamil) for India
2) Seek empirical evidence to guide decision on developing separate or combined item banks for amblyopia and isolated strabismus based on the number of common items
3) Examine the number of items that are common across Australia and India to explore the possibility of creating universal item banks in future

Part 4: Psychometric validation and optimisation of the item banks (Chapter 6)

The aim of Part 4 was to test the psychometric properties and validate the amblyopia and strabismus- specific item banks using Rasch analysis, a modern psychometric technique based on the Rasch measurement theory.

The objectives were to

1) Evaluate the measurement properties of the twelve QoL item banks namely, symptoms - frequency, symptoms - severity, symptoms - bothersome, activity limitation, driving, mobility, concerns, emotional impact, social impact, convenience, economic impact and coping
2) Optimise sub-optimal psychometric properties whenever possible

Epistemology underpinning Part 4 is presented in **Chapter 5** which describes the concept of psychological measurement and measurement theories used in the development of PROMs. A detailed description of Rasch analysis which is used in Chapter 6 for psychometric validation is provided. Chapter 6 presents the complete validation of the Indian item banks and interim results of the Australian item banks.

Part 5: Item calibration and CAT simulation (Chapter 7)

The aim of Part 5 was to test the efficiency of the twelve Indian item banks by running a CAT simulation programme.

The objectives were to

1) Test for local item dependency (LID) and obtain item calibrations that are free from the effects of LID
2) Run CAT simulations to determine the average number of items required to measure each QoL construct with moderate and high precisions.

The thesis concludes with **Chapter 8** which comprises the overall discussion, study implications, limitations and future work.

1.8 Contribution to knowledge

This doctoral work has made substantial contributions in the field of amblyopia and strabismus with respect to patient reported outcome measurement of QoL. The extant PROMs available for amblyopia and strabismus vary in their content and measurement qualities. By reviewing these, the chapter 2 provides researchers the guidance to select the right PROM for the right purpose. The results of the systematic review have been published.[115] Chapter 3 enhances the understanding about the several impacts that amblyopia and strabismus have on QoL by qualitative exploration with patients. The chapter comprised of two independent studies in Australia and India, which to my

knowledge are the first to investigate the impact of different types of amblyopia on adults. A part of the qualitative findings in Australia which elaborated the functional limitations recognised by those with amblyopia in real life have been published.[162] This complements the prior knowledge about the functional deficits of amblyopia identified by psychophysical and experimental investigations.[5, 76, 163] Chapter 4 presented the systematic protocol followed to develop item banks in English for Australian population and in three languages for Indian population. The Indian item bank was first developed in English and then translated into two regional languages – Hindi and Tamil. These methodological approaches can be referred to by researchers in health outcome research aiming to develop item banks for other purposes. The item banks validated in chapter 6 and pretested by CAT simulation in chapter 7 has promising potential to measure the QoL impact of amblyopia and strabismus precisely and efficiently.

From the twelve QoL item banks, each measuring an important aspect of QoL such as activity limitations, emotional impact and social impact, researchers and clinicians can choose the ones that suit their purpose. Implementing the item banks via a CAT system in routine clinical practices would enable real-time data acquisition, documentation and live results that would be useful in providing better clinical care.[155, 164] It also presents clinicians with the scope of prioritising patients based on the degree of QoL impact for treatment (e.g. strabismus surgery). Researchers can use this tool for testing the efficiency of adult strabismus and novel adult amblyopia interventions from patient's perspectives. Overall, the contributions of this research towards understanding and measuring the QoL impacts of amblyopia and strabismus in adults have significant clinical and research applications.

CHAPTER 2 PATIENT REPORTED OUTCOME MEASURES IN AMBLYOPIA AND STRABISMUS – A SYSTEMATIC REVIEW

2.1 Introduction

Several PROMs exist to measure the impacts caused by amblyopia and strabismus.[131] They vary in developmental methodology, content, measurement qualities and have been developed for different populations and purposes. As patient reported outcomes influence clinical decisions and health policies,[165] it is imperative to select the right PROM for the right purpose. Using PROMs with inappropriate content or poor measurement quality may be misleading.[152] It is thus crucial to evaluate the quality, content appropriateness and comprehensiveness of the PROMs to choose the one that best suits the research question.[166]

2.2 Aim and objectives

This chapter systematically reviews the PROMs that were used to assess the impact of amblyopia and/or strabismus on various aspects of QoL.[115] The aim was to identify the PROMs that provide reliable, valid and comprehensive (has a range of items to address all important attributes of QoL such as physical, emotional and social wellbeing) measurement of QoL.

The objectives were to

1) Identify all the extant PROMs used to study the impacts of amblyopia and strabismus
2) Examine the characteristics and content of the amblyopia and strabismus specific (disease-specific) PROMs to find those that provide comprehensive measurement of QoL
3) Evaluate the quality of content, psychometric properties, validity, reliability and responsiveness of the amblyopia and strabismus specific PROMs to find those with good measurement qualities

The rest of the chapter is divided into three sections, addressing each of these objectives.

2.3 PROMs used to assess the impacts caused by amblyopia and strabismus

A systematic search was carried out to identify all PROMs used/ developed in the literature to evaluate the impact of amblyopia and/or strabismus and its treatment. The systematic review and analysis were carried out by me and Dr Jyoti Khadka independently and any discrepancy was resolved by discussion and consensus.

2.3.1 Methods

2.3.1.1 Databases and search syntax

The electronic databases of Pubmed, Cochrane, Web of Science and PsycINFO were searched using the following syntax:

(Amblyopia OR "Lazy eye" OR Strabismus OR Squint OR Exotropia OR Esotropia OR Hypotropia OR Hypertropia OR "Cross* eye*") AND ("self-report*" OR "symptom*" OR "self-esteem" OR Satisfaction OR "Patient reported outcome" OR Questionnaire OR Driving OR Concern OR Disability OR "Psycho*" OR Emotional OR Social OR "Quality of life")

2.3.1.2 Inclusion criteria

No age restriction was applied. Articles in English published prior to July 2016 were included if they 1) described the development or validation of a PROM for amblyopia or strabismus (OR) 2) used a PROM to study the impact of amblyopia and/or strabismus on QoL or any of its attributes. The bibliographies of the articles included were hand searched for additional relevant references.

2.3.1.3 Exclusion criteria

Qualitative articles, conference abstracts, review papers and PROMs measuring the impact of the condition on family (other than self) were excluded.

2.3.1.4 Article selection

A total of 4151 articles was obtained cumulatively from the databases. Table 2-1 displays the number of articles obtained from each database.

Table 2-1 Number (No.) of articles retrieved from the databases

Database Searched	No. of articles retrieved
PubMed	1994
Web of Science	1662
PsycINFO	303
Cochrane	192
Total	**4151**

Systematic screening of the articles was performed to identify articles that matched the inclusion criteria. The screening was carried out in four stages, represented by the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA)[167, 168] flow diagram (Figure 2-1). In stage 4, eight articles[169-176] were excluded as they measured constructs different to QoL. Reasons for exclusion are displayed in Appendix 4.

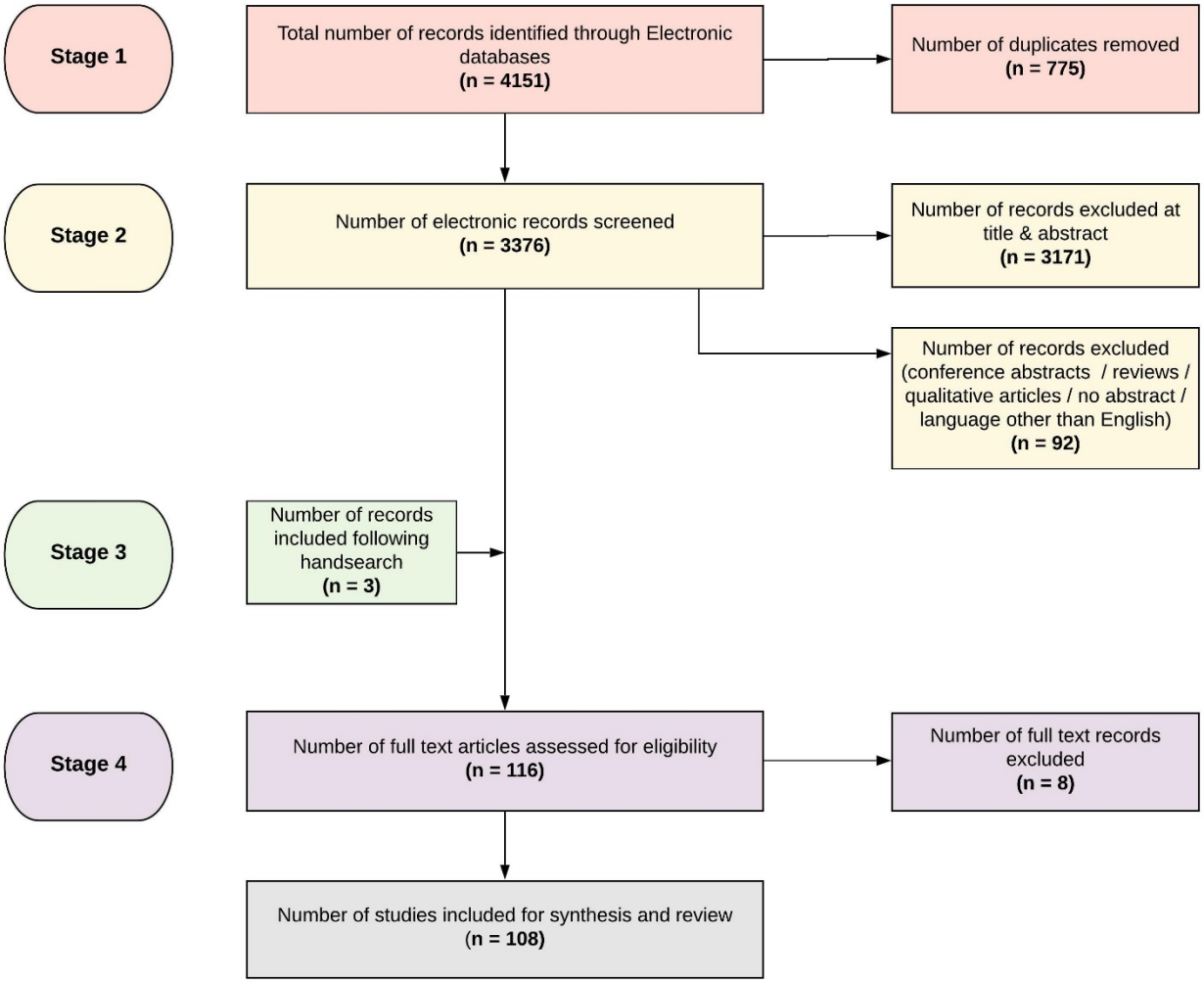


Figure 2-1 PRISMA flow diagram displaying article screening and selection process

2.3.2 Results

2.3.2.1 PROMs used for measuring impacts of amblyopia and strabismus

The screening process yielded 108 articles which encompassed 71 PROMs (number of articles is not equal to number of PROMs as same PROMs were used by multiple studies; refer to 'n' in Table 2-2). Out of the 71 PROMs, three were generic health related, two vision-specific, 32 disease-specific (amblyopia and/or strabismus specific), 14 psychological measures, 5 behavioural inventories, 3 measured beliefs and cognition, 1 social support, 5 appearance related concerns, 4 physical functional measures and 2 utilities. Out of the 32 disease-specific PROMs, 12 were amblyopia specific, 18 were strabismus specific and 2 were developed for both amblyopia and strabismus. Table 2-2 lists out these PROMs and the number of studies that used them. Several studies used more than one PROM to study different aspects of QoL. For example, McBain HB *et al.,* 2014 used Adult Strabismus questionnaire (AS-20), a condition-specific PROM along with the Hospital Anxiety and Depression Scale (HADS) and eight psychosocial measures to explore the factors associated with mood and QoL of patients experiencing strabismus.[108]

Table 2-2 PROMs used to study the impact amblyopia, strabismus or its treatment

PROM type	Names of PROMs and number of studies that used them
Generic *Measures general HRQoL*	1. Medical outcomes short form health surveys & variants: SF-36 (n=3)[177-179]; SF-20 (n=1)[180]; SF-12(n=1)[140] ; SF-8 (n=1)[74] 2. WHOQoL - Bref (n=2)[181, 182] 3. Paediatric Quality of Life Inventory (PedsQL) (n=3)[105, 183, 184]
Vision specific *Measures aspects of VRQoL*	1. National eye institute visual function questionnaire (NEIVFQ-25): English (n=7)[74, 140, 185-189] ; Chinese (n=4)[145, 148, 190, 191] ; German (n=1)[129] 2. Visual function 14 (VF-14) (n=3)[177, 192, 193]

Amblyopia specific *Measures QoL aspects affected by amblyopia and its treatment*	1. Amblyopia survey (n=1)[138] 2. Patching Success Questionnaire (PSQ) (n=2)[194, 195] 3. Amblyopia Treatment Index (ATI): English (n=7)[14, 98, 100, 113, 196-198]; Chinese (n=1)[199] 4. Child Amblyopia Treatment Index (n=1)[197] 5. Perceived Psychosocial Questionnaire (PPQ) (n=1)[200] 6. Emotional impact of amblyopia treatment questionnaire (n=2)[201, 202] 7. Occlusion patch Comfort Questionnaire (OCQ) (n=1)[203] 8. Child amblyopia treatment questionnaire (CATQoL) (n=1)[204] 9. Children's Vision for Living Scale (CVLS) (n=1)[205] 10. 46 item QoL questionnaire (n=1)[206] 11. QoL questionnaire for children with anisometropic amblyopia (n=1)[97] 12. Socio professional integration questionnaire (n=1)[207]
Strabismus specific *Measures QoL aspects that are affected by strabismus and its treatment*	1. Adult strabismus quality of life questionnaire (AS-20): Original (n=24)[58, 59, 99, 103, 108, 109, 137, 185, 186, 188, 189, 208-220]; Adapted (n=1)[144]; Chinese (n=4)[145, 148, 149, 221]; Danish (n=1)[147] 2. Intermittent Exotropia Questionnaire (IXTQ) (n=8)[101, 102, 105, 136, 218, 222-224 3. Perspectives questionnaire (n=1)[104] 4. Disability questionnaire (n=3)[143, 225, 226 5. Repertory grid (n=1)[57] 6. Perceived visibility of strabismus (n=2)[108, 220 7. Expectations of Strabismus Surgery Questionnaire (ESSQ) (n=1)[220] 8. Psychosocial Experience Questionnaire (PEQ) (n=1)[130] 9. Vision function scale (n=1)[180] 10. 8 item QoL instrument (n=1)[106] 11. Exotropia symptom questionnaire (n=1)[227] 12. Effect of Diplopia Questionnaire (EDQ)(n=1)[228] 13. Post strabismus surgery symptom questionnaire (n=1)[229] 14. Psychosocial effects of strabismus pre and post-operative questionnaire (n=2)[230, 231] 15. Strabismus survey (n=1)[135] 16. Satisfaction of surgical outcome (n=1)[232]
Strabismus specific *Modified from generic PROMs to assess impact of strabismus*	1. Visual analog scale (n=1)[181] 2. Modified RAND health insurance study QoL instrument (n=1)[233]
Amblyopia and Strabismus specific *Measures QoL aspects affected by both amblyopia and strabismus*	1. Amblyopia and Strabismus Questionnaire (A&SQ): Dutch (n=3)[140, 234, 235]; English (n=5)[75, 143, 179, 185, 215]; Chinese (n=2)[145, 236]; Italian (n=1)[146] 2. Psychological Impact Questionnaire (PIQ) (n = 2)[107, 139]

Psychological measures *Assess psychological impact and contains items that address a range of psychological disorders*	1. Center for epidemiologic studies depression scale – Revised (n=1)[216] 2. Children's depression inventory (n=1)[237] 3. DS-14 distressed personality questionnaire (n=1)[216] 4. Hopkins Symptom Checklist (n=2)[135, 138] 5. Hospital Anxiety & Depression Scale (HADS) (n=8)[108, 178, 181, 182, 191, 220, 238, 239] 6. Liebowitz Social Anxiety Scale (n=2)[178, 238] 7. Perceived Stress Index (n=1)[200] 8. Psychiatric Symptom Checklist 90- revised (n=1)[238] 9. Screen for child anxiety related emotional disorders (n=1)[237] 10. Harter self-perception profile for children (n=1)[240] 11. Fear of negative evaluation scale (n=1)[108] 12. Rosenberg self-esteem scale (n=1)[6] 13. Screening for anxiety (n=1)[241] 14. Screening for depression (n=1)[241]
Behavioural inventories *Measures anomalous behaviours and problems in social adjustment*	1. Behaviour assessment system for children (n=1)[84] 2. Korean child behavior checklist (n=1)[198] 3. Rutter scale (n=1)[80] 4. Bristol social adjustment guides (n=1)[80] 5. Revised Rutter parents scale for preschool children (n=1)[201]
Beliefs and Cognition *Measures perception and beliefs of the patient about themselves and their condition*	1. Revised illness perception questionnaire (n=1)[108] 2. Treatment representations inventory (n=1)[108] 3. Pictorial scale of perceived competence & social acceptance for young children (n=1)[78]
Social support *Assess support from family and others*	1. Multidimensional scale of perceived social support (n=1)[108]
Appearance –related *Measures appearance related distress and perceptions*	1. Derriford Appearance Scale (DAS) DAS 59 (n=3)[181, 182, 208]; DAS 24 (n=2)[220, 239] 2. Salience of appearance scale (n=2)[108, 239] 3. Valence of appearance scale (n=2)[108, 239] 4. Iowa - Netherlands comparison orientation measures (n=1)[239] 5. Physical appearance discrepancy questionnaire (n=1)[239]
Functional measures *Measures difficulties in performing activities of daily living*	1. Child's balance performance in daily life (n=1)[78] 2. Index of Activities of Daily Living (ADL) (n=1)[177] 3. Instrumental ADL (n=1)[177] 4. Sheehan disability scale (n=2)[178, 238]
Utilities *Measures utility value*	1. Time trade off (n=5)[51-53, 193, 242] 2. Standard gamble (n=2)[52, 242]

2.3.2.2 QoL constructs measured by non-disease-specific PROMs

The medical outcomes short form (SF-36)[177-179] and the paediatric quality of life inventory (PedsQL)[105, 183, 184] are the two generic PROMs that have been widely used in adults and children respectively. The SF-36 measures HRQoL across eight domains:

physical functioning, role limitations due to physical problems, social functioning, bodily pain, general mental health, role limitations due to emotional problems, vitality and general health perceptions.[177] The PedsQL measures physical, emotional, social and school functioning of children.[184]

The National Eye Institute Visual Function Questionnaire (NEIVFQ-25) has been used predominantly to measure VRQoL and for validating new instruments.[243] The NEIVFQ-25 measures difficulties with near and distance activities, limitations in social functioning, role limitations, dependency on others, mental symptoms, driving difficulties, limitations with peripheral vision and colour vision and ocular pain.[188]

The Hospital Anxiety & Depression Scale (HADS) [108, 178, 181, 182, 191, 220, 238, 239] and the Derriford Appearance Scales (DAS-59 & DAS-24) [181, 182, 208, 220, 239] have been widely used to evaluate the psychological problems and appearance-related distress and anxiety in adults with strabismus, respectively. The HADS is a validated 14-item PROM that detects the state of depression and anxiety of those undergoing treatment for physical health problems.[239] The DAS was developed for those with congenital and acquired facial or bodily disfigurements and deformities. It measures distress and problems in social functioning that are caused by appearance. The domains include general self-consciousness of appearance, social self-consciousness of appearance, sexual and bodily self-consciousness of appearance, negative self-concept, facial self-consciousness of appearance, physical distress and dysfunction and focus on potential benefits of plastic and aesthetic surgery.[208]

Time trade off method was commonly used to estimate the utility value of amblyopia[52, 242, 244] and strabismus.[51-53, 193] It is calculated by 1 – (number of years the patient is willing to trade off in return for perfect health / life expectancy estimated by the patient). A value of 1 means that the person has chosen not to trade any portion of his life expectancy, presumably indicating perfect QoL and a value of 0 indicates that the person would trade off his whole life, indicating the worst QoL or death.[244]

2.3.2.3 Merits and demerits of non-disease-specific PROMs

The major advantage of using HRQoL and VRQoL PROMs is that, owing to their generic nature (containing non-disease-specific questions), these enable comparison of QoL impacts across diseases and eye conditions.[139] Similarly, the psychological and behavioural inventories measure general depression or behavioural problems that are not specific to a disease and hence enable comparison of levels of depression caused

by different health conditions. Utilities, which provide a global measure of QoL, also has this advantage and in addition play a vital role in cost-utility analysis to measure the value of an intervention against the cost of resources expended.[244]

However, there are several reasons why disease-specific PROMs are preferred over these.[125, 132]

1) The non-disease-specific PROMs offer limited understanding of a person's QoL as they do not contain disease/condition specific items to capture the real life implications specific to a particular disease.[186, 189] This can be visualised by ceiling effects in data obtained using non-disease-specific PROMs due to items that are inappropriate (not targeted to the respondent's ability).[189]

2) They lack sensitivity to detect and quantify small yet important changes post intervention (Responsiveness).[132] For example, the adult strabismus questionnaire (AS-20) has been shown to be more responsive than the NEIVFQ-25 questionnaire in detecting changes in QoL post strabismus surgery.[188]

3) They lack discriminatory ability – the ability to distinguish between individuals with different levels of the latent trait.[132] For example, non-disease specific PROMs such as VF-14, SF-12 and NEIVFQ-25 were found to have lower discriminatory abilities compared to condition-specific PROMs (PIQ and A&SQ) developed for amblyopia and strabismus.[139, 140]

Therefore, non-disease-specific PROMs may not be the best choice when the aim of the research is to measure specific concerns associated with a particular disease or to evaluate treatment outcomes.[245]

2.3.2.4 Disease-specific PROMs

Out of the 108 studies, 82 used disease-specific PROMs: 19 amblyopia specific PROMs, 54 strabismus specific PROMs and 13 used PROMs developed for both amblyopia and strabismus (these numbers are not mutually exclusive as four studies[143, 145, 185, 215] used a combination of disease-specific PROMs). The widely used disease-specific PROMs are the amblyopia treatment index (ATI),[113] the A&SQ[140] and the AS-20.[137]

The first strabismus specific survey was developed by Satterfield *et al*, 1993 to assess the psychosocial implications of strabismus.[135] Following this, Packwood *et al*, 1999, developed a survey to measure the psychosocial effects of isolated amblyopia (non-

strabismic amblyopia).[138] From then on, multiple PROMs have been developed: 32 have been developed over the past 24 years, out of which 14 came into existence since 2012.

The numerous choices of PROMs available in the literature poses uncertainties among researchers and clinicians about which one to choose. This leads us to the questions 'Which condition-specific PROM(s) offer comprehensive measurement of QoL?' and 'Which of these condition-specific PROM(s) have good measurement properties?'

2.4 Characteristics and content of amblyopia and strabismus specific PROMs

The characteristics of all amblyopia and/or strabismus specific PROMs were reviewed, and their content was evaluated to identify the PROM(s) that offered the most-comprehensive measurement of QoL specific to amblyopia and strabismus. As a further step, items from each of these PROMs were pooled together to examine the QoL domains that were most and least represented.

2.4.1 Methods

2.4.1.1 Characteristics

Each PROM was examined for the population for which it was developed, language, type (self-administered or proxy), the primary aim(s) for which the PROM was developed, and the format of questions and response categories.

2.4.1.2 Content evaluation

As authors have used different definitions of QoL domains to classify items, it is quite challenging to compare content across the various PROMs. Hence, a standard method of examining the content was adopted. This is described below.

All PROMs whose items were reported (excluding proxy measures) were included for content evaluation. The content of each item was examined and the item was classified according to the definitions of eight QoL domains identified by the Eye-tem bank research group: activity limitation, concerns, emotional impact, social impact, economic, convenience, symptoms (visual, ocular and general), and mobility (Table 2-3).[2, 153, 246] The domain "coping" was not included for this systematic review as it was a new domain identified later.[133] Upon classifying all the items, each PROM was

examined for the main attributes it measured.

Next, items from all these PROMs were pooled together under respective QoL domain and items similar in content were replaced with a single unique item. Then the number of unique items under each QoL domain was ascertained to find 'what these PROMs predominantly measure when put-together' and to identify the QoL domains that are least represented.

Table 2-3 Ophthalmic QoL domains and definitions

QoL Domain	Definition
Activity limitation	The difficulties an individual has in executing vision-specific physical, social, or recreational activities due to impairment resulting from an eye disease/condition and its treatment/s
Concerns	The health-specific issues that affect an individual's attention, interest, care, safety, welfare or happiness associated with an eye disease/condition and its treatment/s
Social impact	An individual's inability to engage in social activities and fulfil social obligations due to impairment resulting from an eye disease/condition and its treatment/s.
Emotional impact	The emotional and psychological issues or disorders an individual has to face due to an eye disease/condition and its treatment
Symptoms	Visual: The unwanted visual sensations arising from or accompanying an eye disease/condition and its treatment/s Ocular surface: The unwanted non-visual signs and sensations in and around the eyes arising from or accompanying an eye disease/condition and its treatment/s General: The unwanted non-ocular sensations or manifestations in the body that arise from or accompany an eye disease/condition and its treatment/s
Convenience	The quality of an individual's comfort, time, needs, desire and purposes compromised due to an eye disease/condition and its treatment/s
Economic impact	The economic implications and impacts associated with an eye disease and its treatment/s. These include, but are not limited to, cost of illness (i.e. cost of treatment and accessing health service/s), and impact on employment, productivity and income
Mobility	The difficulties an individual has in performing vision-specific tasks related to mobility situations due to impairment resulting from an eye disease/condition and its treatment/s

2.4.2 Results

2.4.3 Characteristics

2.4.3.1 Amblyopia specific PROMs

The characteristics of all amblyopia specific PROMs are summarised in Table 2-4.

Out of the 12, only two PROMs: the amblyopia survey[138] and the socio-professional integration questionnaire[207] measures the impact of amblyopia itself.

The remaining ten PROMs namely the patching success questionnaire (PSQ)[195], the amblyopia treatment Index (ATI),[113] the child amblyopia treatment index (cATI),[197] perceived psychosocial questionnaire (PPQ),[200] emotional impact of amblyopia treatment,[201] the occlusion patch comfort questionnaire (OCQ),[203] child amblyopia treatment questionnaire (CATQoL),[204] children's vision for living scale (CVLS),[205] 46-item QoL questionnaire[206] and a QoL questionnaire for anisometropic amblyopia[97] measures the impact of amblyopia treatment.

The amblyopia survey was the only PROM developed for adults; it measures the psychosocial impact of amblyopia.[138] All treatment related questionnaires were developed for children and six of them were proxy (measures the impact on children as reported by parents).[113, 195, 200, 201, 203, 206] The treatment-related PROMs predominantly explored the experiences of children undergoing treatment (e.g. treatment-related inconveniences, psychosocial issues related to occlusion therapy).

Whilst most PROMs were developed generally for amblyopia (irrespective of type), two were developed specifically for isolated amblyopia (amblyopia without strabismus): the amblyopia survey measures the impact of non-strabismic amblyopia[138] and the QoL questionnaire measures the impact of treating anisometropic amblyopia on children.[97]

Out of all, the ATI was the widely used amblyopia specific PROM; it contains items that address three treatment-related subscales - adverse effects, compliance and social stigma.[113]

Table 2-4 Characteristics of amblyopia specific PROMs

Name of the PROM Country of Origin; Intended Population	No of items; Language; Type: self/proxy	Proposed Aim	Question format (QF) & response categories (RC)
Condition-specific			
Amblyopia survey[138] USA; over 15 years	8 items; English; Self	To assess the psychosocial effects of growing up and living with non-strabismic amblyopia	QF: Did amblyopia interfere with work? RC: 5-point multiple types
Socio professional integration questionnaire[207] Romania; 12-17 years	12 items; unspecified; Self	To evaluate the socio-professional difficulties faced by Amblyopic patients	QF: Not reported RC: Not reported
Treatment-specific			
Patching success questionnaire (PSQ)[195] Netherlands; children	60 items; English; Proxy	To explore impact of amblyopia and its treatment	QF: I am concerned about my child's visual impairment RC: 5-point multiple types
Amblyopia treatment index (ATI)[113] USA; child 3 to 6 years	20 items; English; Proxy	To assess the impact of amblyopia treatment on the child and family	QF: My child does not seem to mind wearing the patch once it is on RC: 5-point agreement scale
Child amblyopia treatment index[197] USA; over 7 years	19 items; English; Self	To assess the impact of amblyopia treatment from the child's perspective	QF: It bothers me to use the drops. RC: 5-point frequency scale
Perceived psychosocial questionnaire (PPQ)[200] UK; child	10 items; English; Proxy	To measure the psychosocial effects of occlusion therapy as perceived by carers	QF: Not reported RC: Not reported
Emotional impact of amblyopia treatment questionnaire[201] UK; over 3 years	15 items; English; Proxy	To explore experience of treatment for child & family, child's general wellbeing since diagnosis	QF: How well has your child been coping with his/her treatment? RC: Multiple types

Occlusion patch comfort questionnaire (OCQ)[203] Netherlands; child	21 items; English; Proxy	Evaluate comfort of wear with different eye patch used in amblyopia treatment	QF: How much pain did your child have when removing the patch from the skin? RC: Multiple types
Child amblyopia treatment questionnaire (CATQoL)[204] UK; 4 to 7 years	11 items; English; Self	To assess the HRQoL implications of amblyopia treatment from child's perspective	QF: My patch has not made me feel sad RC: 5- or 6-point severity scale - part of the question stem
Children's vision for living scale (CVLS)[205] Saudi Arabia; 5 to 12 years	21 items; Arabic; Self	To assess the vision-related quality of life of children with amblyopia who are undergoing treatment	QF: How much do you think that you are good looking? RC: 5-point difficulty scale
46 item QoL questionnaire[206] Romania; 4 to 16 years	46 items; Romanian; Proxy	To measure QoL of parents and children with amblyopia and assess the psychosocial implication for their family and adherence to treatment	QF: Not reported RC: Not reported
QoL questionnaire for children with anisometropic amblyopia[97] China; 7 to 12 years	16 items; Chinese; Self	To assess the impact of amblyopia treatment on HRQOL through the perspective of children undergoing amblyopia treatment	QF: How difficult do you feel when reading paper books in the daytime? RC: 5-point difficulty scale

2.4.3.2 Strabismus specific PROMs

Table 2-5 displays the characteristics of all strabismus specific PROMs.

Out of the eighteen strabismus specific PROMs, sixteen were developed specifically for strabismus and two were adapted from non-strabismus specific PROMs.

Out of all, six instruments namely the adult strabismus questionnaire (AS-20),[137] the intermittent exotropia questionnaire (IXTQ),[136] the vision function scale (VFS)[180], the perceived visibility of strabismus,[108] strabismus survey[135] and an eight item QoL instrument[106] were developed to measure the impact of strabismus on QoL.

The disability questionnaire,[225] the repertory grid,[57] the psychosocial experience questionnaire,[130] psychosocial effects of strabismus questionnaire,[231] the exotropia symptom questionnaire,[227] satisfaction of surgical outcome,[232] the adapted visual analog scale[181] and the modified RAND health insurance questionnaire[233] were mainly developed to assess treatment outcomes (e.g. improvement in psychosocial wellbeing post strabismus surgery).

The expectations of strabismus surgery questionnaire,[220] the perspectives questionnaire[104] and the post-surgery symptom questionnaire[229] measures the patient's expectations about post-operative symptoms and concerns about treatment outcome. The effect of diplopia questionnaire[228] is the only diplopia-specific instrument and measures the impact of postoperative diplopia on daily life.

The IXTQ is the only questionnaire with age specific self-report and proxy versions to measure the impact of intermittent exotropia on children. The eight-item QoL questionnaire, the RAND health insurance questionnaire, the vision function scale and the effect of diplopia questionnaire were also used to study the impact on children; however, the former two are proxy measures and latter two were not specifically developed for children.

Among all, the AS-20 questionnaire has been used most widely to study the QoL impact of strabismus and to evaluate treatment outcomes. In its original form, it addresses two QoL domains namely psychosocial (10 items) and functional impact (10 items). The AS-20 has been widely used and translated into different languages (Chinese,[148, 149] Hindi, Telugu[219] and Danish[147]).

Table 2-5 Characteristics of strabismus specific PROMs

Name of the PROM Country of Origin; Intended Population	No of items; Language; Type: self/proxy	Proposed Aim	Question format (QF) & response categories (RC)
Condition-specific			
Adult strabismus questionnaire (AS -20)[137] USA, Adults	20 items; English; Self	To assess the HRQoL of adults with strabismus	QF: I worry about what people will think about my eyes RC: 5-point frequency scale
Intermittent exotropia questionnaire (IXTQ)[136] USA, Children	12 items; English; Self: Child 5-7 years (C1) & Child 8-17 years (C2) Proxy (P): (2-17 years)	Impact of IXT upon HRQoL of children and parents	QF: (C1) Are you worried about your eyes? RC: 3-point frequency scale (C1) and 5-point frequency scale (P an C2)
Vision function scale[180] USA, 8 – 46 years;	9 items; English; self	Measure visual function of IXT patients	QF: How often have you had episodes of blurred vision and/or double vision during the past 4 weeks? RC: Multiple types
Perceived visibility of strabismus[108] UK, over 17 years	1 item; English; Self	To assess the perceived visibility of strabismus from the patient's view	QF: Rate the visibility of the strabismus on a 7-point scale RC: 1 (not at all visible) to 7 (extremely visible)
Strabismus survey[135] USA, over 15 years	25 items (including medical history); English; Self;	To assess the impact of noticeable strabismus	QF: The effect of strabismus on relations with same-sex friends RC: Multiple types
8 item QoL instrument[106] India; under 16 years	8 items; native language (unspecified); Proxy	Evaluate the psychosocial and emotional consequences of strabismus on the child and family	QF: How distressed does the child get when other people remark about the facial feature (squint) of your child? RC: Multiple types

Treatment-specific			
Disability questionnaire[225] USA; Adults	6 items; English; self 105 items; English; Self	To measure the disability of people with strabismus before and after strabismus surgery	QF: Please indicate on a scale from 1 to 10, the degree to which your strabismus (eye misalignment) affects your life in the ways described, now and before your surgery RC: Visual analog scale 1 (no effect) to 10 (severe effect)
Repertory grid[57] UK; over 18 years	105 items; English; Self	To assess the impact of noticeable strabismus in adults and the psychosocial effects of surgical correction	QF: Personality traits X 7 scenarios (grid) RC: 5-point multiple types
Psychosocial experience questionnaire[130] USA; over 14 years	11 items preoperative version & 6 items post-operative version; English; Self	To assess psychosocial difficulties faced by patients with strabismus	QF: Did strabismus embarrass you? RC: 2-point ordinal (Yes or No)
Expectations of strabismus surgery questionnaire[220] UK, over 16 years	17 items, English, Self	To assess expectations about outcomes post strabismus surgery	QF: Please rate how you expect surgery to change the various aspects of your life RC: 5-point options
Effect of diplopia questionnaire[228] China, 6 – 68 years	6 items, unspecified language, Self	To measure the impact of postoperative diplopia on daily life	QF: Not reported RC: 2-point ordinal
Perspectives questionnaire[104] USA; Adults (patient & practitioner)	5 items; English; Self	To assess patient and provider perspectives on various factors contributing to strabismus treatment and care	QF: Please rate the severity of your strabismus before and after treatment RC: Multiple types
Post strabismus surgery symptom questionnaire[229] Korea; Adults	9 items; unspecified language; Self	To evaluate patient's expectation of symptoms post strabismus surgery	QF: Rate each symptom on a scale of 0 to10 RC: scale of 0 (absent) to 10 (severe)
Psychosocial effects of strabismus pre and post-operative questionnaire[231] China; over 16 years Adapted from Menon V et.al, 2002[230]	17 items preoperative version and 8 items postoperative version; English; Self	To assess the impact of strabismus on social & personal life preoperatively and post operatively	QF: Do you notice any change in your appearance? RC: Multiple types

Exotropia symptom questionnaire[227] Korea; children	15 items, English; Self & proxy	To evaluate clinical preoperative symptoms and postoperative changes in patients with exotropia	QF: Not reported RC: 5-point severity scale
Satisfaction of surgical outcome[232] Australia; Adults	1 item; English; Self	Satisfaction on surgical outcome of adult strabismus surgery	QF: Comment subjectively on the surgical outcome RC: 5-point satisfaction scale
Visual analog scale[181] UK; over 15 years	7 items; English; self;	To assess the psychosocial impact of strabismus after a year of surgery	QF: To what extent has your strabismus affected your lifestyle?'' RC: Visual analog scale (0 to 10)
Modified RAND health insurance study QoL instrument[233] USA; under 15 years	41 items; English; proxy	Evaluate the psychosocial effects of childhood strabismus surgery	QF: Does your child avoid eye contact with you when you talk? RC: Multiple types

2.4.3.3 Amblyopia and strabismus specific PROMs

Table 2-6 displays the characteristics of two PROMs namely, the amblyopia and strabismus questionnaire (A&SQ)[140] and the psychological impact questionnaire (PIQ)[139] that were developed to *measure the impact of both amblyopia and strabismus*.

The A&SQ was developed to address five domains of QoL namely fear of losing eye (2 items), problems in distance estimation (10 items), visual disorientation (3 items), double vision (4 items) and problems in social contact and cosmetic problems (4 items).[140] The PIQ used eight items to assess the psychological impact in daily life and specifically due to spectacle-wear, having a weaker eye (amblyopia) and having noticeable strabismus.[139]

Both these PROMs were developed for adults. The A&SQ was first developed in Dutch and later translated into English,[143] Chinese[145] and Italian[146] and has been used widely.

Table 2-6 Characteristics of PROMs developed for both amblyopia and strabismus

Name of the PROM Country of Origin; Intended Population	No of items; Language; Type: self/proxy	Proposed Aim	Question format (QF) & response categories (RC)
Amblyopia and strabismus questionnaire (A&SQ)[140] Netherlands, Adults	26 items; Dutch; Self	To assess the quality of life of people with amblyopia and strabismus	QF: I am afraid of losing my better eye RC: 5-point frequency scale
Psychological impact questionnaire (PIQ)[139] UK; over 15 years	33 items; English; self	To assess the psychological impact of amblyopia and amblyopia without strabismus	QF: In your general daily life how often do you become frustrated? RC: Multiple types

2.4.4 Content evaluation

Three hundred and eighty-nine items were pooled from 22 PROMs (5 amblyopia specific, 15 strabismus specific and 2 both amblyopia and strabismus specific). On examining the content of each item, some were found to be generic, measuring general/ overall impact (e.g. overall satisfaction of strabismus surgery) and some could not be classified as they measured constructs different to that of QoL (e.g. knowledge about the condition). Such items were not considered for item evaluation.

2.4.4.1 QoL constructs measured by the disease-specific PROMs

Table 2-7 displays the spread of the number of items in each PROM across the eight ophthalmic QoL domains.

It was evident that the amblyopia specific PROMs predominantly measure activity limitations, emotional impacts related to treatment, in addition to concerns and inconveniences caused by the treatment. The strabismus specific PROMs chiefly measure concerns related to appearance and treatment outcome. The two PROMs developed for both amblyopia and strabismus measure activity limitation, concerns and emotional impact. None of the disease-specific PROMs contain a range of items across all ophthalmic QoL domains to assess QoL comprehensively. This can be visualised by the gaps in Table 2-7.

Table 2-7 Content coverage of the amblyopia and/or strabismus specific PROMs

PROMs considered for item extraction	No of items classified	No. of items across the QoL domains							
		Activity limitation	Concerns	Emotional impact	Social impact	Economic impact	Convenience	Symptoms	Mobility
Amblyopia specific PROMs									
Amblyopia survey	8	1	4	2	-	1	-	-	-
Child amblyopia treatment index	18	-	5	1	-	-	11	1	-
Child amblyopia treatment questionnaire	11	-	1	5	-	-	4	1	-
Children's vision for living Scale	19	11	1	1	5	-	-	-	1
QoL questionnaire with anisometropic amblyopia	15	5	4	5	1	-	-	-	-
Strabismus specific PROMs									
Adult strabismus quality of life questionnaire	20	3	10	3	1	-	1	2	-
Intermittent exotropia questionnaire - child	12	-	9	-	1	-	2	-	-
Perspectives questionnaire†	0	-	-	-	-	-	-	-	-
Disability questionnaire	6	1	1	1	1	1	-	1	-
Repertory grid	98	-	21	42	35	-	-	-	-
Perceived visibility of strabismus	1	-	-	-	-	-	-	1	-
Expectations of strabismus surgery questionnaire	17	-	17	-	-	-	-	-	-
Psychosocial experience questionnaire	16	1	8	2	2	2	-	1	-
Vision function scale	8	3	1	1	-	-	-	3	-
Exotropia symptom questionnaire	15	2	2	-	1	-	-	9	1
Effect of diplopia questionnaire	5	2	3	-	-	-	-	-	-
Post strabismus surgery symptom questionnaire	9	-	9	-	-	-	-	-	-
Psychosocial effects of strabismus pre and post-operative questionnaire	22	2	12	4	4	-	-	-	-
Satisfaction of surgical outcome†	0	-	-	-	-	-	-	-	-
Visual analog scale	6	-	5	-	-	-	-	1	-
Amblyopia and strabismus specific PROMs									
Amblyopia and strabismus questionnaire	26	7	6	2	2	-	-	5	4
Psychological impact questionnaire	9	1	3	3	1	-	-	-	1

† all items were either generic/ global or could not be classified under any QoL domain

2.4.4.2 Most assessed QoL domain

Out of the 389 items, 117 were unique. The domains - concerns (41), activity limitation (24) and emotional impact (19) were the widely assessed QoL domains, which is indicated by the high number of unique items. The domains - economic impact (2) and mobility (3) had the least number of unique items and were least represented in the existing amblyopia and/or strabismus specific PROMs.

The limited number of the items (Figure 2-2) across the eight QoL domains suggests that even when items from all PROMs were pooled together, they may not be sufficient to measure all the important constructs of QoL.

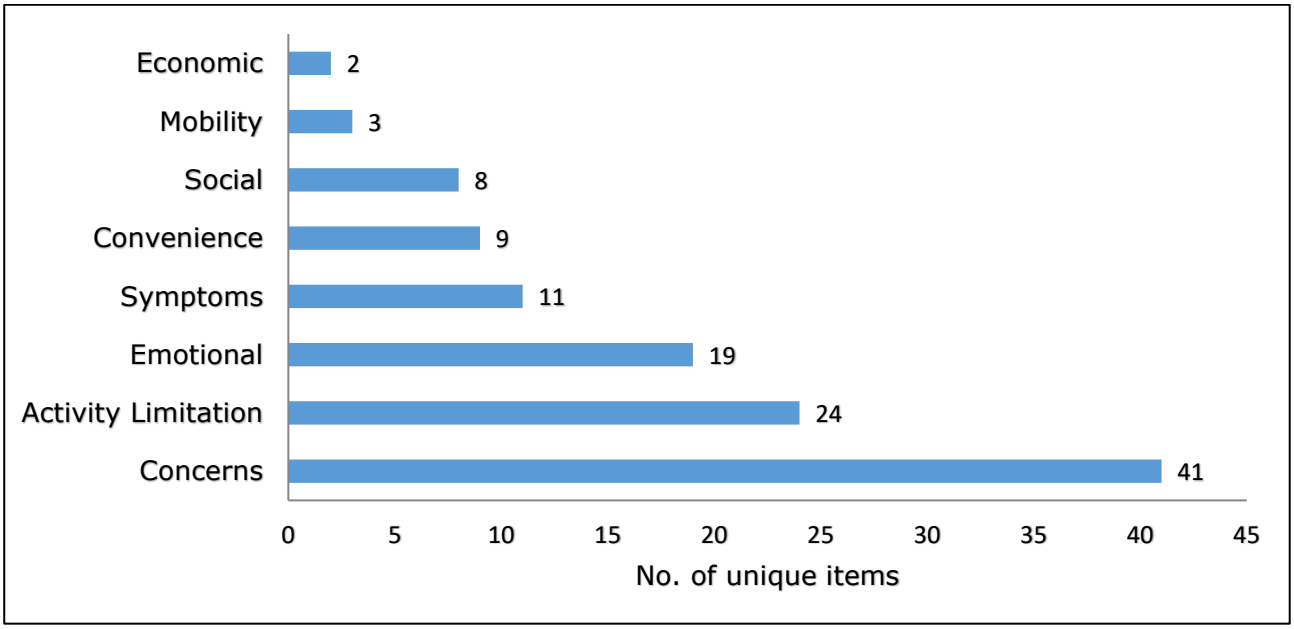


Figure 2-2 Content coverage: showing number of unique items across the ophthalmic domains of Quality of life (QoL)

2.5 Quality assessment of amblyopia and strabismus specific PROMs

A comprehensive quality assessment of amblyopia and strabismus specific PROMs was conducted to identify those that can provide valid and reliable measurement of QoL constructs.

2.5.1 Methods

The quality of content, psychometric properties, measures of validity, reliability and

responsiveness of all amblyopia and/or strabismus specific PROMs were examined using quality standards displayed in Table 2-8. These quality standards were adapted from Khadka *et al*, 2013[131] and comply with the FDA[110] and Consensus-based Standards for the selection of health Measurement Instruments (COSMIN)[247, 248] standards for evaluating quality of PROMs. This has been used by the Eye-tem bank research group to appraise PROMs developed for various eye diseases.[2, 131, 249, 250]

Below is an overview of the quality assessment criteria.

2.5.1.1 Quality of content

PROMs that are patient-derived are regarded more valid as they reflect the QoL of the patients through their own perspectives. Therefore, PROMs developed based on comprehensive consultation with patients and whose item selection was guided by pilot testing of the instrument using Rasch or factor analysis received high quality grading.[152]

2.5.1.2 Psychometric properties

Classical Test Theory (CTT) and Rasch Measurement Theory (RMT) are two measurement models that have been used to evaluate the psychometric properties of PROMs in the field of ophthalmic patient reported outcomes. These have been elaborated in Chapter 5.

The CTT falsely assumes that all items have equal difficulty and the distance between each response options are equal and uses summary scoring of the ordinal values that are assigned to response options.[89, 251] It relies on Cronbach's α for its reliability and unidimensionality is tested using factor analysis.[252] Unlike RMT, the findings produced by using CTT are both sample and scale dependent and are affected by missing data.[89, 96, 252] Therefore, the validity of PROMs validated using CTT alone are less reliable.

The RMT is probability based and has its foundation on explicit mathematical models. It transforms ordinal data into interval measures (logits) and places the item difficulty and person ability on a single continuum interval scale so that equal amount of constructs could be measured along the entire scale.[89, 252] It is superior to CTT as it offers important information about the essential features of measurement such as unidimensionality (whether the instrument measures a single construct), targeting (how well the items' difficulty in the instrument matches the ability of the individuals in the sample) and measurement precision (ability to distinguish between people with

different levels of the latent trait). It also assesses if the response categories are ordered (and properly utilised) and if there are any differential item functioning (if people with similar ability respond differently to an item, indicating bias).[89, 131, 152]

2.5.1.3 Grading measurement qualities

Instruments validated based on CTT received high quality grading if they had ≤ 5% of missing data, end-point responses ≤ 5% for majority of items, internal consistency by Cronbach's α in the range 0.70 to 0.95 and inter-item correlations less than 0.30. Dimensionality of the instrument was graded superior if the 1st factor loading was greater than 0.40 for all items, variance explained by the measure using Principal Component Analysis (PCA) was > 60% and the eigenvalue of the first contrast was less than 2.0.[92, 96, 253, 254]

Instruments validated using RMT received a high grading if the response categories were ordered and evenly spaced, variance explained by the measure was ≥ 60% and eigenvalue of the first contrast was less than 2 (indicating unidimensionality), Person Separation Index (PSI)≥ 2.5 (indicating measurement precision), item fit mean squares between 0.70 and 1.30, Differential Item Functioning (DIF) < 0.5 logits and difference between item and person measures ≤ 1 logit (indicating targeting).[131, 152]

2.5.1.4 Validity, reliability and responsiveness

In addition to psychometric properties, measures of validity (convergent, discriminant, concurrent and known group), reliability (test-retest, inter observer / inter mode agreement) and responsiveness (score changes over time and effect size) of the disease-specific PROMs were examined.

Instruments demonstrating correlation of 0.3 to 0.9 tested against appropriate measure were graded high for convergent and concurrent validity and correlation of less than 0.3 against appropriate measure was graded high for discriminant validity.[131, 152] Significant difference noticed between appropriate clinical groups was given high grading for known group validity. An intra-class correlation of ≥ 0.8, Limits of Agreement (LOA) < Minimally Important Difference (MID), weighted kappa >0.8, inter modal correlation > 0.70, score changes over time > MID and effect size ≥ 1 were graded high.[131, 152]

2.5.1.5 Overall quality

PROMs that received several high grades across all the quality assessment criteria

were considered superior to others.

Table 2-8 Quality assessment criteria

Content Development[131, 152]	
Item Identification	**A** Comprehensive consultation with patients, experts and literature review **B** Minimal consultation with patients, experts and literature review **C** No consultation with patients
Item Selection	**A** Pilot instrument was developed and tested with Rasch analysis or factor analysis; Items with floor and ceiling effects were removed; missing data considered; Statistical justification is given for selecting and reducing items **B** Only some of these techniques were employed **C** No pilot instrument was developed or no statistical justification of selecting items were provided
CTT Based psychometric properties[92, 96, 152, 253, 254]	
Acceptability	**A** The percentage of missing data for majority of items: ≤5% **B** The percentage of missing data for majority of items: >5% ≤ 40% **C** The percentage of missing data for majority of items: > 40%
Targeting	**A** End-point responses (floor & ceiling effects) ≤ 5% for majority of items **B** End-point responses > 5% or ≤ 40% for majority of items **C** End-point responses > 40% for majority of items
Internal Consistency	**A** 0.95 ≥ Cronbach's α ≥ 0.70 **B** 0.70 > Cronbach's α ≥ 0.60; or Cronbach's α > 0.95 **C** Cronbach's α < 0.60
Item dependency	**A** Inter-item correlations <0.3 **B** Inter-item correlations ≥ 0.3 or < 0.6 **C** Inter-item correlations ≥ 0.6
Dimensionality	**A** 1st factor loading >0.4 for all items; Principal component analysis (PCA): Variance explained by the measure > 60% and eigenvalue of 1st contrast <2.0 **B** 0.7 < Cronbach's α > 0.90; PCA: variance explained by the measure ≥ 50% or < 60% and eigenvalue <2.0 **C** Cronbach's α < 0.70 or > 0.90; PCA: variance explained by the measure < 50% and eigenvalue >2 (indicating multidimensionality)
Rasch based psychometric properties[131, 152]	
Response categories	**A** Ordered response categories or ordering of categories were obtained by repairing disordered categories; evenly spaced response categories **B** Ordered response categories or ordering of categories were obtained by repairing disordered categories; Categories not evenly spaced **C** Unrepairable disordered categories
Dimensionality	**A** PCA of residuals: variance explained by the measure ≥ 60% and eigenvalue of the first contrast < 2.0 **B** PCA of residuals: variance explained by the measure ≥ 50% to < 60% and eigenvalue <2.0 **C** PCA of residuals: variance explained by the measure < 50% and eigenvalue > 2.0 (indicating multidimensionality)
Measurement precision	**A** Person separation index (PSI) ≥ 2.5; reliability (α) > 0.85 **B** 2.0 ≤ PSI < 2.50; 0.80 ≤ α < 0.85 **C** PSI < 2.0; α < 0.80

Item fit Statistics	**A** All items with infit and outfit mean squares between 0.70 to 1.30 **B** Most items within 0.70 to 1.30 and one or two items within the 0.50 to 1.50 limit **C** More than two items within or outside 0.50 to 1.50 limit
Differential item functioning	**A** All items with DIF < 0.50 logit **B** Some items with DIF 0.50 to 1 logits and at the most DIF for one item >1 logit **C** More than one item > 1.0 logit
Targeting	**A** Difference between item and person means ≤ 1 logit **B** Difference between item and person means > 1 to ≤ 2 logit **C** Difference between item and person means > 2 logits
Validity[131, 152]	
Convergent	**A** Tested with appropriate measure and correlation: 0.30 to 0.90 **B** Tested with debatable choice of measure and correlation: 0.30 to 0.90 **C** Correlation < 0.30 or > 0.90
Discriminant	**A** Tested against an appropriate measure and correlation: < 0.30 **B** Tested against debatable choice of measure and correlation: < 0.30 **C** Correlation ≥ 0.30
Concurrent	**A** Tested with an appropriate clinical measure and correlation: 0.30 to 0.90 **B** Tested with a debatable clinical measure and correlation: 0.30 to 0.90 **C** Correlation < 0.30 or > 0.90
Known group	**A** Tested between appropriate clinical groups and significant difference is found between groups **B** Tested between debatable clinical groups and significant difference is found between groups **C** Insignificant difference between groups
Reliability and responsiveness[131, 152]	
Test-retest agreement	**A** Intra-class correlation (ICC) ≥ 0.80 **B** 0.60 ≤ ICC < 0.80 **C** ICC < 0.60
Inter-observer / intermodal agreement	**A** Limits of Agreement (LOA) < Minimally important difference (MID), Weighted kappa > 0.80, intermodal correlation > 0.70 **B** LOA broader but still close to MID; kappa: 0.6 to 0.79; intermodal correlation 0.50 to 0.70 **C** LOA > MID, kappa < 0.60, intermodal correlation <0.50 or incorrect statistical test or inadequate sample (n <30)
Responsiveness	**A** Score changes over time > MID or change with intervention; Effect size ≥ 1 or responsiveness statistics given **B** Changes over time but relationship to MID not reported; Effect size ≥ 0.50 to <1; small sample or inadequate time frame **C** Score changes ≤ MID; Effect size < 0.50
A: High / positive quality B: fair / minimal acceptable quality C: negative / poor quality	

2.5.2 Results

2.5.2.1 Quality assessment

2.5.2.2 Amblyopia specific PROMs

The quality assessment of the amblyopia specific PROMs is summarised in Table 2-9.

The children's vision for living scale (CVLS) is the only PROM that was developed based on patient's perspectives and has been validated using Rasch analysis. However, the scale shows multidimensionality.[205] The amblyopia treatment index (ATI),[98, 196] the child amblyopia treatment index (cATI)[197] and the QoL questionnaire for anisometropia[97] that were developed based on extant literature and the clinician's perspectives showed good acceptability, internal consistency and dimensionality based on CTT and factor analysis but has not been validated using modern psychometric theories. The amblyopia survey[138] which is the only PROM developed for adults, has not been validated.

Table 2-9 Quality assessment of amblyopia specific PROMs

Study details	Subscales or Factors (no of items)	Content Development	CTT Based Psychometric properties	Rasch based Psychometric Properties	Measures of validity / reliability & responsiveness
Amblyopia treatment index – English					
Cole *et al.* (2001)[113] United States n=64	Unclassified (20) FA revealed 11 items	Item Identification: C Item Selection: B	Acceptability: A Targeting: B Internal Consistency: A (for 11 items) Item Dependency: NR† Dimensionality: A (for 11 items)		
Holmes *et al.* (2003)[98] United States n=364	3 factors (16) Adverse effects of treatment (8) Difficulties with compliance (5) Social stigma of the treatment (3)		Acceptability: A Targeting: B Internal Consistency: A Item Dependency: NR† Dimensionality: A		
Holmes *et al.* (2008)[196] United States n=794	3 factors (16) Adverse effects of treatment (8) Treatment compliance (5) Social stigma (3)		Acceptability: A Targeting: B Internal Consistency: A Item Dependency: NR† Dimensionality: A		
Amblyopia treatment index – Chinese					
Xu *et al.* (2014)[199] China n=109	3 factors (16) Adverse effects of treatment (6) Difficulties with compliance (6) Social stigma (4)		Acceptability: A Targeting: B Internal Consistency: A Item Dependency: NR† Dimensionality: A		Reliability (ICC)‡: A

Child Amblyopia treatment index (the child ATI) – English					
Felius *et al.* (2010)[197] United States n=233	2 factors (10) Adverse effects (7) Treatment compliance (3)	Item Identification: C Item Selection: B	Acceptability: A Targeting: B Internal Consistency: A Item Dependency: NR† Dimensionality: A		
Children's Vision for Living Scale (CVLS) – Arabic					
Bokhary *et al.* (2013)[205] Saudi Arabia n=48	Unclassified (21)	Item Identification: A Item Selection: A	Internal consistency: A Dimensionality: C	Model: PCM§ Response category: A Dimensionality: C Measurement precision: B Item fit statistics: A DIF: B Targeting: A	
HRQoL questionnaire for Anisometropic Amblyopia – Chinese					
Chen *et al.* (2016)[97] China n=44	4 factors (16) Visual function (6) Psychosocial impact (6) Social interaction (2) Worries about vision (2)	Item Identification: C Item Selection: B	Acceptability: A Targeting: NR† Internal Consistency: A Item Dependency: NR† Dimensionality: A		Reliability (ICC)‡: A Responsiveness: B
A: High / positive quality B: fair / minimal acceptable quality C: negative / poor quality; †NR: Not reported; ‡ICC: Intra-class correlation; §PCM: Partial credit model					

2.5.2.3 Strabismus specific PROMs

The IXTQ is the only strabismus specific PROM for children that was developed using patient's perspectives and validated. The quality assessment of the IXTQ is shown in Table 2-10. Despite holding good CTT based psychometric properties, the instrument (child and proxy versions) does not demonstrate good measurement precision and unidimensionality when validated using the Rasch model.[223]

The quality assessment of the strabismus specific PROMs developed for adults are shown in Table 2-11.

The AS-20 questionnaire has been translated into many languages and validated by multiple studies. It has been shown to have good reliability,[189] responsiveness[188] and validity.[186] However, validation of the English AS-20 using Rasch analysis revealed that two of its subscales (interaction and general function) fall short of measurement precision.[212] The Hindi and Telugu versions of the AS-11 scale and the 8 item psychosocial and 9 item functional subscales shows good dimensionality, fit and targeting but only satisfactory measurement precision.[219] The Chinese[148, 149] and the Danish[147] AS-20 were found to have high ceiling effects and the 9 item functional subscale of Chinese AS-20 lacked precision. The Danish AS-20 has not been tested using RMT.

The clinician derived expectations of strabismus surgery questionnaire (ESSQ) showed good internal consistency and acceptable dimensionality; however it has not been validated by RMT.[220]

Table 2-10 Quality assessment of strabismus specific PROMs for children

Study details	Subscales or Factors (no of items)	Content Development	CTT Based Psychometric properties	Rasch based Psychometric Properties	Measures of validity /reliability & responsiveness
Intermittent exotropia questionnaire (IXTQ) - English					
Hatt *et al.* (2010)[136] United States n=33 Child & proxy version	1 factor (12)	Item Identification: A Item Selection: A	Acceptability: A Targeting: A Internal Consistency: A Item Dependency: NR† Dimensionality: C		Known group validity: A
Hatt *et al.* (2010)[105] United States n = 51					Known group validity: A Convergent validity: B (for proxy version)
Leske *et al.* (2015)[223] United States n=575 Child (5 to 7 years) version	unclassified (11)			Model: ARS‡ Response category: A Dimensionality: C Measurement precision: C Item fit statistics: B DIF: A Targeting: B	
Leske *et al.* (2015)[223] United States n = 575 Child (8 to 17 years) version	unclassified (11)			Model: ARS‡ Response category: A Dimensionality: C Measurement precision: C Item fit statistics: B DIF: C Targeting: B	

Leske *et al.* (2015)[223] United States n = 575 Proxy version	unclassified (11)	Model: ARS Response category: A Dimensionality: C Measurement precision: C Item fit statistics: B DIF: C Targeting: C
A: High / positive quality B: fair / minimal acceptable quality C: negative / poor quality; †NR: Not reported; ‡ARS: Andrich rating scale model		

Table 2-11 Quality assessment of strabismus specific PROMs for adults

Study details	Subscales or Factors (no of items)	Content Development	CTT Based Psychometric properties	Rasch based Psychometric Properties	Measures of validity /reliability & responsiveness
Adult Strabismus questionnaire (AS-20) - English					
Hatt *et al.* (2009)[137] United States n=29 pilot testing & 32 final testing	2 factors (20) Psychosocial (10) Function (10)	Item Identification: A Item Selection: A* *FA revealed 49 items but 10 items with highest loading in each factor was chosen	Acceptability: A Targeting: NR† Internal Consistency: A Item Dependency: NR† Dimensionality: A		Known group validity: A
Hatt *et al.* (2009)[186] United States n=84					Known group validity: A (for subscales)
Hatt *et al.* (2010)[188] United States n=106					Responsiveness: A
Leske *et al.* (2010)[189] United States n=55					Reliability (ICC)‡: A

	Self-perception (5)		Model: ARS§ Response category: A Dimensionality: A Measurement precision: A Item fit statistics: B DIF: B Targeting: B
	Interaction (5)		Model: ARS§ Response category: A Dimensionality: A Measurement precision: C Item fit statistics: B DIF: A Targeting: C
Leske *et al.* (2012)[212] United States n=348		Item Identification: A Item Selection: A	
	Reading (4)		Model: ARS§ Response category: A Dimensionality: A Measurement precision: A Item fit statistics: B DIF: B Targeting: A
	General function (4)		Model: ARS§ Response category: A Dimensionality: B Measurement precision: C Item fit statistics: B DIF: B Targeting: A

Adult Strabismus questionnaire (AS-11) & 2 subscales - Hindi & Telugu					
Gothwal *et al.* (2015)[219] India n=584	Overall (11)	Item Identification: A Item Selection: A		Model: ARS§ Response category: A Dimensionality: A Measurement precision: B Item fit statistics: A DIF: B Targeting: A	
	Psychosocial (8)			Model: ARS§ Response category: A Dimensionality: A Measurement precision: B Item fit statistics: A DIF: B Targeting: A	
	Functional (9)			Model: ARS§ Response category: A Dimensionality: A Measurement precision: B Item fit statistics: A DIF: B Targeting: A	
Adult Strabismus Questionnaire (AS-20) - Chinese					
Yu *et al*. (2013)[149] China n=102	2 factors Psychosocial (10) Functional (10)		Acceptability: NR† Targeting: B Internal Consistency: A Item Dependency: NR† Dimensionality: A		Known group validity: A Reliability (ICC)‡ : A
Wang *et al.* (2013)[148] China n=255	Translated from original 2 factors Psychosocial (12) Functional (6)		Acceptability: NR† Targeting: NR† Internal Consistency: A Item Dependency: NR† Dimensionality: B		Known group validity: A Convergent validity: B (only functional subscale)

Wang *et al.* (2014)[145] China n=304	Translated from original		Targeting: B Internal Consistency: A		Known group validity: A Convergent validity: C
Wang *et al.* (2015)[221] China n=247	Psychosocial (11)		Item Dependency: A	Model: ARS§ Response category: A Dimensionality: B Measurement precision: A Item fit statistics: A DIF: A Targeting: A	
	Function (9)		Item Dependency: A	Model: ARS§ Response category: A Dimensionality: B Measurement precision: C Item fit statistics: A DIF: A Targeting: A	
Adult Strabismus Questionnaire (AS-20) - Danish					
Ali *et al.* (2016)[147] Denmark n=64			Acceptability: A Targeting: B Internal Consistency: A Item Dependency: B Dimensionality: NR†		Known group validity: A
Expectations of Strabismus surgery questionnaire (ESSQ) - English					
McBain *et al.* (2016)[220] United Kingdom n=220	3 factors (17 items) Intimacy & appearance-related issues (5) Visual functioning (7) Social relationships (5)	Item Identification: C Item Selection: B	Acceptability: A Targeting: B Internal Consistency: A Item Dependency: NR† Dimensionality: B		Convergent validity: B Concurrent validity: A (for visual functioning subscale)
A: High / positive quality B: fair / minimal acceptable quality C: negative / poor quality; †NR: Not reported; ‡ICC: Intra-class correlation; §ARS: Andrich rating scale model					

2.5.2.4 Amblyopia and strabismus specific PROMs

Table 2-12 displays the quality assessment of the A&SQ. The Dutch and English versions of the A&SQ were shown to have good acceptability and internal consistency.[140, 143] However, only the English version has been validated using Rasch analysis and was found to lack unidimensionality. In addition, the targeting of the instrument to the ability of the respondents was just fair for the isolated amblyopia group as compared to good targeting for the strabismus group.[75] The Chinese and Italian versions had high ceiling and floor effects, demonstrating fair or poor targeting.[145, 146] The psychological impact questionnaire has not been validated.

Table 2-12 Quality assessment of PROMs developed for both amblyopia and strabismus

Study details	Subscales (no of items)/ Factors (no of items)	Content Development	CTT Based Psychometric properties	Rasch based Psychometric Properties	Measures of validity /reliability & responsiveness
Amblyopia and Strabismus questionnaire (A&SQ) - Dutch					
van de Graaf *et al.* (2004)[140] Netherlands n=68 outpatients and 174 cohort		Item Identification: B Item Selection: B	Acceptability: A Internal Consistency: A		Convergent validity: B Known group validity: A
van de Graaf *et al.* (2007)[234] Netherlands n=137					Concurrent validity: A
van de Graaf *et al.* (2009)[235] Netherlands n=245	6 Factors (24): fear of losing better eye (3), near distance estimation (5) , far distance estimation (4), visual disorientation (3), diplopia(4), problems with social contact and cosmetic problems(5)		Dimensionality: A		
Amblyopia and Strabismus questionnaire (A&SQ) - English					
Felius *et al.* (2007)[143] United States n=150	5 subscales (26)		Acceptability: A Targeting: B Internal Consistency: A Item Dependency: NR† Dimensionality: NR†		Convergent validity: B Concurrent validity: A

Vianya-Estopa *et al.* (2010)[75] United Kingdom n=102	Unclassified (23 - strabismic group; 21 isolated amblyopia group) Identified 2 subscales: Visual function & psychosocial as a result of Rasch analysis		Model: ARS‡ Response category: A Dimensionality: C Measurement precision: B Item fit statistics: B DIF: C Targeting: A (strabismus group) / B (Isolated Amblyopic group)
Amblyopia and Strabismus questionnaire (A&SQ) - Chinese			
Wang *et al*. (2014)[145] China n=304	5 subscales (23)	Targeting: C Internal Consistency: A	Known group validity: A Convergent validity: B
Bian *et al*. (2015)[236] China n=202	6 factors (22 items) Far distance estimation (7) Social contact and appearance (4) Visual disorientation (3) Near distance estimation (3) Double vision (2) Fear of losing eye (3)	Acceptability: NR† Targeting: NR† Internal Consistency: A Item Dependency: NR† Dimensionality: A	Convergent validity: A Known group validity: A Reliability (ICC)§: A

Amblyopia and Strabismus questionnaire (A&SQ) - Italian			
Marcon *et al.* (2014)[146] Italian n=99	7 factors Fear of losing better eye (3) Object's interaction (5) Spatial interaction (6) Visual disorientation (3) Diplopia (2) Social contact (3) Appearance (3)	Acceptability: A Targeting: C Internal Consistency: B Item Dependency: NR† Dimensionality: A	Known group validity : A Reliability (ICC)§: A
A: High / positive quality B: fair / minimal acceptable quality C: negative / poor quality; †NR: Not reported; ‡ARS: Andrich rating scale model; §ICC: Intra-class correlation			

2.6 Discussion

This chapter recognises the limitations in the current PROMs and establishes the rationale to develop technologically advanced and scientifically sound PROMs for amblyopia and strabismus. The systematic review carried out in this chapter identified 71 PROMs from 108 articles; however, it was found that only 32 PROMs were amblyopia and/or strabismus specific. As it is recognised that the disease-specific PROMs offer targeted measurement of QoL affected by the disease and is more responsive to changes post treatment, the chapter focussed on reviewing these.

First, the characteristics and content of the disease-specific PROMs were reviewed. It was found that most of the amblyopia specific PROMs were developed for children and measured the impact of amblyopia treatment, while most of the strabismus specific PROMs were developed for adults and measured concerns related to appearance and treatment outcome; none of these PROMs had a range of items that addressed all domains of QoL comprehensively.[115] The only amblyopia specific PROM for adults, the amblyopia survey, is limited in content and has not been validated.[138] None of the existing PROMs offer comprehensive measurement of QoL for children and adults. Even when extant items from all self-report PROMs were pooled together, gaps in content to address all important constructs of QoL was noted.

Next, the quality of these PROMs in terms of content and measurement properties was assessed using established quality standards.[92, 96, 131, 152, 247, 248, 254] Of the 32 PROMs, only 8 had been validated – the amblyopia treatment index (ATI), the child ATI, the children vision for living scale (CVLS), the HRQoL questionnaire for anisometropic amblyopia, the intermittent exotropia questionnaire (IXTQ), the adult strabismus questionnaire (AS-20), the expectations of strabismus surgery questionnaire (ESSQ) and the amblyopia and strabismus questionnaire (A&SQ). Out of these, only the CVLS, IXTQ, AS-20 and A&SQ had been validated using the Rasch model that appraises all essential features of measurement.

The CVLS and the IXTQ was developed for children with amblyopia and strabismus (intermittent exotropia) respectively. Upon validation, it was evident that both PROMs lacked unidimensionality – an important attribute for valid measurement.[152] The AS-20 was developed for adults with strabismus and was found to have good psychometric properties than others;[212] however, its use in people with non-strabismic amblyopia is unknown. The A&SQ is the only validated questionnaire for adults that

claims to measure the impact of both amblyopia and strabismus; however, it was not patient-derived. Moreover, the scale showed multidimensionality, differential item functioning and sub-optimal targeting for people with isolated amblyopia.[75]

Several studies have used PROMs to assess the impacts caused by amblyopia; however, these have produced discrepant results. While some claim that amblyopia influences QoL, [78, 84, 138, 139, 206, 207] others contradict.[129, 183] It should be noted that all these studies have either used non-disease specific or non-validated PROMs. The use of PROMs with poor quality and inappropriate or inadequate content could be the reason for such discrepancies. Although those with amblyopia have increased risk of bilateral visual impairment and blindness,[255, 256] this lack of understanding about the overall QoL impact of amblyopia limits the cost appraisal of vision screening programmes and hinders economic decisions.[69, 70]

It is noteworthy that all studies that evaluated the impact of amblyopia treatment[97, 194, 197, 200-203, 240] or its outcome[98, 100, 176, 195] have focussed on children. While treatment for amblyopia is considered most effective during the critical period of visual development, there is increasing evidence about its effectiveness in older children and adults.[72, 257] Several new interventions to treat the residual plasticity of visual system later than the critical period are thus being developed and tested.[12, 16, 27, 30, 31, 72, 258] However, the effectiveness of these have not been evaluated from patient's perspectives.[259] Although important, this evaluation is limited by the unavailability of an amblyopia specific PROM for adults that is comprehensive and valid.

This also stands true for strabismus related QoL investigations. Surgical correction for chronic, non-diplopic strabismus was considered 'purely cosmetic' until functional benefits (e.g. expansion of binocular visual fields, regained stereopsis) were substantiated.[54, 56] However, most studies that evaluated the patient's experiences of treatment outcomes, focussed mainly on the psychosocial benefits and not on other attributes of QoL.[57, 130, 135, 181, 182, 230, 231, 233] A holistic evaluation of QoL is necessary, especially after recognising the value of strabismus surgery in people who are barely able to visualise their ocular misalignment due to severe bilateral visual impairment[60] and in those who were classified as surgical failures by standard clinical criteria.[59]

Studies have shown that people with socially noticeable strabismus are perceived negatively,[45, 260] not given preference for employment[49, 50] and have problems in finding a life partner.[46] In addition, those with strabismus are at a risk for developing

mental illness and psychiatric disorders.[172, 261] However, many of these issues are not reflected in the content of the existing PROMs. Furthermore, the primary concerns of people with diplopic and non-diplopic strabismus vary; patients with diplopia have greater functional impact and lesser psychosocial impact compared to those without diplopia.[86, 186, 188] More comprehensive evaluation is necessary to further delineate the differences across all recognised QoL domains.

Although a myriad of PROMs exists, only a few have been used more than once (Table 2-2) and newer PROMs have been constantly developed. This could be due to inadequacy in content of extant PROMs. This may also be the reason why studies use multiple PROMs to address their research questions.[108, 198, 220] Moreover, 31 out of 32 disease specific PROMs reviewed in this chapter have been developed for high or middle income countries and about 75% (24 out of 32) are in English (Appendix 1). This may limit the applicability of the extant PROMs to low income country settings such as India.

An indispensable need for the development of an amblyopia and strabismus specific PROM with high quality and comprehensive nature is thus explicit. Because amblyopia and strabismus are closely associated, further research is needed to ascertain whether two PROMs that target each condition separately are necessary. The eight ophthalmic QoL domains[2] used for evaluating the content of amblyopia and strabismus specific PROMs were drawn from other studies[153, 246] and hence may not adequately represent all the QoL constructs important to this disease group. Therefore, an extensive qualitative research is crucial to confirm these domains and to facilitate the development process.

The limitation of the systematic review carried out in this chapter is that it only considered articles published until July 2016. To the best of my knowledge, 25 articles that used PROMs to measure the impacts of amblyopia and strabismus have been published from July 2016 to October 2019. 23 out of the 25 studies used extant PROMs;[55, 262-284] the AS-20 (n=8)[55, 265-267, 270, 271, 275, 276] and A&SQ (n=3)[265, 267, 281] were widely used in adults and the IXTQ (n=6)[264, 268, 269, 273, 282, 284] and CATQoL (n=3)[262, 263, 278] were widely used in children. Out of the 23, one study reported the validation of the CATQoL using Rasch analysis. During validation, disordered thresholds were optimised, and three items were removed owing to misfit and local dependency. However, the final 8-item scale had sub-optimal measurement precision (0.74) and targeting (-1.715).

The remaining two studies reported new PROMs: 1) a parental questionnaire that assessed children's attitude towards amblyopia treatment[285] and 2) a QoL questionnaire for Chinese adults which included items on symptoms, appearance, ADL, personal development and social interaction.[286] Although the new QoL PROM for Chinese adults was developed based on extensive qualitative exploration, the questionnaire was not validated.[286]

The other limitation of this study is that the overall quality of the PROMs reviewed was ascertained by the number of high grades; PROMs that received several high grades were considered superior to other. It is to be acknowledged that there is a bit of arbitrariness in applying this criterion (e.g. many PROMs might receive same number of high grades despite possessing different psychometric properties). It is therefore recommended to go through all the quality indicators in the quality assessment tables and use qualitative judgement rather than just relying on the total number of high grades.

To summarise, the impact of amblyopia and strabismus on adults is not fully understood. None of the currently available PROMs provide precise and comprehensive measurement of the impact caused by these conditions and it is not clear whether these conditions require separate PROMs for improved measurement. Most PROMs are developed for high resource country settings and its content appropriateness to other settings/ culture is not clear. Thus, the main aim of this doctoral research was to develop and validate technologically advanced amblyopia and strabismus specific PROMs in the form of QoL item banks for adults living in Australia and India, by a multi-staged systematic process.

CHAPTER 3 QUALITATIVE EXPLORATION OF THE QUALITY OF LIFE IMPACTS OF AMBLYOPIA AND STRABISMUS ON ADULTS

3.1 Introduction

Well-designed, carefully implemented and thoroughly documented qualitative methods are crucial foundations of PROM development.[287] Having recognised the need for developing item banks to measure the long-term QoL impacts of amblyopia and strabismus (Chapter 2), a qualitative exploration was ventured in Australia and India. This chapter presents the results of the qualitative research.

3.1.1 Quantitative versus Qualitative research

Qualitative research provides rich understandings of the human aspect of an issue (e.g. individual's perceptions, feelings and experiences) which cannot be examined in depth using quantitative methods.[288] It is the method of choice when the research question is 'to explore' rather than 'to confirm' a phenomenon.[289] While quantitative studies pursue statistical inferences of numbers assigned to a phenomenon, qualitative studies pursue contextual interpretation of textual descriptions of a phenomenon.[289, 290] The objectives of quantitative techniques are to quantify variation, predict causal relationships or describe population characteristics whereas the objectives of qualitative techniques are to describe variation, individual experiences or relationships; it is beyond the scope of this chapter to describe all the differences that exists between the two approaches.[289, 290]

The flexibility of qualitative techniques (e.g. the use of open-ended questions, an iterative approach to data collection and analysis) makes it a preferred method for exploratory research that aims to obtain responses that are salient to the participants and those that are unknown or unanticipated by the researcher.[289] Combining both qualitative and quantitative methods thoughtfully, capitalises on the strengths of each other.[291, 292] In the field of PROM development, the roles of qualitative and quantitative methods are complementary and crucial; qualitative methods such as focus groups, interviews and cognitive debriefing supports construction of the PRO instrument[293] and quantitative psychometric techniques supports its validation.[251]

3.1.2 Role of Qualitative research in PROM development

The importance of qualitative research in the development of PROMs have been recognised by the FDA and other regulatory bodies,[293-296] specifically to base the claims of novel treatment benefits on evidence generated by PROMs that are patient-derived. The inclusion of patients who experience a phenomenon, in this case, amblyopia or strabismus, into the development process of PROMs is essential to ensure its patient-centeredness and content validity.

3.1.2.1 Patient-centeredness

Patient-centeredness underpinning the development of PROMs is fundamental for scales to have both relevance and meaning to the target population.[297] Although PROMs are patient-reported, not all are patient-centered.[298] The distinction between the two is that patient-centered PROMs measures the patient's experience of concepts (outcomes) that originated from patients and are important to them rather than those concepts that are of interest to the clinicians or researchers.[299] Concept elicitation by qualitative research with patients maintains the primacy of patients' perspective and is thus crucial in PROM development.[300]

3.1.2.2 Content validity

The ultimate goal of measurement is to quantify a concept (construct or latent trait)[295] and PROMs have been designed to achieve that goal.[300] It is therefore vital that PROMs exhibit content validity which is defined as 'the extent to which the PROM captures the concept that it intends to measure'.[88, 251, 300] According to the FDA, content validity is manifest by i) empirical qualitative evidence that the concept measured is the concept of interest for the target population ii) evidence that the items that form the instrument were patient-derived, comprehensive and comprehensible and iii) the characteristics of study sample used to draw the evidence represents the target population.[88, 287] The lack of patient involvement into the construction PROMs and lack of evidence that all important and relevant patient experiences are captured (saturation) have been identified as significant threats to content validity,[287, 295] making rigorous qualitative inquiry with patients and thorough documentation an absolute necessity.[293, 300, 301]

3.1.3 Extant PROMs for amblyopia and strabismus

Chapter 2 identified 32 extant PROMs developed for measuring the QoL impacts of

amblyopia and strabismus.[115] Of these, 18 PROMs have been used to study the impact on adolescents and/or adults: the amblyopia survey, socio-professional integration questionnaire, adult strabismus questionnaire, vision function scale, perceived visibility of strabismus, strabismus survey, disability questionnaire, repertory grid, psychosocial experience questionnaire, expectations of strabismus surgery questionnaire, effect of diplopia questionnaire, perspectives questionnaire, post strabismus surgery symptom questionnaire, psychosocial effects of strabismus pre and post-operative questionnaire, satisfaction of surgical outcome questionnaire, visual analog scale, amblyopia and strabismus questionnaire and psychological impact questionnaire.

Although all these PROMs were 'patient-reported', the only PROM that considered patients' perspectives in identifying themes that were important to them was the adult strabismus questionnaire (AS-20).[137] The AS-20, despite being patient-derived, does not address all QoL issues elicited by the qualitative research. Short-form questionnaires requires all respondents to answer all items, unlike item banks administered via CAT systems. Therefore, the number of items in AS-20 was reduced from 181 (extracted from qualitative study) to 20 in order to minimise respondent burden.[137] The complete set of initial items have been recently published.[277]

Out of all adult PROMs for amblyopia and strabismus, the AS-20 and the amblyopia and strabismus questionnaire (A&SQ) have been used widely. While the AS-20 measures the impacts caused by strabismus, the A&SQ aims to measure impacts caused by both amblyopia and strabismus. However, the content for A&SQ was not patient-derived; it was only in the later stages of development when patients were involved.[140]

As both these widely used PROMs measure impacts of strabismus, a recent study performed a combined analysis of their content to identify which QoL aspects were represented by these PROMs.[265] Using factor analysis, the study identified six factors, four of which were dominant QoL dimensions (in terms of variance explained): the first factor explained 23% of the variance and had items measuring psychosocial impacts from both questionnaires (8 from AS-20 and 5 from A&SQ), the second factor explained 18% of the variance and had items on depth perception (1 from AS-20 and 9 from A&SQ), the third factor explained 13% of the variance and had 7 items measuring functional limitations from AS-20 and the factor 4 explained 14% of the variance and had 7 vision-related items from A&SQ. Overall, the psychosocial QoL

dimension was well represented by both the questionnaires. The AS-20 lacked items specific to amblyopia such as fear of losing the better eye and the A&SQ items lacked items related to symptoms and functional limitations. The QoL issues related to depth perception was over-represented by A&SQ and least by AS-20.[265]

This quantitative factor analysis supports the qualitative content analysis (Table 2-7) which pointed out gaps in the content of extant PROMs in Chapter 2. Apparently, both these questionnaires are not self-sufficient in content to measure the impact of both amblyopia and strabismus nor combinedly-sufficient to address the multifaceted QoL issues which includes economic, emotional and convenience dimensions. The limited content of A&SQ can be attributed to the lack of patient consultation while identifying items and the preconceptions (*a priori*) held by the developers during construction.[265] Although the AS-20 stemmed from extensive patient consultations, the developers' primary focus was strabismus and not amblyopia.

Whether amblyopia and strabismus need separate PROMs for QoL measurement is currently a contested issue. While Vianya *et al*.[75] supports the need for individual PROMs catering strabismus and amblyopia based on the psychometric analysis of A&SQ, van de Graaf *et al*.[265] argues that a single PROM would suffice as both conditions co-exists in many cases. In-depth qualitative exploration of impacts faced by patients experiencing a range of amblyopia and strabismus diagnosis is crucial to answer this question and to develop a patient-centered PROM with sound content validity.

3.2 Aim and objectives

The aim of the study described in this chapter was to elicit concepts (identify content) for the development of the amblyopia and strabismus specific item banks for adults in Australia and India. Two qualitative studies were conducted – one in each country. The chapter reports and documents the qualitative findings to substantiate the content validity of the item banks developed.

The objectives were to

1) Identify the QoL dimensions that are important to adults with amblyopia and/or strabismus
2) Explore differences in perspectives and QoL experiences of adults in two economically and culturally different settings (Australia and India)

3) Compare the QoL issues faced by participants experiencing different amblyopia and strabismus diagnosis: isolated amblyopia, isolated strabismus and both amblyopia and strabismus

3.3 Methodology

This section describes the qualitative approaches, data collection methods, sampling and data analysis techniques pertinent to the development of PROMs. Evidences on best practices from the literature have been articulated.

3.3.1 Qualitative approaches

Several qualitative approaches are used in the health and social sciences to collect, analyse and interpret data and present results, of which ethnography, phenomenology and grounded theory are the most common.[87] These approaches vary in their focus, methods and goals; for example, ethnography focuses on understanding 'culture' while phenomenology focuses on understanding the 'experience of a phenomenon'.[290] The choice of the qualitative approach therefore depends on the research question – the focus and expected research outcome.

Combining phenomenological methodological approach with grounded theory data collection and analytical methods has been suggested by several authors as the best way to accurately incorporate the voice of patients into the development of PROMs.[287, 300, 302, 303] Phenomenology focusses on how people experience a particular phenomenon such as a disease or its treatment and seeks to understand the meaning of the lived experiences through the eyes of the stakeholder (patient) themselves.[287, 290] Whilst phenomenological approach helps in eliciting concepts that are important to patients, grounded theory methods enables generation of concepts that is grounded in empirical data through the process of inductive reasoning (bottom-up approach).[87, 287]

Grounded theory in its purest form is free from preconceptions about the concepts of interest.[293] However, in the development of PROMs, this approach is adapted, allowing for 'sensitizing concepts'.[293, 300] Sensitizing concepts are not definite concepts; they act as starting points and guide the research focus.[304] According to the sociologist Blumer, these do not prescribe the outcome of the research but rather suggest the direction in which the researcher should look.[305] While conducting qualitative research for the development of PROMs, extant literature, expert opinions and/or clinical experience of researchers are used to sensitize concepts and build interview guides

that would facilitate data collection.[302] These guides are semi-structed, open-ended, not read verbatim, flexible and adaptable (include new concepts that emerge from iterative analysis of data).[287, 293]

3.3.2 Qualitative data collection methods

Qualitative interviews and focus groups are commonly used to elicit concepts and identify items for the construction of PROMs.[300] Both these methods have inherent advantages and limitations. The most striking difference between the methods is that focus groups enable exploration of a range of perceptions and experiences through group dynamics and interactions while interviews enable an in-depth exploration of an individual's experience, especially areas of life that may be sensitive to disclose in public.[293] Employing both focus groups and interviews for investigation enhances the rigour of the qualitative study as they provide two different viewpoints;[302, 306] however, resources available, budget and practical constraints influences the method of choice.[307]

3.3.3 Sampling

Unlike quantitative research that emphasizes on random selection of subjects by probability sampling, qualitative research advocates purposive selection of participants whose experiences are relevant to the topic under study, by theoretical sampling.[293] The goal is not to have a representative sample but to have a sample with a range of representative experiences.[287] In order to adequately embrace the range of experiences, especially for concept elicitation purposes, participants with diverse clinical and demographic characteristics which are similar to the target population should be included.[303]

Saturation is the end point of data collection in qualitative research.[308] Saturation is considered to be achieved when no new concepts (themes) or concept-relevant information is being elicited by the data collection.[295] The attainment of saturation is crucial to ensure that the items generated out of the qualitative study represents the universe of content pertaining to the concept under exploration.[295] Although sample size estimations are irrelevant in qualitative research, researchers have pointed out that saturation generally occurs with four to six focus groups[306] and twelve interviews,[309] independent of each other. However, this number may vary depending on the research question and the diversity of the experiences within the sample.[293]

3.3.4 Data analysis

In qualitative research, data analysis is performed alongside data collection, iteratively.[287] According to the International Society for Pharmacoeconomics and Outcome Research (ISPOR) task force report, the goal of analysis in the development of PROMs is "*to understand, organize and communicate the meaning of data and translate that meaning into a set of items that can be scored to represent the targeted concept(s) quantitatively*."[300]

This is achieved by adopting the grounded theory approach to analysis. Transcribed verbatim of the audio or video recorded focus groups or interviews are first familiarised by the researcher by reading it several times (data immersion).[310] The data is then coded inductively by a method of constant comparison.[293, 303] The constant comparison technique enables the researcher to compare and contrast the experiences narrated by participants within and across transcripts, iteratively.[287, 303] The inductive coding process ensures that the idea/concept generation from patients are not biased by the concepts generated prior to the research (sensitising concepts).[300, 311] Coding is done using expressions and phrases used by the patients and broader themes (domains) are aggregated from specific concepts (items). The broader themes together represent the core PRO concept (e.g. QoL).[303]

3.4 Study methods

To address the aims and objectives of this chapter, two independent qualitative studies were conducted in Australia and India. The study in India was initiated on completing the study in Australia. The methodological principles described above underpinned both the studies: a phenomenological approach, purposive sampling and grounded theory-based methods and analysis (inductive coding and method of constant comparison) were adopted.

The study was approved by the Southern Adelaide Clinical Human Research Ethics Committee, Australia (Approval number: 469.11, Appendix 2) and the Research cell committee, Vision Research Foundation, Sankara Nethralaya, India (Appendix 3). It adheres to the Tenets of declaration of Helsinki for human study.

3.4.1 Preparation

In the preparation phase, collaborations were established with various eye care

providers in Australia and a tertiary eye care hospital in Tamil Nadu state of India for potential recruitment of participants. An information pack (Appendix 5) consisting of written information about the research and an informed consent was developed in English and Tamil (main language spoken in Tamil Nadu). A semi-structured interview guide was formulated in both languages to facilitate data collection (Appendix 6). The guide was developed based on the sensitising concepts that were elicited based on extant literature (Chapter 2) and my previous clinical experience. It contained open-ended questions that tap into the various aspects of QoL such as difficulties in performing activities of daily living, work, social and emotional impact. The drafted interview guide was validated by my supervisors, who verified whether the guide comprised open-ended questions and covered all important aspects of QoL identified in the systematic review in Chapter 2.

3.4.2 Participants

3.4.2.1 Inclusion criteria

Participants over 18 years of age, with a primary diagnosis of amblyopia or strabismus were eligible to participate in the study. Those with any co-existing ocular morbidities that may affect QoL (e.g. glaucoma, diabetic retinopathy), known cognitive impairment or psychological disorders were excluded.

The study adopted the modern definition of amblyopia used by the Dunedin multidisciplinary health and development study (2013)[6] which defines the presence of amblyopia as 'best corrected visual acuity of 6/9 or worse in at least one eye without any underlying organic cause'. The current definition was preferred instead of the classical definition (visual acuity cut off of 6/12), in order to be inclusive of individuals with milder form of amblyopia (best corrected visual acuity of 6/9 to 6/12 in the amblyopic eye).[80]

The classification proposed by Attebo *et al.* was used to classify amblyopia.[7, 8]

i. Anisometropic amblyopia was defined as amblyopia in the presence of at least 1 dioptre of refractive error difference between the eyes in any optical meridian, in the absence of strabismus.
ii. Strabismic amblyopia was defined as amblyopia in the presence of heterotropia or microtropia, in the absence of anisometropia or high ametropia (high refractive errors).
iii. Mixed or combined mechanism amblyopia was defined as the co-existence of

anisometropic and strabismic amblyopia.

iv. Deprivational amblyopia was defined as amblyopia that resulted from obstruction of vision during the critical period of visual development due to causes such as congenital cataract or high ametropia.

Isolated strabismus was defined as the presence of heterotropia in the absence of amblyopia.[145, 183] This included strabismic participants who had been successfully treated for amblyopia (e.g. history of strabismic or combined-mechanism amblyopia), strabismic patients who never had amblyopia (e.g. alternating exotropia) and acquired strabismus (e.g. cranial nerve palsies).

3.4.2.2 Recruitment

For the Australian study, participants were recruited from Optometry and Ophthalmology practices in South Australia and Victoria, Australia. Information about the research and inclusion criteria was shared with the eye care practitioners, who referred eligible patients for the study. In addition, participants were recruited from the community through flyers and newspaper advertisements. For the Indian study, all participants were recruited prospectively from the amblyopia outpatient department of a tertiary eye care hospital in Tamil Nadu, India, by a research collaborator.

All eligible participants in both studies were provided with the written information pack and participation was voluntary. Participants signed an informed consent to take part in the study and provided an additional consent to access clinical details about their eye condition such as ocular diagnosis, best corrected visual acuity, ocular deviation and refractive error from their eye care practitioner; some self-reported their clinical details. They also provided demographic details such as age, gender, country of birth, education and marital status.

3.4.3 Procedure

Depending on logistics and convenience, participants in Australia chose to participate in either focus group discussions or individual interviews (face to face or telephonic). A time was fixed with the participants and they were reminded 2-3 days before the scheduled date. Focus group discussions and face to face interviews were conducted in a facility at Flinders University, Adelaide. English was the medium of communication.

The participants from India were interviewed via telephone from Adelaide. A time was fixed with the potential participants by the research collaborator in India, keeping in mind the time difference between India and Adelaide. All telephone calls were made in a private space in Flinders University and interviews were conducted in either English or Tamil, based on the participant's preference.

Despite differences in recruitment and data collection methods, the same protocol and analytical techniques were followed in both studies; these are described below.

All discussions and interviews were based on the interview guide and was facilitated either by me or a co-researcher. Both had prior training/experience in qualitative research, data acquisition and analysis. The sessions were recorded using a digital audio recorder. The sessions started with a brief introduction about the research and the participants were asked to describe their eye condition and the experiences relevant to their eye condition and its treatment. Open-ended questions and probes were used to guide the discussion; however, the interviewer was sensitive and open to the emergence of newer concepts. Any new concepts that emerged were pursued by emergent probing and were iteratively incorporated in the guide for exploration in subsequent interviews. Notes were taken during the sessions and the interviewer summarised the key points at the end. Before the closure of the session, the participants were encouraged to articulate any other experiences that were not covered in the session. The sessions concluded with a thank you note. All participants who participated in focus group discussions or face-to-face interviews received AUD20 as reimbursement for travel expenses. Data analysis was pursued alongside data collection and data collection was pursued until thematic saturation was achieved.

The focus groups and interviews were transcribed; all transcripts were imported, stored and managed by the NVivo qualitative data analysis software, QSR International Pty Ltd. Version 11, 2015. The transcripts were familiarised, coded inductively and analysed iteratively using a method of constant comparison. The words and phrases used by participants to describe their experiences were used to code the data to closely represent the perspectives of the patients. The study in India had interviews in English and Tamil languages; however, for uniformity and ease of analysis, the interviews in Tamil were also coded in English by conceptual translation. Following the process of coding, codes describing similar concepts were aggregated to form categories and relationships between different categories and participant's characteristics were explored to form emergent themes. A case classification sheet

created in the NVivo 11 software to classify participants by clinical and demographic characteristics was used to facilitate the process. All coding was performed by me and was validated by Dr Jyoti Khadka and any discrepancies were resolved by discussion. The final categories and emergent themes were confirmed by the panel comprising of the PhD candidate, Dr Jyoti Khadka and Prof Konrad Pesudovs. The goal of this entire process was to determine emergent themes that signify the impact of amblyopia and strabismus on QoL and to identify potential items for the item banks. The process by which items were extracted from the participant narratives is described elsewhere in Chapter 4.

To address the secondary objectives, the themes that emerged from the studies in Australia and India were compared for meaning qualitatively. Next, the data from both studies were integrated and the QoL experiences of participants with isolated amblyopia, isolated strabismus and amblyopia associated with strabismus were compared; a matrix coding query was run in NVivo 11 software to facilitate the comparison of participant narratives and occurrence of topics (QoL issues underlying each theme) across diagnosis.

3.5 Results

3.5.1 Sample characteristics

A total of four focus groups comprising of 16 participants and 33 individual interviews were conducted in Australia and a total of 30 individual interviews were conducted in India. The demographic and clinical details of the participants are displayed in Table 3-1.

3.5.1.1 Study 1: Australia

Forty-nine participants took part in the qualitative study conducted in Australia. Out of them, 16 participated in one of the four focus group discussions and others took part in in-depth individual interviews (face to face interviews, n=3 and telephonic interviews, n=30). The duration of the focus group ranged from about 35 to 52 minutes and the interview sessions ranged from about 6 to 42 minutes. Saturation was obtained in the focus groups and interviews.

The median age of the participants was 54 years (range: 21 to 82 years) and 21 (42.9%) were male. Of the 49 participants, 37 had amblyopia (strabismic n=23, anisometropic n=5, combined-mechanism n=7 and deprivational n=2) and 12 had

strabismus without amblyopia (isolated strabismus). Out of those with isolated strabismus, two had been successfully treated for amblyopia, four had congenital esotropia, two had alternating exotropia, one had decompensated fusional vergence causing exotropia and three had a sixth nerve palsy. All participants were residents of Australia, which was the country of birth for all except 10. More participant characteristics are provided in Table 3-1.

3.5.1.2 Study 2: India

Thirty participants from India participated in an in-depth individual interview. The duration of the interviews ranged from about 7 to 40 minutes. The median age of the participants was 23.5 years (range: 18 to 36 years) and 21 (70%) were male. Of the 30 participants, 7 had strabismic, 15 anisometropic and 8 combined-mechanism amblyopia. The country of birth all participants was India and participants were from various Indian states: northern (Himachal Pradesh, n=1; Uttar Pradesh, n =1), southern (Tamil Nadu, n= 17; Karnataka, n = 1), central (Madhya Pradesh, n= 2), eastern (Bihar, n= 3; West Bengal, n=3) and western (Maharashtra, n=1; Gujarat, n=1). 17 interviews were carried out in English and 13 interviews were carried out in Tamil. More participant characteristics are displayed in Table 3-1.

Table 3-1 Participant characteristics - Australia and India

Clinical and demographic variables	n (%)	
	Australia (n=49)	India (n=30)
Diagnosis		
Strabismic amblyopia	23 (46.9%)	7 (23.3%)
Anisometropic amblyopia	5 (10.2%)	15 (50%)
Combined-mechanism amblyopia	7 (14.3%)	8 (26.7%)
Deprivational amblyopia	2 (4.1%)	
Isolated strabismus	12 (24.5%)	
Visual acuity in the amblyopic eye		
0.2 to 0.5 logMAR (6/9.5 to 6/19)	13 (35.1%)	17 (36.7%)
0.6 to 1 logMAR (6/24 to 6/60)	8 (21.6 %)	12 (40%)
> 1 logMAR (> 6/60)	9 (24.3%)	1 (3.33%)
Ocular deviation (among those with strabismic /combined-mechanism amblyopia and isolated strabismus)		
Type of deviation		
Horizontal	32 (80%)	10 (66.7%)
Vertical	3 (7.5%)	
Oblique	4 (10%)	2 (13.3%)
Microtropia		3 (20%)
Orthotropic after strabismus surgery	2 (5%)	
Magnitude		
less than or equal to 25 prism dioptres	18 (45%)	9 (60%)
greater than 25 prism dioptres	11 (27.5%)	4 (26.7%)

Prior treatment/s		
Refractive error correction	33 (67.4%)	28 (93.3%)
Patching therapy	22 (44.9%)	22 (73.3%)
Atropine	4 (8.2%)	
Vision therapy	4 (8.2%)	18 (6%)
Prism glasses	6 (12.2%)	1 (3.3%)
Strabismus surgery	17 (34.7%)	1 (3.3%)
Education		
Post-graduation	7 (14.3%)	4 (13.3%)
Bachelor's degree	10 (20.4%)	14 (46.7%)
Undergraduate, diploma or certificate	19 (38.8%)	9 (30%)
No post school qualification	9 (18.4%)	3 (10%)

Sum of the percentages for some variables may not be 100% due to missing data

3.5.2 Themes

Eight themes signifying the multifaceted impact of amblyopia and strabismus on QoL emerged from the qualitative analysis of both studies. These themes were similar in both Australia and India; the number of coding references underlying these emergent themes and the number of participants who endorsed each theme from either study are displayed in Table 3-2. As described in section 3.3.3 concepts rather than frequencies (number of occurrences) are important in qualitative studies; sometimes the rarest finding might be the most significant one that positions other findings in context.[308] Therefore, the numbers in Table 3-2 are reported solely for documenting that similar themes emerged from both studies and should not be used for quantitative inferences.

Table 3-2 Themes, number of participants who endorsed each theme and the number of coding references from qualitative studies conducted in Australia and India.

Themes	Australia No. of participants (No. of coding references)	India No. of participants (No. of coding references)
1. Symptoms associated with amblyopia and strabismus	48 (508)	30 (270)
2. Functional limitations in everyday life	47 (590)	28 (182)
3. Concerns posed by the eye condition	49 (1240)	30 (423)
4. Impacts on social life and participation	38 (199)	16 (106)
5. Impacts on emotional wellbeing	49 (489)	19 (68)
6. Impacts on study, work and finance (Economic impact)	38 (165)	19 (68)
7. Inconveniences associated with the eye condition	46 (304)	26 (120)
8. Adaptation and coping strategies used to combat the impacts	48 (432)	28 (114)

The rest of the results section is divided into three sections. The first section describes

the eight emergent themes in detail by consolidating the experiences of participants with a range of amblyopia and strabismus diagnosis from both Australia and India data. Each theme is substantiated by direct illustrative participant quotes.

The second and third sections presents the differences in experiences and perceptions that were identified between the two studies (Australia versus India) and across participants with different amblyopia and strabismus diagnosis (isolated amblyopia versus isolated strabismus versus amblyopia associated with strabismus) respectively.

3.6 The multifaceted QoL impact of amblyopia and strabismus: Emergent themes

3.6.1 Theme 1: Symptoms associated with amblyopia and strabismus

Participants enumerated several visual, ocular and general symptoms they thought were associated with their eye condition (Figure 3-1). These include poor vision in the amblyopic eye, misalignment of eyes (strabismus), double vision, eye strain, glare, increased sensitivity to light, headaches and watery eyes.

> *"It [left eye] is more sensitive to light. I have to shut it or like keep one eye closed when going into an exceptionally bright room or something." IND INT 14*
>
> *"Your eye just gets tired because you're actually trying to work it harder." AUS FGD 1.2*
>
> *"I have no vision in it and it sort of angles outwards, I should say, so I don't have straight vision in both eyes." AUS INT 15*

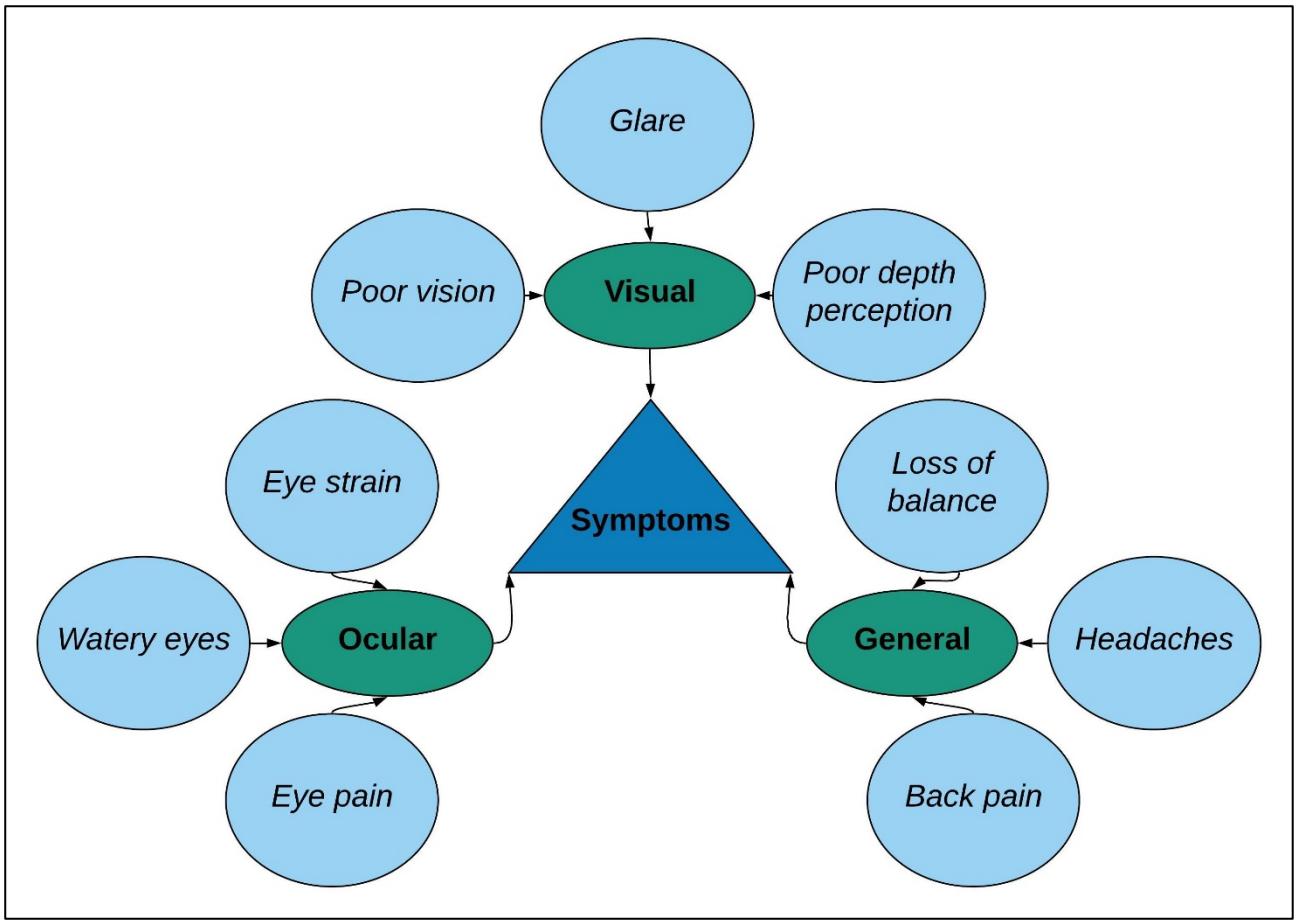


Figure 3-1 Examples of symptoms reported by study participants

They also had trouble in concentrating, focussing eyes, judging distances/ depth and eye-hand coordination, visual disorientation (confusion) and loss of balance.

> *"Yeah, it [pouring liquids, using tools] was a bit dis-co-ordinated. I have difficulty in gauging distances." IND INT14*

> *"I just tend to trip over a lot. I don't know if it's just how I grew up or I'm just one of those people who lacks balance and a general sense of co-ordination." AUS INT 29*

Abnormal head turn and tilt due to the eye condition, altered body posture (spinal issues), back and neck pain were also reported.

> *"I look at the TV on a side angle and stuff and when I talk to people, I still look at people on the side angle to compensate I guess…" AUS INT 12*

> *"My posture has been affected because I have a head tilt. That's put my spine out so that's been a major problem…" AUS INT 18*

"I've been told by people that I have a head tilt when I'm trying to write things, closely to things, but I don't notice it myself. I've had my chiropractor say that I have got a slight bend in my spine, probably because of it" AUS INT 19

Participants felt that the symptoms they faced influenced their QoL by affecting tasks they could perform and narrated several lived experiences that signified the impact (Figure 3-2).

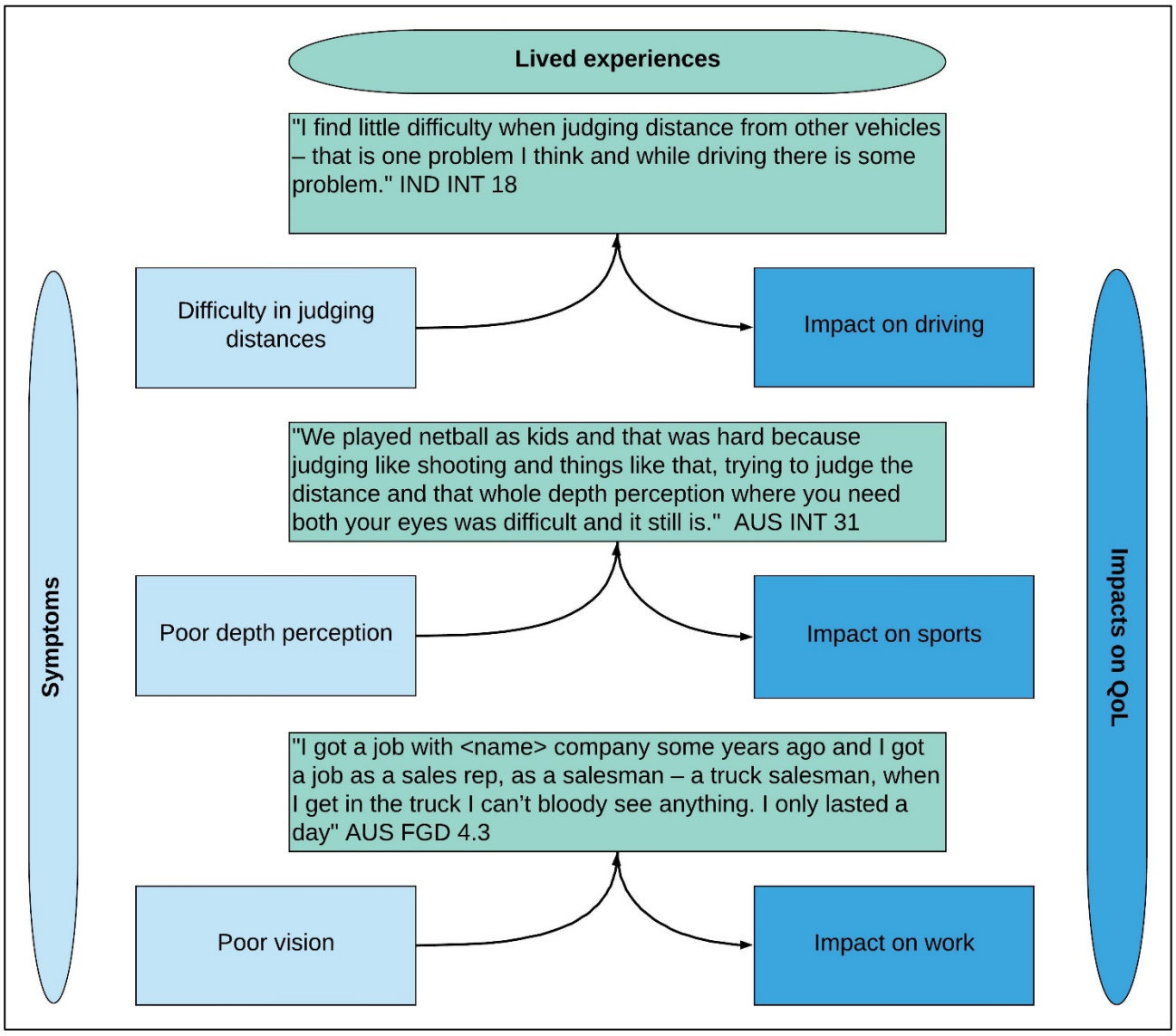


Figure 3-2 Examples of lived experiences signifying the influences of symptoms on QoL

3.6.2 Theme 2: Functional limitations in everyday life

Participants admitted that their eye condition was associated with several functional limitations. Five subthemes describing impacts on 1) driving cars and riding

motorbikes, 2) reading, 3) sports, 4) mobility and 5) other everyday tasks lead to the emergence of this broader theme (Figure 3-3).

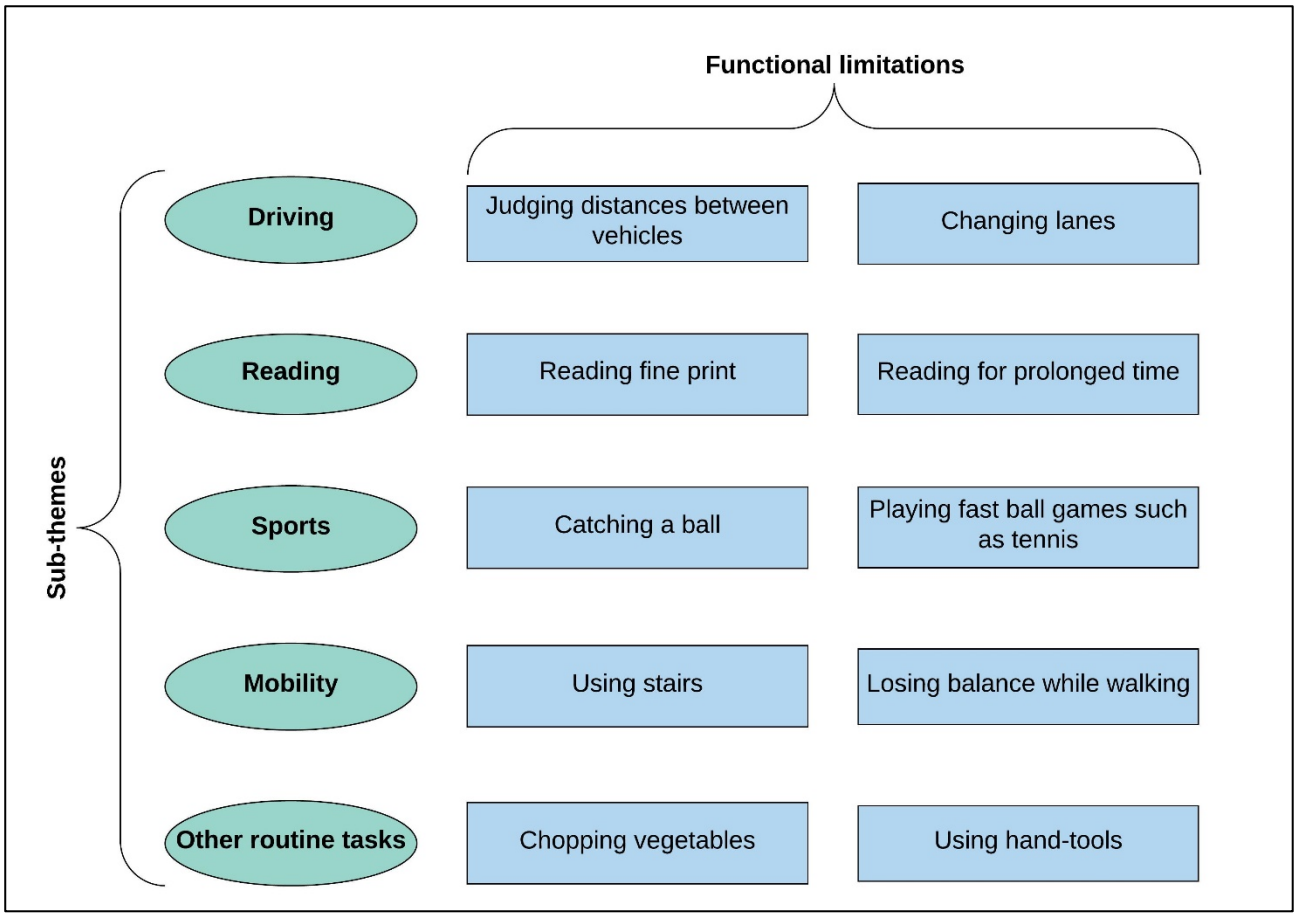


Figure 3-3 Sub-themes that lead to the emergence of the broader theme 'Functional limitations' with examples of limitations experienced by participants

3.6.2.1 Subtheme 1: Impact on driving cars & riding motorbikes

Participants described difficulties they faced in driving cars and riding motorbikes, especially at night-time. Difficulty at night was mainly due to glare from headlights of oncoming vehicles and difficulty in seeing.

> *"Yeah yes riding my bike during night very [inaudible] wearing glasses but I don't know if it happens to me only or others also... I can't bear the beam of light coming towards me. I have to stop my bike aside so that the opposite light, the vehicles pass. Couldn't bear any of the beam of light, during night" IND INT 24*

> *"I stopped riding at night because at night was so hard. I couldn't see the lines and it was just getting too dangerous, so I stopped riding at night." AUS FGD 1.1*

They articulated difficulties in parking, particularly parallel parking and reversing the

car. These difficulties were attributed to poor judgement of distances and inability to see through the affected eye.

> *"I don't do much of the parallel parking. Never liked parallel parking and that could well be because of my eyesight because you do back in onto your left and that's where my judgment isn't so good." AUS INT 20*

Trouble seeing road markings, speed breakers, street signs and noticing things (other vehicles, pedestrians) on the side of their affected eye while driving were reported.

> *"At night-time when I went - when I'm driving bike, I am not able to see the speed breaker... I go with speed." IND INT 26*

> *"While driving my car, many have told that I am not seeing properly the things on my left side and I go very close to it as though I am going to crash onto something." IND INT 10 (translated from Tamil)*

Changing lanes in traffic, judging the lane of the oncoming traffic at intersections and gauging the speed of other vehicles ahead of them were challenging.

> *"For instance, another example would be if I'm at a major traffic intersection and its dual lane and I have traffic approaching me, from a distance I have no idea what lane they're in, so I just have to be patient." AUS INT 4*

> *"Whenever I drive the car, I used to go very close and do the brake. So my friends used to advise me, they used to ask me 'why are you going so close and doing it?' you are putting brakes very close by - so I just think that like it should be either my miscalculation or like a – I am not able to understand, but I do that one" IND INT 9*

Participants recalled car scratching, crashes and accidents which they attributed to their eye condition. Being cautious, they tend to maintain a safe distance from other vehicles and avoid long drives.

> *"Driving was – I haven't tried it now but before I couldn't judge what speed we were going. Like the faster I'd go the – like I can't see the depth so I'm not sure how fast – like I'm not sure how fast we were going so I always end up crashing and I can't see over there so I usually crash into something because I can't see peripherally; it was very dangerous." AUS INT 12*

> *"I don't know if I drive more carefully because I'm generally accident prone. I've always been a bit clumsy." AUS INT 29*

3.6.2.2 Subtheme 2: Impact on reading

Despite good visual acuity in the non-amblyopic eye and near correction for presbyopia, participants articulated problems in reading fine prints such as the phone book, prints on coloured backgrounds and certain type of fonts (e.g. Times New Roman).

> *"I still can't read the phone book, no matter what the glasses prescription is, it's too small. I can't read the Rolodex either." AUS FGD 3.1*

> *"Reading's the worst… Eye strain. Times New Roman is the worst possible script. Absolutely hopeless." AUS FGD 1.3*

They had difficulty in reading closely spaced content and missed words /numbers while doing so.

> *"I used to have trouble with was adding up long columns of figures on lined paper and I would miss figures or do one twice." AUS FGD 2.3*

Reading for a long time caused symptoms such as eye strain, headaches and watery eyes which deterred many from reading.

> *"I think after reading [for] a long time then my eye starts watering. After continuous reading then my eye pain starts." IND INT 20*

> *"When I'm trying to read long documents, that's when it [eye] starts to get strained." AUS INT 19*

Some felt that their ability to read at a fast pace was affected because of their eye condition. Reading from boards and overhead screens during academic or work-related presentations were troublesome.

> *"I am not a fast reader. I have problem reading. I read quite well but when compared to others, I feel I could read much faster if my vision was alright." IND INT 11 (translated from Tamil)*

> *"I'm not able to see things clearly when written on the board – that too when I am sitting in the back bench." IND INT 18*

Closing the amblyopic eye alleviated problems and eased reading efforts for some.

> *"If I go outside and I've got to try and read 'meeting room' and I strain my eyes I have to virtually close my right eye." AUS FGD 1.4*

"Yeah when you get down to the small numbers on texting you've got to close your eye and pull it around, yeah." AUS FGD 1.5

3.6.2.3 Subtheme 3: Impact on sports

Playing ball games, especially catching and hitting a ball was challenging.

"The thing that I find is that right through my life, through sport and so forth, I can't even catch a ball type of thing and that annoys me. Grandchildren throw a ball at you and you can see it coming but you just can't catch it." AUS FGD 1.5

"I find it difficult sometimes to catch the ball. I don't have problem when the ball comes straight to me. But when it comes from above, I find it hard" IND INT 11 (translated from Tamil)

Fast sports such as cricket and tennis were hard due to difficulties in seeing the ball in motion and judging depth, distances and direction of ball movement.

"I had a lot of problems playing sport and just really - because we had to play sport in school so I'm just generally terrible at sport now. Anything that involves a small ball I can't see, can't follow it, can't play it." AUS INT 29

"…sports like netball, basketball, I was okay at because the ball was bigger but the smaller sports, yeah, trying to co-ordinate the ball to hit the racquet as it was supposed to was - yeah, that's why I hated tennis and I still hate tennis to this day." AUS INT 31

Fear of getting injured in the eye while playing sports impacted their confidence and their ability to play well. Injuries associated with sports were reported.

"I will be very careful while playing that the ball should not hit my eye. When I field in cricket, I stand very far. I don't stand closer. I think to myself that it is okay to miss the catch. It is okay to get out than to get hurt in the eye" IND INT 3 (translated from Tamil)

While some participants expressed concerns about not being selected for team sports, others were concerned about failures and refrained from engaging in sports.

"…it made you more introverted and because you weren't chosen for sporting teams - as you were saying you're the last one in the line as far as catching balls and things like that went - you were left out…" AUS FGD 2.2

"I tried but would try out and would fail miserably. I played basketball and I played tennis and I've done all of that, but I've only played the occasional game and it was just

humiliating so I just never went back and did it." AUS INT 30

Athletics, swimming, rowing and horse riding were some activities that participants preferred to engage instead of ball games.

"I wasn't sporty because I could never see the ball or ball sports, and yet when I was in my 40s, I took up rowing and that was fine because I didn't need to have that hand eye co-ordination, it was just hand." AUS FGD 3.2

3.6.2.4 Subtheme 4: Impact on mobility

The eye condition impacted the ability of the participants to walk / navigate safely. Using stairs, especially stepping down steps and curbs, was challenging and was attributed to poor judgement of depth. As a result, some avoided stairs or were extremely cautious while using them.

"I think I feel afraid when I'm climbing down [stairs]. I think that is because of this amblyopic I think" IND INT 4

"Stumbling was pretty often. The stumbling, the depth perception, the distance and depth perception was a bit off" IND INT 14

"I avoid stairs if I can and tend to do one step at a time. I avoid stairs if I can because I can be a bit clumsy on them." AUS INT 30

Trouble crossing road, judging doorways and negotiating obstacles on the path was reported. These were attributed to poor vision and lack of peripheral awareness in the amblyopic eye.

"I do because I can't really see out of that right – like if I'm looking at a road to cross it I don't trust my right eye, so I do look a couple of times properly because I can't sort of see to my far right out of" AUS INT 1

"Sometimes, it happens. When I walk, something might be straight ahead of me, but I wouldn't have noticed it. So, I slip" IND INT 23 (translated from Tamil)

Participants reported that they lost balance while walking and often bumped onto things.

"Well I move over that way and when I'm near people I'll be very, very careful I don't bump into them because I'm walking straight and all of a sudden I'll lose my balance and I have to do a dodgy trick and get out of it or otherwise I'll be bumping into them." AUS FGD 2.5

"I used to walk very crooked, I walked like a drunk person, and whenever I walked down the street with my boyfriend or my sister or something, or friends, I constantly walked into them because I just zigzagged. I don't know why, but I always have." AUS INT 12

Falls and accidents due to these challenges were recalled.

"Again, on the blind side, if I'm going to bump into anything… Mind you, I did have one big one, one day when I tripped myself up and fell flat on my face and broke both my elbows and I was cold stone sober at the time. No, I've managed to maintain my footing most of the time, but just again on that blind side, that shadowy side." AUS INT 17

"There was one occasion when I was actually very frightened. Climbing down a glacier in New Zealand and I hadn't – of course ice was carved into steps and there was just a bit of a rope to hold onto and – wearing crampons on boots – but if I'd just slipped or tripped it was about half a kilometre down to the ground and so all this ice, the same colour without binocular vision to tell exactly where the edges of each step were, trying to lift my feet over each one was – it was really scary." AUS FGD 4.2

3.6.2.5 Subtheme 5: Impact on other everyday tasks

Participants described themselves as 'being clumsy' as they faced challenges in cutting and chopping vegetables safely, pouring a drink without spilling and picking or putting back cups on the table without dropping.

"When I'm chopping vegetables, cutting things, you know. Yeah, I'm likely to cut my thumb off. Kids used to say, 'oh God we're going to be eating tomato sauce again; mum's cut her finger'." AUS FGD 1.1

"…there are times when I try to pour the liquid in the glass, and it will spill out. There are times and it's maybe because of my eye problem…" IND INT 18

"Reaching and grasping I find are hard, like I can get a cup" AUS INT 18

Limitations in seeing 3D movies, doing fine tasks, using mobile phones, hand tools and instruments such as stereomicroscopes that require binocular viewing were reported.

"I tried once but I didn't see any significant difference – that is normal for me; I can't see 3D." IND INT 13

"Yeah but I find it annoying when I'm trying to do something – as I say, that game or

typing – I'm always hitting the wrong key, even when I'm texting. The key on the sides but not the key I want." AUS FGD 1.1

"Another thing is too is – now you'll laugh at this – is putting the screwdriver into the head of a crew. I've been in the building industry for 40 odd years and when you get down to those fine things you've really got to close your eye and concentrate on the other eye to get that screwdriver to do the screw." AUS FGD 1.5

Participants also expressed that their eye condition impacted grooming and personal care.

"It's frustrating when you're shaving in the morning. You've kind of got to look that way and so I have to close my left eye so I can see the left side of my face and that sort of thing" FGD 2.4

"And sometimes, you know, when I have to put eye liner also, I am not going to do that because when I close my left eye, I notice all the things go blurry and without lenses it is even difficult to differentiate what is that thing or… obviously it is kind of painful to believe that" IND INT 18

3.6.3 Theme 3: Concerns posed by the eye condition

Participants expressed numerous concerns and worries they had in relation to their eye condition, treatment and its impact on them (Figure 3-4). These are described below.

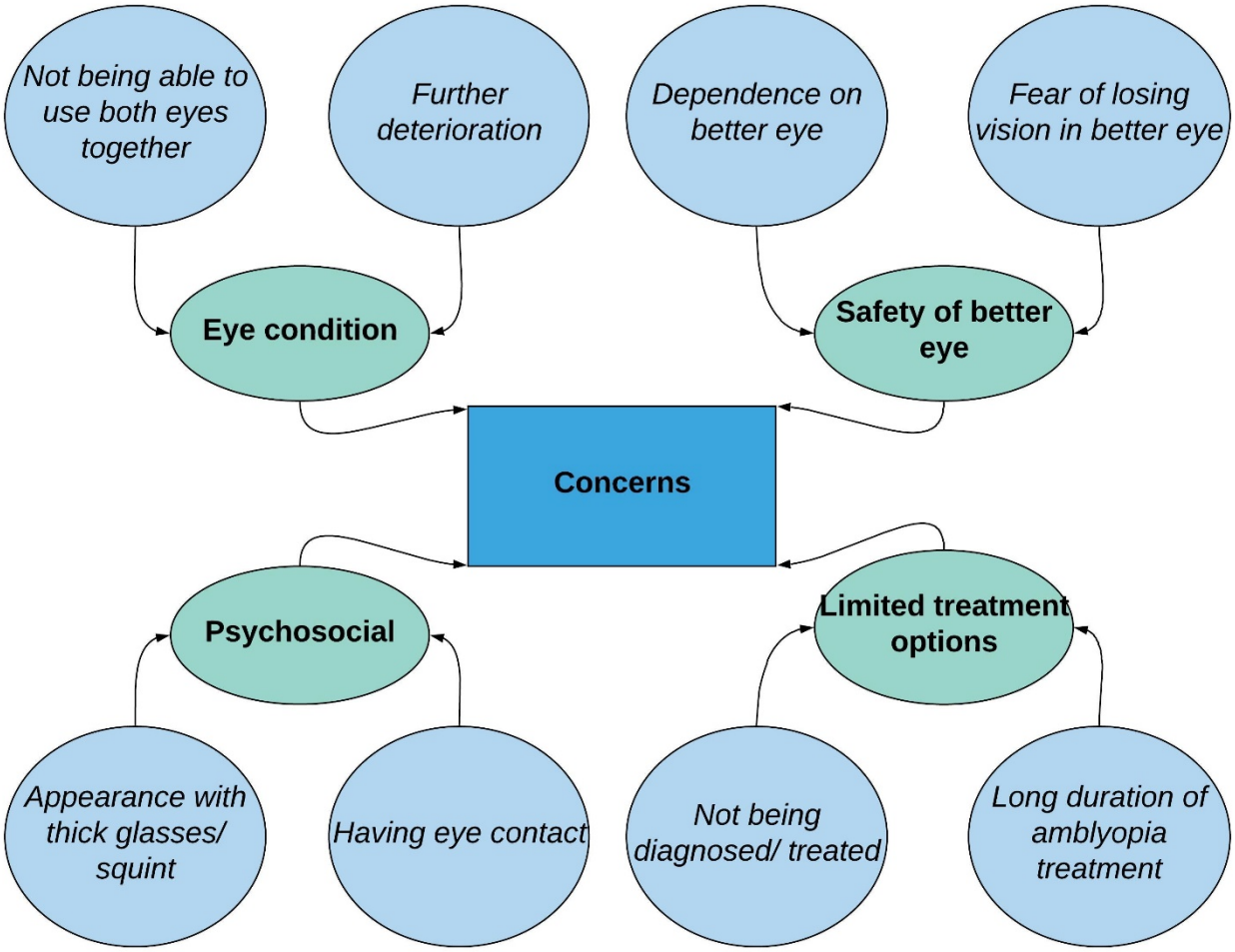


Figure 3-4 Examples of concerns reported by participants

3.6.3.1 Concerns about the eye condition

Participants were concerned that they are not able to use both their eyes together effectively.

> *"One thing is… I feel if I am able to use both my eyes properly, I will be able to read fast. It will lead to better perception. But I don't know if that is true!" IND INT 11 (partially translated from Tamil as participant used both Tamil and English)*

Fear that their eye condition may deteriorate further was present in some. Participants using prismatic glasses for alleviating diplopia (isolated strabismus – paralytic) were concerned if their condition would deteriorate to a point where it cannot be corrected by prismatic glasses.

> *"Well, I'm not a highly anxious, worrying person, but it's something I've thought of, how much further it is going to deteriorate, yes." AUS INT 21*

> *"I have a fear that – because two years later I had the glasses re-done, just with a*

matter of time, and yeah I have a fear - I hope they don't run out of options for the prism they put in it. I think they can still play around with prisms until I die probably." AUS INT 2

The other concern participants had in relation to their eye condition was whether their eye condition was hereditary. They worried about the possibility of their children inheriting the eye condition. Being cautious, they were watchful for any signs of visual problems in their children and made sure they had regular eye examinations.

"My only concern is whether my eye condition is hereditary. I enquired the doctor if anything might happen to my child" IND INT 10 (translated from Tamil)

"I've already taken them [my sons] to the eye doctor to have their eyes checked because I know the issues I went through and I don't want them to…" AUS INT 31

3.6.3.2 Concerns about the safety of the better eye

Fear of losing eyesight in the better eye was predominant among participants with amblyopia. They were concerned about the safety of the non-amblyopic eye and worried about getting injured or age-related disease.

"I always make sure that if I'm mowing the lawn or doing whipper snipping, anything like that, that I wear safety goggles because I can't afford to get a stick or something in my good eye." AUS INT 27

"Only one eye I have, and I have to protect that. I have got power [refractive error] in that [good eye] also – because I am using only that eye you know... I'm more worried about the good eye than the bad eye." IND INT 4

The sole reliance on the better eye underpinned this concern and made participants overly conscious, sensitive and protective about their eyes. Some even refrained anyone from going near or touching their eyes, even for the sake of an eye examination.

"What I feel is in my whole life is I should take care of my right eye and I should use my right eye perfect to avoid any problems in the future." IND INT 30

"I've had a real phobia with anyone going near my eye." AUS INT 1

They believed that their better eye worked hard to compensate for the affected eye and wondered if their amblyopic eye would start to function in case something happens to their better eye.

"I have really good vision in my left eye so it's obviously doing double the work almost." AUS INT 13

"If I damage that one good eye then, well, I don't know if the other eye can be fixed. I don't think it can be, so you can't really take risks." AUS INT 4

These concerns increased with age due to perceived vulnerability of eye problems.

"As I get older, I wouldn't like to think my right eye would deteriorate in sight because I know that I can't see well enough out of my left eye to cope. That'd be the main problem that I - you know, I would hate for me - I'm nearly 58." AUS INT 27

3.6.3.3 Concerns related to treatment

Participants were predominantly concerned about the lack of definite cure for amblyopia and the limited options they had.

"When I was a kid I had – the doctors, they were always arguing over whether I should have a patch on the good eye…" AUS FGD 1.5

"I feel no one will feel good with this eye condition. Everyone wants their eye to be okay... But, what to do… I went almost throughout India for this request. But they said they could not operate, laser operation or anything" IND INT 24

They expressed grief for not being diagnosed at a younger age or not treated appropriately.

"My parents did not find that I have a problem. I have never checked my eyes in hospital, before one week, I had a hurt in my head and I went to hospital and checked my eyes, the doctor said that my left eye is so weak and it's so lazy…" IND INT 16

"When I was three my mum noticed it turned in and went to a doctor while we were still in England and I was too young for any treatment. When we got over here I was five and a half. Took me back to a doctor who said oh no, I was too old; she should have brought me when I was younger." AUS FGD 2.1

The long duration of patching therapy for amblyopia and the slow visual prognosis discouraged participants from adhering to treatment in childhood.

"Yeah past year three but it was weird because I wanted to make my eye better but it just – it was getting better too slowly and, as I said to you, the headaches were just unbearable… If my eyesight was progressing better, say, I don't know, ten percent better per year, I most probably would have stuck with it [treatment]." AUS INT 4

Non-compliance to treatment as a child was a source of guilt in adulthood as participants regretted not taking care of their eyes.

> *"Unfortunately, I was very kiddish [childish]. I just left it all [treatment]. I didn't take it as a serious issue. I don't think I took it right. If I had taken it seriously, I would have avoided these kinds of issues." IND INT 9*

Some of them who persevered through amblyopia treatment as a kid or adult felt that after all the efforts they had put in, the improvement was not significant enough to be felt in real life, although it was clinically significant.

> *"My vision improved from 6/60 to 6/36 after treatment. On day to day life, I don't feel anything because 6/60 or 6/36 does not matter at all, but still when I'm seeing with both eyes, only my right eye is seeing... because it doesn't matter whether it is 6/36 or 6/60 it doesn't matter - yes." IND INT 13*

While some participants with strabismus were concerned about undergoing surgery, others were concerned about the chances of recurrence post-surgery. Concerns that the surgery is purely cosmetic and wouldn't improve vision in the amblyopic eye were also apparent.

> *"It is a concern because I never wanted to [have] squint surgery. I was scared if - even my dad is a bit scared - like doing all the cosmetic surgery maybe if something goes wrong, or what, because you are touching a part of your body that is very sensitive and you really can't take a chance." IND INT 12*

> *"When I was in my teens I did look to have corrective surgery on it back then but the doctor at the time sort of scared me off it saying that there was a pretty reasonable chance that I could end up cross-eyed so I sort of opted out of doing it at that stage and haven't looked back at it since." AUS INT 15*

Participants who underwent strabismus surgery were concerned that they were not treated for amblyopia post-strabismus correction nor given any follow-up instruction.

> *"My parents weren't given any follow up after the operation. There was no - other people have sort of said things like this, there should have been follow ups and I should have been wearing patches but there was none of that at all. When I did find out, my parents were still alive, and I spoke to them and they said 'no that was just it. You were just sent home and that was the last of it'." AUS INT 30*

> *"I had an operation when I was only a couple of months old or only a few months old,*

to adjust it and, yeah, it initially fixed it but then over the years I never developed, I suppose, the ability to use both my eyes together." AUS INT 9

Although participants admitted that wearing glasses has become common nowadays, some were hesitant about using them. In contrast, some felt that the glasses protect their eyes as well mask the noticeable strabismus.

"I hate wearing glasses like some people hate wearing hats." AUS FGD 2.3

"In one way, I feel wearing spectacles is good - it acts like a shield to my eyes." IND INT 11 (translated from Tamil)

"Actually, if I am wearing specs you can't notice it [strabismus] more. If you're looking so keenly, only then you can make out." IND INT 12

3.6.3.4 Concerns about appearance and self-image

Participants with noticeable strabismus and those wearing thick spectacle lenses owing to high anisometropia or ametropia were concerned about their appearance.

"Yes, obviously I one of the - when I - the glasses of my left eye are quite thicker than the glass of my right eye and when it looks - my even my eye to a third person looks smaller and thicker because of the thickness of the glasses. I feel [it is a] problem." IND INT 24

"I used to get really upset with the act that my glasses were coke bottles and my eyes were so much bigger than everybody else's and so of course being a pimply teenager with thick glasses and everything that goes in with that social, learning, emotional state, yeah, I used to put it down to my glasses and I hated it." AUS FGD 3.1

Concerns about appearance hindered them from having eye contact and made them shy away from being photographed.

"It just made me withdraw more into myself because you was afraid of talking to people and you couldn't look at them straight in the face, you had to look – well, you'd look downwards rather than straight in the face." AUS FGD 2.5

"When I look at some photos that get taken of me wearing glasses my eyes look really big. Yes, I take my glasses off a lot when I'm getting photos taken." AUS INT 24

"I wouldn't stand for taking photos. I avoid it by saying something or the other. I shiver when I have to be in a photo. When I think about going for a marriage function, I would be very concerned as they would take photos." IND INT 3 (translated from Tamil)

Participants worried about how others perceived them. They were concerned about what other people would think, especially because of their misaligned eyes and inability to maintain eye contact. Suspicion, lack of respect, discrimination and prejudice regarding their ability were articulated by lived experiences.

> *"I suppose the – it does affect how people perceive you I think, and I think that concerned me… Yeah I think how people perceive you is very important." AUS INT 5*

> *"But, yeah, just people in general kind of thinking that I'm a bit shifty because when I communicate with them, I look at them in the face for a couple of seconds, then I turn my head and continue to talk to them." AUS INT 4*

> *"The major worry is that I can't talk to others by looking at them straight in the face. This is the only worry I have. They would think I am not looking at them and looking somewhere else. So, I minimised talking to others. This is bit of a concern to me." IND INT 22 (translated from Tamil)*

Concerns about talking to strangers, making friends, dating and getting into a marital relationship were apparent.

> *"Yeah, hesitation and one more thing, if I talk with a new person, I will think what they will talk about, you know… I'm totally - I'm not comfortable" IND INT 26*

> *"It [eye condition] also affected my love interests I guess because I'd get a crush on someone and I felt like I couldn't do anything about it." AUS INT 12*

> *"Nowadays, I feel very worried. When my family members talk about finding a marriage alliance for me, I would be very concerned - thinking whether people would reject me, at this age itself [because of my eyes]. I feel bad thinking that I am not like others." IND INT 5 (translated from Tamil)*

Although these psychosocial concerns eased with age, it didn't wear-off completely.

> *"The squint is - the appearance is, like you say, when you were young… that was more so but even when you get older, I mean it doesn't look – I don't like the look of it, I must admit." AUS FGD 4.2*

3.6.4 Theme 4: Impacts on social life and participation

Social life and participation in social activities were affected in several ways (Figure 3-5).

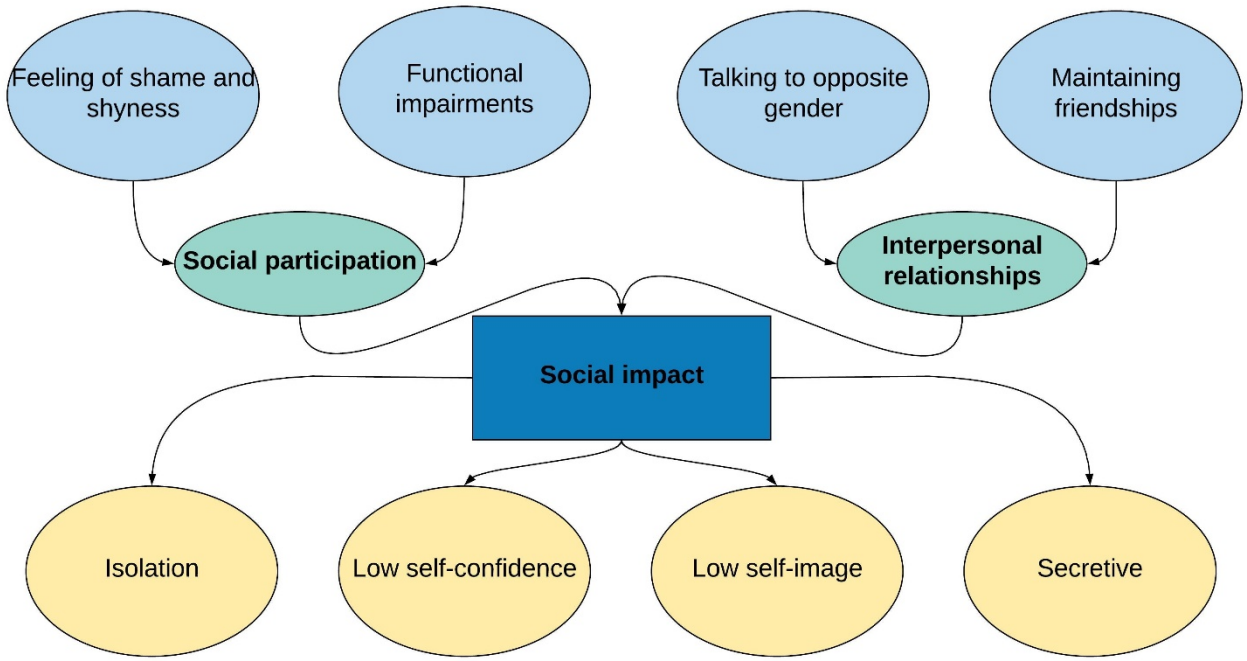


Figure 3-5 Examples of social impacts faced by participants and underlying factors

Concerns about one's appearance and self-image impacted social life and participation in social activities.

> *"I got the idea in my head that everyone was always looking at me funny, so I never felt comfortable in public." AUS INT 12*

> *"…when I talk and when I look into someone else's eyes and I can see both of my eyeballs are not looking at the same place, they are not aligned, so that lessened my confidence" IND INT 18*

Participants avoided going out with friends and socialising because they feared being bullied and embarrassed. They gauged people's attitude towards them before engaging in conversations and chose friends cautiously.

> *"I avoid going out with my friends and socialising with others thinking what others would think about me. I don't talk with anyone and I don't go anywhere." IND INT 22 (translated from Tamil)*

> *"I was always self-conscious in I'm always really shy in a new group of people and I think that stemmed from when I was a withdrawn – not a withdrawn – I wasn't a withdrawn child. I'd always gauge what the group was like before I – because I always felt it was my eyes and my glasses..." AUS FGD 3.1*

They tried to avoid crowded public places and social gatherings as they felt shy.

Socialising in groups was more challenging than socialising with individuals.

> *"I think twice about going to public places. I feel uncomfortable. I would fear that someone may look at my eyes and comment. I fear going to any public places or marriage celebrations. I don't know if everyone has this – I fear when I see crowds. I will have fear in my eyes – I feel shy. I don't know if it is my character or because of my eyes." IND INT 3 (translated from Tamil)*

> *"I would always have a very – like the worst thing was socialising in groups where everyone was standing around in a circle or standing in front of a class and doing a presentation; I hated it and would avoid it in every possible way. Yeah it was horrible." AUS INT 9*

Maintaining close interpersonal relationships and talking to opposite gender was problematic.

> *"My late wife used to get upset because she didn't know whether I was looking at her or the other eye was looking at the girl over there, but she got used to it." AUS FGD 4.2*

> *"When I was in college, all the girls would be seated onto my left side. I cannot face them or talk to them. I would be very scared. Even if a girl calls me, I wouldn't turn immediately. I think a lot before turning towards them." IND INT 3 (translated from Tamil)*

Reactions from family and society affected their confidence and influenced socialising.

> *"People can't help their reaction and people often ask me about it [my eye] and its quite obvious I find so I'm like 'yeah, whatever'. But like I worked as a waitress and I'd serve little kid customers and they'd cry and stuff. I know I'm not that weird but to them it was!" AUS INT 12*

> *"I don't think I really had any name calling or bullying, it was just people being astounded that I couldn't actually see what they could see and looking at me like as if to say 'well, how come? You've got two eyes; how come you can't see it?' People just don't understand." AUS INT 20*

Apart from these appearance-related concerns, other functional impacts such as difficulties in driving and sports influenced social participation.

> *"I suppose it might've affected my social life in that I'm not inclined to drive out at night so to that extent it has a little bit, although a number of my friends say that they're happy to pick me up and take me places." AUS INT 33*

"I am very concerned that I cannot go to places I like because of the restrictions caused by my eye condition." IND INT 23 (translated from Tamil)

"When I went to 3D movie with my friend, I couldn't feel anything. I was a very concerned if someone would ask something about what I saw in the movie. I was very happy when no one asked me anything!" IND INT 3 (translated from Tamil)

Some participants worried that their own family failed to understand the disability caused by their eye condition. This affected their relationship with them.

"I can't watch 3D and I can't see through stereoscope. My husband gets frustrated at me because he tries to tell me 'wow this stereoscope's so cool' and I'm like 'don't know what you're on about; it's just two pictures'." AUS FGD 3.1

"I do find it very difficult to see things, to see distances, and my husband's always pointing things out into the distance and I can't see them, and he gets a bit ratty about it, a bit of lack of understanding I think, of the difficulties…" AUS INT 5

While most participants tend to be secretive about their eye condition to avoid social consequences, few chose to be open and share their problems with others.

"If I tell about my eye condition – my feelings to others, they will bully me. They will tell others about the fault in my eyes. We should never tell others about our problem. If we tell them, they would hurt you by mentioning it. That's why I wouldn't trust anyone…" IND INT 3 (translated from Tamil)

"I don't have a great deal of friends. Anyone who I become friends with knows that that's the problem because I'm liable to walk into doors and I don't want them to think I'm drunk. I don't hide it. Anyone who I get close to I do let them know and it's just - yeah, I don't think it's affected me at all in that respect, no." AUS INT 30

Some participants articulated that people get used to them over a period of time and see beyond their defect.

"I'm still really good friends with the girls I went to high school with and they probably don't even see it now, it's just part of me. They would know I have it, but I think – you know, it's like people with facial disfigurements, once you get to know them and their personality you don't see those disfigurements anymore." AUS FGD 3.3

3.6.5 Theme 5: Impacts on emotional wellbeing

Numerous emotional reactions and several underpinning factors were evident from the

participant's narratives of lived experiences (Figure 3-6).

Figure 3-6

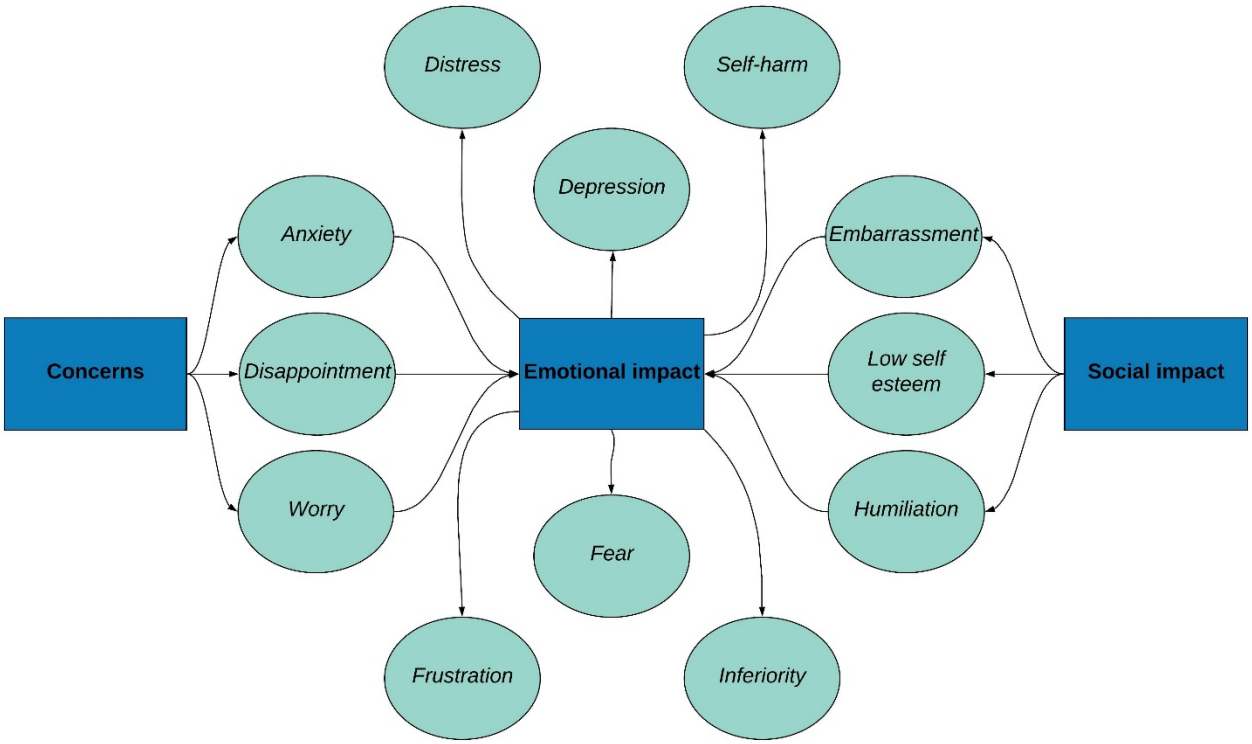


Figure 3-6 Examples of emotional impacts faced by participants

Worry, feelings of hopelessness and disappointment that their condition could not be cured, anxiety, fear and stress about the safety of their good eye were apparent. Concerns about their eye condition underpinned these feelings.

> *"It does worry me a little bit, but I think it's just how it is. Like I'm never going to get my vision back in my right eye." AUS INT 29*

> *"Even my dad kept on searching for new-new things [treatment]. But till now, everywhere it was a disappointment [they will say no, nothing is possible] not a good feeling to say I literally feel so bad. You know!" IND INT 12*

> *"I always used to be concerned about, you know, if my good eye goes bad then what about - because I have slight power [refractive error] in my good eye so I always tensed 'what if my good eye also goes bad?'" IND INT 28*

Socially noticeable strabismus influenced emotional wellbeing and participants who faced social issues such as bullying and rejection articulated feelings of frustration, embarrassment and humiliation.

"It's most probably most frustrating, I would say, in circumstances, for example like a job interview or even speaking to the opposite sex, just things like that. As you can imagine it's not the best." AUS INT 4

"It is not a little grief I had! At a point in life I even decided that I should never marry – I should not spoil a girl's life. I thought I had a [eye] disease – a disease like cancer." IND INT 3 (translated from Tamil)

Participants felt that their eye condition impacted their self-confidence and self-esteem. Some admitted that they suffer from anxiety and depression because of their eye condition.

"I absolutely loathe crowds and I think because ever since I was 12 years old, I have suffered from anxiety and depression and I strongly believe that my condition with my eyesight is affiliated with my anxiety and depression." AUS INT 4

"I had very low self-esteem because of it I think…Yeah and lacking in confidence. I have no confidence in anything I do." AUS INT 32

Emotional distress, outbursts of anger and episodes of self-harm were articulated by participants and were attributed to the eye condition.

"I get very angry – get angry very often. I don't understand. I think I get angry because of my eye problem – when I see the difference between myself and others, I get angry." IND INT 6 (translated from Tamil)

"I got bullied a lot and it affected my self-esteem a lot and I ended up cutting my wrists." AUS INT 12

"I get very upset when people call me by names. I don't know how to cope up with it." IND INT 5 (translated from Tamil)

"When I was diagnosed with the condition for the first time, we [family] were scared… scared about the societal reaction especially being a girl… At first, I cried as nothing could be done…" IND INT 23 (translated from Tamil)

The limitations imposed by the eye condition on career choice and work also impacted emotional wellbeing.

"It was quite hard at first when I knew - because I wanted to be an [army officer] when I was young, so I couldn't get into it as for army, you need perfect vision, so I can't be an army officer, it was difficult at first but now I'm used to it." IND INT 13

"I wanted to be a police officer when I was 16 so gutted, cried for a week. I ended up as a secretary; what else do you do!" AUS FGD 3.1

"[In my workplace, when people react about my eyes] I have to try not to take it too personally and carry on with my job and it's just – it was a bit hard sometimes." AUS INT 12

Participants compared themselves with others; as a result, some felt unfortunate, inferior to others and some envied people who had normal eyes.

"I have three other siblings and they do not have it so lucky the." AUS INT 16

"I mean I had my friends, but I think in some ways it made you a little inferior to other people because you just couldn't see things they were talking about." AUS INT 20

"I'm a bit envious of those people who've got their perfect vision but, you know, it doesn't sort of upset me that I can't see things generally speaking." AUS INT 20

On the contrary, some thought that they were fortunate to have at least one good eye compared to those with serious health issues or blinding eye conditions.

"While it was annoying perhaps to have this problem there are lots of people who have much worse problems than I do." AUS INT 33

"I work at a train station… I see so many blind passengers and that and it's very disturbing how they can get - not disturbing but I admire how they can get around without any sight at all. I just think to myself how lucky that I've got one good eye, so you've got to appreciate what you've got." AUS INT 27

In general, most participants wished that they hadn't had this eye condition and looked forward to some type of cure in the future.

"I don't like it [glasses], I want to get rid of it. In fact, I don't want to wear glasses at all, but this is something that I cannot help it." IND INT 18

"I wish I could do something about it but, you know, maybe in the future they'll have some new technology or cure." AUS INT 13

3.6.6 Theme 6: Impacts on study, work and finance (Economic impact)

Participants articulated several ways in which their eye condition affected their education, career choice, work performance and achievements in life (Figure 3-7).

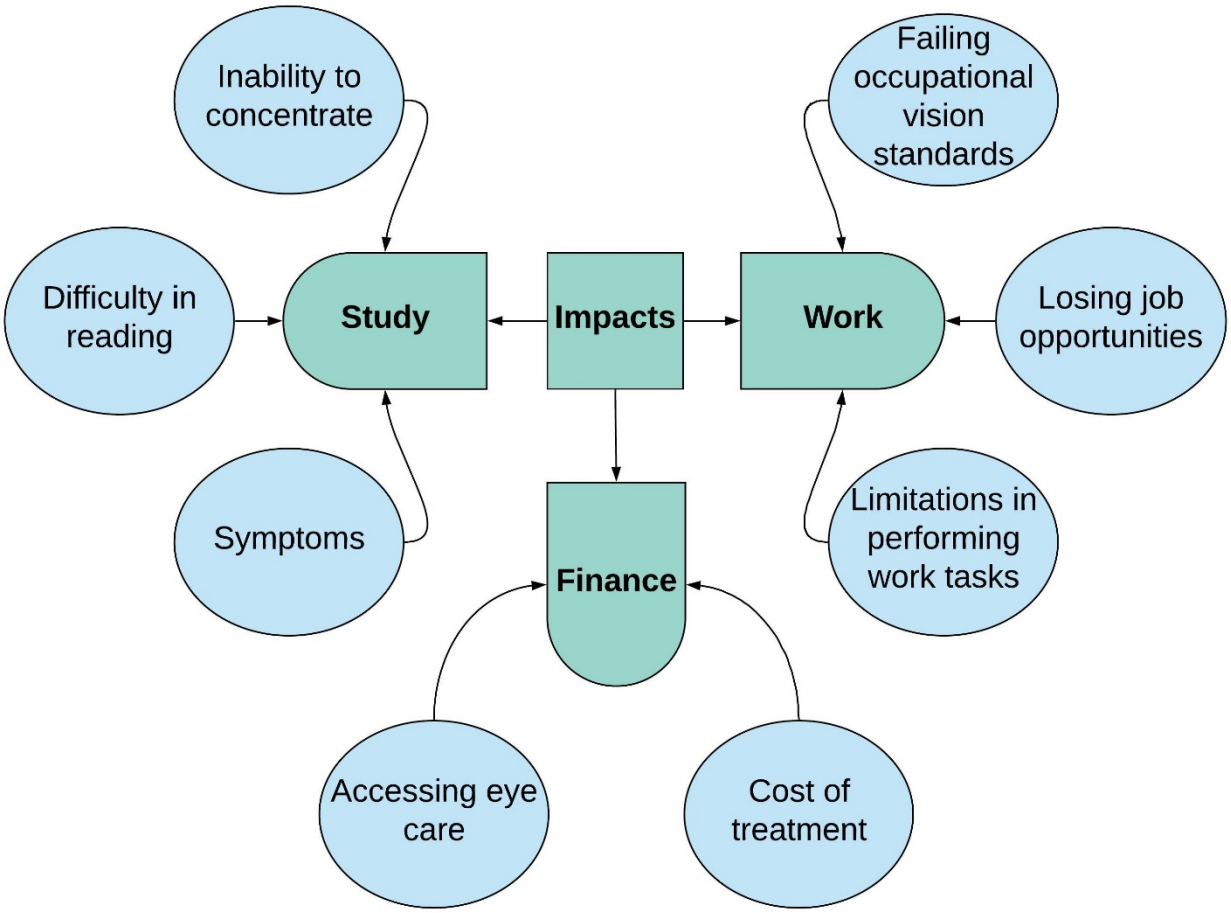


Figure 3-7 Examples of factors underpinning the impacts on study, work and finance

They believed that their academic performance was affected due to their inability to concentrate, read for a long time and the symptoms such as eye strain and headaches that aggravated while reading.

> *"For my MBA studies, I have to do a project. I am not able to do it because of my eye condition. If I take a subject to read, I can only read for a particular amount of time. After that I cannot read, how much ever I try... I feel my studies has been affected because of my eye condition." IND INT 23 (translated from Tamil)*

> *"I just can't even – yeah I just haven't got that concentration. Even with glasses I just don't have that concentration anymore so I'm behind in my studies at the moment." AUS INT 7*

They admitted that they were not able to study like their normal peers. Some articulated that they were not able to choose the field of study they liked because they failed to meet the set vision standards in the amblyopic eye.

> *"I was a university student and what have you and I knew I couldn't study like my*

contemporaries were studying. I just – my eyes wouldn't allow me to do the study that I knew I could have been doing or should have been doing." AUS FGD 1.3

"I wished I studied marine engineering a lot, because of my eyesight I lost it." IND INT 17

Not meeting vision requirements for selected jobs precluded participants from pursuing the career of their choice. These lost opportunities instigated a sense of failure.

"Yeah, I used to get upset, you know, like failure - like pass and then fail eyesight, remembering that I failed - firstly I failed with the locomotive engineer. Secondly, I failed with the navy. Thirdly I failed with the police force. Fourthly I failed as a technician." AUS INT 17

"Many opportunities was lost – like I can't go into army, I can't be a police man as it all requires perfect vision... Many opportunities have been taken away. Like there's only doors closed… you can't go there! Because my father was an [army officer] I wanted to be one and that can't happen now." IND INT 13

Participants with noticeable strabismus lacked confidence during job interviews and felt that they were discriminated.

"I don't know about much more frustrating things besides talking to someone who I find important, say for example like a job interview, and having one of my eyes drift off." AUS INT 4

"Well lots of places I went – I know you're not allowed to discriminate but I always felt like they didn't hire me because of it [strabismus]." AUS INT 12

Those who were employed had trouble in performing jobs that required social interaction.

"Sometimes it can with - in retail when I get - like customers don't know whether I'm looking at them or not, especially if my eyes really turned in, and that can be quite embarrassing." AUS INT 32

"I am a teacher. I can't have eye contact with my student. When I talk to someone, the other student nearby asks whether I am talking to him. I feel bad that I am not like other teachers. It would be very embarrassing. Really, I feel very bad! For this reason, I try to memorise all my students' name and call them by names instead of just pointing out at them." IND INT 5 (translated from Tamil)

"Well I was a nurse and I chose theatre because that way you hide, don't you, because you're like this. So, I suppose in a way on reflection you could think that's perhaps why I chose theatre." AUS FGD 2.2

Participants whose eye condition was not obvious to others chose not to disclose their eye condition to employers for the fear of losing job opportunities.

"No. I don't tell employers or anything like that [about my eye condition] because I don't want it to have any effect on my job or anything like that." AUS INT 14

Participants articulated how the functional impairments affected their career goals and work performance.

"I wanted to be in IT [information technology sector] for longer… But now, after about 3 years of job [with computers], even I feel that I have to leave [quit] – because it obviously going to affect [sooner or later] it's going to impact your eyes." IND INT 12

"Oh, well, myself I would have avoided jobs. Like I said to you, I enjoy tinkering with mechanics. Well, there's no way known I would have become a mechanic because I knew that I couldn't, you know – you couldn't see, and you just couldn't do it for eight hours a day because you'd end up with such massive headaches trying to…" AUS FGD 1.4

"At work I drive a vehicle, a forklift, and it takes me longer to focus on the exact position I have to be in than other people who don't wear glasses. I have to get it exactly right before I do it." AUS INT 24

The functional impairments, especially the lack of depth perception hindered participants from performing certain binocular tasks related to their job.

"I'm an optometrist it's probably affected me because I don't have depth perception for using some binocular instruments… I can imagine, yes, foreign body removal, those fine things, it would have affected. I'd have a bit more difficulty than perhaps other students." AUS INT 18

"I can't use a stereo microscope… I did train as a conservator, but I probably won't practice as a conservator… If I was a conservator I'd be spending a lot longer looking at paintings through microscopes, working on them for prolonged periods, colour matching, in-painting really tiny areas, so I think if I was a conservator I would probably have an issue…" AUS INT 21

"I'm a doctor and one of the things I couldn't do is surgery. Even assisting at surgery, I

actually really struggled with it early on and then did a bit of assisting and realised that it was my vision that I couldn't actually see the depth so that was a big thing." AUS INT 5

Participants supposed that they would have been more successful in life if they hadn't experienced their eye condition.

"I think if I didn't have the condition or I had a – not so much… then I think I would have been more of a confident person and I would have gone on to bigger job opportunities or I would have been more ambitious." AUS INT 9

Other economic implications posed by the eye condition was the financial burden of travelling to access eye care from places offering treatment for adult amblyopes, cost of doctor appointments, treatment (surgery, in-office vision therapy) and private health insurance.

Yeah… hard thing is that I have visited all the places in India, all the hospitals in India just because of my eyes that's one thing - I am going there and see if it is possible – so we will be booking our tickets and going there and again would get disappointed that it is not possible." IND INT 12

"There's definitely financial implications because you've got to pay for regular glasses and if you want sunglasses you've got to pay for prescription sunglasses so there's definitely - and if you want to go down contacts, all that type of thing." AUS INT 28

Participants with high refractive errors expressed that they had to buy expensive glasses to look more appealing.

"My glasses have to be quite heavy so it's very expensive to get glasses with lenses that don't make me feel uncomfortable, ashamed and embarrassed because of the level of magnification." AUS INT 3

"[I have a] high prescription - so to make them thinner they cost more. But if I could have an operation to make my lenses thinner, I'd do it tomorrow, like if it was covered under Medicare and stuff…" AUS FGD 3.1

3.6.7 Theme 7: Inconveniences associated with the eye condition

The eye condition, treatment and the associated impact caused several inconveniences to participants (Figure 3-8).

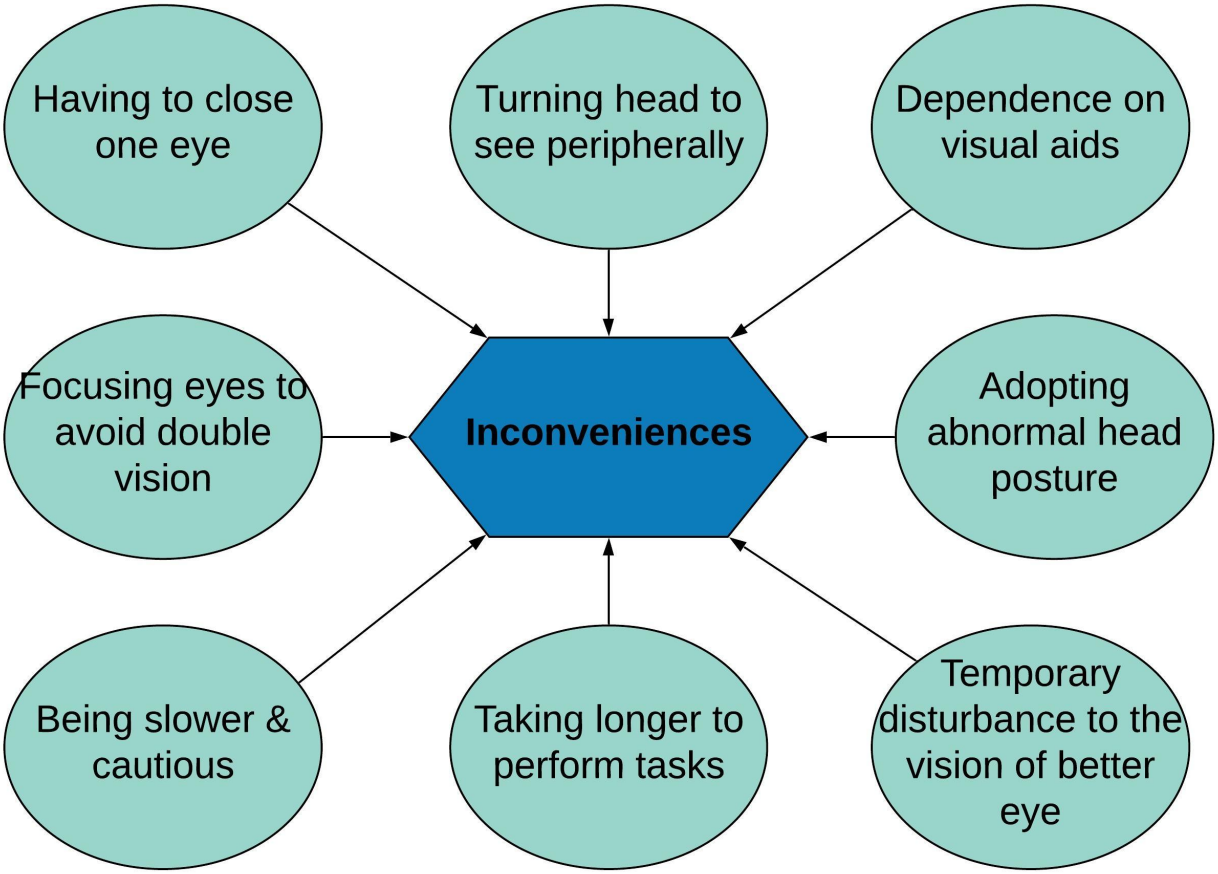


Figure 3-8 Inconveniences faced by participants in relation to their eye condition and treatment

The symptoms associated with the eye condition such as glare and light sensitivity demanded participants to close one or both eyes in the presence of bright lights. Poor vision in the amblyopic eye demanded participants to turn their head considerably to see things onto the affected side.

> *"I can't bear the beam of light coming towards me... I have to stop my bike aside so that the opposite light, the vehicles pass... Couldn't bear any of the beam of light, during night." IND INT 24*

> *"Sometimes you really have to turn your head or move your head in quite a substantial manner to do that [changing lanes while driving]. AUS INT 11*

Although closing one eye was a useful strategy to alleviate symptoms of double vision or to focus things clearly, doing so was troublesome.

> *"Closing one eye is my current strategy for diplopia... Like if I'm going to have my glasses on, I'll put a tissue around the right lens. Yeah, palm to the eye or literally just shut it if it's really bad and I'm having a lot of problems…" AUS INT 29*

"Yeah when you get down to the small numbers on texting you've got to close your eye and pull it around, yeah." AUS FGD 1.5

Being dependent on their good eye, amblyopic participants articulated inconveniences caused by temporary disturbances in the vision of their good eye due to eye infections, insect bite or dirt.

"I think actually that is an issue in that if I get a bit of grit under the lens in my right eye, especially if it's something like I'm driving, if it's grit that's really painful, then I'm just blind because I can't open my right eye and my left eye doesn't work." AUS INT 5

Participants who were dependent on glasses articulated inconveniences related to glass-wear. They articulated that it was troublesome to wear spectacles always, but they had no choice. Because of the fear of losing or damaging them, they always had to keep a spare pair accessible.

"I always, always, always wear my glasses so I'm completely dependent on visual aids. Without visual aids, well, it would be a very different matter… Yeah, it upsets me how dependent I am on my glasses - It's the expense and dependency on visual aids." AUS INT 3

"I depend on my spectacles. Wearing them, I find it hard to travel in crowded buses or trains." IND INT 1

"I've always got two pairs of glasses that I've got as a backup, that if anything ever happens with my contacts or I run out I've always got glasses." AUS INT 11

Contact lens users reported inconveniences in complying with user instructions and participants using prism glasses reported trouble in adaptation.

"I can't sleep with my contact lenses. I can't wash my face. I should use sunglasses when I go out in order to avoid dust in my lens. I travel a lot –I cannot keep wearing it for a long time. I can only use it for a specific period of time" IND INT 23 (translated from Tamil)

"I think they [prism glasses] did [help] but the difficulty is that I have to search in the [prism] glasses for a spot that brings things into focus which exaggerated - the further away you get the more exaggerated it becomes. I still have that issue with ghosting." AUS INT 22

To combat the limitations imposed by their eye condition, participants adopted slow and cautious behaviour, especially while doing tasks that were difficult for them.

Although these adaptations were necessary, they were associated with some forms of inconveniences. For example, driving slowly and cautiously turned out to be inconvenient for other drivers on the road who were held up behind and for the driver himself as he took longer to reach his destination.

> *"I'm always careful what I do. Anything that might mean, say, hammering a nail into a wall sort of thing, because I'm not handy…" AUS FGD 4.3*

> *"I get cut in a lot because I leave a lot of distance between the car in front and my car. I would leave three or four car distances and I get continuously cut in because I'm playing the safety margin. I don't want to go too close to the car in front of me and often a car will come out behind me whereby you might think it's some distance away it's 'oh he's pretty close' so I'll slow down." AUS FGD 4.3*

3.6.8 Theme 8: Adaptation and coping strategies

Coping with the functional impairments were by behavioural and adaptive mechanisms (Physical) while coping with the psychosocial impacts were mostly by cognitive and avoidance techniques (Emotional). Examples of physical and emotional coping strategies used by participants are presented in the Figure 3-9.

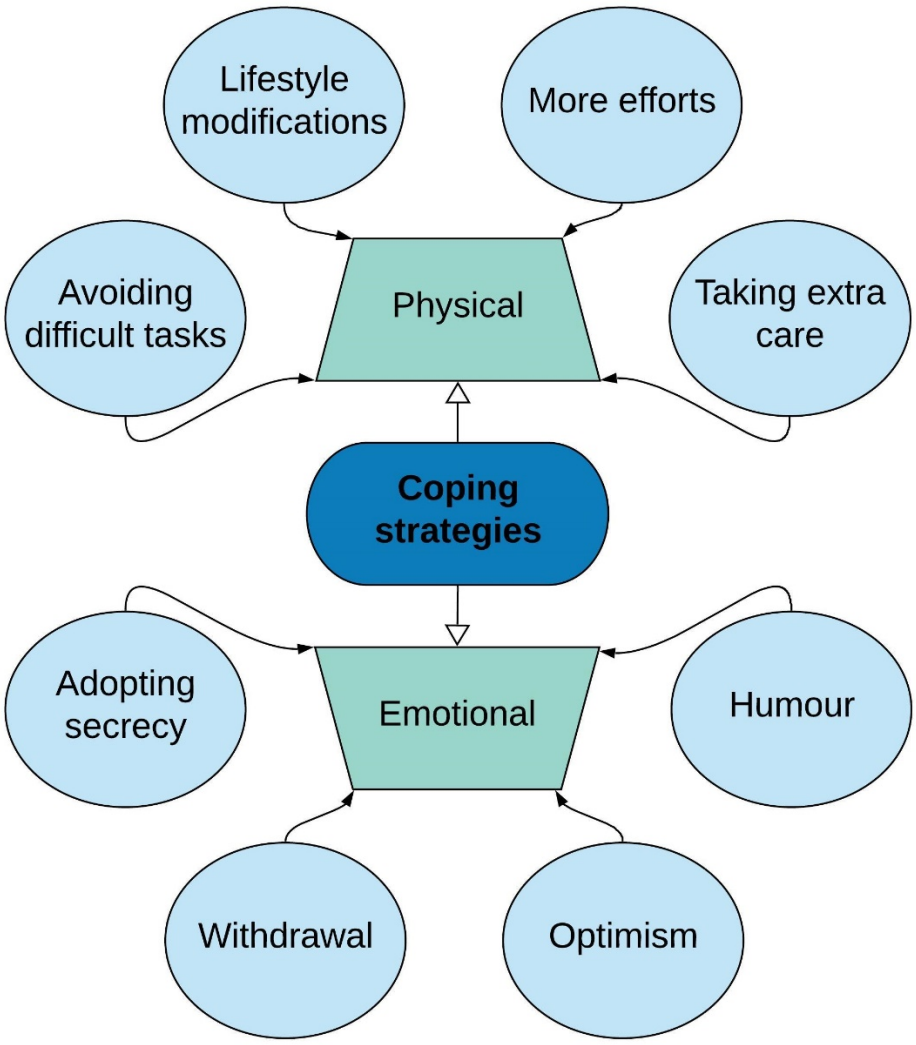


Figure 3-9 Examples of coping strategies used by participants

Participants coped up with the functional impairments and disabilities caused by their eye condition by using visual aids, closing one eye, being slower and careful or by taking extra efforts to accomplish tasks. Although some of these adaptations were conscious efforts initially, it became habits eventually.

> *"I've done that [closing one eye] for a long time and as soon as I want to see something, I sort of automatically go like that." AUS FGD 1.1*

Having lived with their eye problems long enough, some considered it as a part of themselves and had learned to cope up with it.

> *"I have l literally grown up with it, so it has become a part of me." IND INT 12*

> *"Well I mean I've had this condition from birth, so I mean I've managed to deal with it." AUS INT 15*

Some articulated that their awareness of what they are missing because of their eye condition is limited (e.g. meaning of depth perception) as they have never experienced normal vision before.

> *"I do not know how other people see so I never have any difficulty and I don't know how it's normal or how [they perceive that]. For me this is normal…" IND INT 13*

> *"I guess not having had a sense of binocular vision - you don't miss what you haven't had… I'll say, you know, I've never seen so - this is my world, so my world is my world and that's it so it's not a... I don't know what I'm missing so I haven't been inconvenienced; it's just how I am." AUS INT 18*

Those troubled by the psychosocial impacts of noticeable strabismus tried to hide their eye condition (adopt secrecy) by avoiding eye-contact or using sunglasses.

> *"I used to wear sunglasses all the time, so I didn't have to sort of look at people. Other than that, yeah, if I didn't have glasses on – and even now I avoid eye contact with people. I don't really look at people in the eye." AUS FGD 1*

Others isolated themselves from others in order to avoid stress factors such as bullying and embarrassment.

> *"I avoid talking to others as they would point out fault [in my eyes]. I don't have any friendships. I had friendships earlier but not now - I avoided it." IND INT 22 (translated from Tamil)*

Some used humour (making a joke of oneself) to cope socially.

> *"Sometimes but you sort of make a joke out of it yourself. You sort of say 'you can take me anywhere but out'. You just make a joke out of it yourself…" AUS INT 30*

Participants also coped by being positive, not thinking about their eye condition or by considering themselves fortunate than others with more serious health issues. These were evident in participants who tried to accept their eye condition.

> *"I don't want to think about something that should not happen [losing vision in better eye]. I want to be positive side and I just want to carry forward. Now as I know that I have only one good eye – I have to protect my left eye." IND INT 9*

3.7 Australia versus India: A comparison of perspectives and QoL experiences

Despite similar overall QoL themes, some differences in experiences and perceptions were noted across participants in Australia and India. These are described below.

1. **Participants from Australia more readily associated the problems they faced in their day to day life with their eye condition**

Although participants in both studies were aware about their ocular diagnosis, participants in the Australian study more readily related the difficulties they faced in their daily life to the characteristics of their eye condition; for example, participants related difficulties in catching a ball and falls to lack of depth perception.

> *"I've had several falls, mainly because of eyesight perception." AUS FGD 2.2*

However, participants in the Indian study, despite facing similar challenges in their daily life, did not assume or completely attribute the difficulties to their eye condition.

> *"I can't feel 3D effect that well. I tried watching a 3D movie – but I couldn't feel any effect – out of 100% I could feel about 60%. But I am not sure if the problem was with the 3D movie or with my eyes! So, I can't say for sure that it was due to my lazy eye." IND INT 6 (translated from Tamil)*

2. **Different challenges in driving was observed between Australia and India**

Difficulties in changing lanes and seeing road markings clearly were articulated by participants in Australia alone where roads are well laid (with distinct lanes and road markings) and driving behaviour is orderly. These challenges did not come up in the Indian study. In contrast, participants in the Indian study articulated challenges in seeing speed breakers; speed breakers are often not painted to enhance contrast and there are no signs of warning about an approaching speed-breaker in many places in India, unlike in Australia. Refer 3.6.2.1 for supporting participant statements.

Challenges in driving a car was predominately reported in the Australian study and challenges in riding motorbikes was predominantly reported in India. This could be because cars are common than motorbikes in Australia, which is *vice versa* in India.[312]

3. **Impact on sports was more pronounced by the Australian sample**

Many participants in India, did not engage in sports after school or university education and out of those who pursued sports, many were occasional players. Hence participants could not recognise/recall the impacts their eye condition had on sports. In contrast, many participants in Australia pursued sports throughout their life. They enumerated limitations in a variety of sports such as tennis, soccer, netball, cricket and swimming. Those who had to give-up sports due to their eye condition reported that they engaged in alternate activities (e.g. rowing, horse riding).

Participant statements denoting impact on the Australian sample are provided in section 3.6.2.3. Participant statements supporting less participation rate and less pronounced impact on Indian sample is provided below.

> *"I don't have any problems and I played from when I was young; I don't have any problems in catching a ball." IND INT 13*

> *"I have played basketball in school till year 9. I did not realise that I had an eye problem at that time." IND INT 23 (translated from Tamil)*

4. **Economic concerns and financial implications of the eye condition was influenced by differences in health care system and accessibility of care**

Despite living in economically different country settings with different health care systems,[313] participants from both countries shared similar experiences about delayed amblyopia diagnosis and denial of treatment in childhood; they were concerned about limited treatment options and the cost associated with treatment (3.6.3.3).

Distinctly, participants in India reported inconveniences and financial implications of travelling to different places to access eye care (hospitals catering services for adults with amblyopia and strabismus) whereas participants in Australia were concerned that health insurance wouldn't cater (partially or completely) the cost of treatment (glasses, vision therapy, surgery) and that they couldn't afford private health insurance.

> *"I feel no one will feel good with this eye condition. Everyone wants their eye to be okay... But, what to do… I went almost throughout India for this request. But they said they could not operate, laser operation or anything." IND INT 24*

> *"Now private health [insurance] doesn't cover you because it's a pre-existing illness if*

you had private health!" AUS FGD3.2

5. **Societal and cultural differences between Australia and India influenced kinds of impact on participants and their family**

Irrespective of culture, participants from both countries, both male and female, expressed concerns about appearance and self-image. However, strabismus, was considered as a sign of luck by some in India (an old myth),[314] which deterred early diagnosis and treatment.

> *"Many thought that I have a lucky eye. They did not know that I have problems with my vision and so did not take me to the doctor. Only after I told them, they came to know that I can't see through this eye." IND INT 5 (translated from Tamil)*

While problems in dating was apparent in both countries, participants in India articulated societal influences and difficulties faced by their family members in finding them a partner for an arranged marriage, which is common in India.

> *"The only thing - only place I find that things may go wrong or something like that because- even my parents tend to hide it [my eye condition] – they say you should not tell it – because obviously you are going through a [arranged marriage] the [partner's] family will not accept it. They always want perfect, but you have this issue." IND INT 12*

3.8 Differences in QoL experiences: Isolated amblyopia versus isolated strabismus versus amblyopia associated with strabismus

Theme-wise comparison of the occurrence of topics across the three groups of participants namely isolated amblyopia (n=20), isolated strabismus (n=12) and amblyopia associated with strabismus, which includes both strabismic and combined-mechanism amblyopia (n= 45) are displayed in Table 3-3. Only selected topics underpinning each theme are presented to ease reading. Due to small number of participants with deprivational amblyopia (n=2), they were excluded from the comparison table.

Table 3-3 Occurrence of topics underpinning each QoL theme across three groups of participants: isolated amblyopia, isolated strabismus and amblyopia associated with strabismus

QoL themes & topics	Isolated amblyopia (n=20)	Isolated strabismus (n=12)	Amblyopia associated with strabismus (n=45)
Theme 1: Symptoms			
Poor vision in one eye			
Misalignment of eyes			
Double vision			
Abnormal head posture			
Eye strain			
Headaches			
Light sensitivity			
Watery eyes			
Difficulty in distance and depth judgement			
Difficulty in concentrating			
Loss of balance			
Theme 2: Impact on everyday tasks			
Driving cars & riding motorbikes			
Reading			
Sports			
Mobility			
Cutting or chopping vegetables/ food			
Pouring a drink			
Using binocular instruments			
Grooming & self-care			
Seeing 3D movies/ pictures			
Theme 3: Concerns posed by the eye condition			
Concern about further deterioration of condition			
Passing on their eye condition to next generation			
Concern about being dependent on better eye			
Safety of the better eye			
Straining/ overloading better eye			
Concerns about limited treatment options			
Outcome of strabismus surgery and recurrence of strabismus			
Concerns about appearance			
Being in photographs			
Having eye contact with people			
Psychosocial concerns about what other people think and react			

Concerns about not being able to do things they like now and in future			
Theme 4: Impacts on social contact and participation			
Making friends			
Socialising in groups			
Talking to opposite gender			
Participation in social activities			
Getting support from family			
Theme 5: Impacts on emotional wellbeing			
Worry			
Disappointment			
Regretful			
Fear			
Anxiety			
Frustration			
Embarrassment			
Humiliation			
Low self-confidence			
Theme 6: Impacts on study, work and finance			
Not meeting vision standards			
Losing job opportunities			
Impact on education			
Cost associated with treatment			
Work tasks affected			
Discrimination in job interviews			
Theme 7: Inconveniences caused by eye condition			
Turning head to see peripherally			
Closing one eye in bright lights / to focus			
Being dependent on better eye			
Having to be slow and cautious			
Theme 8: Adaptation and coping			
Physical adaptations			
Adopting secrecy (e.g. avoiding eye contact)			
Withdrawal			
Positive attitude			

Red represents nil occurrence of the topic and green represents occurrence

All the QoL experiences (topics) displayed in the Table 3-3 were common to those who experienced both strabismus and amblyopia (strabismic and combined-mechanism amblyopia). This has been indicated by green colour coding in the last column on the right.

However, some unique QoL experiences were noted between participants experiencing isolated amblyopia and isolated strabismus. Nil occurrence of a topic in a particular disease group is indicated by red colour coding. This could be observed in the first two colour coded columns. These unique QoL experiences are elaborated below and substantiated using participant quotes.

Unlike participants with isolated amblyopia, participants with isolated strabismus were not bothered by poor vision in their amblyopic eye. This precluded concerns about the safety of their unaffected (better) eye and concerns about going blind.

> *"No. I'm lucky, I think I feel happy that I've got both eyes can see equally. I think if one eye was weak, if one was 6/12, that I would be a bit more upset probably, a bit more cautious or careful, but given they both see equally and I can alternate I don't prize one eye more than the other." AUS INT 18 (Participant with isolated strabismus)*

While participants with isolated amblyopia had trouble performing day to day activities and work tasks due to poor vision in the amblyopic eye, participants with isolated strabismus had trouble because of double vision.

> *"I actually do find little difficulty when driving because the right eye - right side vision is not that clear." IND INT 18 (Participant with isolated amblyopia)*

> *"When I'm in the car, cars coming towards me, when they're at a certain distance from me, I see two of them." AUS INT 33 (Participant with isolated strabismus)*

Although concerns about appearance were reported by both participants with isolated strabismus due to their misaligned eye and participants with isolated amblyopia due to thick spectacles, psychosocial impacts were more pronounced by those experiencing socially noticeable strabismus.

> *"As soon as I look at some photos that get taken of me wearing glasses my eyes look really big." AUS INT 24 (Participant with isolated amblyopia)*

> *"…the quality of my vision is the same in both eyes. I can't notice a difference between the quality but, yeah, it's just been really just a cosmetic thing that I've had to deal with all my life." AUS INT 9 (Participant with isolated strabismus)*

Lost job opportunities because of not meeting vision standards and the associated emotional and economic impacts were specific to isolated amblyopia.

> *"It was for Tata TISCO apprentice. I cracked all the exams and interviews, but it was the last day - the medical exam and I got rejected because of my eyes." IND INT 24 (Participant with isolated amblyopia)*

Inconveniences due to diplopia and use of prism glasses were specific to acquired/ paralytic strabismus (isolated strabismus) while inconveniences related to use of thick spectacle lenses were specific to those with high refractive errors (isolated

amblyopia).

> *"I've only just recently got some glasses that sort of correct the double vision to the extent that when I'm sitting watching television, I wear them... Just for sort of everyday use they're just not right to wear in that they sort of distort in a way how I go to walk, I think." AUS INT 33 (Participant with isolated strabismus)*

> *"A lot of people have asked me about that one - 'why are one of your eyes' - like 'why are the glasses so thick and the other one is thin?" IND INT 9 (Participant with isolated amblyopia)*

Finally, it was observed that participants with isolated amblyopia tend to be more positive and accepted their eye condition in contrast to participants with strabismus who adopted secrecy or isolated themselves in order to cope up socially.

> *"Yeah it's just - I've known it's been there for so long; I've accepted it and it's part of me and I get on with it, yeah." AUS INT 28 (Participant with isolated amblyopia)*

> *"Well, luckily I sit on the right side so they'd be there so I could use my dominant eye to see them." AUS INT 28 (Participant with isolated strabismus)*

Despite these differences, participants shared several similar QoL experiences leading to the emergence of similar themes, as described under section 3.6 which is indicated by the green colour coding in the first two colour coded columns of Table 3-3.

3.9 Discussion

Amblyopia and strabismus, when not adequately treated in childhood become chronic eye problems that continues into adulthood.[20] This chapter explored the impact of amblyopia and strabismus by eliciting the lived experiences of adults experiencing these conditions. The qualitative studies in Australia and India illustrated the multifaceted implications of amblyopia and strabismus and identified eight emergent themes that signified the impact on various dimensions of QoL. These QoL themes, being patient-derived, represent the QoL concepts that are important to individuals experiencing these conditions and therefore form the foundation for the development of item banks (Chapter 4) that are patient-centered.

Previous qualitative studies on amblyopia focussed on clinician's perspectives[82] and the impact of amblyopia treatment on children.[18, 83, 84, 315] In contrast, the current chapter investigated the impact of amblyopia on adults qualitatively, compared the

impact faced by adults living in high income country (Australia) versus low income country (India) and contrasted the impacts caused by isolated amblyopia, isolated strabismus and amblyopia associated with strabismus. Although the psychosocial impacts of strabismus are well known, this chapter expands our understanding about the other kinds of impact, both strabismus and amblyopia have on QoL such as functional limitations in everyday life, inconveniences and financial implications.

As amblyopia is often associated with either strabismus or refractive error, it is hard to delineate the sole impact caused by each condition. From my experience in interviewing patients, patients often see their eye problem as one entity. For example, participants with anisometropic amblyopia, when asked to describe the impact caused by their eye condition, articulated QoL experiences specific to both amblyopia (e.g. concerns about safety of better eye) and refractive error (e.g. inconveniences using glasses). Although those with strabismic amblyopia were able to differentiate the psychosocial impacts caused by their misaligned eye (as it was obvious), they attributed functional limitations such as in driving or playing sports to their eye condition as a whole. Complexity exists in distinguishing the effects of amblyopia alone from strabismus or refractive error when they occur together; however, it is debatable if such delineation is necessary.[316]

The chapter identified some unique experiences amidst several similar QoL experiences across participants with isolated amblyopia, isolated strabismus and amblyopia associated with strabismus. While QoL issues due to poor vision was specific to the isolated amblyopia group, issues related to misaligned eye were specific to the isolated strabismus group; the combined group faced all QoL issues caused by both amblyopia and strabismus. Despite these differences, similar themes emerged from all three groups; although the theme 'impact on social contact and participation' was more relevant to those with socially noticeable strabismus (isolated and combined group), it was not completely insignificant for participants with isolated amblyopia as they articulated how functional limitations affected their social life and relationships with family and friends (refer section 3.6.4). Similar QoL themes and comparable QoL issues suggest that common item banks would suffix both amblyopia and strabismus. Following item extraction, the number of items that are common to both amblyopia and isolated strabismus will be calculated as further evidence to support this claim in Chapter 4. *Note: Item extraction is the process of drawing items from sources such as qualitative studies and literature to develop questionnaires (or item banks as in this case).*

Similar themes and QoL issues emanated from Australia and India data in this study is similar to the findings of a previous study which noted similar problem statements among visually impaired in different population settings.[317] Despite similarities, the study identified that the context and the level of impacts varied between populations.[317] This is also true in the current study (section 3.7) which substantiates the need for the development of country-specific measurement system.

The chapter enumerated several symptoms that impacted the participants' QoL. These ranged from visual symptoms (e.g. poor vision in amblyopic eye), ocular comfort symptoms (e.g. eye strain), symptoms related to binocular dysfunction (e.g. poor depth perception), to general bodily symptoms (e.g. headache). While some of these symptoms such as poor vision and depth perception are clinically obvious, the study identified other uncommon symptoms such as glare, increased light sensitivity, back and neck pain. This is not a completely novel finding as some of these symptoms were previously reported by adults with strabismus in a qualitative study by Hatt *et al*.[86] However, the current study identified that these symptoms are common among all types of amblyopia including anisometropic amblyopia and isolated strabismus. Further investigation is necessary to quantify its association with the eye condition and its prevalence in the population.

The chapter underlined several limitations faced by participants in their day to day life. Participants reported many limitations in driving (e.g. difficulties in judging distances, speed, changing lanes and driving in dim illumination) which made them accident-prone. It is interesting to note that adults with amblyopia/ strabismus experience issues such as difficulty in judging distances despite having lived with the condition for long. Reports of accidents in the study ranged from minor (e.g. bumping into roadside curbs) to major road traffic accidents and supports the association found between moderate and severe amblyopia and road traffic accidents.[80] To combat the difficulties encountered while driving, participants in our study adopted a more cautious driving behaviour, which is similar to that observed in stereo-reduced motorists by a methodologically different study.[163] It is worthwhile to note that the impact for some in our study was significant in that that they gave up driving or limited driving to familiar places or closer distances. In countries like Australia, where self-driving is common and is the preferred mode of transport,[318] an inability to drive might have more significant consequences affecting independence, work and social participation.

Reading, especially for a prolonged time was affected by symptoms (e.g. eye strain), font style, size and spacing. These qualitative findings supports the reading impairments identified in children with microstrabismic amblyopia,[77] adults with strabismic amblyopia[76] and children with anisometropic amblyopia.[319] While it is known that reading fine print with the amblyopic eye is impaired by crowding,[320] participants in our study noted this difficulty even under their habitual binocular reading conditions. A possible explanation for this could be related to the suppression scotoma apparent during binocular reading as suggested by Kanonidou *et al,* 2014,[76] which further explains why some participants in our study preferred to read by closing one eye, although this involved associated inconvenience. These findings indicate that the impacts on reading are notable and significant to participants in daily life, although not reflected in the evidence of current population-based investigations.[6, 80] Nonveridical visual perception (misperceptions) may be present in amblyopia and these should be considered while interpreting the problems reported by the participants, especially in performing high contrast and high spatial frequency tasks such as reading.[321] The other major finding of the study was the impact on engaging in sporting activities which supports the findings of Satterfield *et al*, 1993[135] and Packwood *et al*, 1999[138] who investigated the psychosocial impacts of strabismus and amblyopia respectively through surveys. Our study adds to this knowledge by enumerating the difficulties that participants' face (e.g. catching a ball, judging a ball's flight in motion). These impairments in turn influenced the choice of sports; participants chose sports/ activities that were less visually demanding as an alternative to those that were more difficult. This could be the reason why Rahi *et al*, 2006 did not find an association between amblyopia and participation in sports.[80] Nevertheless it should be noted that participants in our study, despite engaging in some kind of sports expressed regret about not being able to pursue the ones they liked.

Participants in our study recognised difficulties in moving around safely, especially while going downstairs and reported difficulties with their balance, tripping and falling. These findings are not surprising because of the known relationship between impaired contrast sensitivity, stereopsis and decreased visual field (common visual deficits associated with amblyopia and strabismus[5]) and falls[322] and gait instability.[323] Trouble negotiating obstacles and bumping into objects, articulated by our study participants, further supports the known effects of long-standing reduced stereoacuity associated with amblyopia on adaptive gait.[324] Considering the increased odds of falling in those

with unilateral visual impairment,[325] the challenges encountered by participants in navigating the real word environment safely should not be underestimated.

In addition to the well-known impact of amblyopia on career choice (owing to failure in meeting occupational vision standards)[5, 326, 327] and the negative implications of socially noticeable strabismus in gaining employment and promotions,[328] the current study expands our understanding of the functional impacts on work. These include limitations in performing certain work-tasks (e.g. impaired depth perception excluding a doctor from performing surgery) and being less efficient/ productive (e.g. taking more time to finish a task). In addition to these, the study identified several functional limitations in other everyday tasks which ranged from chopping vegetables safely in the preparation of food to capacity for personal grooming. Although there was no explicit mention in the participant narratives about the speed with which participants were able to perform fine motor tasks such as sewing, craft and using hand tools, it was clear that these tasks were challenging. This could be because of the impairments in performing manual dexterity tasks with speed and accuracy.[5, 163, 329] It is interesting to note that many of our study findings (e.g. difficulties in driving, reading, using stairs, walking) are similar to a previous study which explored the quality of life in adults with diplopic and non-diplopic strabismus;[86] nevertheless, our study focussed on both amblyopia and strabismus, and provides a more exhaustive qualitative narrative.

While the participant responses in our study did not suggest if the limitations experienced were more pronounced during childhood or now, we noted that the participants' priorities and concerns changed over time. For example, a participant who was concerned about not being good at sports in childhood was no longer bothered about it; instead limitations in driving was her main concern now. The limitations faced by the participants influenced the activities that they chose to undertake; they avoided tasks that were difficult if they had a choice. For instance, participants avoided visually demanding sports, driving at night-time and career that demanded performing tasks that were challenging for them. Adaptations to tasks that they chose to undertake was mainly being slow and cautious (e.g. driving slowly, taking more time to complete work tasks). With advancing age, participants admitted that they try to accept their limitations and learn to live with their eye condition.

Similar to previous studies,[138, 140] the fear of losing vision in the better eye was predominant among participants with amblyopia in the current study. This further

supports the correlation found between the domain 'fear of losing the better eye' of the A&SQ and the utility measured by time trade-off method.[52] As amblyopes have increased risk of bilateral visual impairment,[79, 255, 330, 331] this concern is legitimate and affects the emotional wellbeing of individuals by posing fear, worry and anxiety. These findings emphasises the need for early amblyopia diagnosis and treatment.[332]

Non-compliance with amblyopia treatment is common in childhood due to social stigma and the other impacts of occlusion therapy.[17, 18, 84, 194] While these are well known, the current study recognised that participants who were non-compliant as a child develop a sense of guilt and self-reproach. This feeling exacerbates when they come to know that amblyopia may not be successfully treated at later stages. Future investigations are necessary to weigh the negative effects of amblyopia treatment during childhood against the life-long emotional consequence of non-compliance.

The psychosocial and psychological correlates of noticeable strabismus have been well understood; strabismus is known to be associated with social phobia,[237, 238] depression,[216, 241] anxiety[241] and psychiatric disorders.[261, 333] The current study re-emphasises the manifestation and implications of these impacts in the present age in both high and low income countries (Australia and India) with different cultural and environmental settings. Social discrimination, trouble making friends and finding a life partner, embarrassment, strong emotional reactions (e.g. anger), distress (e.g. crying) and self-harm (e.g. cutting of wrists) were evident (sections 3.6.4 and 3.6.5). As this study did not include individuals with a known diagnosis of mental illness and it is unlikely for those who are highly impacted to take part in research, the impacts in the population may be more intense than those reported in this chapter.

Strabismus surgery in adults have found to be beneficial from both psychosocial and functional perspectives;[54, 56] however, adults delay getting surgical intervention. Coats *et al*.[36] identified several reasons for this delay. Among these were 'surgery not offered by the doctor', 'surgery declined by the patient' and 'patient been told that surgery can make the condition worse'.[36] All these factors were identified as concerns in the current study. In addition to these, the study identified the lack of awareness about the potential functional benefits of strabismus surgery, as some participants deferred surgery believing it to be purely cosmetic.

Participants with strabismus in the current study coped using several ways, similar to that identified by Hatt *et al*.[86] and James *et al*.[239] In addition, the current study

identified other ways by which participants coped with their functional impairments posed by amblyopia and strabismus (section 3.6.8). Coping emerged as an important theme in this study and studying how well an individual cope may be an indicator of QoL.

It is worthwhile to note that the QoL themes identified in this chapter are similar to those that were previously identified in the development of other disease modules of the Eye-tem bank project, which were also patient derived.[2, 153, 246] This indicates that similar QoL constructs are important for people experiencing a range of ocular diseases and that it is important to measure each of these constructs to comprehensively understand the impact of the eye disease on one's QoL. However, it should be noted that these constructs, despite being similar across disease groups, are each measured by items that are disease specific. For example, the construct 'Symptoms' is measured by different sets of items that are specific to diabetic retinopathy[246] and glaucoma;[153] these items were derived from comprehensive patient consultations and the modules were developed independent of each other.[153, 334] Similarly, the results of this study will be used to extract items for the construction of amblyopia and strabismus specific item banks for Australia and India (Chapter 4) and the item banks developed will be calibrated on an interval scale using modern psychometric analysis based on the Rasch measurement theory (Chapter 6).

Several measures were taken throughout the study to ensure rigour, patient-centeredness and content validity. Rich qualitative data, the adoption of qualitative methods that are appropriate for the development of PROMs (phenomenological approach, inductive analysis by method of constant comparison), triangulation of data (from different countries – Australia and India, different sources – community, optometry practices and hospital set-up) and diversity in sample characteristics demonstrate validity of the content elicited by the study for item banks development.

Nevertheless, there are some limitations in sample selection, methods and analysis that should be noted. The Australian sample were predominantly recruited from eye care practices in Australia while the Indian sample was recruited from a tertiary eye care hospital in India. As these collaborations were researcher's choices based on logistics and convenience, selection bias may be present. The Australian sample had no representation of indigenous population and the Indian sample had no representation of the presbyopic population. In addition, the Indian study had no sample with isolated strabismus. This could be because the sample for the Indian

study was recruited from an adult amblyopia clinic of a tertiary eye hospital where it is more likely for younger adults with amblyopia to be referred for treatment. This limitation was addressed by testing the item banks developed based on this qualitative analysis on participants with isolated strabismus recruited from other out-patient departments in Phase 2 (Chapter 6).

Adult amblyopia treatment is not common yet; however, it was offered at the adult amblyopia speciality in India from where the participants were recruited. Therefore, it is more likely that these participants were treated compared to the participants in Australia who may have visited their eye care practitioner for a general check-up. Extensive information on this is not available and hence it is difficult to comment how this may have influenced their perception, awareness and experiences.

Both focus groups and interviews were adopted in Australia whereas only interviews were possible in India, as it was done over telephone from Australia. Focus groups allows group dynamics and ideas exchange which is not possible in individual interviews. This could be the reason why the Australian sample pronounced more impact (listed more QoL issues) than the Indian sample.

For uniformity and ease of item extraction (Chapter 4), data coding of the Indian narratives was done in English although some interviews were in Tamil. Complete data analysis of both countries was carried out by a single person, which might have introduced researcher bias. However, this bias was minimised by expert panel consensus of the codes, categories and emergent themes.

Unilateral amblyopia and strabismus may be underestimated in terms of its real-life impact owing to the presence of one eye with clinically normal visual acuity. By identifying and describing the several impacts perceived by individuals themselves in normal day to day situations, this chapter widens our knowledge about the impact of these conditions on QoL.

CHAPTER 4 CONTENT EXTRACTION AND DEVELOPMENT OF AMBLYOPIA AND STRABISMUS SPECIFIC QUALITY OF LIFE ITEM POOLS FOR AUSTRALIA AND INDIA

4.1 Introduction

Chapter 3 presented the results of the qualitative studies conducted in Australia and India to elicit content for the amblyopia and strabismus specific item banks in development. This chapter presents the next stage in which item pools addressing all important QoL constructs recognised by patients was developed. A systematic rigorous process[2, 159] was adopted to identify and incorporate content catering the full spectrum of latent trait (QoL constructs) in the population and to develop item banks that are robust.[300]

Chapter 1 and 2 established the rationale for developing item banks for a high-income country setting (Australia) and low-income country setting (India). Unlike Australia, where English is the primary language of communication,[335] India is a diverse country with many regional languages.[336] In order to construct item banks that can be applied to a wide majority of the Indian population, it was decided to develop the Indian item banks in three languages – English, Hindi and Tamil. English is the second commonly spoken language in India and is the primary medium of instruction in most tertiary education. English and Hindi are the official languages of the Indian federal government.[336] Hindi is the most commonly spoken language in India and 4th in the world; nearly 50% of the Indian population (over 550 million people) speak Hindi.[336] Tamil is the sixth commonly spoken language in India and is the primary language of communication in Tamil Nadu state,[336] where the study collaboration was established.

4.2 Aim and objectives

The aim of this chapter was to obtain optimal sets of representative items addressing all important aspects of QoL to enable comprehensive measurement of the impact of amblyopia and strabismus on adults.

The objectives were to

1) Develop QoL item pools in English for Australia and in three languages (English, Hindi and Tamil) for India

2) Seek empirical evidence to guide decision on developing separate or combined item banks for amblyopia and isolated strabismus based on the number of common items
3) Examine the number of items that are common across Australia and India to explore the possibility of creating universal item banks in future

The amblyopia and strabismus specific item pools for Australia was constructed first, followed by the development of the Indian version. This chapter is therefore divided into two broad sections: 1) Development of amblyopia and strabismus specific item pools for the Australian population and 2) Development of amblyopia and strabismus specific item pools for the Indian population. The underlying principles and methods (content identification, evaluation and construction) are similar in both these constructions. The Indian item banks were first developed in English and later translated into Hindi and Tamil languages.

This chapter is laid out such that each methodological process is immediately followed by respective results. This layout is followed throughout the chapter to minimise burden on the reader to follow the multiple processes involved in the constructions.

4.3 Development of amblyopia and strabismus specific item pools for Australian population

A systematic step-wise qualitative item review process was adopted for the development of the item banks: 1) Content identification 2) Item evaluation 3) Item construction and 4) Pre-testing (Figure 4-1).[2, 153, 246]

In step 1, content for the item banks were identified from existing amblyopia and/or strabismus specific PROMs, published qualitative literatures and an extensive qualitative research with individuals experiencing amblyopia and/or strabismus. Items generated from these sources formed the initial item pool (section 4.3.1.4). These items were evaluated iteratively in step 2 using binning and winnowing processes explained in section 4.3.2. Following the iterative process, the items were structured by constructing item stems and response categories (Step 3, section 4.3.3) and revised by pretesting with experts and cognitive interviews (Step 4, section 4.3.4). Each step is described below.

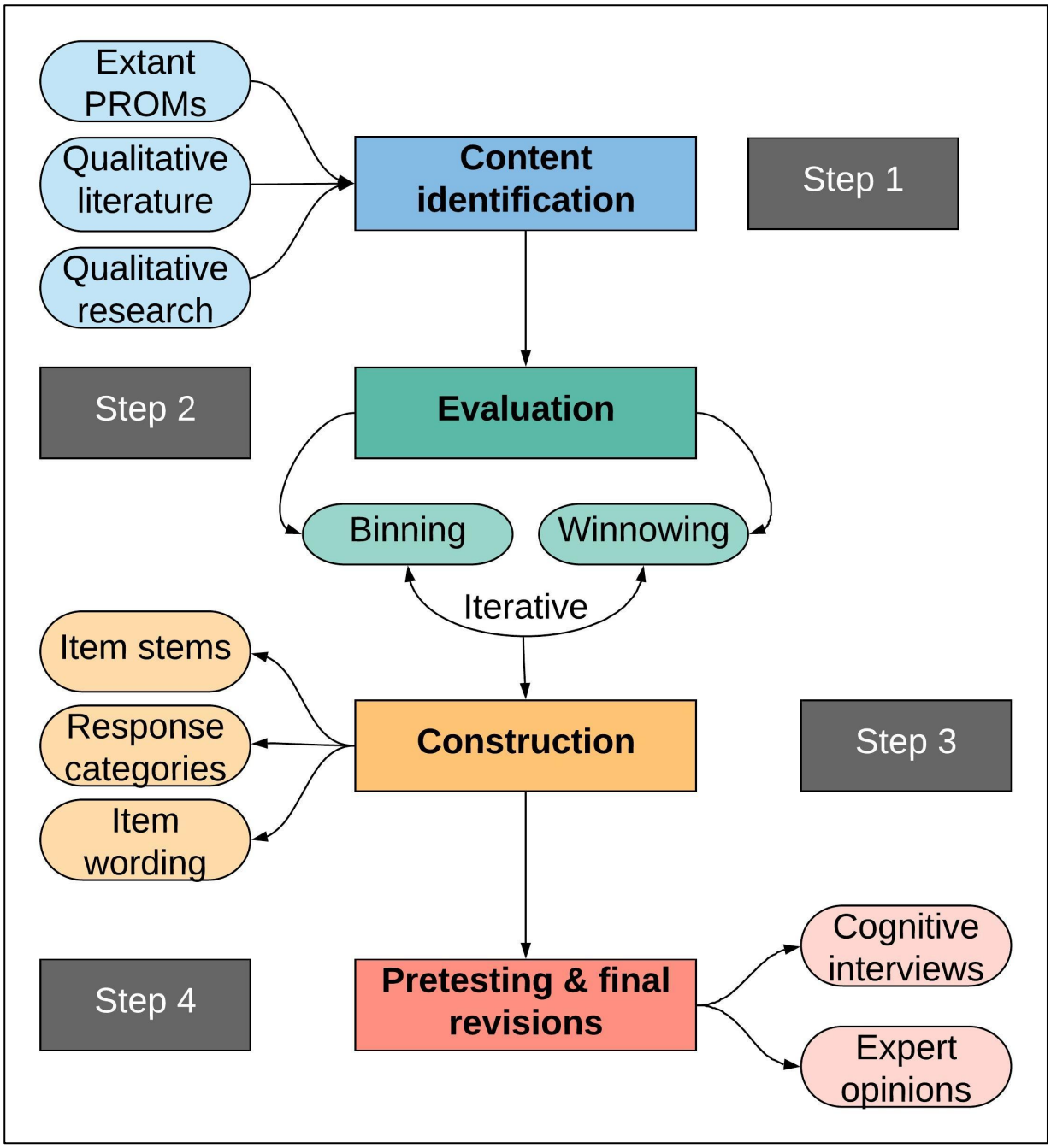


Figure 4-1 Steps in the development of the Australian item pools

4.3.1 Content identification

Following the extensive literature review in Chapter 2, content for the item bank was identified from three sources – existing amblyopia and/or strabismus specific PROMs, published qualitative articles and a prospective qualitative study (Chapter 3). The aim was to identify all relevant items that covered a range of experiences of adults living with amblyopia and/or strabismus.

4.3.1.1 Content extraction from extant disease-specific PROMs

All self-report amblyopia and/or strabismus specific PROMs identified by the systematic review in Chapter 2 was considered for item extraction. These PROMs were identified by a systematic search in electronic databases of PubMed, Cochrane, Web of Science and PsycINFO. More details about the search, inclusion and exclusion criteria can be found in Chapter 2, section 2.3.1.

The systematic review identified 32 disease-specific PROMs developed for amblyopia and/or strabismus (Table 4-1). As the aim of this doctoral thesis was to develop item banks specifically for adults, it was initially thought to extract items only from adult PROMs as PROMs developed for children may contain items that are specific to children and their life (e.g. How easy is it for you to draw, colour in a picture or write words at school? – item from children vision for living scale). However, on examination of the items, it was found that some items from the children PROMs were relevant to any age group (e.g. How much do you enjoy reading the smallest print in your textbook? – another item from children vision for living scale).

On closer examination of the child-specific PROMs, it was found that most of the proxy measures (PROMs that measured the impact on children from caregiver's or parent's perspective) assessed issues or impact related to amblyopia treatment on children that were not very relevant to adults (e.g. Have you had any difficulties getting your child to wear his/her glasses? – item from emotional impact of amblyopia treatment questionnaire; My child does not seem to mind using the drops – item from amblyopia treatment index) and some assessed the impact of the condition or treatment on parents (e.g. I experience anxiety as a result of my child's visual impairment – item from patching success questionnaire; How much do you worry about the squint of your child? – item from 8-item QoL questionnaire). Hence, it was decided to include all PROMs developed for adults and those PROMs that were developed as self-report for children (i.e. excluding proxy measures). Items from both validated and non-validated PROMs were considered, as the aim was to obtain all relevant items at this stage.

Table 4-1 Content identification from extant disease-specific PROMs

Disease-specific PROMs	Age group	Self/ Proxy	Items reported	No. of items	Considered for item evaluation
Amblyopia Survey	Adolescents & adults	Self	Yes	8	Yes
Socio professional integration questionnaire	Adolescents & adults	Self	No	12	No
Patching success questionnaire	Children	Proxy	Yes	60	No
Amblyopia treatment index	Children	Proxy	Yes	20	No
Child amblyopia treatment index	Children	Self	Yes	19	Yes
Perceived psychosocial questionnaire	Children	Proxy	No	10	No
Emotional impact of amblyopia treatment questionnaire	Children	Proxy	Yes	15	No
Occlusion patch comfort questionnaire	Children	Proxy	Yes	21	No
Child amblyopia treatment questionnaire	Children	Self	Yes	11	Yes
Children's vision for living scale	Children	Self	Yes	21	Yes
46 item QoL questionnaire	Children	Proxy	No	46	No
QoL questionnaire for children with anisometropic amblyopia	Children	Self	Yes	16	Yes
Adult strabismus questionnaire	Adults	Self	Yes	20	Yes
Intermittent exotropia questionnaire	Children	Self & proxy	Yes	12	Yes
Vision function scale	Children and adults	Self	Yes	9	Yes
Perceived visibility of strabismus	Adults	Self	Yes	1	Yes
Strabismus survey	Adolescents & adults	Self	No	15	No
8 item QoL instrument	Children	Proxy	Yes	8	No
Disability questionnaire	Adults	Self	Yes	6	Yes
Repertory grid	Adults	Self	Yes	105	Yes
Psychosocial experience questionnaire	Adolescents & adults	Self	Yes	17	Yes
Expectations of strabismus surgery questionnaire	Adolescents & adults	Self	Yes	17	Yes
Effect of diplopia questionnaire	Children and adults	Self	Yes	6	Yes
Perspectives questionnaire	Adults	Self	Yes	5	Yes
Post strabismus surgery symptom questionnaire	Adults	Self	Yes	9	Yes

Psychosocial effects of strabismus pre and post-operative questionnaire	Adolescents & adults	Self	Yes	25	Yes
Exotropia symptom questionnaire	Children	Self & proxy	Yes	15	Yes
Satisfaction of surgical outcome	Adults	Self	Yes	1	Yes
Visual analog scale	Adolescents & adults	Self	Yes	7	Yes
Modified RAND health insurance study QoL instrument	Children	Proxy	Yes	41	No
Amblyopia and strabismus questionnaire	Adults	Self	Yes	26	Yes
Psychological impact questionnaire	Adolescents & adults	Self	Yes	33	Yes
Total number of extant items				637	
Total number of items considered for item evaluation				389	

The 32 disease-specific PROMs comprised a total of 637 items. Eighty-three items from four PROMs were not reported in literature, which resulted in a total of 554 items from 28 PROMs. Out of the 28 PROMs, six proxy measures (165 items) were excluded; thus 389 items remained for item evaluation (next step). Out of the 389 items, 75 were from amblyopia specific PROMs (n=5), 255 from strabismus specific PROMs (n=15) and 59 from PROMs developed for both amblyopia and strabismus (n=2).

An item library in Microsoft Excel spreadsheet was created to record these items and the following details regarding each item: name of the PROM from which the item was extracted, item format (item stem or preceding statement), response categories and domain /subscale to which the item belong (if reported in the literature). A unique alphanumeric ID was created for each item that identified the parent PROM and the order of the item in the PROM. This was done to identify items easily and to facilitate the item evaluation process.

4.3.1.2 Content extraction from published qualitative articles

The systematic search in Chapter 2 identified five qualitative studies that described the impact of amblyopia (n=3) and strabismus (n=2). Out of the five studies, three were investigations on children and one explored the clinician's perspectives of the impact; only one explored the impact on adults. However, for reasons stated earlier, all the five studies were considered for item identification and all items relevant to the

QoL experience of adults were extracted. Table 4-2 displays the aims of these qualitative studies and the themes that emerged out of them.

Table 4-2 Published qualitative studies

Reference	Aim	Sample; qualitative method	Themes / Topics
Koklanis *et al.*, 2006[84]	To explore the psychosocial impact of amblyopia and its treatment from both the children and their parent's perspectives	41 children (3 to 15 years) and their parents / guardians; In-depth interviews	4 themes: The stigma of amblyopia treatment, Managing stigma, Spoiled identity and spoiled relationships, Management of personal identity
Hatt *et al.*, 2007[86]	To study the effects of strabismus on the QoL of adults to develop a strabismus specific questionnaire for adults	30 adults with strabismus; In-depth interviews	48 topics (e.g. anxiety, driving, meeting people)
Hatt *et al.*, 2008[85]	To identify the concerns of parents and children who are experiencing intermittent exotropia to aid questionnaire development	24 children (5 to 17 years) and one parent; In-depth interviews	18 topics from child interviews (e.g. worry, self-consciousness, troubled by double vision) 22 topics from parent interviews (e.g. comments from others, self-confidence, school)
Carlton, 2011[82]	To explore the clinician's perspectives about the impact of amblyopia and its treatment	13 practicing orthoptists (clinicians); Focus groups	9 themes: Adult quality of life issues, Appointments to the hospital, Appearance, Glasses-wear, Patching treatment, Atropine, Limited activities, relationships with family, Treatment compliance
Carlton J, 2013[83]	To identify potential themes for a paediatric amblyopia specific QoL instrument	59 children (3 years 9 months to 9years 11 months); In-depth interviews	11 themes: Physical sensation of the treatment, Pain, Being able to play with other children, How other children have treated them, Ability to undertake schoolwork, Ability to undertake other tasks, Sad or unhappy, Cross, Worried, Frustrated, Feelings toward family members

Full text articles of each of these studies were exported into the NVivo qualitative data analysis software by QSR International Pty Ltd. Version 11, 2015. Each QoL issue described under the emergent themes/ topics were coded as items into the software

inductively. A total of 87 items that were relevant to experiences of adults were extracted from 179 coding references (number of phrases coded).

4.3.1.3 Content extraction from prospective qualitative research

To complement the extant items identified from existing disease-specific PROMs and published qualitative literature, a comprehensive qualitative study was conducted with adults aged over 18 years who were experiencing amblyopia and/or strabismus (Chapter 3). The demographics and clinical characteristics of the participants (n=49) are provided in Chapter 3, section 3.5.1. The participants were asked to describe the ways in which their eye condition (amblyopia and/or strabismus) was affecting their life. A semi-structured interview guide (Appendix 6) developed based on extant literature and investigator's clinical experience was used to facilitate the sessions. All sessions were audio recorded. Thematic saturation was considered as the end point of data collection. More details about the study methodology is found in Chapter 3.

The verbatim transcripts of all interviews and focus groups were stored, managed and analysed using the NVivo 11 software. After data familiarisation, each participant statement (utterance) was examined iteratively for potential items using constant comparative method, whereby the utterances across and within the transcripts were systematically coded by comparison.[337] All relevant participant phrases and words were coded as nodes into the NVivo software by me; this initial set of codes were validated by Dr Jyoti Khadka. A total of 454 items were extracted from 3927 coding references. Examples of participant utterances and codes are shown in Table 4-3.

Table 4-3 Examples of coding from direct participant quotes

Direct participant quotes	Codes
"I got bullied a lot and it affected my self-esteem a lot and I ended up cutting my wrists." *Interview 12*	Bullying Impact on self-esteem Suicidal tendencies
"I certainly am more clumsy. I certainly miss because I have no depth, so I do knock things over and trip over things a lot." *Interview 18*	Being clumsy Poor depth perception Knocking things over Tripping / Stumbling
"**I love tennis, but I really couldn't see the ball** and I'd actually get very cross with myself that I couldn't do it because I loved it." *Interview 5*	Difficulty in seeing the ball while playing sports **Difficulty in seeing ball while playing tennis** Getting cross/ upset Not being able to do things they liked

"Well I was a nurse and I chose (to work in operation) theatre because that way you hide, don't you, because you're like this." *Focus group 2 (participant 2)*	Impact on career choice / occupation Hiding the eye defect Self-conscious Withdrawal
"It just made me withdraw more into myself because you was afraid of talking to people and you couldn't look at them straight in the face…" *Focus group 2 (participant 5)*	Concern about looks Withdrawal Talking with people Having eye contact with people

Each segment of the participant quotation and their corresponding code is highlighted in the same colour for the ease of identification.
Highlights: Green=Green, Blue=Blue, Yellow=Yellow
Some parts of the participant statements were coded into two different codes.
Represented by font: Red = Red

4.3.1.4 Initial item pool

At the end of the content identification step, 930 items (drawn from three different sources) constituted the initial item pool. (Table 4-4).

Table 4-4 Initial pool of items drawn from extant PROMs, qualitative literature and prospective qualitative research

Source	No. of items
Existing PROMs (n=22)	389
Published qualitative articles (n=5)	87
Prospective qualitative study (n=49)	454
Total	930

4.3.2 Item evaluation

The items in the initial item pool were not unique in content but an accumulation of all potential items that addressed a wide range of QoL constructs such as limitations in performing daily living activities, impact on social life and emotional impact. In order to form scales that were unidimensional, it was necessary to group items that measured the same construct. At this stage, the grouping was solely based on qualitative judgement of semantic meaning and not tested by psychometric analysis. Considering the vast number of items, it was also necessary to reduce the number of items by eliminating the ones that were less relevant. Hence the items were evaluated.

Each item in the initial item pool was examined for its content and the underlying latent trait (construct). The grouping (binning) and elimination (winnowing) of items were based on qualitative judgement that was guided by a systematic process of item evaluation. The protocol for this evaluation was adapted from the Patient Reported Outcomes Measurement Information System (PROMIS) group[150, 338] and have been

successfully employed in the development of other disease modules of the Eye-tem bank project.[153, 246]

4.3.2.1 Binning

Binning is a process by which items that measure a specific construct (latent trait) are classified (grouped). The purpose of binning is to obtain sets of relevant items that adequately capture the meaning of particular domains.[338] By this systematic process, it is also possible to identify the items that are redundant in meaning/ content and the ones that are unique and informative.[338]

The QoL constructs identified by the qualitative research in Chapter 3, which was similar to the QoL domains identified by the Eye-tem bank research group acted as 'bins' for classifying items from the initial item pool (Table 4-5). The content of each item in the initial item pool was examined against the QoL domain definitions (Table 2-3) and were classified under the respective QoL domain bin based on the construct it measured. For example, all items describing difficulties in performing tasks were classified under the 'Activity limitation' bin and all items describing emotions/ emotional reactions due to the condition or its treatment were grouped under the 'Emotional impact' bin.

Out of the 389 items drawn from extant PROMs (Table 4-1), 46 could not be classified as they were either generic (global items), irrelevant or measured aspects other than QoL. For example, items measuring self-perception of a person's intelligence (repertory grid),[57] the individual's perception about the relative contributions of various factors affecting strabismus surgery outcome (perspective questionnaire)[104] and the overall satisfaction of surgical outcome[232] were discarded. The remaining 343 items were classified under the nine QoL domains (Figure 4-2); most of the items from amblyopia specific PROMs measured activity limitation (n=17), inconveniences (n=15) and emotional impact (n=14) whilst most the items from strabismus specific PROMs measured concerns (n=98), emotional impact (n=53) and social impact (n=45). Overall, the domain concerns had highest number of items (n=121) followed by the domain emotional impact (n=72); the domains economic impact (n=4) and coping (n=2) had the least number of items.

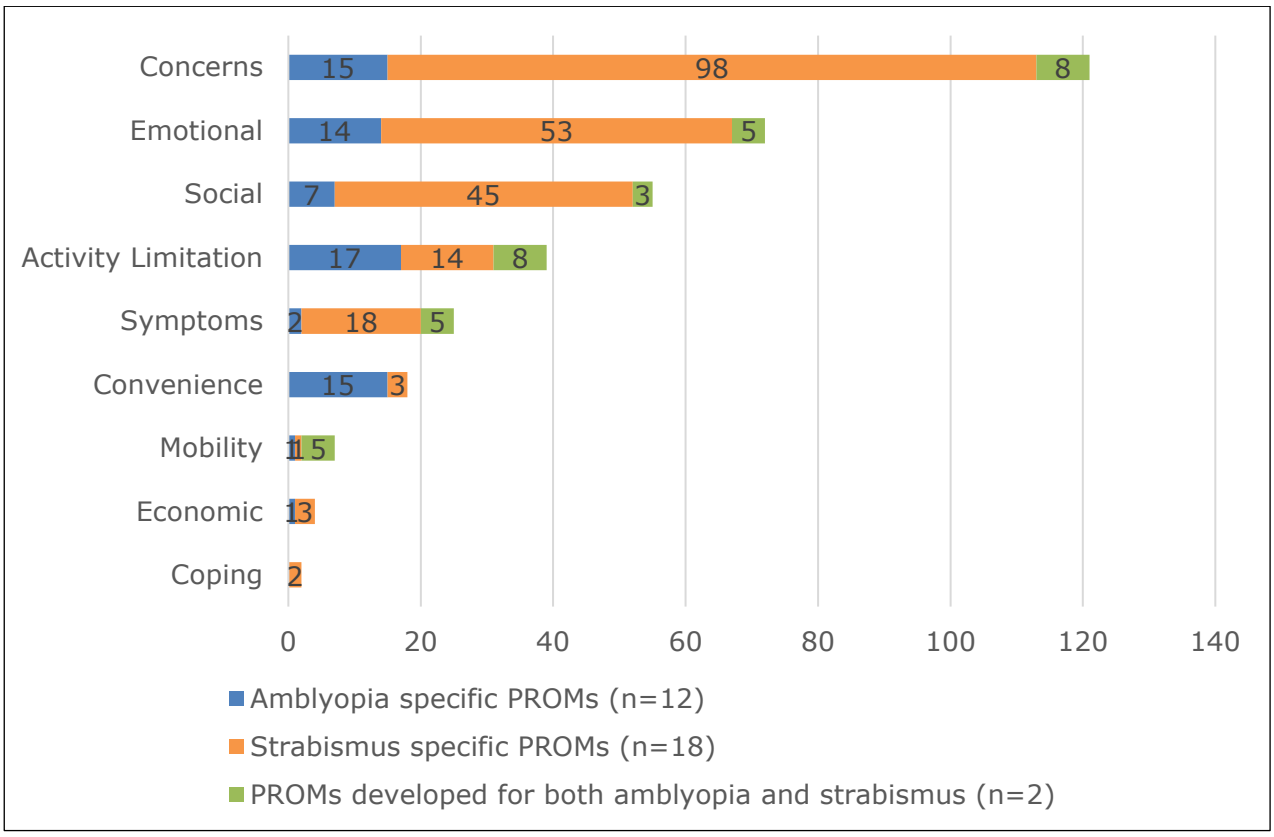


Figure 4-2 Classification of the extant items drawn from amblyopia and/or strabismus specific PROMs

Out of the 87 items extracted from published qualitative literature, the majority of the items was classified under the bins concerns (n=18), emotional impact (n=18) and symptoms (n=15). Of the 454 items drawn from the prospective qualitative research, bins activity limitation (n=100), emotional impact (n=92) and concerns (n=81) had highest number of items. Table 4-5 displays the distribution of the items in the initial item pool across the nine QoL domain bins. It should be noted that these are not the number of unique items, but the initial number of extant items pooled under each domain.

Table 4-5 Initial item pools - Item distribution across the QoL domains

QoL domain bins	Existing PROMs	Qualitative literature	Qualitative research	Total
Symptoms	25	15	36	76
Activity Limitation	39	6	100	145
Mobility	7	5	10	22
Concerns	121	18	81	220
Emotional impact	72	18	92	182
Social impact	55	9	44	108
Convenience	18	6	25	49
Economic	4	1	21	26
Coping	2	9	45	56
Items not classified	46	-	-	-
Total	389	87	454	**930**

Almost 49% of the total items (454 out of 930 items) in the initial item pool were contributed by qualitative research (Chapter 3) alone. Table 4-6 displays examples of items drawn from the qualitative research, the number of participant utterances that corresponded to the item and the total number of participants who endorsed it.

Table 4-6 Examples of items drawn from qualitative research

QoL Domain	Item	No. of participant utterances (%)	No. of participants who endorsed the item
Symptoms	Difficulty in focussing eyes Sensitivity to light	15 (2.95%) 28 (5.51%)	10 21
Activity Limitation	Pouring a drink Catching a ball	9 (1.64%) 12 (2.19%)	12 11
Mobility	Going down steps or stairs Navigating in dim light	19 (17.43%) 18 (16.51%)	12 16
Concerns	Being dependent on good eye Concern about appearance	34 (2.46%) 20 (1.45%)	20 17
Emotional impact	Have low self-confidence Feel frustrated	15 (2.69%) 16 (2.87%)	10 8
Social impact	Engaging in social activities Making a presentation in front of a group	6 (2.76%) 6 (2.76%)	5 6
Convenience	Having to drive slower and more carefully Needing longer to do things	4 (1.16%) 7 (2.03%)	3 5
Economic	The cost of buying glasses or other visual aids Losing job opportunities	48 (27.59%) 9 (5.17%)	30 6
Coping	Accepting the eye condition Avoiding difficult tasks	16 (3.46%) 5 (1.08%)	11 5

% provided is out of the total number of coding reference in each domain

4.3.2.2 Winnowing

Winnowing is a process by which large item sets are reduced to minimally representative sets of items.[338] The following criteria were used to eliminate items from the bins: redundancy (items that were similar in meaning/ content to another item), clarity (items that were ambiguous/ vague/ confusing) and applicability (items that were too narrow to have wider application).[159, 338] This process also facilitated the identification of items that were incorrectly binned and mobilisation of them to their respective bins. The goal was to minimise the number of items within each QoL domain yet retain all unique and relevant items. Examples of items deleted during the winnowing process are displayed in Table 4-7.

Table 4-7 Examples of items eliminated during the winnowing process

Items	Sources	Problem	Action
Did you have trouble making eye contact?	Psychosocial experience questionnaire	Redundancy: Items were redundant in meaning	Items were replaced by 'Having eye contact with people'
Difficulty in making eye contact	Exotropia symptom questionnaire		
Effect of strabismus on eye contact with individual	Psychosocial effects of Strabismus questionnaire		
I have difficulty making eye contact in a one-on one conversation	Amblyopia and Strabismus questionnaire		
I have difficulty making eye contact with people in a group conversation	Amblyopia and Strabismus questionnaire		
Struggle to look people in the eye	Qualitative literature (Hatt *et al*., 2007)		
Look away from people	Qualitative literature (Hatt *et al*., 2007)		
Trouble having eye contact *"I couldn't look at them straight in the face, I had to look – well, downwards rather than straight in the face."*	Focus group 2 (Qualitative research)		

Difficulty in walking	Disability questionnaire	Clarity: Items were considered difficult to relate (imprecise) as participants did not have impairment in walking but had trouble walking with normal posture/ without losing balance	Items were replaced by 'Walking steadily with normal posture/ gait'
Trouble walking	Qualitative literature (Hatt *et al*., 2007)		
Walking crooked *"I used to walk very crooked, I walked like a drunk person"*	Interview 12 (Qualitative research)		
Trouble walking straight *"…when I'm walking straight, all of a sudden I'll lose my balance…"*	Focus group 2 (Qualitative research)		
How clearly (well) can you see the smallest writing on the board at school?	Children's vision for living scale	Applicability: Blackboard was considered too specific	Items were replaced with 'Reading from a board or overhead screen'
How difficult do you feel when reading words on the blackboard?	QoL Questionnaire for children with anisometropic amblyopia		
Straining to see the blackboard *"when I was at school, I had to strain to look at the blackboard"*	Interview 25 (Qualitative research)		

4.3.2.3 Multiple iterations

The binning and winnowing processes were iterative and was guided by the consensus of an expert panel comprising of the PhD candidate, Dr Jyoti Khadka and Prof Konrad Pesudovs. Although item evaluation started by classifying items into bins of known QoL domains, the expert panel was open to the emergence of newer domains, particularly guided by items drawn from the prospective qualitative research. However, no new QoL construct emerged and all items could be mapped to respective QoL domain bin based on its semantic meaning.

The iterative process allowed multiple evaluations and flexibility in classifying and eliminating items. 76 items that were initially classified under the bin symptoms were reclassified into three bins – visual, ocular and general symptoms based on domain definitions (Table 2-3). Multiple evaluations also enabled identification and regrouping of items that have been incorrectly binned. Considerable change took place in the bin 'social impact'. During the process, it was identified that many items under social

impact did not assess the individual's ability to engage in social activities or fulfil social obligations (according to its domain definition – Table 2-3) but rather measured psychosocial concerns or emotional impact. For example, items such as 'trouble having eye contact with people', 'kids ask what is wrong with my eyes' were moved to bin 'concerns' and items such as 'feel uncomfortable in public' and 'feel uneasy when people stare' were moved to bin 'emotional impact'. The other major change happened in the bin 'emotional impact' wherein items such as 'feel like people do not pay respect' and 'not being successful' were moved to bin 'concerns'.

After multiple iterations of binning and winnowing processes, the initial item pool of 930 items was reduced to a minimally representative set of 322 items across 11 QoL domains namely: visual symptoms, ocular symptoms, general symptoms, activity limitation, mobility, concerns, emotional impact, social impact, economic impact, convenience and coping. Three out of six iterations are displayed in Table 4-8.

Table 4-8 Iterations of item evaluation process

Iterations	Bins representing QoL domains												UC	Total
	VS	OS	GS	SY	AL	MB	CO	EM	SC	CV	EC	CP		
Initial item pool	-	-	-	76	145	22	220	182	108	49	26	56	46	930
1st iteration	17	13	8	-	102	11	110	99	45	26	21	45	-	497
4th iteration	12	7	5	-	63	10	90	61	22	27	13	25	-	335
6th iteration*	15	12	10	-	64	15	64	54	23	26	15	24	-	322

VS: Visual symptoms; OS: Ocular symptoms; GS: General symptoms; AL: Activity limitations; MB: Mobility; CO: Concerns; EM: Emotional impact; SC: Social impact; CV: Convenience; EC: Economic impact; CP: Coping strategies; UC: Unclassified
*Final iteration

The bins activity limitations and concerns had the highest number of items, 64 each. The activity limitation bin encompassed a wide range of activities including items targeting reading ability (12 items) and driving skills (18 items) and the concerns bin encompassed items assessing a wide range of concerns including psychosocial (16 items) and treatment/ eye care related concerns (9 items). However, any further theoretical subdivisions of the domains were not pursued at this stage and was put-off to be tested by psychometric analysis (Chapter 6).

4.3.3 Item construction

The 322 items that remained at the end of the item evaluation process were in its raw form (as derived from extant PROMs, qualitative literature or qualitative research), i.e. the items were not in a structured format to be administered. In order to make these

items suitable for pre-testing, item stems and response categories had to be constructed. The parts of a typical closed-ended item[159] is given in Figure 4-3.

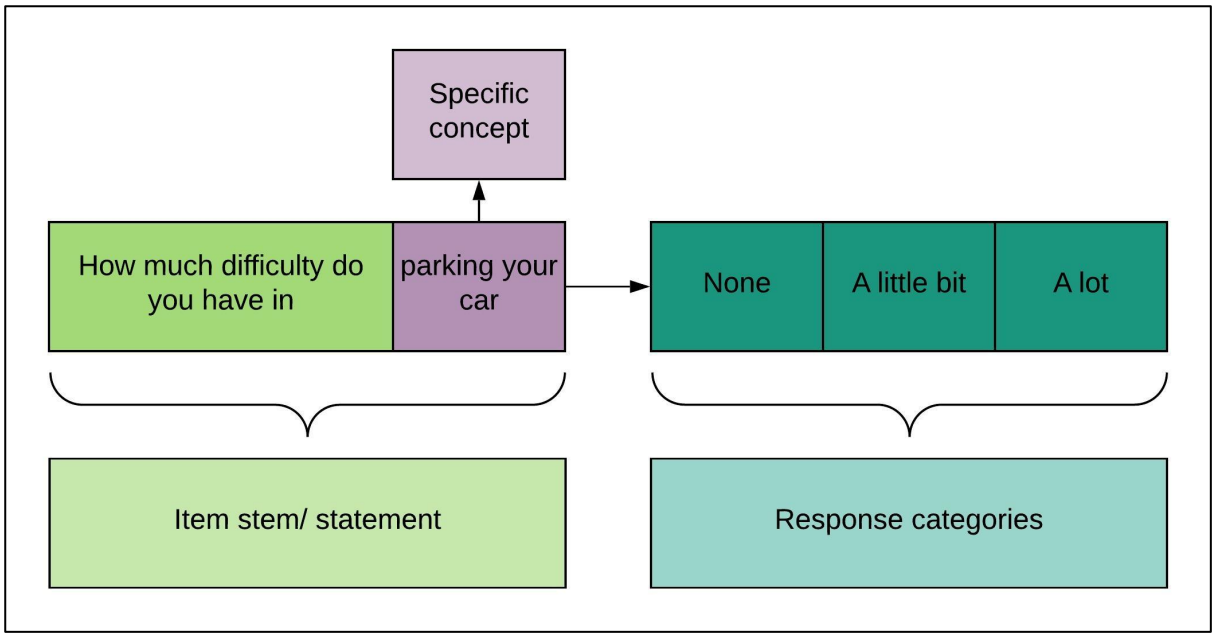


Figure 4-3 Parts of a typical closed-ended question

Item stem is the first part of a question that presents the item to the respondent for their endorsement. Response categories are the options of endorsement that are presented to the respondent, with regard to the question asked. It encompasses a possible set of answers (range of options), from which the respondent could choose the one that closely matches his/her perception or experience. The number of response categories may vary from dichotomous (two response options; e.g. agree-disagree, yes-no) to polychotomous (more than two response options; e.g. never-sometimes-always, agree-neutral-disagree). Response categories also vary in type depending on the item stem (Table 4-9).

Table 4-9 Response categories and item stems

Item stem	Response category type	Response options
How severe is <item>	Severity scale	1 Very severe 2 Moderate 3 Mild
How frequently do you experience <item>	Frequency scale	1 Always 2 Often 3 Sometimes 4 Rarely 5 Never
<Statement>	Agreement scale	1 Strongly agree 2 Agree 3 Disagree 4 Strongly disagree

The Eye-tem bank project employs QoL domain-specific item stems and 4 to 5 response options which is uniform across its various disease modules.[2] Homogeneity of item stems and response categories for items within the same QoL domain was preferred to be consistent in style and ease the cognitive efforts of the respondents.[338] These were developed based on the guidelines put forward by Khadka *et al*, 2012[339] and the empirical evidence of working response categories developed for ophthalmic QoL constructs such as activity limitation.[340] For the QoL domain - symptoms (visual, ocular and general), three separate rating scales measuring the frequency of symptoms (frequency scale), the severity of symptoms (severity scale) and how much the symptoms bothers the individual (bothersome scale) had been employed as all three aspects are important and non-interchangeable.[341, 342] For newer QoL constructs such as concerns and convenience, the item stems and response categories were developed by expert panel consensus.[246] These item stems and response options work optimally for most scales in modules of diabetic retinopathy,[93] and hereditary retinal diseases.[343]

The future aim of the eye-tem bank project is to link item banks developed for various eye diseases. Hence to be consistent, the amblyopia and strabismus specific module shared similar item stems and response categories used for other disease modules. As no new QoL construct emerged in the development of this module, the need for the generation of new item stems and response options were precluded. All QoL domains (except symptoms that had four response options) had five response categories with additional options of 'not relevant' and 'refuse to answer'. The item stems of these (except emotional impact) did not carry a recall time frame to omit recall bias and record participant's current QoL experiences. As emotions can vary considerably even within the same day, the domain emotional impact assessed the average frequency of the items (emotional issues) in the last 4 weeks (time period).

In contrast to other eye-tem bank modules, the extreme response option 'unable to do because of my vision' for domains activity limitation, mobility and social impact[2] was replaced by 'unable to do because of my eye condition'. This change was made because factors other than vision such as misalignment of eyes and poor depth perception can cause difficulties in people experiencing amblyopia and/or strabismus.

Once the item stems and response options were constructed, the items in its raw form were rephrased to match the question structure, without altering its meaning and concept. As item structure and wording affect item measures (difficulty level of the

item) and pose risk for valid measurement,[340] this step was crucial and was guided by the participant narratives from the qualitative research (verbal expression of the participants)[293] and expert panel consensus. Specific examples of certain QoL issues were included in some items as memory cue to help participants quickly relate the item to their life.[293] For instance, the item 'how much difficulty do you have playing fast ball games' was followed by examples – tennis and cricket and the item 'how much difficulty do you have using hand tools' was followed by an example – a screwdriver.

Finally, the following statement, 'Please consider ONLY your amblyopia (lazy eye) and/or strabismus (crossed eye) and its current treatment (e.g. patching therapy, action video game therapy, vision therapy) when you answer these questions', was included in the narrative before the questionnaire. In order to obtain realistic QoL responses, participants were advised to answer how they feel with their habitual refractive correction. To make it clear, the following statement was also included in the narrative: "If you usually use glasses, contact lenses or low vision devices, please answer according to how you can see when using them."

In addition to this, a preceding statement 'Because of your eye condition or its treatment' was reinforced at the beginning of the item stem of each domain to remind participants to consider only their amblyopia and/or strabismus while answering the questionnaire.[293] Table 4-10 displays the final structure of the item banks representing the 11 QoL domains.

Table 4-10 Item stems, sample items and response categories of the 11 QoL domains

QoL domain	Item stem	Sample items	Response categories
Visual symptoms Ocular symptoms General symptoms	Because of your eye condition or its treatment, how often do you experience…?	Double vision Eye strain Headache	Never Occasionally Quite often Very often
	Because of your eye condition or its treatment, how severe is/are the…?		Not at all Mild Moderate Severe
	Because of your eye condition or its treatment, how much of a problem is/are the…?		None A little Quite a bit A lot

Activity Limitation Mobility	Because of your eye condition or its treatment, how much difficulty do you have…?	Catching a ball Crossing a street or road	None A little Quite a bit A lot Unable to do because of my eye condition This task is not relevant to me / don't do the task Refuse to answer
Concerns	Because of your eye condition or its treatment, how concerned are you about…?	Safety of your eyes Your looks	Not at all A little bit A moderate amount A lot Extremely This issue is not relevant to me Refuse to answer
Emotional impact	Because of your eye condition or its treatment, during the past four weeks, how often did you…?	Feel unhappy Feel anxious	None of the time A little of the time Some of the time Most of the time All of the time Refuse to answer
Social impact	Because of your eye condition or its treatment, how much of a problem do you have…?	Chatting with people Making new friends	None A little Quite a bit A lot Unable to do because of my eye condition This task is not relevant to me / don't do the task Refuse to answer
Convenience	Because of your eye condition or its treatment, how much trouble is…?	Having to drive slowly and more carefully Needing longer to do things	None A little A moderate amount Quite a lot Extremely This is not relevant to me Refuse to answer
Economic impact	Because of your eye condition or its treatment, how concerned are you about...?	The initial and ongoing cost of buying your glasses Losing your job	None A little A moderate amount Quite a bit Extremely This issue is not relevant to me Refuse to answer

Coping strategies	Given that you know about your eye condition, how much do you cope by...?	Being organised and careful Getting support from others	Not at all A little bit A moderate amount A lot Extremely Not relevant Refuse to answer

4.3.4 Pretesting and final revisions

4.3.4.1 Rationale for pretesting

Questionnaires that are poorly designed can lead to poor data quality and measurement performance.[344] The respondents' ability to understand the items and response categories, recall relevant information, make an estimation or judgement of the right answer and the social desirability or perceived accuracy of the answer are the key cognitive factors that influence the responses to the questions asked.[344, 345] These issues cannot be identified while field testing (pilot testing),[344] the objective of which is to get responses to the items and these issues cannot be remedied after data collection. Cognitive interviewing (de-briefing) bridges the gap between designing the questionnaire and field testing by probing into issues that can disrupt data quality.[346] It helps in understanding whether the items are clear and relevant to the respondents and identify items that may be sensitive or offensive.[293, 301] Out of the many cognitive interviewing techniques,[344] think-aloud and verbal probing are commonly used.[346] In addition to cognitive interviewing of patients, questionnaire evaluation through expert opinions is valuable in identifying linguistic problems with regard to questionnaire structure and to identify items that are irrelevant or prone to non-response.[347]

4.3.4.2 Pretesting

For pretesting the amblyopia and strabismus specific item banks, both cognitive interviewing with people experiencing amblyopia and/or strabismus (4.3.4.2.1) and expert opinions with clinicians and researchers (4.3.4.2.2) were used. Although concurrent think-aloud or verbal probing technique of cognitive interviewing are useful in eliminating recall bias,[346] considering the length of the questionnaire and the time that the process might take, a retrospective verbal probing technique was used in this study. Probing retrospectively enabled realistic presentation of items and minimised response bias that may result from probing concurrently while answering each item.[338]

The participants completed a printed questionnaire and was retrospectively inquired with open-ended questions soliciting their responses on the clarity and comprehensibility of the instructions, items and response options. In addition, all participants were asked if they found any question to be socially sensitive and were asked to comment if any relevant item/s were missing in the questionnaire. The experts provided additional inputs on whether all clinically relevant items were included in the questionnaire and whether the classification (binning) of items under each QoL domain were meaningful. These pretesting methods provides evidences of the face and content validity of the item bank.[88] The inputs from the participants were iteratively incorporated into the item bank upon consensus of the PhD candidate, Dr Jyoti Khadka and Prof Konrad Pesudovs. Pretesting with participants continued until no new issues arose.

4.3.4.2.1 Cognitive interviews

The participants for the cognitive interview (n=13) were recruited by purposive sampling from optometry practices in Melbourne, Victoria and Adelaide, South Australia. In order to test whether the items were appropriate and comprehensible for those experiencing different types of amblyopia and isolated strabismus (strabismus without amblyopia), participants with a range of amblyopia and strabismus diagnosis were recruited. All participants were over 18 years of age (median: 51 years; range: 21-68 years) and fluent in English. Nine had amblyopia and four had isolated strabismus. More sociodemographic and clinical details of the participants are displayed in Table 4-11. The participants first completed the questionnaire at their convenience and were interviewed later [face to face (n=2); telephone (n=11)].

Table 4-11 Sociodemographic and clinical characteristics of cognitive interview participants

Sample characteristics	n (%)
Gender	
Male	6 (46.1%)
Female	7 (53.9%)
Country of birth	
Australia	13 (100)
Diagnosis	
Amblyopia	9 (69.2%)
Strabismic amblyopia	3 (23.1%)
Anisometropic amblyopia	3 (23.1%)
Combined-mechanism amblyopia	2 (15.4%)
Deprivational	1 (7.7%)
Isolated strabismus	4 (30.8%)
Alternating exotropia	1 (7.7%)

Paralytic	3 (23.9%)
Visual acuity in the amblyopic eye	
0.2 to 0.4 logMAR (6/9.5 to 6/19)	7 (77.8%)
0.50 - 1.0 (6/18 - 6/60)	1 (11.1%)
> 1 logMAR (> 6/60)	1 (11.1%)
Ocular deviation (among those with strabismic /combined-mechanism amblyopia and isolated strabismus, n=7*)	
Type	
Horizontal	6 (85.7%)
Oblique	1 (14.3%)
Magnitude of deviation†	
20 prism dioptre or less	4 (57.1%)
>20 prism dioptre	2 (28.6%)
Highest level of post school education†	
Bachelor's degree or higher	8 (61.5%)
Diploma or vocational qualification	2 (15.4%)
No post school qualification	3 (23.1%)
* 1 participant with strabismic amblyopia and 1 with mixed amblyopia were orthotropic after strabismus correction. Hence n is not equal to 9 †Sum of the percentages is not equal to 100% due to missing data	

4.3.4.2.2 Expert opinions

Expert opinions (n=7) were sought from 4 Optometrists practicing in Australia, 2 researchers experienced in patient reported outcomes and questionnaire development (1 optometrist and 1 ophthalmologist) and 1 vision science researcher from a different area of expertise (myopia). Their median age was 41 years (range: 25-62 years) and their clinical and research experience ranged from 3 to 42 years.

4.3.4.3 Results of pretesting

4.3.4.3.1 Amendments to items

Based on the cognitive interviews and expert opinions, 22 items were rephrased, one was split into two, three new items were added and 14 were deleted. Examples of amended items are presented in Table 4-12.

Table 4-12 Examples of changes made following cognitive interviews and expert opinions

QoL domain	Item	Issue	Action taken
Visual symptoms	How often do you experience *blurred vision?*	Participant was ambiguous whether the item was referring distance or near.	Item was split into two: blurred vision for distance and blurred vision for near

Activity limitation	How much difficulty do you have *using a mobile phone?*	Participant suggested the inclusion of this item.	Item was added to the domain
Activity limitation	How much difficulty do you have *seeing at your car's dashboard clearly, e.g. Satnav screen, speedometer?*	Participants felt Satnav screen was too specific and some were not aware of what it was. Fuel gauge was suggested instead.	Item rephrased as 'Seeing at your car's dashboard clearly, e.g. speedometer, fuel gauge'
Concerns	How concerned are you about *one of your eyes wandering around?*	Item was considered vague and redundant in concept with 'how concerned are you about having a misaligned or turned eye?'	Item deleted
Emotional impact	During the past four weeks, *how often did you feel stupid?*	Item was considered too strong and sensitive.	Item deleted

4.3.4.3.2 Other amendments

Participants did not have trouble in understanding the item stems or response categories of any domain except coping. Difficulty in relating the coping item stem to its response options and trouble in articulating answers to the question was noted to by participants. Hence, based on their feedback and suggestions from experts, the item stem was changed from 'Given that you know about your eye condition, do you cope by...?' to 'Given that you know about your eye condition, how much do you cope by...?'

Another useful suggestion that came up from the cognitive interview was to repeat the response category header in every page of the printed questionnaire so it can be referred to with ease.

4.3.4.4 Final draft

The final draft (Appendix 7) of the amblyopia and strabismus specific item banks comprised of a total of 312 items (Table 4-13). These items proceeded to the next phase for pilot testing and psychometric analysis (Chapter 6).

Table 4-13 Final number of items following pretesting

QoL domain	No. of items
Visual symptoms	15
Ocular symptoms	12
General Symptoms	10
Activity Limitation	64
Mobility	14
Concerns	62
Emotional impact	49
Social impact	22
Convenience	26
Economic	14
Coping	24
Total	312

4.3.5 Amblyopia versus isolated strabismus: Item comparison

Amblyopia and strabismus are closely related ocular conditions, yet two separate entities. It was evident in Chapter 3 that amongst many similar QoL experiences, some unique issues exist between amblyopia and isolated strabismus. For instance, poor vision in the amblyopic eye was of concern to people with amblyopia, double vision was of concern to those with acquired strabismus. However, the number of common issues versus unique issues were not estimated by the qualitative study.

To determine whether amblyopia and isolated strabismus need separate PROMs, the number of items in the final draft of amblyopia and strabismus specific item banks that emerged from the prospective qualitative study alone (n=302) were examined for the ones that were endorsed by both groups (common items) and the ones endorsed by just one group (unique items). The items that were drawn from extant PROMs alone (n=10) were not included in this evaluation in order to base the decision solely on empirical evidence that emanated from patients' experiences (n=37 with amblyopia and n=12 with isolated strabismus).

On examination, it was found that 67.2% (n=203) of the total number of items were common to both groups (Table 4-14). Upon domain-wise examination, the percentage of common items was found to range from 46.2% to 87.5%. The domains coping (87.5%) and mobility (81.8%), followed by concerns (77.4%) and convenience (76.9%) had the highest percentage of common items. The only domain that encompassed less than 50% of common items was economic impact (46.2%); this domain had the largest number of unique items endorsed by the amblyopia group

(46.2%). Across all domains, the amblyopia group had the highest number of unique items (examples are displayed in Table 4-15). Overall, only 14 items (4.6%) were unique to strabismus group (items endorsed by strabismus group only).

Table 4-14 Common and unique items: Amblyopia versus isolated strabismus

QoL domain	No. of items in the item bank*	No. of items (%) common to both groups	No. of items (%) unique to amblyopia group	No. of items (%) unique to isolated strabismus group
Visual Symptoms	14	10 (71.4)	4 (28.6)	0 (0)
Ocular Symptoms	10	6 (60)	3 (30)	1 (10)
General Symptoms	10	6 (60)	4 (40)	0 (0)
Activity limitations	61	35 (57.4)	24 (39.3)	2 (3.3)
Mobility	11	9 (81.9)	2 (18.2)	0 (0)
Concerns	62	48 (77.4)	14 (22.6)	0 (0)
Emotional impact	49	29 (59.9)	14 (28.6)	6 (12.2)
Social impact	22	13 (59.1)	6 (27.3)	3 (13.6)
Convenience	26	20 (76.9)	5 (19.2)	1 (3.9)
Economic impact	13	6 (46.2)	6 (46.2)	1 (7.7)
Coping	24	21 (87.5)	3 (12.5)	0 (0)
Total	302	203 (67.2)	85 (28.2)	14 (4.6)
*Number of items in the final draft that emanated from qualitative research alone				

Table 4-15 Examples of unique items endorsed by the amblyopia group

QoL domain	Examples of unique items endorsed by amblyopia group
Visual Symptoms	Poor vision in one eye
Ocular Symptoms	Dry eyes
General Symptoms	Difficulty in concentrating
Activity limitations	Doing small, fiddly tasks
Mobility	Walking in crowded situations
Concerns	Having just one good eye
Emotional impact	Feel overprotective about your eyes
Social impact	Engaging with your children or grandchildren in playing, e.g. ball games
Convenience	Having to put in more effort in order to do certain things, e.g. reading, driving
Economic impact	Not meeting vision requirements for certain jobs e.g. pilot, police
Coping	Using peripheral vision of worse eye to see things onto its side

The high percentage of common items suggests that one calibrated item bank may suffice both amblyopia and isolated strabismus groups. The presence of unique items may be problematic if the objective of this research was to develop static paper and pencil-based questionnaires as the unique items may pose unnecessary respondent burden. This may also affect the targeting of the scale to different subgroups of

population. However, these issues can be overcome by the administration of the item bank through a CAT system, which allows customisation of the test to individuals based on their clinical or demographical characteristics. Considering the small number of unique items and the overarching aim of the research which was to develop item banks that can be administered via a CAT system, the final draft of the amblyopia and strabismus specific item bank was advanced as such (without splitting) to the next phase for testing of its psychometric properties. Pilot testing of these items on different groups of individuals in the next phase would provide more evidence on its performance and validate the decision made.

Although the chapter 3 identified unique QoL issues pertaining to isolated amblyopia versus other types of amblyopia, it was decided not to split these conditions for the purpose of QoL measurement. Constructing a single scale that measures a range of QoL impact across people experiencing different types of amblyopia was considered more meaningful to compare the level of impact suffered by individuals with different amblyopia diagnosis and estimate how different groups of amblyopia respond to interventions on the same scale.

4.4 Development of amblyopia and strabismus specific item pools for Indian population

The development of the amblyopia and strabismus specific item banks for Indian population followed the development of the Australian version. Even though the item banks were developed for the same disease group (amblyopia and strabismus), some differences were anticipated between these countries in terms of content, structure and wording due to cultural, economic and semantic differences. Therefore, the aim was to develop an India-specific item bank for amblyopia and strabismus and to compare it with the final draft of item banks designed for Australia for similarities and uniqueness.

Rather than just adapting the Australian version of the item bank to the Indian population (top-down approach), the development of the Indian version was based on empirical evidence that emerged from the qualitative interviews with people in India who were experiencing amblyopia and/or strabismus (bottom-up approach) as recommended by the FDA.[294] Considering the lack of any extant qualitative studies in India with regard to these conditions, the qualitative research carried out (in Chapter 3) was extremely important. Following the qualitative research in India, a systematic

protocol of item evaluation and construction similar to that used in the development of the Australian item banks, was followed.

4.4.1 Content identification

Participants over 18 years of age, experiencing amblyopia and/or strabismus took part in in-depth qualitative interviews (in English or Tamil) and described how amblyopia and strabismus affected their QoL. The demographics and clinical characteristics of the participants (n=30) are provided in Chapter 3, section 3.5.1. All interviews were audio recorded, transcribed verbatim, read several times, coded in English (both Tamil and English interviews) and iteratively analyzed using NVivo 11 software. Thematic saturation was the end point of data collection. More details about the study methodology are provided in Chapter 3.

Items were inductively extracted from the participant narratives in a way similar to the qualitative study conducted in Australia (described in section 4.3.1.3). Examples of participant narratives and corresponding codes are shown in Table 4-16. A total of 300 items were extracted from 1531 coding references.

Table 4-16 Examples of coding from direct participant quotes

Direct participant quotes	Codes
"My left eye… it is more sensitive to light. I have to shut it or like keep one eye closed when going into an exceptionally bright room or something" *Interview 14*	Sensitivity to bright lights Having to close one eye
"I din't take care of my eyes for these long years. Right now I'm feeling little bad that I should have really taken care because I'm finding objects to be blurred now" *Interview 9*	Negligence about eye care Guilty for not taking care of the eyes Blurred vision
"நான் போட்டோக்கு நீக்கவே மாட்டேன். அவாய்ட் பண்ணிடுவேன். எனக்கு போட்டோனாலே ஷிவரிங் ஆயிடும். *Interview 3 (Tamil)* *"I never pose for photos, I avoid it. I shiver if some takes photo of me." (Conceptual translation of the above quote)*	Avoid taking photos of myself Anxious about being in photos
"எல்லாரும் என்னை ஒன்றை கண்ணு, டோரி கண்ணு - அந்த மாதிரி கிண்டல் பண்ணுவாங்க. கஷ்டமா இருக்கும். ஆனா அதை ஹாண்டில் பண்ண எனக்கு தெரியாது." *Interview 5 (Tamil)* People tease by calling me by names such as 'one-eyed' and 'dory-eye'. I would feel sad. But, I don't know how to handle such situations" *(Conceptual translation of the above quote)*	Called by names – bullied Feel sad Don't know how to cope/ handle these situations

Each segment of the participant quotation and their corresponding code/s is highlighted in the same colour for the ease of identification.
Highlights: Green=Green, Blue=Blue, Yellow=Yellow
Some parts of participant quotes were coded into two different codes.
Represented by font: Red = Red

4.4.2 Item evaluation

The 300 items extracted from the qualitative research together with the 343 items from extant amblyopia and strabismus specific PROMs that had been classified according to QoL domain definitions (Table 4-5) formed the initial item pool of 643 items. These items were evaluated iteratively using binning and winnowing techniques described in section 4.3.2 and was reduced to a representative set of 277 items ranging across the 11 QoL domains (Table 4-17).

Table 4-17 Indian item pools: initial and final number of items during the item evaluation process

Iterations	Bins representing QoL domains												Total
	VS	OS	GS	SY	AL	MB	CO	EM	SC	CV	EC	CP	
Initial item pool	-	-	-	64	97	20	185	115	76	43	18	25	643
Final iteration	11	12	9	-	61	12	58	37	20	24	13	20	277
VS: Visual symptoms; OS: Ocular symptoms; GS: General symptoms; AL: Activity limitations; MB: Mobility; CO: Concerns; EM: Emotional impact; SC: Social impact; CV: Convenience; EC: Economic impact; CP: Coping strategies													

Examples of items drawn from the qualitative research, the number of participant utterances that referred to the item and the total number of participants who endorsed it are displayed in Table 4-18.

Table 4-18 Examples of items drawn from qualitative research

QoL Domain	Item	No. of participant utterances (Coding references)	No. of participants who endorsed the item
Symptoms	Watery eyes	19	15
	Headaches	29	15
Activity Limitation	Riding a bike at night-time	5	4
	Reading for a prolonged period of time	7	7
Mobility	Going down steps or stairs	4	3
	Walking on a bumpy road	1	1
Concerns	Having a misaligned or turned eye	16	10
	Safety of your eyes	18	15
Emotional	Feel embarrassed because of your appearance	7	5
	Worry about your eye condition	15	9
Social	Chatting with people	4	3
	Making new friends	5	4
Convenience	Having to squint or shut one eye in bright sunlight	6	5
	Having to be slower or more careful	6	6

Economic	Having to take time off work to do undergo treatment Losing your job	4 1	3 1
Coping	Learning to live with your eye condition Hiding your eye defect	10 7	9 4

4.4.3 Item construction

As the raw items were in English, the construction of the Indian item banks was first completed in English and was later translated into Hindi and Tamil languages. The item stems and the response categories of the Indian English version followed the same structure of the Australian item banks for uniformity and the raw items were rephrased to match the corresponding QoL domain - item stem and response categories. During this process, the items that were similar in content to the Australian item banks were phrased alike. However, this was not possible for all common items; some items (n=22), despite measuring similar concept, required slightly different wording due to dialect/ cultural differences and preferences. Examples of items in Australian English version and its equivalent in Indian English version are displayed in Table 4-19.

Table 4-19 Examples of differently worded items measuring similar construct - Australian and Indian English versions

QoL domain	Item – Australian English version	Item – Indian English version	Reason for difference
Activity Limitation	Doing any small, fiddly tasks	Doing any small, fine tasks	'fiddly' is not a common word used in India
Activity Limitation	Playing basketball, netball or football	Playing basketball or football	Netball is not common in India
Concerns	Having a misaligned or turned eye	Having a misaligned or turned eye (squint)	Misaligned eye is commonly called 'Squint' in India
Coping	Withdrawing into yourself	Withdrawing yourself from others	Rephrased for better comprehension

4.4.4 Translation

The aim of the translation process was to obtain equivalent Indian item banks in English, Tamil and Hindi. Conceptual, semantic and operational equivalences rather than literal (verbatim) translation were the focus of the process at this qualitative phase.[348] Currently many techniques exists and are being followed for translation and cross-cultural adaptation of HRQoL questionnaires;[348] however, there is a lack of consensus about one best method.[349] Guidelines put forward by the International

Society for Pharmacoeconomics and Outcomes Research (ISPOR) Task Force for translation and the cultural adaptation,[350] the European Regulatory Issues and Quality of life Assessment (ERIQA) group,[348] the WHO[351] and the FDA[352] supports the adoption of a multistep process in order to ensure rigour and robustness of the translation. Taking these guidelines into consideration, a translation protocol was developed encompassing 6 steps (Figure 4-4). Each step is elaborated below. The results of the entire translation process were documented and consolidated.

4.4.4.1 Forward translation

Forward translation is the process by which the original version of the questionnaire (source) was translated into the target languages - Hindi and Tamil. Two individuals who were fluent in the target language and English (bilingual) were selected for this process. At least one of them was an eye care practitioner (Optometrist/ Ophthalmologist). It was emphasised to the translators to focus on conceptual rather than literal translation and to keep the translations simple and concise (avoiding long and complex sentences) in order to facilitate better comprehension.[344]

4.4.4.2 Synthesis and reconciliation

Committees (Hindi and Tamil committees) formed by the translators involved in the forward translation, the PhD candidate, and an additional bilingual speaker reviewed the forward translations. Any discrepancies between translations were resolved by consensus and a single version of Hindi and Tamil item banks were created.

4.4.4.3 Back translation

Another bilingual speaker translated (conceptually) the reconciled version back into English. The objective of back translation is to verify if the same meaning is being captured by translating the target language back to the original language and hence the back translators were blinded to the source during translation.

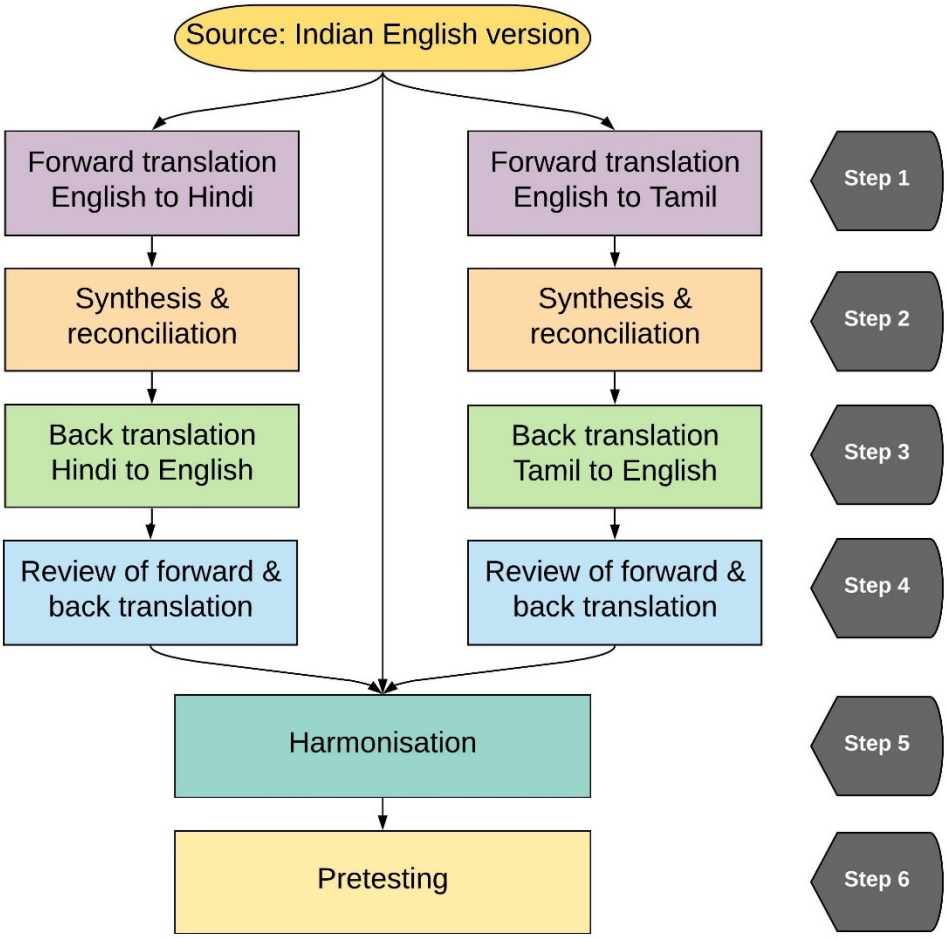


Figure 4-4 Translation protocol followed to translate the item banks from source (English) to target languages (Hindi and Tamil)

4.4.4.4 Review

Following back translation, I reviewed the back translated version against the source in order to identify discrepancies that might have arisen from mistranslation or inadequate translation in steps 1 and 2. Upon investigation, the reconciled versions (4.4.4.2) were revised based on discussions with the translators.

4.4.4.5 Harmonisation

This was an essential step to identify any discrepancies that existed between the three language versions of the item banks. The back translated versions of the target languages were compared with each other and with the original version to validate equivalence across languages and revisions were made.

4.4.4.6 Pretesting

The final step in the translation process was pretesting. The English and the revised Hindi and Tamil versions were pretested with three bilingual laypersons (persons proficient in English and Tamil or English and Hindi), one language expert (individual with tertiary qualification in the target language) and one bilingual subject expert (eye care practitioner). The comprehension, interpretation and wording of the item banks were tested with laypersons. The language experts provided feedback on the typographical and grammatical correctness and the subject expert verified the conceptual equivalence, relevance and comprehensiveness of the content. Revisions were made as necessary and equivalence across the three versions was maintained.

4.4.4.7 Results of translation

A total of 18 individuals (country of birth = India) were involved in the translation process. They all had a minimum educational qualification of a bachelor's degree or higher. Table 4-20 displays their demographic details and the stages of translation process they were involved.

Table 4-20 Demographics of individuals involved in the translation process

Demographics (Age, Gender, Education/Occupation, Place of birth)	Translation steps involved in
29 years, female, Optometrist, Tamil Nadu	FT, RC (Tamil) RV (Tamil and Hindi), HR
45 years, female, Ophthalmologist, Tamil Nadu	FT, RC, RV (Tamil)
32 years, male, Human resource professional, Tamil Nadu	RC (Tamil), HR
29 years, female, Assistant Professor (Optometry), Tamil Nadu	BT, RV (Tamil), HR
32 years, female, Nurse, Tamil Nadu	PT (Tamil)
59 years, female, Retired nurse, Tamil Nadu	PT (Tamil)
34 years, male, Placement officer (Engineer), Tamil Nadu	PT (Tamil)
55 years, female, High school Tamil teacher, Tamil Nadu	PT (Tamil)
29 years, female, Lecturer (Optometry), Tamil Nadu	PT (Tamil)
32 years, male, Senior lecturer (Optometry), Assam	FT, RC, RV (Hindi), HR
29 years, female, Microbiologist (unemployed), Delhi	FT, RC (Hindi)
33 years, female, Unemployed, Kerala	RC, RV (Hindi), HR
30 years, female, Assistant Professor (Optometry), West Bengal	BT, RV (Hindi), HR
32 years, female, Nurse (unemployed), Maharashtra	PT (Hindi)
48 years, female, Social worker, Punjab	PT (Hindi)
35 years, male, Social worker, Kerala	PT (Hindi)
58 years, female, High school Hindi teacher, Jharkhand	PT (Hindi)
28 years, female, Optometrist, Odisha	PT (Hindi)

FT: Forward translation; RC: Reconciliation; BT: Back translation; RV: Review; HR: Harmonisation, PT: Pretesting

4.4.4.7.1 Item stems & response categories

At the end of the translation process, the item stems and response categories of the final Indian English version remained the same as the Australian version except for the domain Coping. Based on pretesting with laymen the word 'manage' was added in brackets to clarify the meaning of cope. Hence, the item stem for the coping (Indian English) read as 'Given that you know about your eye condition, how much do you cope (manage) by...?'

The initial item stems and response categories of the Hindi and Tamil versions of the item banks (obtained on forward translation) underwent multiple amendments during the translation process. Table 4-21 displays the final Hindi and Tamil item stems and response categories.

Table 4-21 Item stems and response categories - Hindi and Tamil versions

QoL domain	Hindi		Tamil	
	Item stem	Response categories	Item stem	Response categories
Symptoms - Frequency	आपके आँखों की स्थिति या इलाज के वजह से इनमे से किन चीज़ो को अक्सर अनुभव करते है?	कभी नहीं कभी कभी अक्सर बहुत ज्यादा	*உங்கள் கண் பிரச்சனையினால் அல்லது கண் சிகிச்சையினால் கீழ்கண்ட அறிகுறிகளை எவ்வளவு அதிகமாக அனுபவிக்கிறீர்கள்?*	*ஒருபோதும் இல்லை* *எப்போதாவது* *அடிக்கடி* *மிகவும் அடிக்கடி*
Symptoms - Severity	आपके आँखों की स्थिति या इलाज के वजह से इनमे से किन चीज़ो को ज्यादा मात्रा (गंभीर) में अनुभव करते है?	कभी नहीं थोड़ा मध्यम बहुत ज्यादा	*உங்கள் கண் பிரச்சனையினால் அல்லது கண் சிகிச்சையினால் கீழ்கண்ட அறிகுறிகள் எவ்வளவு கடுமையாக உள்ளது?*	*இல்லவே இல்லை* *லேசாக உள்ளது* *மிதமாக உள்ளது* *கடுமையாக உள்ளது*
Symptoms - Bothersome	आपके आँखों की स्थिति या इलाज के वजह से आपको कितनी परेशानी होती है?	कुछ भी नहीं" थोड़ा थोड़ा सा ज्यादा बहुत ज्यादा	*உங்கள் கண் பிரச்சனையினால் அல்லது கண் சிகிச்சையினால் ஏற்படும் கீழ்கண்ட அறிகுறிகள் எவ்வளவு பிரச்சனையாக உள்ளது?*	*இல்லவே இல்லை* *சிறிதளவு* *ஓரளவு* *அதிகம்*
Activity Limitation Mobility	आपके आँखों की स्थिति या इलाज के वजह से, इन चीज़ो के करने पर आपको कितनी मुश्किल होती है?	कुछ भी नहीं थोड़ा थोड़ा सा ज्यादा बहुत ज्यादा मेरे आँखों की स्थिति की वजह से कार्य करने में असमर्थ मेरे पर यह लागू नहीं होता / मैं यह नहीं करता उत्तर देने से इनकार	*உங்கள் கண் பிரச்சனையினால் அல்லது கண் சிகிச்சையினால் கீழ்கண்டவைகளை செய்ய எவ்வளவு கஷ்டமாக உள்ளது?*	*கஷ்டமே இல்லை* *சிறிதளவு கஷ்டம்* *ஓரளவு கஷ்டம்* *மிகவும் கஷ்டம்* *என் கண் பிரச்சனையினால் இதை செய்ய இயலவில்லை* *இந்த வேலையை வேறு காரணத்தினால் நான் செய்வதில்லை / இது எனக்கு பொருந்தாது* *பதிலளிக்க மறுக்கிறேன்*

Concerns	आपकी आंख की स्थिति या उपचार के कारण आपको निम्नलिखित के बारे में कितने चिंतित हैं?	कभी नहीं थोड़ा थोड़ा सा ज्यादा बहुत ज्यादा अत्यंत यह मेरे लिए प्रासंगिक नहीं है उत्तर देने से इनकार	*உங்கள் கண் பிரச்சனையினால் அல்லது கண் சிகிச்சையினால் கீழ்கண்டவைகளைக்குறித்து எவ்வளவு கவலைப்படுகிறீர்கள்?*	*கவலை இல்லை* *சிறிதளவு கவலை* *ஓரளவு கவலை* *அதிகமான கவலை* *மிக அதிகமான கவலை* *இது எனக்கு பொருந்தாது* *பதிலளிக்க மறுக்கிறேன்*
Emotional impact	पिछले चार हफ्तों के दौरान, आपकी आँखों की स्थिति या उसके इलाज के कारण, आपने कितनी बार...?	कभी नहीं थोड़े समय कुछ समय अधिकतर समय हमेशा उत्तर देने से इनकार	*கடந்த நான்கு வாரங்களில், உங்கள் கண் பிரச்சனையினால் அல்லது கண் சிகிச்சையினால் எவ்வளவு அதிகமாக...?*	*ஒருபோதும் இல்லை* *எப்பொழுதாவது* *சில நேரம்* *பெரும்பாலான நேரம்* *எப்போதும்* *பதிலளிக்க மறுக்கிறேன்*
Social impact	आपकी आँखों की स्थिति या उसके इलाज के कारण, आपको कितनी समस्या होती है?	कुछ भी नहीं थोड़ा थोड़ा सा ज्यादा बहुत ज्यादा मेरी आँखों की स्थिति के कारण ऐसा करने में असमर्थ यह कार्य मेरे लिए प्रासंगिक नहीं है /मैं यह कार्य नहीं करता हूँ उत्तर देने से इनकार	*உங்கள் கண்களில் உள்ள பிரச்சனையினால் அல்லது கண் சிகிச்சையினால் கீழ்கண்டவைள் எவ்வளவு கஷ்டமாக உள்ளது?*	*கஷ்டமே இல்லை* *சிறிதளவு கஷ்டம்* *ஓரளவு கஷ்டம்* *மிகவும் கஷ்டம்* *என் கண் பிரச்சனையினால் இதை செய்ய முடியவில்லை* *இதை வேறு காரணத்தினால் நான் செய்வதில்லை / இது எனக்கு பொருந்தாது* *பதிலளிக்க மறுக்கிறேன்*

Convenience	आपकी आँखों की स्थिति या उसके इलाज के कारण, आपको कितनी परेशानी (असुविधा) है...?	कुछ भी नहीं थोड़ा थोड़ा सा ज्यादा काफी अत्यंत यह मेरे लिए प्रासंगिक नहीं है उत्तर देने से इनकार	*உங்கள் கண் பிரச்சனையினால் அல்லது கண் சிகிச்சையினால் கீழ்கண்டவைள் எவ்வளவு சிரமமாக (அசௌகரியமாக) உள்ளது?*	*சிரமம் இல்லை* *சிறிதளவு சிரமம்* *ஓரளவு சிரமம்* *அதிக சிரமம்* *மிக அதிக சிரமம்* *இது எனக்கு பொருந்தாது* *பதிலளிக்க மறுக்கிறேன்*
Economic impact	आपकी आँखों की स्थिति या उसके इलाज के कारण, आप कितने चिंतित हैं...?	कुछ भी नहीं थोड़ा मध्यम थोड़ा सा ज्यादा अत्यंत यह मेरे लिए प्रासंगिक नहीं है उत्तर देने से इनकार	*உங்கள் கண் பிரச்சனையினால் அல்லது கண் சிகிச்சையினால் கீழ்கண்டவைகளைக்குறித்து எவ்வளவு கவலைப்படுகிறீர்கள்?*	*கவலை இல்லை* *சிறிதளவு கவலை* *ஓரளவு கவலை* *அதிகமான கவலை* *மிக அதிகமான கவலை* *இது எனக்கு பொருந்தாது* *பதிலளிக்க மறுக்கிறேன்*
Coping strategies	अपनी आँखों की स्थिति के साथ सामना करने के लिए आप कितनी बार निम्न विधियों का उपयोग करते हैं	कुछ भी नहीं थोड़ा थोड़ा सा ज्यादा बोहोत ज्यादा अत्यंत उत्तर देने से इनकार	*உங்கள் கண் பிரச்சனையினால் ஏற்படும் பாதிப்பை, எவ்வளவு அதிகமாக கீழ்கண்ட முறைகளைப்பயன்படுத்தி சமாளிக்கின்றீர்கள்?*	*இல்லவே இல்லை* *சிறிதளவு* *ஓரளவு* *அதிகமாக* *மிக அதிகமாக* *பதிலளிக்க மறுக்கிறேன்/* *இது எனக்கு பொருந்தாது*

4.4.4.7.2 Items

From the initial draft in step 1 (forward translation) to the final version of the item banks in step 6 (pretesting), a total of 194 amendments were made to the items in the Hindi item bank and 101 amendments were made to the items in the Tamil item bank. The number of amendments at each stage of the translation process across the 11 QoL domains is displayed in Table 4-22.

Table 4-22 Number of amendments during the translation process - Hindi and Tamil items

QoL domains	No. of items amended					
	Reconciliation (Step 2)		Review (Step 4)		Pretesting (Step 6)	
	Hindi	Tamil	Hindi	Tamil	Hindi	Tamil
Visual symptoms	7	3	2	2	2	1
Ocular symptoms	4	3	3	0	2	1
General symptoms	2	1	0	0	1	2
Activity limitation	19	5	13	3	13	20
Mobility	4	2	2	1	1	2
Concerns	32	11	14	2	4	7
Emotional	13	6	5	3	2	1
Social	8	1	1	0	1	4
Convenience	10	7	7	2	3	4
Economic	8	1	2	1	0	2
Coping	8	2	1	0	0	1
Total	115	42	50	14	29	45

Examples of discrepancies identified in the review of back translated versions and source (4.4.4.4) and the amendments made are displayed in Table 4-23.

Table 4-23 Examples of amendments in Step 4: Review

Original source	Reconciled version	Back translation	Issue	Amended version
Tamil				
Noticing when the car in front of you is speeding up or slowing down (Domain: Activity limitation)	முன்னே செல்லும் வாகனத்தின் வேகம் அதிகரிக்கும் போது அல்லது குறையும் போது, அதை சரியாக கணித்தல்	Predicting correctly when the car in front slows down or increases its speed	Noticing was mistranslated as 'Predicting'	முன்னே செல்லும் வாகனத்தின் வேகம் அதிகரிக்கும் போது அல்லது குறையும் போது, அதை சரியாக கவனித்தல்

Having to remove glasses when doing some tasks, e.g. sports (Domain: Convenience)	ஒரு சில வேலைகளைச்செய்ய கண்ணாடியை கழற்ற வேண்டிருப்பது	Needing to remove spectacles for doing certain work	Example was missing	ஒரு சில வேலைகளைச்செய்ய கண்ணாடியை கழற்ற வேண்டிருப்பது, உதா. விளையாடும் போது
Feel overprotective about your eyes (Domain: Emotional impact)	கண்களின் பாதுகாப்பைப்பற்றி அதிக கவலைப்பட்டீர்கள்	feel worried about your eye's protection	The meaning 'overprotective' was not conveyed	உங்கள் கண்களின் பாதுகாப்பைக்குறித்து அளவுக்கு அதிகமாக கவலைப்பட்டீர்கள்
Hindi				
Seeing speed breakers on the road while driving (Domain: Activity limitation)	सड़क पर स्पीड ब्रेक्स का देखना	Observing speed breakers on the road	'While driving' was missing	गाड़ी चलाते समय सड़क पर स्पीड ब्रेक्स का देखना
Having eye contact with people while talking (Domain: Concerns)	लोगो से नज़रे मिलाना	Having eye contact with people	'While talking' was missing	बात करते वक्त लोगो से नज़रे मिलाना
Having to concentrate harder on things (Domain: Convenience)	चीजों पर ध्यान केंद्रित करना	Having to focus on things	Concept of 'harder' was not conveyed	चीजों पर ज्यादा ध्यान केंद्रित करना

On harmonising the three versions of the item banks for equivalence across translations (4.4.4.5), the original source underwent 22 amendments. Examples in Table 4-24. The final Indian item banks in English, Hindi and Tamil are provided in Appendix 8.

Table 4-24 Examples of amendments to original source on harmonisation

Original source	Hindi version	Tamil version	Amended source
Not being successful (Domain: Concerns)	जीवन में सफल नहीं हो पाना	வாழ்க்கையில் வெற்றிகரமாக இல்லை என்று	Not being successful in life
Difficulty in judging distances / perceiving depth (Domain: Symptoms)	दो चीज़ों की दूरियां (गहराई) का अंदाज़ा करने में मुश्किल	இரண்டு பொருட்களினிடையே உள்ள தூரம் அல்லது ஆழம் எவ்வளவு என்பதை சரியாக அறிவதில் சிரமம்	Difficulty in judging distances /perceiving depth between two objects
Feel discriminated against (Domain: Emotional)	अपने खिलाफ भेदभाव अनुभव करना	பிறர் உங்களை பாரபட்சம் பார்ப்பது போல உணர்ந்தீர்கள்	Feel discriminated against by others

Your career being compromised (Domain: Economic impact)	अपनी पसंद के कैरियर (या काम) को न कर पाना	நீங்கள் விரும்பிய தொழிலை செய்ய முடியாமல் போனதைக்குறித்து	Not being able to pursue the career of your choice
Communicating with people about your eye condition (Domain: Coping)	अपनी आँखों की स्थिति के बारे में लोगों को बताना	பிறரிடம் உங்கள் கண் பிரச்சனை குறித்து பகிர்ந்து கொள்ளுதல்	Sharing with people about your eye condition

4.5 Australia versus India: Item comparison

Following the development of the item bank for the Indian population, the items were compared (conceptually) to the items of the Australian item bank and the number of common and unique items were examined (Table 4-25). As these are the first set of amblyopia and strabismus specific item banks developed for high and low income country settings, empirical evidence was sought about the magnitude of commonness (despite cultural and economic differences) and uniqueness (country-specific concepts), in order to explore the possibility of common item linking and development of universal item banks in future.

Table 4-25 Common and unique items: Australian and Indian item banks

QoL domains	Total number of items		Common items, n (%)	Items unique to Australia, n (%)	Items unique to India, n (%)
	Australia	India			
Visual symptoms	15	11	11 (73.3)	4 (26.7)	0 (0)
Ocular symptoms	12	12	11 (84.6)	1 (7.7)	1 (7.7)
General symptoms	10	9	9 (90)	1 (10)	0 (0)
Activity limitation	64	61	49 (64.5)	15 (19.7)	12 (15.8)
Mobility	14	12	12 (85.7)	2 (14.3)	0 (0)
Concerns	62	58	55 (84.6)	7 (10.8)	3 (4.6)
Emotional	49	37	37 (75.5)	12 (24.5)	0 (0)
Social	22	20	20 (90.9)	2 (9.1)	0 (0)
Convenience	26	24	24 (92.3)	2 (7.7)	0 (0)
Economic	14	13	12 (80)	2 (13.3)	1 (6.7)
Coping	24	20	20 (83.3)	4 (16.7)	0 (0)
Total	312	277	260 (79)	52 (15.8)	17 (5.2)

79% items (260 out of 312 items) were common to both Australian and Indian item banks with more than 60% of common items in every QoL domain. Domains convenience (92.3%), social impact (90.9%) and general symptoms (90%) had the

highest percentage of common items. The number of unique items in the Australian item bank ranged from 1 to 15; domains visual symptoms (26.7%) and emotional impact (24.5%) had the highest percentage of unique items. The Indian item bank did not have any unique items in 7 out of 11 QoL domains (Table 4-25) and the domain activity limitation (15.8%) had the highest percentage of unique items. Examples of common and unique items under domain activity limitation (items related to driving) are portrayed in Figure 4-5.

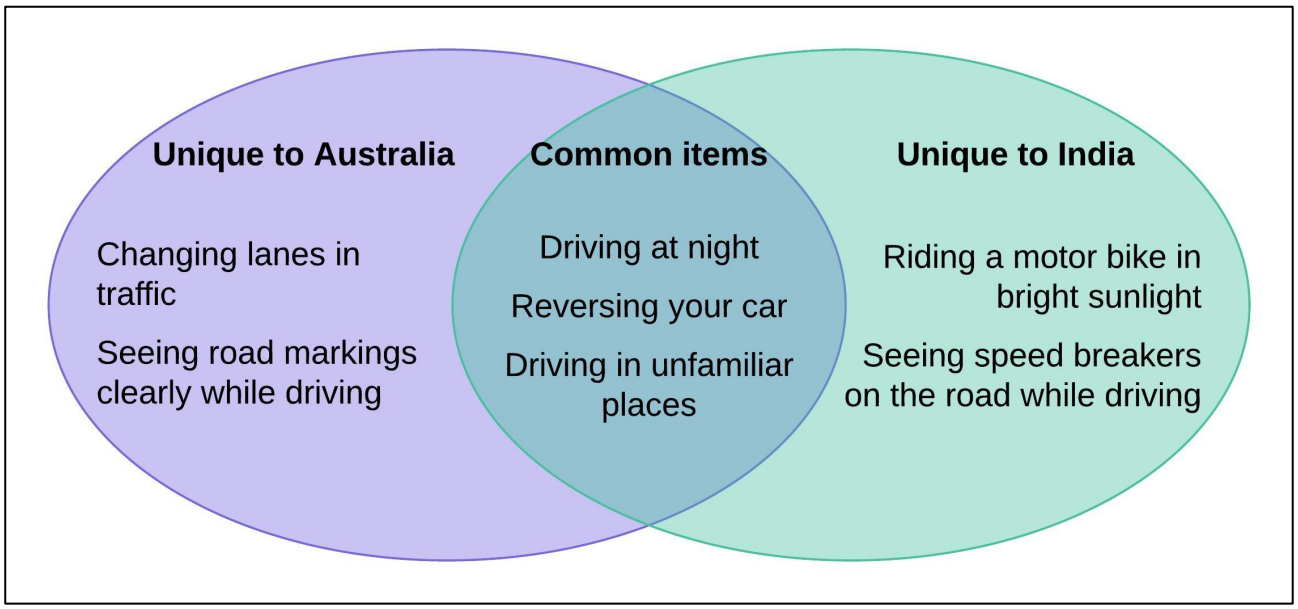


Figure 4-5 Item comparison between Australia and Indian item banks: Examples of common and unique items related to driving from domain - activity limitation

4.6 Discussion

This chapter described the development of preliminary amblyopia and strabismus specific item banks for adults living in Australia (English) and India (English, Hindi and Tamil). About 67% of the items were common to both amblyopia and isolated strabismus, suggesting one calibrated item bank implemented via CAT system may suffice both disease groups. Despite cultural and economic differences, about 79% of the items were common to both Australia and India, favouring the possibility of developing universal item banks in future.

The key strength of this chapter was the adoption of a systematic rigorous process, in which each step was guided by a set of well-defined criteria and expert consensus. This minimised the inherent bias resulting out of the qualitative nature of the process.[246] The other important strength was the construction of item banks from empirical evidence that emanated out of qualitative research with patients

themselves. Items endorsed by just one participant /those uttered only once were also included extracted in order to maximise content validity.[303] Furthermore, participant narratives were used to guide item nomenclature (phrasing). The incorporation of patient's experiences and perspectives into the development of the item banks increases the likelihood of the item banks being comprehensive and more appropriate to the stakeholders when field tested, enabling precise and valid measurement.[353]

Each QoL domain is a single item bank measuring a particular construct or underlying trait; therefore, 11 item banks measuring 11 QoL domains has been constructed. These QoL domains are theoretical and have not yet been confirmed by psychometric analysis. These were identified to be important ophthalmic QoL domains by previous research[2, 153, 246] and was confirmed to be relevant to individuals experiencing amblyopia and strabismus by qualitative exploration (Chapter 3). To be consistent with other modules of the Eye-tem bank project and to enable measurement across disease groups in future, items were classified into bins (domains) based on established domain definitions.[2] There is a degree of arbitrariness in this process as different sets of items may have resulted if different definitions or classification norms were adopted.[338]

The construction of common item banks for both amblyopia and isolated strabismus disease groups was based on the number of common items and the possibility of customisation of item presentation by implementing item banks via CAT system. However, this decision will be validated in the next phase, when the common items will be pilot tested and examined for any differential item functioning (item bias).

In the development of the item banks for India, a robust protocol was followed for translation. Every best effort was taken to harmonise items and response categories for conceptual and semantic equivalence across the three Indian versions. However, only on testing the psychometric properties in the next phase, one could examine its measurement equivalence (comparable psychometric properties) and item equivalence (response category functioning and presence of any differential item functioning).[348, 354]

Although 79% of the items were common to Australia and India, two separate item banks were created due to language and dialect differences. In the next phase, data collected on these independent item banks will undergo psychometric analysis (based

on Rasch measurement theory) and county-specific calibrations. In future, a pooled analysis will be performed combining both item banks to explore the possibility of calibrating the items on the same scale (a universal scale).

Chapter 6 presents the quantitative phase of the item bank development (Phase 2) in which the psychometric properties of the Indian item banks were tested. Due to time constraints, only the validation of the Indian item banks is presented in this thesis. Phase 2 Australia is work in progress; its interim results are documented.

CHAPTER 5 EPISTEMOLOGY OF MEASUREMENT, MEASUREMENT THEORIES AND RASCH ANALYSIS

5.1 Introduction

Chapter 4 described the development of item pools to measure the QoL impacts caused by amblyopia and strabismus and chapter 6 tests the hypothesis that these item pools are capable of forming valid measurement scales. Before venturing into the next chapter, it is important to understand the scientific meaning of measurement, especially in the context of latent traits.

This chapter presents the epistemology of measurement and theories used in the construction and validation of PROMs. It is presented between the Phase 1 (Chapters 3 and 4) and Phase 2 (Chapters 6 and 7) of this thesis to provide theoretical and analytical context for easy interpretation of the complex analysis in Phase 2.

5.2 Measurement

According to Norman Campbell, an English physicist, measurement requires a deliberate concatenation of measures of equal units.[355, 356] For example, the clock is constructed by concatenating equal units of time and a ruler, equal units of length. Additivity is an essential characteristic of measurement; this means 'adding one more unit adds the same amount of extra, irrespective of the amount to which it is added'.[355] In other words, the measure increases by just one when one more unit is added anywhere along the entire continuum of measurement. The property of additivity is easy to understand in relation to physical sciences; however, this is not straightforward in social sciences where psychological measurement is made.[357]

5.2.1 Psychological measurement

Norman believed that psychological measurement is not practical as it is impossible to "concatenate people's heads".[358] However the American psychologist, Stanley Stevens believed that psychological measurement was possible by conveniently defining measurement as "the assignment of numbers to objects or events according to rule" and measures as "whatever numbers were acquired in the process".[359, 360] According to Steven's definition, numeric labels such as licence number and postal codes could be considered equivalent to scientific measures of length and weight;[90] this misconception violates the fundamental concept of measurement and has led to

several misapplications.[90] This unfortunately has been used in the traditional scoring of PROMs;[360] numerals assigned to observations of participant responses were summed up to represent the quantity of the latent trait measured.[361]

5.2.2 Measures versus numbers

"All measures are numbers but not all numbers are measures".[362] Examples of numbers which are not measures include counts, scores and ranks;[362] although these numbers are obtained by direct observation, these do not qualify to be measures because they are not made up of equal-units and hence lack the property of additivity (interval scaling).[363] On an ability test, ordinal scores 3, 4 and 5 are mere observations; one would not be able to specify the difference in ability between the persons who obtained a score of 3 and 4 nor guarantee that the difference in ability between them is the same as the difference in ability between the persons who obtained a score of 4 and 5. Although one might be convinced that a score of 4 is more than 3 and less than 5, 'how much more and how much less' is ambiguous.[364] Meaningful arithmetic operations such as addition, subtraction, computation of means and standard deviations can be performed only with numbers that are measures.[362, 363]

Unlike observations which occur naturally, measures are devised.[362] No measurement in the real world is perfect because of the presence of some arbitrariness in the instrument used for measurement. For example, yardsticks may vary slightly in their spacing. Despite this, they are useful in measuring length to nearest inch.[362] Similarly, measurements of psychometric latent traits may not be exact and both quantitative and qualitative judgements are necessary to create scales worthy of productive measurement.[365]

5.3 Theories of measurement

Unlike height and weight, psychological variables such as disability, attitude, and QoL cannot be measured directly, but inferred indirectly.[366] Rating scales in the form of questionnaires and surveys are used to measure such latent traits[161] and are validated using traditional (classical test theory) and modern test theories (item response theory and Rasch measurement theory).[367]

5.3.1 Traditional measurement theory

The foundations of classical test theory (CTT) was laid by psychologist, Charles Spearman in 1904.[96] The CTT, also known as the true score theory, is grounded in the Steven's definition of measurement and is based on several assumptions.[366] CTT assumes that each person has a true score and that the observed score (O) could be decomposed into a true score (T) and measurement error (E).[251] It also assumes that the measurement error is random and do not correlate with the true score.[161] In the absence of measurement error, the observed score is the true score and its total quantifies the variable of interest or underlying construct. However, the credibility of CTT is questionable, as the parameters T and E cannot be determined and as the theory itself cannot be verified.[161]

Furthermore, the CTT assumes that all items in a rating scale are of the same level of difficulty and therefore it scores all items in a similar fashion.[89] This has been proved to be incorrect by modern psychometric methods such as Rasch analysis which has established the presence of item hierarchy (items ordered from easy to hard).[368] For instance, driving at night time is harder than driving during the day and therefore should be scored differently.[369] Also, the CTT falsely treats the ordinal response categories to be interval level scales by assuming equidistance between response categories.[89] For example, mild, moderate and severe are given scores such as 3, 2 and 1, so that 2 is equidistant from 1 and 3. Based on this assumption the CTT advocates summary scoring (totalling item scores to provide total scores).[89] This again has been disproved by Rasch analysis.[1] The negative implication of using total test scores is that the same person would get a high score on an easy test and a low score on a hard test;[252] this makes comparison between tests or persons taking the test irrational.[370] In addition to these flaws, ceiling and floor effects in data (observations at extreme ends of the response categories e.g. not at all and always) introduces measurement noise (imprecision)[368] and missing data affects the measurement performance in anonymous ways.[252]

Due to inherent weakness in the theory and its assumptions, the interpretation of the reliability statistics of CTT scaled data is uncertain.[367] In fact, the CTT do not provide any information about how well the items fit the latent construct[368] and if there are any item bias (items answered differently by sub-groups of samples with same ability levels).[371, 372] The most common indicator of reliability used in CTT is the Cronbach's alpha.[96] While Cronbach's alpha provides a measure of inter-item correlation, it does

not indicate whether the instrument measures what it intends to measure (validity).[96] Moreover, it is item-dependent and therefore can be artificially inflated by redundant and locally dependent items.[373]

Another common statistical method, the factor analysis (exploratory and confirmatory), is used to guide item reduction and to investigate dimensionality (whether the scale measures a single or multiple constructs).[252, 368] However, factor analysis alone may be insufficient to draw conclusions about dimensionality[374] because 1) it is sample dependent,[374] 2) uses ordinal level scores (non-linear observations) to compute correlations based on which items are grouped into several domains or factors,[374, 375] 3) items with similar difficulty levels may cluster together as factors[376] and 4) it is impossible to distinguish whether a factor is truly a unique dimension or a secondary dimension (a strand) of a primary construct.[375]

5.3.2 Modern measurement theories

The limitations of CTT led to the development of modern measurement theories - the item response theory and the Rasch measurement theory. Unlike the CTT, which focusses on test-level information, the modern theories focus on item-level information.[377] These probabilistic models transforms ordinal scores into interval level scale and places both item and person parameters along the same continuum of measurement.[378] The person abilities are estimated relative to the item difficulties based on the pattern of responses that a set of persons provide to a set of items.[379]

5.3.2.1 The item response theory (IRT)

The IRT was developed by Lord and his colleagues in 1960s. It is used to test the hypothesis that the model describes the observed data accurately.[379] It assumes that all persons use the same response category thresholds and that the only source of stochastic variability is between person differences in the interpretation of items.[380] The three unidimensional probabilistic models of IRT are 1-parameter, 2-parameter and 3-parameter models.[252] As the name suggests, the 1-parameter model estimates one parameter namely difficulty, the 2-parameter model estimates two parameters - difficulty and discrimination and the 3-parameter model estimates three parameters - difficulty, discrimination and guessing.[252] The a 2-parameter IRT model is given by Equation 1.[370]

$$P(\theta) = \frac{1}{1 + e^{-a-(\theta-b)}}$$

Equation 1: 2-parameter IRT model

P(θ) is the probability of responding correctly to an item

θ is the ability parameter

b is the difficulty parameter

a is the discrimination parameter

e=2.718

['Endorsing an item correctly' or success in educational tests means solving a problem in mathematics or choosing the correct answer in a multiple-choice question in a science test. In health outcome scales such as those that measure quality of life, disability, satisfaction or wellbeing, this means choosing the response category that corresponds to better ability. For example, consider a dichotomous item 'Do you have difficulty in driving a car at daytime?' with response options 'Yes' and 'No' – In this case, endorsing the item correctly means answering 'No' as it corresponds to high ability.]

5.3.2.2 The Rasch measurement theory (RMT)

The RMT was developed by developed by Georg Rasch in 1960. It is used to test the hypothesis that the observed data is consistent with the principles of measurement.[379] Unlike the IRT, RMT assumes that the sources of stochastic variability are the person differences in the interpretation of items and differences in response category thresholds.[380] The only parameter estimated by the RMT is difficulty of items and ability of persons which are estimated on a single scale. The discrimination parameter for all items is fixed at a value of 1.[370] The Rasch model is given by Equation 2.[370]

$$P(\theta) = \frac{1}{1 + e^{-1-(\theta-b)}}$$

Equation 2: Rasch model

P(θ) is the probability of responding correctly to an item

θ is the ability parameter

b is the difficulty parameter

e=2.718

5.3.2.3 IRT versus RMT

The IRT and the Rasch models are often considered as members of the same family of statistical methods. In fact, the Rasch model is thought to be the 1-parameter IRT

model because both estimates just one parameter, which is difficulty.[377] However this is not entirely true. Despite superficial similarities in underlying mathematics, the two models differ in assumptions, fundamental concepts and research aims.[380, 381]

The IRT models are descriptive in nature and prioritizes data over the model.[380] It's aim is to find the best model that fits the data, irrespective of whether linear measures can be obtained or not.[373] If the data doesn't fit one model, another model is suggested. On the contrary, RMT is prescriptive in nature[380] and offers distribution-free estimates of person ability and item difficulty on a linear latent variable.[366] It deliberately implements the property of additivity, an essential feature of measurement and therefore the data must conform to the Rasch model.[357, 368] If the data doesn't fit the model, what went wrong is investigated and only data that meets the model's requirement is selected.[252, 366] While the CTT and IRT tries to describe the data, the RMT aims to obtain data that fits the model.[96]

There is a long debate between researchers about which of these models is better. The IRT proponents believe that the RMT is restrictive and the selection of data that fits the model is a threat to content validity.[161] On the other hand, the Rasch proponents believe that the IRT is too lenient as it accepts data that doesn't fit the fundamental requirements of measurement, which is perceived to be a threat to construct validity.[161] Irreconcilable differences exists between the two groups.[366] One may choose either one depending on their research goals and philosophy.[380]

For the purpose of this research, the aim of which was to construct valid scales for measuring patient reported outcomes, it seemed more appropriate to adopt a model which follows the principles of measurement.[252] Thus, the Rasch model was chosen.

5.4 Properties of the Rasch model

The Rasch model assumes that the probability of a person endorsing an item is a logistic function of the difference between the person ability and item difficulty.[93] Therefore, if a person's ability is greater than the ability required to perform a particular task, the probability of the person endorsing the item successfully is high. Likewise, if the person has a lower ability than what is required to perform the task, the probability of the person endorsing the item successfully is low. It is thus expected that the probability of success increases monotonically with increasing difference between ability and difficulty parameters.[251, 382] The properties of Rasch model that

makes it a distinguishing measurement model are specific objectivity, sufficiency, and conjoint additivity.[355, 383]

Specific objectivity means that the Rasch estimates of person abilities and item difficulties are independent of each other; that is, the person abilities are independent of whichever items are chosen and the item difficulties are independent of the group of respondents from the population of interest.[384] In other words, the difficulty of an item is constant across the population of interest and the ability of a person is identical across all items in the scale.[385] Specific objectivity is key for invariant comparison, an essential feature of measurement.[366]

In Rasch model, the person and item total scores are sufficient statistics to estimate person and item measures respectively.[381] Although the sufficient statistics do not provide the exact estimate, it summarises what is known, on the basis of which the measures are estimated.[386] The idea of sufficiency is theoretical and not always satisfied in reality.[386] Therefore, the observed pattern of data should be compared to the expected to assess whether the data approximates the property of sufficiency closely enough for practical measurement.[386]

Another important property of the Rasch model is conjoint additivity.[357] This means that both the persons and items are measured on the same interval scale and that if the person measure increases by one unit, the item measure also increases by the same amount.[380]

5.5 Rasch models

Based on whether the items in a test are scored dichotomously (2 response categories, e.g. yes and no) or polytomously (more than two response categories, e.g. agree, neutral and disagree), the dichotomous and polytomous Rasch models apply.[252, 385]

5.5.1 Dichotomous Rasch model

The dichotomous Rasch model calculates the probability P, that a person n of ability θ_n endorse correctly an item i of difficulty b_i. The log-odds of a person n successfully endorsing an item i is equal to the difference between the ability of the person (θ_n) and the difficulty of the item (b_i) as given in Equation 3.[356]

$$\log_e\left(\frac{P_{ni}}{1-P_{ni}}\right) = \theta_n - b_i$$

Equation 3: Dichotomous Rasch model

5.5.2 Polytomous Rasch model

The Polytomous Rasch model is similar to the dichotomous model, except for the introduction of category thresholds.[252] The category thresholds have an important role in enabling identification of critical points along the latent trait continuum.[385] The two major polytomous Rasch models are the Masters partial credit model (PCM) and the Andrich rating scale model (RSM).[380] In the PCM, the response category thresholds varies for each item; whereas in the RSM, the response category thresholds are the same across all items or groups of items.[380]

5.5.2.1 Partial credit versus Rating scale model

The RSM is used when the items of a test share the same rating scale structure and the PCM is used when each item of the test has a unique rating scale structure.[380, 385] The downside of PCM is that, absence of observations or very few observations in some response categories of a particular item may result in weak calibration (imprecise difficulty estimates).[387] In contrast, the RSM infers the functioning of the unobserved response category of an item from observations from other items in the test.[388] Moreover, inferences obtained by the PCM are more difficult to communicate compared to RSM which is simple and straight-forward.[388] Unless, each item has a different rating scale structure or there is a meaningful difference between the item difficulties and person abilities obtained from PCM and RSM, RSM is the preferred model for polytomous items.[388, 389]

As the item pools developed in this research has homogenous rating scale structure within each domain (item banks), the RSM was preferred. The RSM calculates the probability P_{nij} that a person n of ability θ_n is observed in a category j of a rating scale of an item of difficulty b_i, as opposed to the probability $P_{ni(j-1)}$ of being observed in category (j-1).[390] For example, j could be 'not at all' and j-1 could be 'sometimes'. This is given by Equation 4.

$$\log_e\left(\frac{P_{nij}}{1-P_{nj(j-1)}}\right) = \theta_n - b_i - F_j$$

Equation 4: Polytomous Rasch model

Fj is the category threshold, also called step calibration or step difficulty.[390]

5.6 Rasch analysis

Rasch analysis is a statistical technique used to test the degree to which a given set of data conforms to the RMT.[161] It provides insights about the psychometric properties of a scale by assessing 1) response category functioning 2) separation and reliability indices 3) fit statistics 4) dimensionality 5) targeting 6) differential item functioning and 7) local item dependency, and thereby tests whether the scale under validation is good enough for measurement construction.[131, 152] These qualities are described in section 5.7

Software programs such as the Winsteps, Facets and RUMM2030 are commonly used to perform Rasch analysis.[391] Each of these vary to an extent in the method by which the parameters are estimated and the Rasch models they support.[391] This doctoral research uses the Winsteps® Rasch measurement computer program, version 4.2.0 (Beaverton, Oregon, USA).[392]

The Winsteps computer program uses PROX algorithm and Joint Maximum Likelihood Estimation (JMLE) method iteratively to obtain reliable calibrations of items, persons, response structures, fit statistics and standard errors.[392] The JMLE was preferred over other estimation methods such as marginal maximum likelihood estimation, conditional maximum likelihood estimation and pairwise maximum likelihood estimation, because of its flexibility in estimating parameters under almost all conditions (e.g. idiosyncratic data, lack of observations in intermediate rating categories)[365].

5.7 Psychometric properties assessed using Rasch analysis

During scale validation, Rasch analysis is performed iteratively until optimal psychometric properties are attained. This section describes the psychometric properties assessed using Rasch analysis and provides guidelines on interpretation. Figures used for illustration are outputs of the original data analysed in this thesis using the Winsteps program (Chapter 6).

5.7.1 Item polarity

A preliminary evaluation of the item polarity is essential before investigating other

psychometric properites.[387] In Rasch analysis, the items and rating scales cooperate together to construct a measurement scale.[387] Therefore, all items should be oriented in the same direction; that is, have the same item polarity. This is particularly important when the scale has both positively and negatively worded items[243] such as 'how difficult is it for you to ride a bike?' and 'how easy is it for you to go for a long walk?' In such cases, care must be taken to score the items alike such that higher score on both questions means the same thing (e.g. greater ability).

The polarity of the items can be examined by inspecting the point-measure correlations in Winsteps table 26 (Figure 5-1).[365] The presence of any negative correlations indicates that the responses to that item is disoriented / contradicts the latent variable defined by the general item consensus.[387] If differential item polarity was evident, the cause should be investigated (e.g. error in scoring, mis-keying) and fixed before proceeding with other evaluations.[340]

Figure 5-1 displays the Winsteps table 26 of the driving item bank validated in this research. The observed and expected point measure correlations in the red box are greater than 0.70 for all items, indicating general item consensus.

PERSON: REAL SEP.: 2.52 REL.: .86 ... ITEM: REAL SEP.: 4.35 REL.: .95

ITEM STATISTICS: CORRELATION ORDER

ENTRY NUMBER	TOTAL SCORE	TOTAL COUNT	MEASURE	MODEL S.E.	INFIT MNSQ	INFIT ZSTD	OUTFIT MNSQ	OUTFIT ZSTD	PTMEASUR-AL CORR.	PTMEASUR-AL EXP.	EXACT MATCH OBS%	EXACT MATCH EXP%	ESTIM DISCR	ITEM
18	953	224	-.30	.12	1.50	3.8	1.41	2.3	.72	.78	65.1	63.4	.70	AL76I
6	548	128	-.51	.16	1.32	1.9	1.10	.5	.75	.78	68.2	63.6	.82	AL56
14	761	216	1.48	.10	1.39	3.4	1.43	3.6	.76	.82	45.0	51.7	.53	AL54
5	535	129	-.13	.15	1.30	1.9	1.12	.6	.76	.79	61.8	60.3	.89	AL55
11	834	205	.16	.11	1.16	1.4	1.27	1.8	.76	.79	55.2	59.3	.77	AL75
17	845	209	.21	.11	1.12	1.1	1.12	.9	.77	.78	54.1	57.7	.88	AL61
16	929	214	-.57	.12	1.02	.2	.83	-.9	.77	.76	66.7	66.0	1.07	AL60
1	588	136	-.74	.15	.97	-.1	1.05	.3	.78	.77	67.5	65.7	1.07	AL47
7	939	211	-.99	.13	.76	-2.0	.62	-1.8	.78	.74	72.0	70.5	1.18	AL64
4	539	130	-.15	.15	1.04	.3	1.18	.9	.78	.79	64.0	60.4	1.00	AL50
15	919	220	-.14	.11	1.05	.4	1.09	.6	.78	.79	62.5	62.0	.95	AL57
13	795	195	.13	.12	.87	-1.1	.83	-1.2	.80	.79	63.2	59.1	1.10	AL53
10	876	205	-.40	.12	.69	-2.8	.68	-1.9	.81	.77	70.0	63.9	1.27	AL74I
3	500	130	.61	.14	1.01	.1	.90	-.6	.81	.81	55.9	53.9	1.02	AL49
12	870	205	-.33	.12	.70	-2.7	.58	-2.8	.82	.77	71.3	63.3	1.33	AL51
9	818	203	.29	.11	.82	-1.6	.70	-2.3	.83	.79	65.2	58.0	1.17	AL73I
8	809	206	.51	.11	.80	-1.9	.74	-2.1	.83	.80	66.9	56.3	1.24	AL72I
2	492	133	.88	.13	.89	-.8	.79	-1.4	.83	.82	57.9	52.8	1.13	AL48
MEAN	752.8	183.3	.00	.12	1.02	.1	.97	-.2			62.9	60.4		
P.SD	163.4	37.5	.59	.02	.23	1.9	.26	1.7			6.8	4.8		

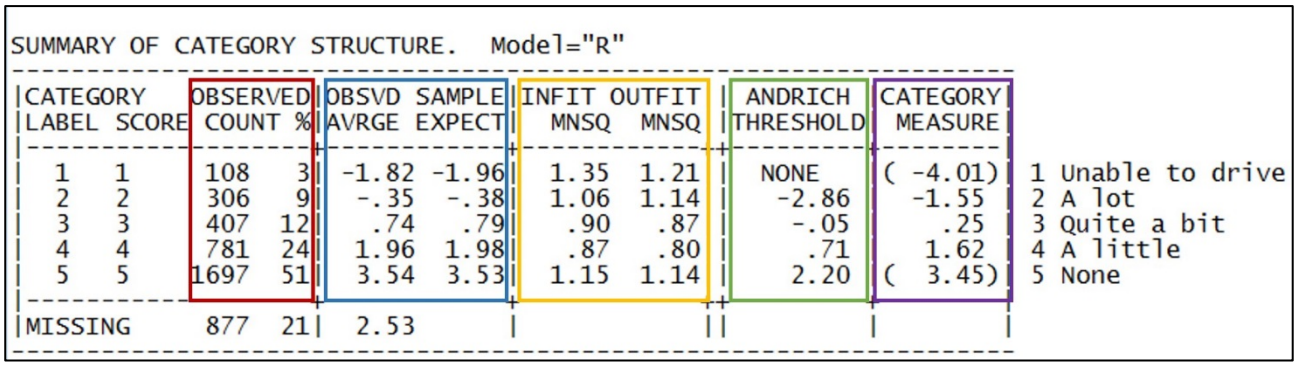
Figure 5-1 Winsteps table 26.1 of Optimised Driving scale - Inspecting Item polarity.

The values within the red box are point-measure correlations observed in the data (left) and expected by the model (right). All correlations are positive and greater than 0.70 indicating consensus in measuring the latent trait.

5.7.2 Response category functioning

As rating scales forms the basis of data collection, the next important step in scale validation is to assess the response categories functioning. The rating scales may not function as intended if the response categories are not clearly defined, qualitatively ordered, and relevant to the population.[339, 363, 393] Too many categories (generally more than five) and complicated item formats may also result in dysfunctional categories,[339] imprecise calibrations,[340] and affect the measurement range of a scale.[394]

The functioning of response categories are assessed by inspecting the frequencies of observations in each response category, the observed average measure, category measures, threshold calibrations and fit statistics.[387] Guidelines for evaluating these parameters are described below. Although these are not deterministic, they provide a useful starting point. Winsteps table 3.2 (Figure 5-2) displays the summary of the category structure statistics.[365]



SUMMARY OF CATEGORY STRUCTURE. Model="R"

CATEGORY LABEL	SCORE	OBSERVED COUNT	%	OBSVD AVRGE	SAMPLE EXPECT	INFIT MNSQ	OUTFIT MNSQ	ANDRICH THRESHOLD	CATEGORY MEASURE	
1	1	108	3	-1.82	-1.96	1.35	1.21	NONE	(-4.01)	1 Unable to drive
2	2	306	9	-.35	-.38	1.06	1.14	-2.86	-1.55	2 A lot
3	3	407	12	.74	.79	.90	.87	-.05	.25	3 Quite a bit
4	4	781	24	1.96	1.98	.87	.80	.71	1.62	4 A little
5	5	1697	51	3.54	3.53	1.15	1.14	2.20	(3.45)	5 None
MISSING		877	21	2.53						

Figure 5-2 Winsteps table 3.2 of Final Driving scale – Evaluation of response category functioning.

Red box: frequency and percentage of observations in each response category; Blue box: Average measures observed (left) and expected (right); Yellow box: Fit statistics - Infit and outfit mean squares (MNSQ); Green box: Andrich thresholds or step calibrations (for 'm' response categories there are 'm-1' thresholds); Purple box: Category measures – values enclosed within () indicates that the calibration is infinite

5.7.2.1 Category frequencies

The frequencies of observed categories are inspected to see if there are any categories with low or nil counts and if the distribution of the frequencies is non-uniform or irregular (not meaningful).[387] As a general guideline, at least ten observations in each category is required for stable threshold calibrations.[388] Meaningful distributions include those in which the category frequency peaks in the central category (unimodal) or in extreme categories (bimodal).[387] When the frequency distributions do not follow a meaningful pattern, it can be problematic; e.g.

adjacent categories with high-low-high observations, skewed categories with very few observations.[387]

In Figure 5-2 (red box), the frequencies of observations in each category advances up the categories, indicating meaningful distribution.

5.7.2.2 Observed average and category measures

Next, the observed average measures and the category measures are inspected. Average measures indicate the average differences between the person ability and item difficulty parameters corresponding to each response category.[365] It describes the sample. Category measures, on the other hand, are sample-free and indicates what would the average measure of the persons who choose a particular category be.[365] As previously described, the higher the person ability, the greater is the probability of endorsing higher categories and *vice versa*.[365] Therefore, it is expected that lower average and category measures correspond to lower categories and that it increases monotonically up the rating scale.[395] If it is not so, the assumption that higher category indicates more of the latent variable is contradicted. This indicates that the meaning of the rating scale is ambiguous for the sample and therefore any measures obtained from the analysis may be deemed unreliable.[387]

In Figure 5-2 blue box, the average measures observed in the data and expected by the model are displayed. It is useful to compare the observed values with the expected to see if there are any marked differences. In the figure, these values are close to each other indicating that the data meets the model expectations. Also, the average measures in blue box and the category measures in purple box increases monotonically with advancing response category.

5.7.2.3 Category probability curves

The Category Probability Curves (CPC) displays the model-probabilities of observing each response category (Y-axis) along the latent variable, relative to the item difficulty (x-axis).[365] It helps us to visualise if the peaks of the response categories and the threshold calibrations (Figure 5-2, green box) are ordered.[96]

As respondents with infinitely high or low abilities are expected to be endorse the extreme categories, the end categories always approach a probability of 1 asymptotically.[387] The distinct peaks in the graph (Figure 5-3) represent the points along the latent variable at which each category is maximum probable.[396] The points

at which the adjacent categories cross over represents the thresholds or step calibrations; at this point the two adjacent categories are equally probable (50% chance of observing either of them).[96]

For higher categories to indicate higher ability, the peaks and threshold values should advance monotonically. The distance between thresholds should not be too close nor far;[396] it is generally recommended that the thresholds advance by at least 1.4 logits for a rating scale with three categories and by at least 1 logit for a rating scale with five categories.[387] When the thresholds advance by more than 5 logits, there is loss of information at the centre of the scale where the respondents are well targeted.[387]

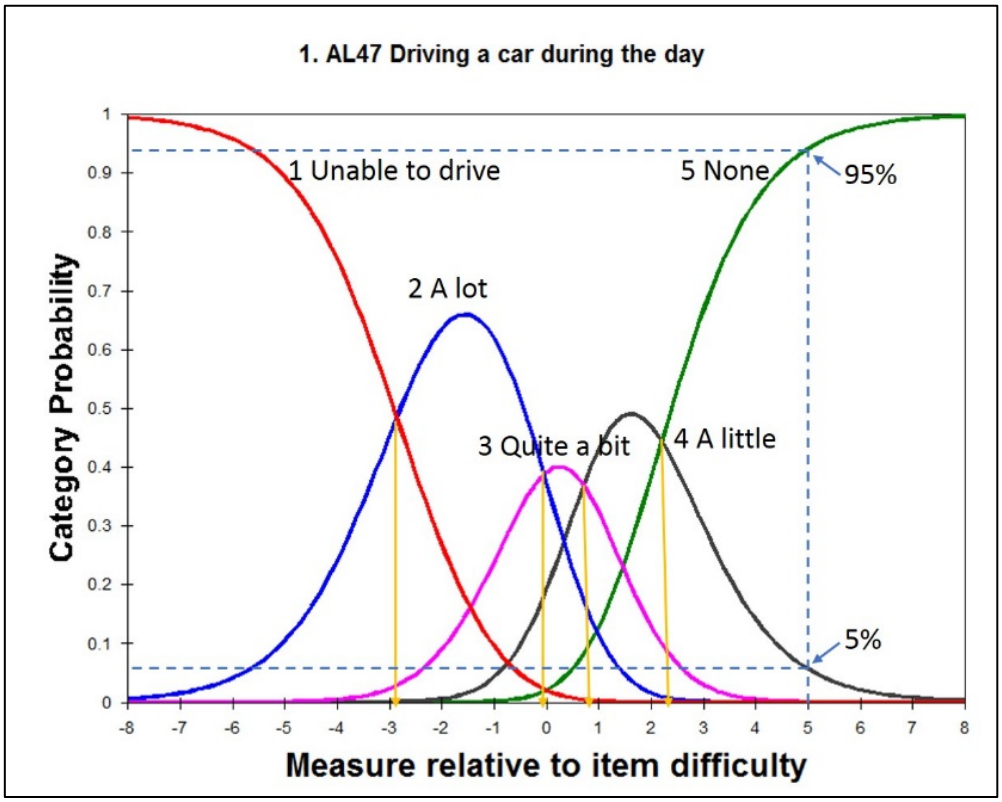


Figure 5-3 Category probability curves of item AL 47 from final Driving scale.

As the rating scale model is applied this structure is constant across all items. The peaks of each category indicate the point along the latent variable where it is more probable than all other categories. The points where adjacent categories intersect (yellow lines) are the category thresholds. Blue dotted lines in the figure indicates that a person with a measure of 5 logits, the probability of endorsing categories 1, 2 and 3 is nil, 4 is about 5% and 5 is about 95%

In the Figure 5-3, the peaks and category thresholds are ordered. As the measure advances along the x-axis, the probability of observing higher categories increases; for example, see the blue dotted lines - for a person measure of 5 logits (high ability), the probability of observing the highest category (5) is about 95%, second highest category (4) is 5% and other lower categories (1,2 and 3) is nil. The distance between the thresholds are reasonable ranging from 0.76 to 2.81 logits (for threshold values

see Figure 5-2, green box).

While some argue that disordered thresholds is not as serious as disordered average measures, others believe that it degrades the reliability and interpretability of the measures obtained from the scale.[387] Threshold disordering can occur when the category represents a very narrow segment of the latent trait, when the frequency of observations is very low or if the number of categories are more than what the respondents can distinguish.[243] Categories with disordered average measures or thresholds are often combined (collapsed) with an adjacent category to obtain a monotonic structure.[397] However, other Rasch parameters such as person separation, reliability, item and person fit statistics should be evaluated to see if these improve or worsen on such recalibration.[93, 398]

5.7.2.4 Category fit statistics

The Rasch model expects that some randomness exists in the data and that it is uniform throughout.[387] The randomness in the data is given by the Mean-Square (MNSQ) fit statistics presented within the yellow box in Figure 5-2.[365] A value of 1 indicates the randomness is uniform; values more than 1 indicates more randomness (underfit) and values less than 1 indicates less randomness (overfit). Both these misfits induce noise in measurement; however, large MNSQ values are considered greater threat to measurement.[387] Values greater than 1.5 are problematic and values greater than 2.0 are detrimental to measurement.[387] No significant misfit is observed in Figure 5-2 as all values are under 1.5 logits.

Inspection of the raw data is useful in identifying idiosyncratic observations which could have caused such misfits; this can be remedied by omitting such responses from the analysis.[365] Other possible solutions are eliminating problematic category or combining it adjacent ones.

5.7.3 Separation and reliability indices

Unlike CTT, Rasch analysis produces both person and item reliabilities. The reliability coefficients indicate the reproducibility of the measures estimated by the test.[365] High reliability means that there is a high probability that persons and items with high measures actually have higher measures than those estimated with lower measures.[365] Reliability is dependent on the standard error; lower the standard error, higher the reliability.[365, 399] The reliability coefficient can only attain a maximum value of 1.0 and therefore changes only by a very small amount when the standard error is

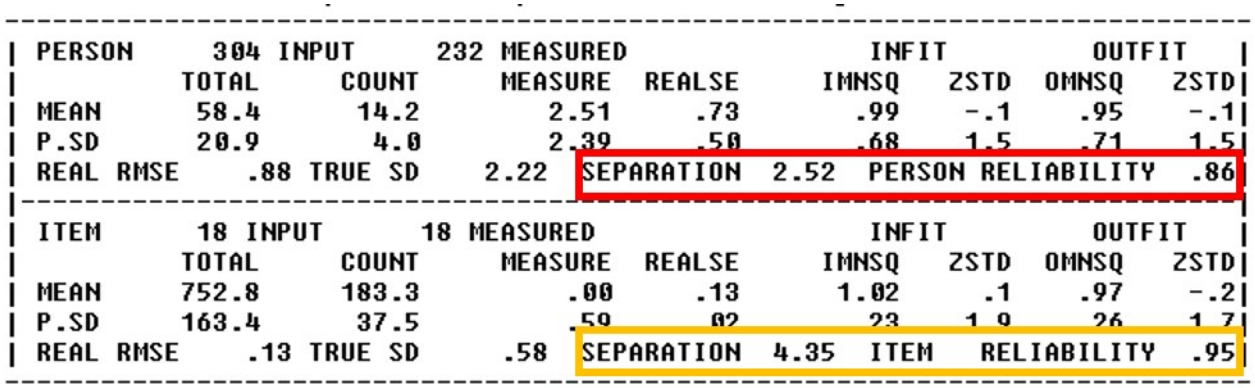
low.[399] To overcome this insensitivity, Ben Wright devised the separation indexes, which increases without boundary as the standard error decreases.[399]

The person and item separation indices are reported by Winsteps alongside their respective reliabilities in Winsteps table 3.1.[365] The Person Separation Index (PSI) signifies the ability of the instrument to distinguish people with different abilities; in other words, it denotes measurement precision of the instrument.[400] Higher the person separation and reliability, higher the measurement precision.[399] A PSI of 2 (corresponding person reliability = 0.8) means that the instrument is able to classify the persons into 3 strata (low-middle-high abilities) and a PSI of 3 (person reliability = 0.9) indicates that the instrument can stratify persons into 4 groups.[365]. PSI lesser than 2 (reliability <0.8) is sub-optimal as the instrument cannot distinguish between persons with high and low abilities.[131, 400]

PSI depends on the variance of ability of the sample tested, the number of items in the test, the number of response categories and how well the test is targeted to the sample.[365] Lower PSI can be improved by increasing the number of test items or by administering the test to more persons with both lower and higher abilities (wider ability range).[365] Extreme scores do not provide any information for item calibration and are sometimes removed from analysis to improve measurement precision during scale construction.[93]

Conventionally, only the person separation is reported in reports of analysis. However, the Item Separation Index (ISI) also provides useful information. It indicates how many strata of item difficulties were perceived by the sample of respondents and is used to verify item hierarchy.[221] An ISI of 3 (item reliability = 0.9) indicates that the persons could classify the test items into four levels of difficulties.[365] Lower ISI indicates that range of item difficulties is narrow, or the sample size is inadequate.[365] Consequentially, it can be improved by increasing the sample size or by including more items with a wide range of difficulties.[365]

Figure 5-4 shows the Winsteps output of summary statistics displaying the separation and reliability indices. PSI of 2.52 indicates that the scale can discriminate people with more than 3 levels of abilities and the ISI of 4.35 indicates that the sample could differentiate items into more than 5 levels of difficulties. Both are satisfactory with reliabilities of 0.86 and 0.95 respectively.



PERSON	304 INPUT	232 MEASURED		INFIT		OUTFIT	
	TOTAL	COUNT	MEASURE	REALSE	IMNSQ	ZSTD	OMNSQ	ZSTD
MEAN	58.4	14.2	2.51	.73	.99	-.1	.95	-.1
P.SD	20.9	4.0	2.39	.50	.68	1.5	.71	1.5
REAL RMSE	.88	TRUE SD	2.22	SEPARATION	2.52	PERSON RELIABILITY		.86

ITEM	18 INPUT	18 MEASURED		INFIT		OUTFIT	
	TOTAL	COUNT	MEASURE	REALSE	IMNSQ	ZSTD	OMNSQ	ZSTD
MEAN	752.8	183.3	.00	.13	1.02	.1	.97	-.2
P.SD	163.4	37.5	.59	.02	.23	1.9	.26	1.7
REAL RMSE	.13	TRUE SD	.58	SEPARATION	4.35	ITEM RELIABILITY		.95

Figure 5-4 Winsteps summary statistics output for Optimised Driving scale.

Person separation and reliability values are enclosed in the red box and item separation and reliability values are enclosed within the yellow box.

5.7.4 Fit statistics

In addition to the fit statistics of response categories, fit statistics for items and persons are reported by Rasch analysis.[365] Fit statistics indicates how well the data meets the Rasch model expectations.[401] It also gives an indication of dimensionality; misfitting items may measure constructs that are different to what is measured by other items on the scale and warrants further evaluation.[243] There are two fit statistics – Infit and Outfit. The infit statistic is inlier-sensitive; it is more sensitive to idiosyncratic (unexpected) responses near the person ability.[89] On the other hand, the outfit statistic is outlier-sensitive; it is more sensitive to idiosyncratic (unexpected) responses away from a person's ability.[89] The fit statistics are reported in terms of mean square (MNSQ) and z-standardized (ZSTD) values.[365]

The MNSQ is a chi-square statistic divided by its degree of freedom. As mentioned before, its expected value is 1 and the actual values can range from 0 to infinity.[401] Values more than 1 indicates underfit (data less predictable than model expectations) and less than 1 indicates overfit (data more predictable than model expectations).[365] For example, an MNSQ of 1.3 indicates 30% more randomness or noise in the data and an MNSQ of 0.70 indicates 30% less randomness than what the model predicted. Larger MNSQ values degrade measurement while smaller MNSQ values inflate reliability and separation statistics.[401] MNSQ values between 0.5 and 1.5 are considered productive for measurement; values between 1.5 and 2 and that less than 0.50 are inefficient, however not degrading.[401] Values over 2 damages measurement.[401] For the item banks, values between 0.5 and 1.5 are considered satisfactory.[3, 93]

The probability of the MNSQ values occurring by chance is given by the ZSTD, a t-test statistic.[365] These are unit-normal deviates and a value of 1.96 (approximately 2) corresponds to 0.05% of 2-sided significance; this means values greater than |2| indicates statistical significance. Negative values indicate overfit and positive values, underfit.[401] The ZSTD are generally referred only when the MNSQ values are unreasonable.[365, 401] Winsteps table 6.1 reports person misfit and 10.1 reports item misfit (Figure 5-5).

TABLE 10.1 \\userKL\K\kuma0136\prefs\Desktop\Pha ZOU829WS.TXTa Mar 18 2019 22:28a data v9 f
INPUT: 304 PERSON 18 ITEM REPORTED: 232 PERSON 18 ITEM 5 CATS WINSTEPS 4.2.0

PERSON: REAL SEP.: 2.44 REL.: .86 ... ITEM: REAL SEP.: 4.24 REL.: .95

ITEM STATISTICS: MISFIT ORDER

ENTRY NUMBER	TOTAL SCORE	TOTAL COUNT	MEASURE	MODEL S.E.	INFIT MNSQ	INFIT ZSTD	OUTFIT MNSQ	OUTFIT ZSTD	PTMEASUR-AL CORR.	PTMEASUR-AL EXP.	EXACT MATCH OBS%	EXACT MATCH EXP%	ESTIM DISCR	ITEM
17	883	224	.48	.10	1.82	6.3	2.12	6.8	A .67	.78	51.0	55.1	.15	AL61
16	943	218	-.52	.12	1.19	1.5	1.42	2.1	B .73	.75	65.3	65.0	.89	AL60
18	953	224	-.29	.11	1.38	2.9	1.23	1.4	C .72	.76	66.2	63.2	.83	AL76I
14	761	216	1.34	.10	1.28	2.5	1.28	2.4	D .75	.80	43.6	51.4	.65	AL54
6	548	128	-.50	.15	1.23	1.4	.97	-.1	E .75	.77	70.8	63.3	.92	AL56
5	535	129	-.15	.14	1.21	1.4	1.03	.2	F .76	.77	63.7	59.8	.99	AL55
11	834	205	.13	.11	1.07	.6	1.17	1.1	G .76	.77	55.6	58.8	.86	AL75
15	919	220	-.14	.11	.97	-.2	1.01	.1	H .77	.77	63.1	61.5	1.03	AL57
4	539	130	-.17	.14	.98	-.1	.99	.0	I .78	.77	64.9	59.8	1.09	AL50
1	588	136	-.70	.15	.89	-.7	.96	-.1	i .77	.76	68.3	64.7	1.14	AL47
3	500	130	.54	.13	.94	-.4	.83	-1.0	h .80	.79	58.8	53.0	1.10	AL49
2	492	133	.79	.13	.84	-1.2	.74	-1.8	g .82	.80	59.0	52.1	1.18	AL48
13	795	195	.11	.11	.83	-1.5	.79	-1.4	f .80	.77	64.4	58.8	1.15	AL53
9	818	203	.25	.11	.76	-2.2	.66	-2.7	e .82	.77	65.8	57.3	1.22	AL73I
8	809	206	.46	.10	.74	-2.5	.68	-2.6	d .82	.78	65.8	55.6	1.29	AL72I
7	939	211	-.92	.13	.70	-2.5	.57	-2.3	c .77	.73	72.9	69.9	1.22	AL64
12	870	205	-.32	.11	.67	-3.1	.55	-3.1	b .81	.76	71.7	63.0	1.34	AL51
10	876	205	-.39	.12	.66	-3.2	.65	-2.2	a .80	.75	69.9	63.7	1.28	AL74I
MEAN	755.7	184.3	.00	.12	1.01	-.1	.98	-.2			63.4	59.8		
P.SD	165.7	38.4	.55	.02	.29	2.4	.37	2.3			7.3	4.9		

Figure 5-5 Winsteps 10.1 of original driving scale showing items in misfit order.
Red box: Item AL61 shows significant misfit (Infit MNSQ = 1.82 and Outfit MNSQ = 2.12)

Misfits can be easily visualised using Bubble charts (Figure 5-6) in which the person and/or item measures are graphically plotted against their infit MNSQ values.[365] The relative size of the bubble represents the size of the standard error. The bubble charts are useful in spotting the outliers.[365]

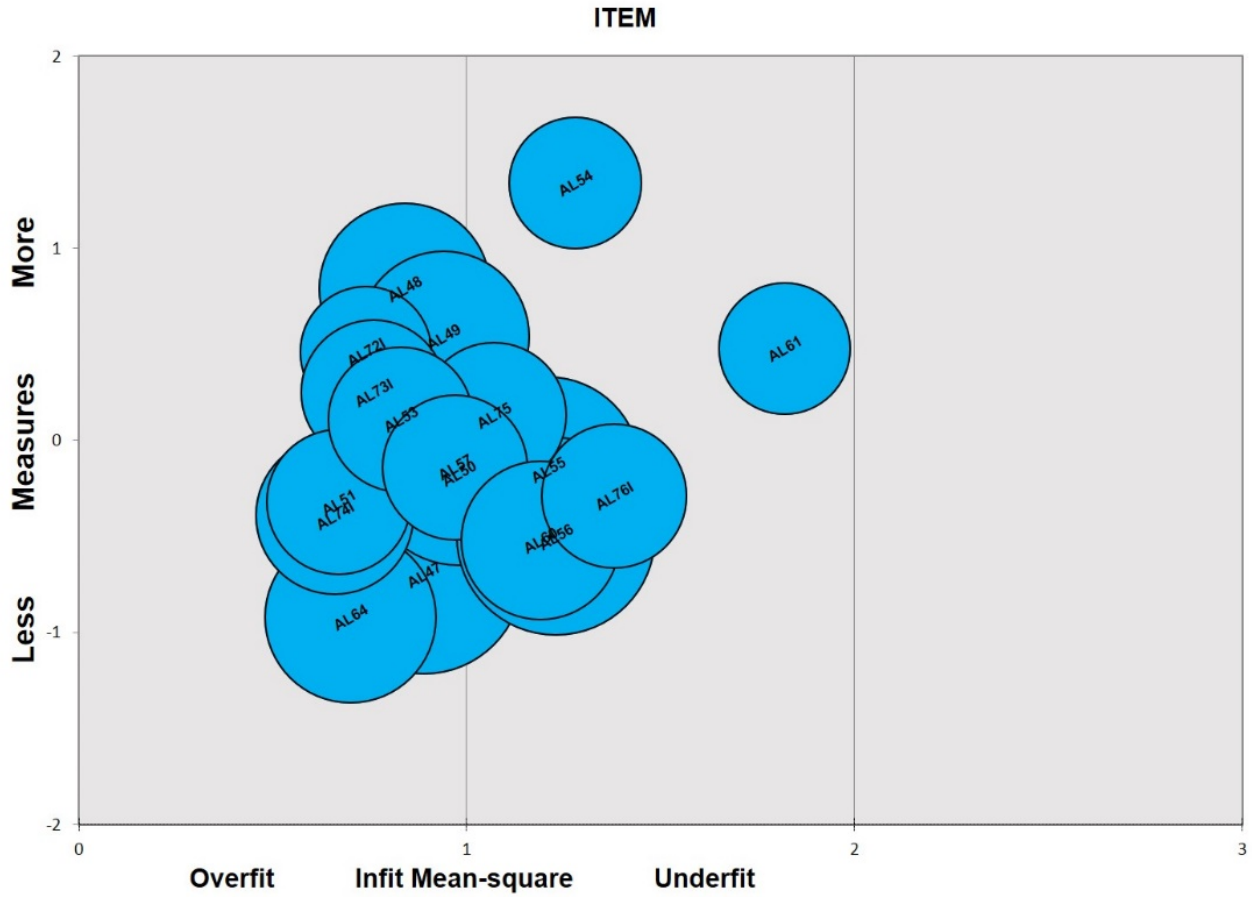


Figure 5-6 Bubble chart of original Driving scale showing item misfit.

Item infit MNSQ (X-axis) are plotted against item measures (Y-axis). No item MNSQ is over 2 logits. AL61 is the most misfitting item with MNSQ 1.82 logits.

The Rasch model treats items and persons the same way and reports fit statistics for both;[365] however, in reality there is a paramount difference between them. As items are the standard (unchanging) part of the scale unlike the persons who take the test, item misfit are governed by strict rules.[401] A few misfitting persons may not affect the measurement quality as much as a few misfitting items that poses doubts on quality of measures obtained and definition of the latent trait.[401, 402] Thus, person misfits are dealt with more leniently than item misfits.[401]

As infit indicates misfit in the region where the item is supposed to be most useful for measurement, it is considered as a greater threat to measurement than outfit.[403] However erroneous pattern of responses leading to large infit are difficult to identify and remedy.[365] Outfits are usually caused by lucky guesses, careless mistakes or errors in data entry which can be identified by inspecting the person responses.[365, 403] A scalogram (Winsteps table 22) can be used for this purpose; it orders responses of persons from high to low abilities in rows and items from easy to hard items in columns.[365] Inspecting scalograms visually are much easier for a dichotomous scale in

which responses transit from 1 (easy items) to 0 (hard items) than a polytomous scale which has a wider transition zone due to the presence of more categories. Alternatively, Winsteps tables 10.4 (Figure 5-7) and 10.5 can be used to identify unexpected item responses.[365] For instance, one would expect that a person who reported no difficulty in driving at night time (high ability) to have no difficulty in driving at day time (easy item) and a person who has difficulty driving at day time (low ability) to have much more difficulty driving at night time (hard item). If this expectation is not met, the response is questionable, which could be due to the carelessness (first case) and guessing (second case).

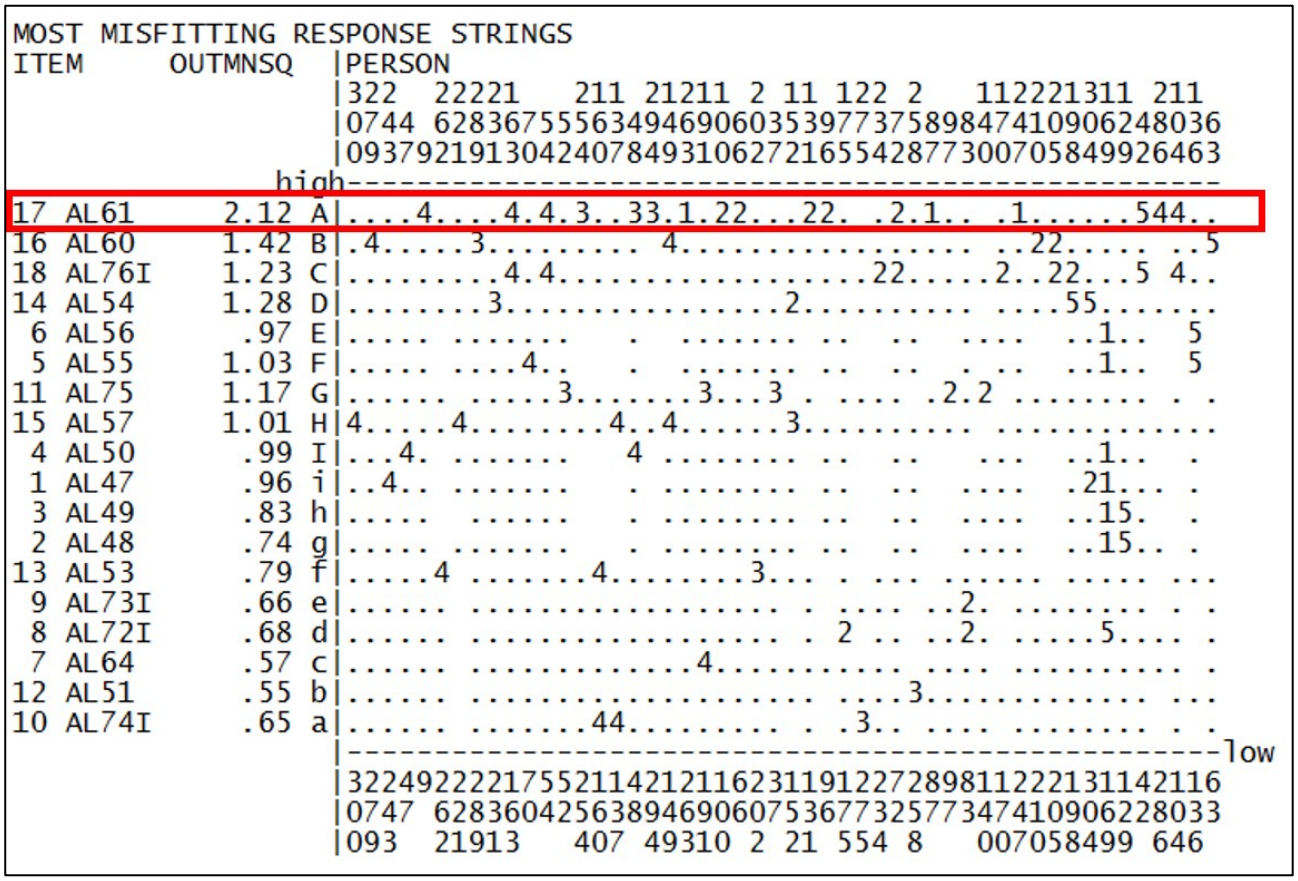
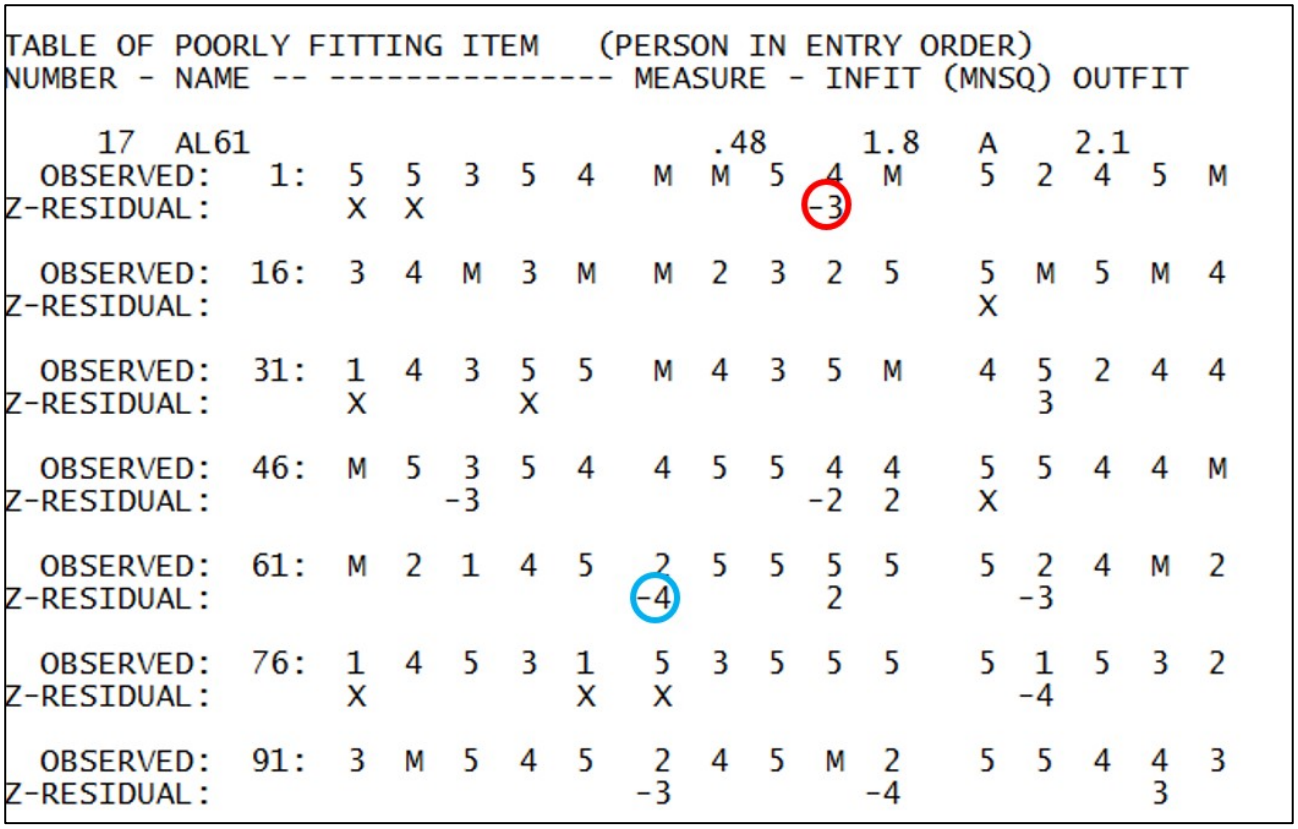


Figure 5-7 Winsteps table 10.4 for original Driving scale showing unexpected responses for items starting from the most misfitting item - AL61.

Each row has the item entry number, item label, item outfit MNSQ, item identity alphabet appearing in infit/outfit plots. The dots indicate that the responses were as expected, and the numbers denote the actual response of the persons that were not expected by the Rasch model.

It is also useful to examine the z-standardised residuals in Winsteps table 11.1 (Figure 5-8) to identify persons who have responded erroneously to the misfitting items (Z-residuals +/-3).[93, 365] The impact of misfit can be evaluated by imputing missing values to such responses and examining the changes to person and item measures.[365, 401] Remedying misfit is an iterative process and should be exercised with caution. In

an attempt to improve the fit of one item, another item may in turn show misfit. The reasons for misfit should be carefully examined and items should be deleted judiciously.[93] This is particularly important in the context of item banks in which the aim is to have as many items as possible.[2]



```
TABLE OF POORLY FITTING ITEM   (PERSON IN ENTRY ORDER)
NUMBER - NAME -- --------------- MEASURE - INFIT (MNSQ) OUTFIT

     17  AL61                          .48     1.8   A    2.1
  OBSERVED:   1:  5  5  3  5  4   M  M  5  4  M    5  2  4  5  M
Z-RESIDUAL:       X  X                       -3

  OBSERVED:  16:  3  4  M  3  M   M  2  3  2  5    5  M  5  M  4
Z-RESIDUAL:                                       X

  OBSERVED:  31:  1  4  3  5  5   M  4  3  5  M    4  5  2  4  4
Z-RESIDUAL:       X        X                          3

  OBSERVED:  46:  M  5  3  5  4   4  5  5  4  4    5  5  4  4  M
Z-RESIDUAL:             -3                -2  2    X

  OBSERVED:  61:  M  2  1  4  5   2  5  5  5  5    5  2  4  M  2
Z-RESIDUAL:                      -4              2       -3

  OBSERVED:  76:  1  4  5  3  1   5  3  5  5  5    5  1  5  3  2
Z-RESIDUAL:       X              X  X                    -4

  OBSERVED:  91:  3  M  5  4  5   2  4  5  M  2    5  5  4  4  3
Z-RESIDUAL:                      -3              -4             3
```

Figure 5-8 Winsteps table 11.1 of original Driving scale used to identify persons who gave unexpected responses

z-residuals greater than |3| are worthy of investigation. The numbers preceding the colon ":" indicates the entry number of the first person of that row. For example, the red circle indicates unexpected response given by person entry number 9 and the blue circle indicates unexpected response given by person entry number 66.

5.7.5 Dimensionality

According to the principles of measurement, all items in a scale should measure a single dominant construct or latent trait (unidimensionality) and should be locally independent.[243] Unidimensionality is fundamental to obtain valid measures; multidimensionality creates ambiguity as to what is being measured.[89] However, in reality, achieving absolute unidimensionality is challenging due to differences in cognition, personality and experiences of test-takers.[371]

It is also possible that a given latent trait is hybrid, comprising several strands (sub-constructs).[365, 400] For example, a scale developed to test arithmetic ability (latent trait) may contain questions targeting different mathematical skills such as addition,

subtraction and multiplication (strands). Similarly, in health measurement, a scale measuring functional limitations (latent trait) may include items targeting difficulty in performing a range of activities such as reading, playing sports and other activities of daily living (strands). Although both these scales may not be truly unidimensional statistically, they can be thought of as unidimensional for practical purposes. Therefore, the aim of dimensionality investigations is to verify if the scale is adequately unidimensional for meaningful measurement.[365]

The fit statistics, described before, gives an indication of how well the data meets the unidimensionality expectations of Rasch analysis; however, it focusses on individual items and is not enough to substantiate unidimensionality.[365] The Principal Component Analysis (PCA) of residuals was thus introduced. In Rasch model, data or observations can be conceptualised as the sum of the Rasch dimension (expectation) and residuals (observed minus expected).[365] The PCA of residuals helps us to identify if the residuals are due to random noise or due to secondary dimensions. To investigate this, Winsteps table 23 (Figure 5-9) is referred.[365]

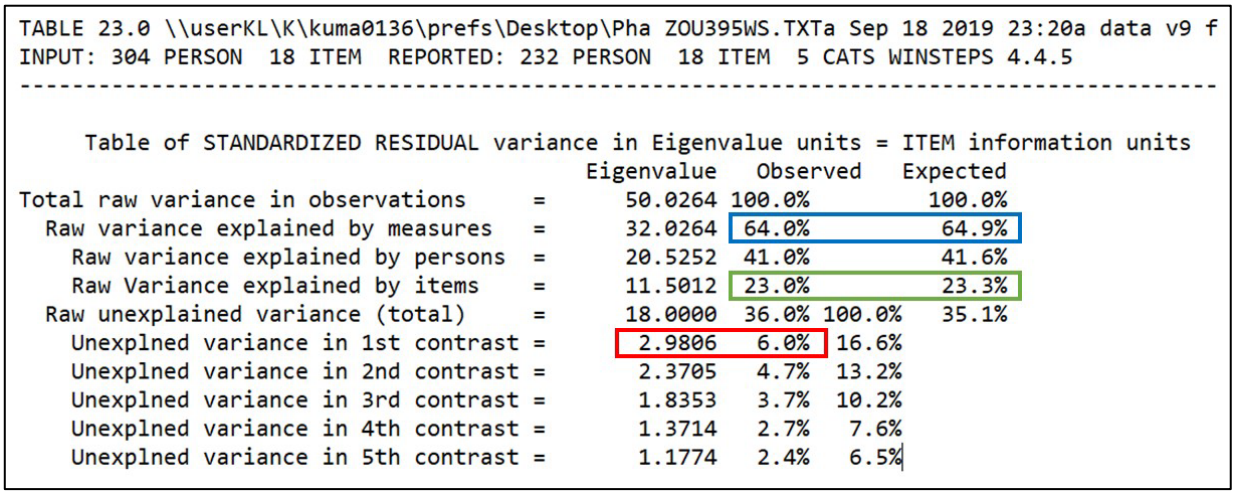


TABLE 23.0 \\userKL\K\kuma0136\prefs\Desktop\Pha ZOU395WS.TXTa Sep 18 2019 23:20a data v9 f
INPUT: 304 PERSON 18 ITEM REPORTED: 232 PERSON 18 ITEM 5 CATS WINSTEPS 4.4.5

Table of STANDARDIZED RESIDUAL variance in Eigenvalue units = ITEM information units

	Eigenvalue	Observed		Expected
Total raw variance in observations =	50.0264	100.0%		100.0%
Raw variance explained by measures =	32.0264	64.0%		64.9%
Raw variance explained by persons =	20.5252	41.0%		41.6%
Raw Variance explained by items =	11.5012	23.0%		23.3%
Raw unexplained variance (total) =	18.0000	36.0%	100.0%	35.1%
Unexplned variance in 1st contrast =	2.9806	6.0%	16.6%	
Unexplned variance in 2nd contrast =	2.3705	4.7%	13.2%	
Unexplned variance in 3rd contrast =	1.8353	3.7%	10.2%	
Unexplned variance in 4th contrast =	1.3714	2.7%	7.6%	
Unexplned variance in 5th contrast =	1.1774	2.4%	6.5%	

Figure 5-9 Winsteps table 23 of final driving scale: Investigation of dimensionality.

Observed raw variance explained by the measures (blue box) and that explained by the items (green box) are close to expectations. The eigenvalue of the 1st contrast is <3 (red box). The ratio of the variance explained by the items to the unexplained variance in the first contrast is high.

It was earlier agreed that the raw variance explained by the measures should be at least 60% to indicate unidimensionality as they correspond to the primary dimension (Rasch dimension).[115, 404] However, now it is realised that the variance unexplained rather than the variance explained is a threat to unidimensionality.[365] This is because, the variance explained depends on how well the scale targets the sample measured and the range of the person and item measures estimated; for instance, if the persons who took the test have similar abilities and the items are of almost equal difficulties,

then the variance explained by the measures will be small.[365] On the contrary, the variance unexplained by the Rasch measures is of concern as it corresponds to all other dimensions and random noise. This needs further investigation.

The PCA of residuals decomposes this unexplained variance into different contrasts (components) representing other dimensions. Winsteps reports five contrasts if they are estimable in order of their strengths. The strength of the contrasts is given by the eigenvalues.[365] Ideally, all items in the scale should share a common Rasch dimension but be locally independent otherwise; therefore, when the Rasch dimension is accounted for, each item should represent a unique contrast of its own, having an eigenvalue of one item. An eigenvalue of two (two items) may occur by chance; if the strength of the eigenvalue is more than two, multidimensionality is suspected.[115] However, in large questionnaires such as item banks, large eigenvalues could be accidental and a lenient criterion of eigenvalue 3 is adopted.[93] When multidimensionality is suspected, post-hoc investigations are warranted.

First, the standardised residual of variances is inspected in Winsteps table 23;[365] the empirical explained variance should approximate the model predicted explained variance. The model variance is the variance that the Rasch measures would have explained if the data fitted the Rasch model perfectly.[365] Noticeable difference between the empirical and modelled variance sizes warrants careful evaluations.

Secondly, the raw variance explained by the items is compared with the variance unexplained in the 1st contrast; ideally the former should be higher than the latter.[365] A scree plot is useful in visualising the variance explained by various components in the data.[365]

Lastly, the size of secondary dimension given by the eigenvalue of the first contrast is inspected to see if the value is greater than that occurring by chance.[365] If the value is greater than 2[243] (greater than 3 for item banks)[93], the content of the items loading on that contrast are examined to see if they are noticeably different from other items on the scale. If multidimensionality is suspected and the following post-hoc investigations are recommended.

The correlation between person measures obtained on each cluster of items identified in the first contrast are examined.[365] Winsteps reports both Pearson and disattenuated correlations. Disattenuated correlations are particularly important as they are free from the influence of measurement error.[400] A value close to 1 indicates that the

person measures from the two clusters of items are measuring the same construct (statistically the same).[365, 400] Very low or negative correlations indicate that they may be measuring different things.[60] A correlation of 0.71 indicates that the two item clusters have more than half of their variance in common (calculated by $0.71^2 * 100 = 50.41\%$).[365] A correlation of 0.82 indicates that the two clusters are twice as dependent as independent (common variance, 67.24% is over two times more than independent variance, 32.76%) and a correlation of 0.57 indicates that their common variance (32.49%) is less than half of the variance they have independently (67.51%).[365, 400] Cross-plotting the person measures obtained from the suspect item cluster versus the other items is useful to visualise if the persons lie along a statistical diagonal and to identify those who are off-diagonal.[365] When the disattenuated correlations are moderate, it is useful to evaluate other evidences such as agreement.[400]

Bland and Altman (B&A) agreement analysis is used to test the agreement of the two scales (sets of items).[405] The average mean differences between the two tests indicates how well the scales agree on average (systematic difference) and a t-test is used to test the hypothesis that there is no bias.[406] The Limits Of Agreement (LOA), given by the mean difference +/- 1.96 * standard deviation indicates how wide apart are the measures obtained by the two scales were for most individuals.[406, 407] This is visually represented in the B&A plot in which the average measures obtained from the two scales (x axis) are plotted against the difference in measures between the two scales (y axis).[405, 408] The narrower the LOA, the better the agreement is.[407]

These statistical guidelines should be used along with qualitative judgement to decide if the scale should be split into subscales or items should be deleted.

5.7.6 Local Item Dependency (LID)

As described earlier, the probability of endorsing an item should be dependent solely on the difficulty of the item and the ability of the respondent.[401] This means that there should be no other relationship between the items; in other words, any given pair of items should be independent of each other except for the underlying trait. This is called as 'Local item independence' and its violation 'Local item dependency' (LID).[371] The presence of LID may result in inaccurate estimation of item parameters (calibrations) leading to misinterpretation of results.[409] This is evaluated by examining the residual inter-item correlations; residual are parts not explained by the Rasch model.[365] High residual correlations indicate the pair of items have some other thing in

common, other than the Rasch dimension.[365]

In Winsteps, raw residuals are produced by PRCOMP=R command and inter-item residual correlations are examined. Pairs of items, whose residual correlations are greater than 0.30 are locally dependent.[93] One item from each pair is deleted to obtain LID free item calibrations.[93]

5.7.7 Targeting and Item hierarchy

The extent to which the difficulties of the items in a scale matches the abilities of the persons tested is referred to as 'Targeting'.[396] Ideally both the person mean and item mean (usually set at zero) should be the same indicating perfect targeting (mean difference = zero).[243] If the person mean is higher than the item mean, it indicates that the items are too easy for this sample and likewise if the person mean is lower, it indicates that the items are too hard for the sample.[89] A difference of +/-1 logit between the person and item means is considered to be notable mistargeting. [243, 396]

The person-item map (also called Wright map, Figure 5-10) is useful to visually inspect the item hierarchy, difference between person and item means, ceiling and floor effects, redundant items (items at the same level of difficulty) and gaps in item coverage.[243, 396] In the item-person map, the person and item measures are placed vertically on a logit scale. The persons are placed on the left and items on the right. Persons with higher ability (more able persons) and items with higher difficulty (harder items) are near the top of the map and persons with lower ability and items with lower difficulty (easy items) are near the bottom of the map; this denotes that persons with higher ability are targeted by harder items and *vice versa*.

By examining the hierarchical order of items in item-person map, which is the operational definition of the measure, one is able to confirm the construct validity of the scale (if the item hierarchy makes sense).[89] When items are clustered at certain points along the continuum, there may be large gaps in the scale; this means that there are not enough items to measure the range of person abilities corresponding to the gaps, indicating poor targeting.[397] Targeting may also be affected when many persons have a higher or lower ability measures than the most or least difficult items respectively.

Targeting is sample-dependent.[219, 404] If the targeting is poor in a particular sample due to high number of persons with higher abilities, administering the test to persons

with lower abilities may optimise targeting. A relatively uniform distribution of items along the continuum (gaps less than 0.5 logits) is important for precise measurement.[365] To address gaps along the continuum (absence of items to measure corresponding person abilities), more items could be added.[253]

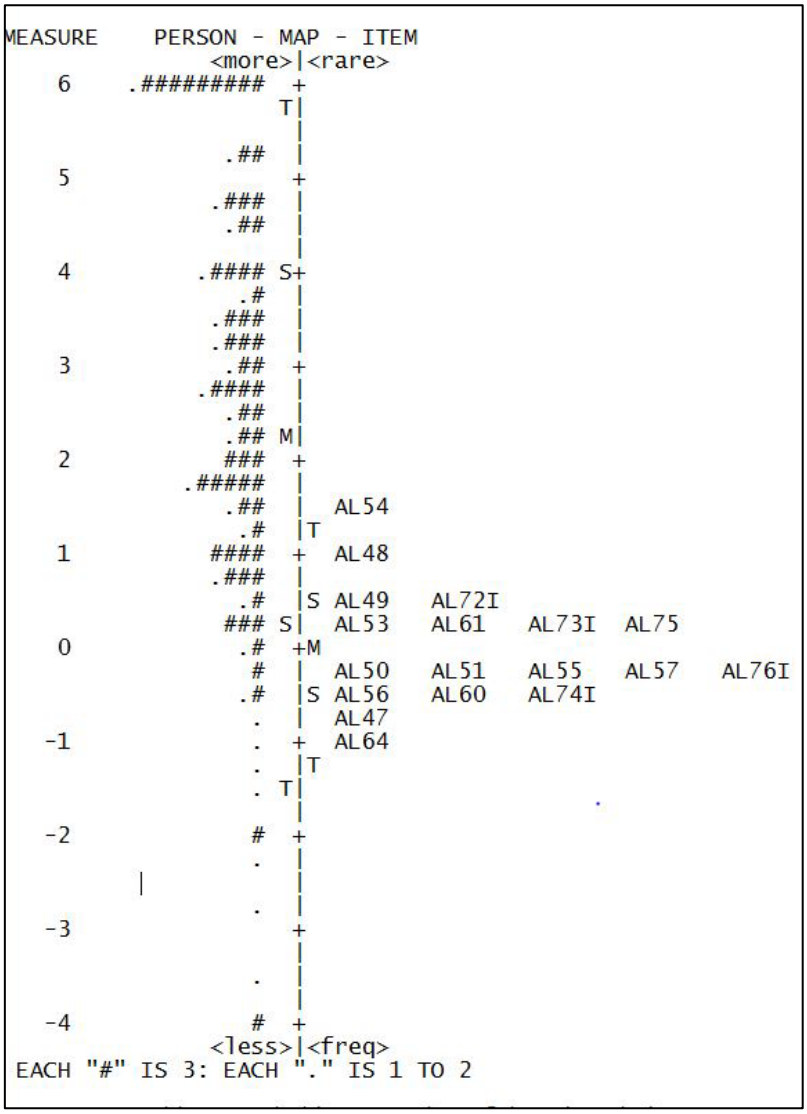


Figure 5-10 Person-item map of optimised Driving scale.

The persons are indicated by symbols ('#' denote 3 persons and '.' denote 2 persons) on the left side and items are represented with the item ID on the right side along the measurement continuum. The difference between the item mean (M on the right side, set at 0) and the person mean (M on the left side) is greater than 2 logits indicating sub-optimal targeting. More number of able persons on the top left side and lack of difficult items on the top right side can be observed.

5.7.8 Differential item functioning (DIF) or Item bias

The property of invariance is fundamental for valid measurement; the items in an instrument should behave the same way for persons with the same level of ability. [243, 410] This means that the probability of endorsing a particular response category for an item should be the same for individuals with the same ability (invariant) irrespective

of other factors.[354, 372] This property is an important prerequisite for valid comparisons of scores between groups of respondents with different demographic, personal, clinical or other characteristics (variables) such as gender, severity of a disease or mode of questionnaire administration.[150, 411, 412] For example, males and females with the same level of driving ability should have the same probability of endorsing 'a little bit' on an item 'how much difficulty do you have in driving at night time?' If not, it indicates DIF and lack of gender equivalence.[150, 410] The presence of DIF violates the property of sufficiency as the raw score is no longer the sufficient statistic; that is the information about the persons is not preserved in the raw score but depends on other factor/s.[411] DIF is an indication of item bias,[372] the presence of which distorts measurement, precludes meaningful comparison between sub-groups of sample and may lead to erroneous conclusions.[411]

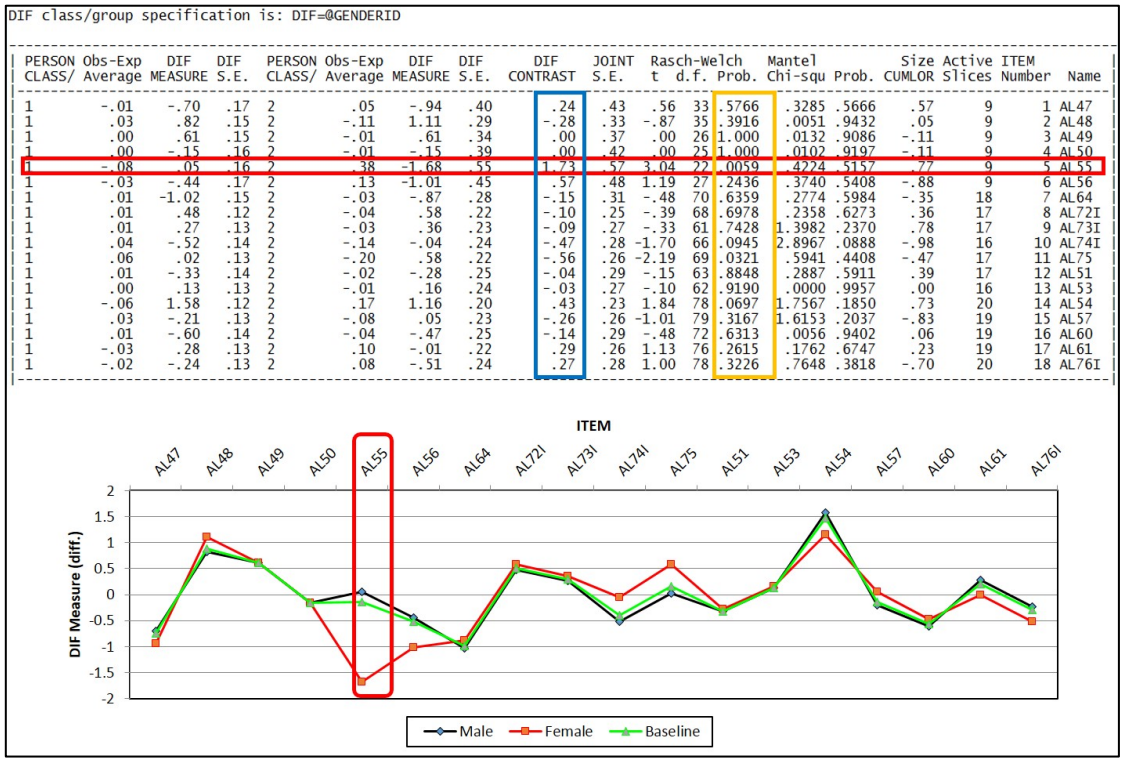
DIF is of two types: uniform and non-uniform.[160] If the item difficulty is consistently different for a group versus the other across the range of person abilities, it indicates uniform DIF.[160] On the contrary, if the item difficulty varies with person abilities, it indicates non-uniform DIF.[160] Non-uniform DIF occurs when there is an interaction between ability and group characteristics.[372] The number of strata across which non-uniform DIF can be meaningfully tested depends on the discriminatory ability of the instrument given by the person separation index (measurement precision). Only the uniform DIF is commonly reported; the non-uniform DIF is relatively harder to explain owing to the complex functioning of the items across different strata of abilities. DIF is sample dependent; to obtain a power greater than 80%, a sample size of at least 200 persons per group is recommended for uniform DIF and a considerably higher sample size for non-uniform DIF.[410, 413] To obtain stable item calibration (measures within +/- 1 logit) at least 30 and 50 persons are required for dichotomous and polytomous items respectively; this means that at least 30-50 persons per sub-group is required to investigate DIF reasonably (e.g. for pilot testing). Technically, uniform DIF is the average of the non-uniform DIF (summary of the distribution of the non-uniform DIF) and Winsteps table 30 reports uniform DIF.

When interpreting the results of DIF analysis, there are two considerations – the effect size given by the DIF contrast and the statistical significance given by the p-value. DIF contrast is the difference between item calibrations obtained for the two sub-groups in logits. Values between 0.5 and 1 logit indicates minimal DIF and that over 1 logit indicates notable DIF.[93, 400] p-values < 0.05 indicates that it is unlikely that the DIF contrast is observed by chance; that is the difference between the item measures is

statistically significant.[93] However, statistical significance alone cannot determine if the item bias is substantial enough to have any practical implication as small DIF contrasts could be statistically significant when tested in larger samples.[243] Therefore, it is necessary to consider both effect size and significance for judicious interpretation.

The Figure 5-11 shows the Winsteps table 30.1 and corresponding DIF plot for gender (male vs female vs baseline). The baseline indicates overall item difficulty. It can be seen that the item AL 55 (highlighted within red box) shows statistically significant, notable DIF. The calibrations for this item are 0.05 for male and -1.68 for female and thus the DIF contrast is 1.73 [calculated by 0.05 – (-1.68)]. The item calibrations indicate that this item is easier for females compared to males. However, on closer evaluation, it was evident that this result could be due to measurement error, given the small number of females who answered that question (20 female vs 90 males). Investigation with larger sample of females is required to substantiate this finding.

When meaningful DIF is observed, the items showing DIF are considered for deletion in the development of short scales. Alternatively, the item could be retained and given group-specific calibrations in item banks administered via computer adaptive testing.[2, 414]



DIF class/group specification is: DIF=@GENDERID

PERSON CLASS/	Obs-Exp Average	DIF MEASURE	DIF S.E.	PERSON CLASS/	Obs-Exp Average	DIF MEASURE	DIF S.E.	DIF CONTRAST	JOINT S.E.	Rasch-Welch t	d.f.	Prob.	Mantel Chi-squ	Prob.	Size CUMLOR	Active Slices	ITEM Number	Name
1	-.01	-.70	.17	2	.05	-.94	.40	.24	.43	.56	33	.5766	.3285	.5666	.57	9	1	AL47
1	.03	.82	.15	2	-.11	1.11	.29	-.28	.33	-.87	35	.3916	.0051	.9432	.05	9	2	AL48
1	.00	.61	.15	2	-.01	.61	.34	.00	.37	.00	26	1.000	.0132	.9086	-.11	9	3	AL49
1	.00	-.15	.16	2	-.01	-.15	.39	.00	.42	.00	25	1.000	.0102	.9197	-.11	9	4	AL50
1	-.08	.05	.16	2	.38	-1.68	.55	1.73	.57	3.04	22	.0059	.4224	.5157	.77	9	5	AL55
1	-.03	-.44	.17	2	.13	-1.01	.45	.57	.48	1.19	27	.2436	.3740	.5408	-.88	9	6	AL56
1	.01	-1.02	.15	2	-.03	-.87	.28	-.15	.31	-.48	70	.6359	.2774	.5984	-.35	18	7	AL64
1	.01	.48	.12	2	-.04	.58	.22	-.10	.25	-.39	68	.6978	.2358	.6273	.36	17	8	AL72I
1	.01	.27	.13	2	-.03	.36	.23	-.09	.27	-.33	61	.7428	1.3982	.2370	.78	17	9	AL73I
1	.04	-.52	.14	2	-.14	-.04	.24	-.47	.28	-1.70	66	.0945	2.8967	.0888	-.98	16	10	AL74I
1	.06	.02	.13	2	-.20	.58	.22	-.56	.26	-2.19	69	.0321	.5941	.4408	-.47	17	11	AL75
1	.01	-.33	.14	2	-.02	-.28	.25	-.04	.29	-.15	63	.8848	.2887	.5911	.39	17	12	AL51
1	.00	.13	.13	2	-.01	.16	.24	-.03	.27	-.10	62	.9190	.0000	.9957	.00	16	13	AL53
1	-.06	1.58	.12	2	.17	1.16	.20	.43	.23	1.84	78	.0697	1.7567	.1850	.73	20	14	AL54
1	.03	-.21	.13	2	-.08	.05	.23	-.26	.26	-1.01	79	.3167	1.6153	.2037	-.83	19	15	AL57
1	.01	-.60	.14	2	-.04	-.47	.25	-.14	.29	-.48	72	.6313	.0056	.9402	.06	19	16	AL60
1	-.03	.28	.13	2	.10	-.01	.22	.29	.26	1.13	76	.2615	.1762	.6747	.23	19	17	AL61
1	-.02	-.24	.13	2	.08	-.51	.24	.27	.28	1.00	78	.3226	.7648	.3818	-.70	20	18	AL76I

Figure 5-11 Winsteps table 30.1 (above) and DIF plot (below) for investigating DIF by gender.

In table above person class 1 is male and 2 is female. DIF contrast and p-values are enclosed in blue and

yellow boxes respectively. Only one item – AL55 shows notable DIF contrast (1.73 logits) and is statistically significant (p-value = 0.0059). This item is highlighted in the DIF plot within the red box.

5.8 Conclusion

This chapter described the principles of measurement and the classical and modern measurement theories. By articulating evidences, it established the rationale for using the Rasch measurement theory in this doctoral work. Epistemological guidance provided in this chapter underlie the psychometric validation of the item banks which is presented in the following chapter.

CHAPTER 6 PSYCHOMETRIC VALIDATION OF THE AMBLYOPIA AND STRABISMUS SPECIFIC ITEM BANKS

6.1 Introduction

Chapter 4 described the development of the amblyopia and strabismus – specific item pools for Australian and Indian populations. Eleven item pools were constructed: visual symptoms, ocular symptoms, general symptoms, activity limitations, mobility, concerns, emotional impact, social impact, convenience, economic impact and coping. Although the symptom items were labelled as visual, ocular and general according to domain definitions in Chapter 4, due to the small number of items in each domain and considering the usefulness of measuring the broader construct 'symptoms' on a single scale, the three domains were merged for analysis in this chapter. However, the three rating scales - frequency, severity and bothersome assigned to symptoms item banks during scale construction (section 4.3.3) were considered separately for validation as each of these represent a unique construct.

Although driving items were initially a part of the activity limitations item bank (in Chapter 4), it was validated separately, considering evidences that limitations in driving can be a valid scale by itself,[400] and that measuring it on an independent scale would provide more useful results for practical application.

The three symptoms item banks and an additional driving item bank accounted to 12 item banks: symptoms- frequency, symptoms- severity, symptoms- bothersome, activity limitations, mobility, concerns, emotional impact, social impact, convenience, economic impact and coping. This chapter presents the psychometric assessment and validation of these 12 item banks.

Two independent studies were conducted for the validation of the Australian and Indian item banks. The 12 item banks were administered to adults with amblyopia and/or strabismus living in the respective countries and data collected was subjected to Rasch analysis. This chapter presents the validation of the Indian item banks. Due to time constraints, only a preliminary analysis of Australian data is presented in this thesis. The Australian study is ongoing, and the complete validation of the Australian item banks is not part of this thesis.

6.2 Aim and Objectives

The aim of this chapter is to test the psychometric properties and validate the twelve amblyopia and strabismus- specific item banks developed using Rasch analysis.

The objectives are to

a) Evaluate the response category functioning, measurement precision, reliability, item fit, dimensionality and targeting of the twelve item banks.
b) Optimise sub-optimal psychometric properties whenever possible.
c) Test the item banks for differential item functioning (item bias).

6.3 Methods

The study was approved by the Southern Adelaide Clinical Human Research Ethics Committee, Australia (Approval number: 469.11, Appendix 2) and the Research cell committee, Vision Research Foundation, Sankara Nethralaya, India (Appendix 3). It adheres to the Tenets of declaration of Helsinki for human study.

6.3.1 Participants

Adults over 18 years of age with a primary diagnosis of amblyopia or strabismus and without any other significant ocular pathology such as cataract, known cognitive or psychological impairment were eligible to take part in the study. Amblyopia and isolated strabismus were defined as before (Chapter 4). Amblyopia was defined as 'best corrected visual acuity of 6/9 or worse in at least one eye without any underlying organic cause' and isolated strabismus as 'the presence of heterotropia in the absence of amblyopia', which includes strabismic patients who never had amblyopia (e.g. alternating exotropia) and those with acquired strabismus (e.g. cranial nerve palsies).

In Australia, participants were recruited from optometry practices namely Flinders Vision, South Australia and Optometry Sunbury Vision for Children, Victoria. In addition, some were recruited from the community through advertisements and news articles. In India, participants were recruited from the amblyopia and binocular vision facility of Sankara Nethralaya, a tertiary eye care hospital, Tamil Nadu and from the community through advertisements. All eligible participants were provided with a participant information sheet and consent form (Appendix 9).

6.3.2 Sample size

There is no general consensus in the sample size required for psychometric validation.[415] A good range of person abilities is necessary for optimal item calibrations and is determined by iterative analysis of the data.[251] As a minimal requirement, atleast 50 respondents are required for validating a polytomous rating scale and atleast 10 responses per response category are required for stable threshold calibrations.[416] For item calibrations and person measures to be within +/- ½ logit of the true value, the recommended sample size is about 110 for scales with good targeting and 250 for scales with poor targeting.[416] In order to obtain reliable item calibrations, sample size of atleast 250 was aimed in this study.

6.3.3 Tool

The Australian and Indian item banks were used for data collection in respective countries (Appendices 7 and 8). The Australian item banks consisted of 386 items in English and the Indian item banks consisted of 341 items in English, Hindi and Tamil languages. The items in each item bank were presented by a preceding statement and item stem (e.g. Because of your eye condition, how much difficulty do you have), followed by response options (e.g. none, a little, quite a bit, a lot and unable to do because of my eye condition). The item stems and response options remained uniform within each item bank but varied across item banks. For example, the activity limitations item bank had a difficulty type rating scale structure while the emotional impact item bank had a frequency type rating scale structure. Although the items in the symptoms pool were qualitatively labelled as visual, ocular and general symptoms, these were considered together for analysis to test if the range of symptoms can be measured on a single valid scale. The questionnaire formats of the item banks are described in detail elsewhere (Chapter 4).

In addition to printed paper questionnaires, country-specific online surveys were created using a surveymonkey portal (SurveyMonkey Inc., San Mateo, California, USA, available at: www.surveymonkey.com). Participants were able to choose either tool (paper or online) based on their convenience. The Indian participants were able to choose the language of the item bank they preferred to answer (English, Hindi or Tamil).

Participants decided how many out of the twelve item banks they wanted to complete. Intermittent breaks were permitted to elude monotony and fatigue. Participants also

completed a background questionnaire (provided at the beginning of the item banks) with details such as age, gender, place of birth, education, occupation, history of treatment and eye condition. Clinical details about their eye condition such as diagnosis, best corrected and habitual visual acuity, magnitude and type of ocular deviation, refractive error and history of treatment were obtained from their eye care provider with additional consent from the participants.

6.3.4 Scoring of response categories

The rating scales used for each item bank was described in Chapter 4. The three symptoms item banks had 4 response categories while all other item banks had 5 response categories plus a 'not applicable' and 'refuse to answer' options.

Rasch analysis assumes qualitatively ordered observations for constructing linear measurement.[363] Qualitative ordering means that the score assigned to each response option represent qualitatively more of what is being observed.[363] To ensure this, the response categories were assigned ordinal scores such that high scores indicate more ability and *vice versa*. For example, consider the domain 'severity of symptoms'; its response categories 'not at all, mild, moderate and severe' were assigned scores of '4 (highest ability), 3, 2 and 1 (least ability)' respectively. In the coping item bank, categories were scored such that the higher categories indicate higher use of the coping strategies and *vice versa*. The response category 'extremely' was given the highest score 5 and 'not at all' was given the least score, 1. The 'not applicable' and 'refuse to answer' response options were considered as missing data points for Rasch analysis.

6.3.5 Data collation

The responses to the paper-based questionnaire were entered manually in an Excel spreadsheet (Microsoft Corporation, Washington, USA) and then imported into the IBM SPSS Statistics software version 23 (IBM Corp, Armonk, New York).[417] All responses to the online survey were directly imported into SPSS software from the surveymonkey portal. All demographic and clinical details of participants were collated in the same file. The entries were checked multiple times for errors in scoring or mis-keying.

6.3.6 Data analysis

SPSS was used to compute descriptive statistics of demographic and clinical variables.

Rasch analysis was performed using the Winsteps® Rasch measurement computer program, version 4.2.0 (Beaverton, Oregon, USA).[392] The MedCalc Statistical Software version 18.10.2 (MedCalc Software bvba, Ostend, Belgium)[418] was used for Bland-Altman agreement analysis when multidimensionality of a scale was suspected.

6.3.7 Psychometric evaluation

The psychometric properties and its interpretation with examples of Winsteps output were elaborated in Chapter 5. Table 6-1 presents the proposed psychometric guidelines for item banking which were used for data analysis in this chapter.[2, 93]

Table 6-1 Guidelines for evaluating the psychometric properties using Rasch analysis

Psychometric properties	Acceptable values while applying Rasch model to item banks
Category functioning	
Average measures	Ordered
Threshold calibration	Ordered
Category misfit	MNSQ <1.50
Separation and reliability statistics	
Person separation index (PSI)	> 2
Person reliability	> 0.80
Item separation index (ISI)	> 3
Item reliability	> 0.90
Item fit statistics	Infit and Outfit MNSQ < 1.50
Targeting (Difference between person and item means)	< 1.0
Dimensionality (Principal component analysis of residuals)	
Variance explained by the Rasch dimension	Observed ≈ Expected
Eigen value of the first contrast	< 3
Ratio of variance explained by the items to the unexplained variance in first contrast	> 3
Differential item functioning	
p-value	>0.05
DIF contrast	<1

Rasch analysis was performed iteratively and sub-optimal psychometric properties were optimised whenever possible, based on both statistical inferences and qualitative judgement. The steps followed in this process are described below.

1. The polarity of the items in each item bank was checked by inspecting the point-measure correlations. Positive correlations indicate general item consensus.
2. The summary statistics were reviewed for person separation index (PSI), item separation index (ISI) and respective reliabilities. The PSI denotes the ability of

the scale to classify people into different levels of ability. This is referred to as the measurement precision. The ISI denotes the ability of the sample to stratify items into different levels of difficulty and is used to verify item hierarchy. The reliability values indicate how reproducible are the location of the person and item measures estimated.

3. The difference between person and item means denotes how well the items are targeted to the sample. Positive difference indicates that the sample is more able and *vice versa*. The person-item map was examined to identify gaps in measurement. The measurement range was noted by reviewing the easiest and hardest item (lowest and highest item measure).
4. The steps 2 and 3 were revisited after every iteration and optimisation attempt in steps 6-9.
5. The functioning of the response categories of each of the item bank was verified by inspecting the category frequencies, average measures, fit statistics and threshold calibrations. The frequencies were inspected to see if they meet the minimal requirement of 10 for stable calibration. Ceiling/ floor effects and underutilisation of categories were noted. Monotonic increase in the category frequencies and the observed averages was expected. Any category misfit was noted.
6. When thresholds were disordered, it was repaired by combining adjacent categories and its effect on other parameters such as item fit and measurement precision was investigated.
7. The infit and outfit MNSQ values of the items were examined for misfitting items. Misfit may indicate multidimensionality. When misfit was evident, erroneous person responses corresponding to each misfitting item (z-residuals >+/-3) was muted iteratively.[401] If this exercise did not improve the fit of an item to acceptable standards, the effect of item deletion on summary statistics and qualitative judgement was used to decide if the item should be deleted or retained.
8. The principal component analysis (PCA) of residuals was reviewed for dimensionality investigation. The variance explained by the measure (the Rasch dimension) was assessed to see if the observed approximates expected variance. The eigenvalue of the first contrast and the ratio of the variance explained by the items to that explained by first contrast were noted. Large eigenvalues and low ratio suggested secondary dimension. In such cases, items loading on the first contrast were reviewed.

9. When multidimensionality was suspected, disattenuated correlation between the items loading on first contrast and the rest of the scale was examined. When the correlation was moderate or low, the scales were subjected to Bland-Altman agreement analysis. All these evidences were collated, and qualitative judgement was used to distinguish true secondary dimension from strands. When splitting up of a scale was thought to be beneficial, the psychometric properties of the new scales was evaluated.
10. The optimised item banks were tested for differential item functioning with respect to gender, age, education, occupation, language of questionnaire, presence of amblyopia, presence of strabismus and visual acuity. Items with significant p value (<0.05) and notable DIF contrast (>1 logit) was noted.

6.4 Results: Indian item bank

6.4.1 Participant demographics and clinical characteristics

304 respondents took part in the study; 283 (93.1%) filled the paper-based questionnaire and 21 (6.9%) took part in the online survey. 290 (95.4%) of them were recruited directly from the tertiary eye care hospital and the rest were recruited from other local practices and community. The number of participants who completed the English, Hindi and Tamil versions of the questionnaire were 185 (60.9%), 74 (24.3%) and 45 (14.8%) respectively. Not all participants completed all the item banks; the sample size for each item bank is given Table 6-2.

Table 6-2 Number of respondents who answered each item bank

Item banks	Sample size
Symptoms - frequency	304
Symptoms - Severity	304
Symptoms - Bothersome	303
Activity limitation	304
Driving	232
Mobility	300
Concerns	301
Emotional impact	299
Social impact	299
Convenience	299
Economic impact	295
Coping	299

The median age of the participants was 24 years (range: 18 to 72 years) and 63.2% were male. The clinical and demographic characteristics of the study participants are

shown in Table 6-3. The participants were from different parts of India; the maximum number of participants were from Tamil Nadu where the study was conducted (33%) and the rest had travelled to Tamil Nadu for ophthalmology consultation. The Figure 6-1 displays the distribution of sample across India.

Table 6-3 Clinical and demographical characteristics of the sample

Clinical and demographic variables	n (%)
Age	
< 40 years	255 (83.9%)
>/= 40 years	49 (16.1%)
Gender	
Male	192 (63.2%)
Female	112 (36.8%)
Diagnosis	
Amblyopia	156 (51.3%)
Strabismic amblyopia	24 (7.9%)
Anisometropic amblyopia	56 (18.4%)
Combined-mechanism amblyopia	64 (21.1%)
Deprivational amblyopia	12 (3.9%)
Isolated strabismus	133 (43.8%)
Laterality of amblyopia	
Right	70 (23%)
Left	73 (24%)
Bilateral	13 (4.3%)
Visual acuity in the worse amblyopic eye	
0.2 to 0.5 logMAR (6/9.5 to 6/19)	87 (28.6%)
0.6 to 1 logMAR (6/24 to 6/60)	51 (16.8%)
> 1 logMAR (> 6/60)	17 (5.6%)
Type of ocular deviation (in those with strabismus)	
Esotropia	38 (12.5%)
Exotropia	139 (45.7%)
Vertical	12 (3.9%)
Oblique	29 (9.5%)
Magnitude of ocular deviation	
< 25 prism dioptres	64 (21.1%)
>/= 25 prism dioptres	115 (37.8%)
History of treatment	
Refractive correction	184 (60.5%)
Patching therapy	46 (15.1%)
Penalization with atropine	17 (5.6%)
Other orthoptic vision therapy	31 (10.2%)
Corrective strabismus surgery	51 (16.8%)
Prism glasses	6 (2%)
Education	
Postgraduate	35 (11.5%)
Graduate	141 (46.4%)
Diploma or certificate	7 (2.3%)
No post school qualification	109 (35.9%)
Country of birth	
India	295 (97.04%)
Others	9 (2.96%)
Mother tongue	
Hindi	93 (30.6%)
Tamil	93 (30.6%)
Others	92 (30.3%)

Sum of the percentages for some variables may not be 100% due to missing data

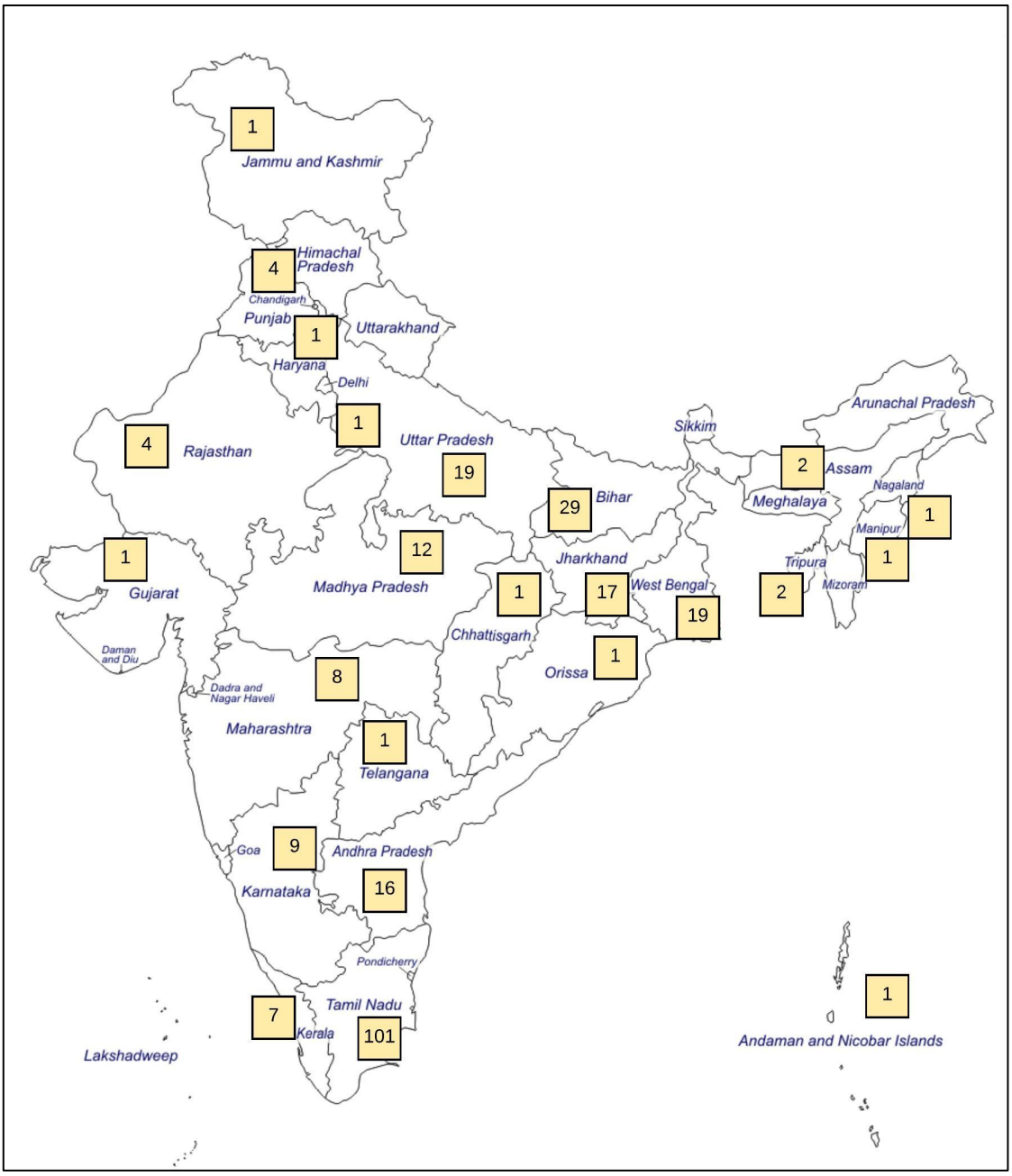


Figure 6-1 Sample distribution across India

Figures in the yellow box represents the number of participants in the respective state/ union territory.

Map source: https://www.d-maps.com/carte.php?num_car=24855&lang=en

The results section is divided into three parts describing 1) rating scale functioning, 2) psychometric properties and 3) differential item functioning of the item banks.

6.5 Rating scale functioning

6.5.1 Item polarity

The range of point-measure correlations are given in the Table 6-4. The items in each item bank was oriented in the same direction and no zero or negative point-measure correlations was observed. Positive correlations between the item and person measures (higher the score, higher the person ability) suggests general item consensus within each item bank.

Table 6-4 Range of point-measure correlations observed in each item bank

Item banks	Range of point-measure correlations
Symptoms - frequency	0.27 to 0.62
Symptoms - Severity	0.27 to 0.61
Symptoms - Bothersome	0.25 to 0.61
Activity limitation	0.36 to 0.71
Driving	0.67 to 0.82
Mobility	0.53 to 0.76
Concerns	0.43 to 0.66
Emotional impact	0.45 to 0.71
Social impact	0.51 to 0.71
Convenience	0.39 to 0.66
Economic impact	0.56 to 0.74
Coping	0.33 to 0.59

6.5.2 Category functioning statistics

The response categories functioning of each item bank was verified by inspecting the category frequencies, average measures, fit statistics and threshold calibrations. The category statistics for all item banks along with the item stems, number and type of response categories and the qualitatively ordered score (ordinal values) assigned to each category are displayed in the Table 6-5. The statistics displayed correspond to the initial iteration of the item banks (analysis with original data without any attempt for optimisation).

Table 6-5 Category statistics of the original item banks

Item banks	Item stem	Rating scale structure			Category count (%)	Observed average measures	Infit MNSQ	Outfit MNSQ	Category thresholds
		No. of categories	Score	Categories					
Symptoms - frequency	How often do you experience <item>?	4	1	Very often	1081 (11%)	-0.1	1.05	1.09	None
			2	Quite often	1100 (11%)	0.24	0.96	0.94	0.04
			3	Occasionally	2376 (25%)	0.7	0.93	0.87	-0.28
			4	Never	5046 (53%)	1.26	1.03	1.04	0.24
Symptoms - severity	How severe is the <item>?	5	1	Severe	918 (10%)	-0.09	1.05	1.07	None
			2	Moderate	1304 (14%)	0.31	0.99	0.96	-0.26
			3	Mild	2036 (22%)	0.76	0.97	0.89	0.11
			4	Not at all	5198 (55%)	1.36	1.01	1.01	0.15
Symptoms - bothersome	How much of a problem is the <item>?	6	1	A lot	922 (10%)	-0.1	1.06	1.14	None
			2	Quite a bit	1043 (11%)	0.31	1	0.99	-0.04
			3	A little	1876 (20%)	0.76	0.96	0.84	-0.04
			4	None	5574 (59%)	1.48	1	1	0.07
Activity limitation	How much difficulty do you have <item>?	5	1	Unable to do	209 (2%)	0.09	1.33	2.37	None
			2	A lot	1092 (10%)	0.28	1.04	1.31	-1.6
			3	Quite a bit	1293 (11%)	0.73	0.97	0.93	0.32
			4	A little	2354 (21%)	1.27	0.91	0.74	0.43
			5	None	6345 (56%)	2.29	1	1.01	0.85
Driving	How much difficulty do you have <item>?	5	1	Unable to do	111 (3%)	-1.25	1.49	1.55	None
			2	A lot	312 (9%)	-0.27	1.09	1.2	-2.57
			3	Quite a bit	411 (12%)	0.7	0.86	0.94	-0.04
			4	A little	786 (24%)	1.81	0.87	0.79	0.63
			5	None	1698 (51%)	3.32	1.11	1.12	1.97
Mobility	How much difficulty do you have <item>?	5	1	Unable to do	10 (0%)	0.6 (-0.72)	2.41	1.89	None
			2	A lot	176 (5%)	0.48 (0.27)	1.39	1.58	-3.08
			3	Quite a bit	277 (8%)	1.01	0.84	0.74	0.27
			4	A little	633 (18%)	2.11	0.93	0.74	0.86
			5	None	2394 (69%)	3.51	0.98	1	1.95

Concerns	How concerned are you about <item>?	5	1	Extremely	1908 (13%)	-0.4	1.03	1.05	None
			2	A lot	1698 (11%)	0	0.97	0.94	-0.07
			3	A moderate amount	1545 (10%)	0.31	0.92	0.82	0.25
			4	A little bit	2600 (17%)	0.66	0.96	0.92	-0.04
			5	Not at all	7496 (49%)	1.14	1.06	1.13	-0.15
Emotional impact	How often did you <item>?	5	1	All of the time	865 (8%)	-0.63	1.21	1.4	None
			2	Most of the time	797 (7%)	-0.13	0.92	0.87	-0.32
			3	Some of the time	1105 (10%)	0.37	0.87	0.71	-0.18
			4	A little of the time	1940 (18%)	0.97	1.04	0.88	0.15
			5	None of the time	6190 (56%)	1.84	1.06	1.16	0.35
Social impact	How much of a problem do you have <item>?	5	1	Unable to do	101 (2%)	-0.58	1.14	1.47	None
			2	A lot	485 (8%)	0.29	1.04	1.19	-1.7
			3	Quite a bit	426 (7%)	0.68	0.87	0.83	0.64
			4	A little	949 (17%)	1.36	0.82	0.93	0.24
			5	None	3746 (66%)	2.21	1.07	1.12	0.82
Convenience	How much trouble is <item>?	5	1	Extremely	461 (8%)	-0.25	1.15	1.3	None
			2	Quite a lot	513 (9%)	0.04	0.94	1.01	-0.24
			3	A moderate amount	637 (11%)	0.37	0.95	0.93	0.01
			4	A little bit	1337 (23%)	0.78	0.95	0.87	-0.14
			5	None	2970 (50%)	1.46	1	1.01	0.37
Economic impact	How concerned are you about <item>?	5	1	Extremely	361 (12%)	-0.59	1.09	1.06	None
			2	Quite a bit	338 (11%)	-0.22	0.85	0.79	-0.43
			3	A moderate amount	306 (10%)	0.25	0.9	0.72	0.15
			4	A little bit	538 (18%)	0.82	0.89	0.98	-0.06
			5	Not at all	1458 (49%)	1.35	1.13	1.16	0.34
Coping	How much do you cope (manage) by using the following ways?	5	1	Not at all	2172 (38%)	-0.86	0.96	0.99	None
			2	A little bit	1030 (18%)	-0.44	1.03	1.05	0.11
			3	A moderate amount	737 (13%)	-0.1	0.92	0.86	0.03
			4	A lot	776 (14%)	0.04	1.03	1.01	-0.11
			5	Extremely	953 (17%)	0.25	1.04	1.05	-0.03

Values in red font indicate high ceiling effect. Yellow box indicates non-monotonicity and orange box indicate category misfit.

6.5.2.1 Category frequencies

Inspection of the category counts and percentages for these item banks revealed that for most (3 scales of symptoms, activity limitations, driving, mobility and convenience), the category count increased with category scores; that is, increasingly more number of participants endorsed higher categories corresponding to better ability. However, monotonicity was not observed in the concerns, emotional impact, social impact and economic impact item banks. In these item banks, the category counts dropped for the middle category/categories indicating underutilisation. In the coping item bank, a reverse pattern of category count was observed; the counts decreased with increasing category scores indicating that increasingly more participants endorsed less use of coping strategies. However, the pattern was not uniform as the category counts dropped in the middle categories.

Ceiling effects were observed in all item banks, except coping. About or more than 50% of the category counts was found in the highest category indicating higher number of able individuals in this study sample. The highest ceiling effects was observed in the item banks, mobility (69%) and social impact (66%). In these item banks, significantly lower counts was observed in the lowest category; the mobility item bank had less than 1% (n=10) and the social impact item bank had 2% (n=101) of category count corresponding to the lowest category 'unable to do because of my eye condition'. Except the lowest category in the mobility item bank which barely met the minimum requirement, all other categories exceeded the frequency required for stable item calibration.

6.5.2.2 Observed average measures

The observed average measures increased monotonically with increasing category scores for all item banks except mobility. This indicated that the meaning of categories was rightly understood by the respondents and as a result, higher abilities (i.e., higher average measures) corresponded to higher response categories.

Disordered observed averages of the lowest categories were observed in the mobility item bank. Contradictory to expectation, the observed value of the category 'unable to do' (0.60) was higher than its adjacent higher category 'a lot' (0.48) and was notably different from the model expected value of -0.72. This could be due to the limited number of observations in the lowest category as pointed out earlier. More stable calibrations could be obtained by administering the item bank to respondents with

lower levels of ability.

6.5.2.3 Fit statistics

Across all item banks, the infit and outfit statistics were satisfactory (MNSQ<1.5) for most response categories (53 out of 57, 93%). Two response categories, 'unable to do' of the activity limitation and mobility item banks had outfit and infit MNSQ values 2.37 and 2.41 respectively. As these values are over 2, these may degrade measurement properties. The other two response categories with outfit MNSQ values between 1.5 and 2 were 'unable to do' of driving item bank and 'a lot' of mobility item bank. However, on optimisation of other psychometric properties, the fit statistics of all item banks, except mobility, improved to the accepted standards (MNSQ<1.5). The fit statistics in the final iteration are reported in the respective sections in which the other psychometric properties of the item banks are elaborated.

6.5.2.4 Category thresholds or Andrich thresholds

The ordering of the category thresholds can be visualised by examining the category probability curves (CPCs) in Figure 6-2. The threshold values were reported in Table 6-5.

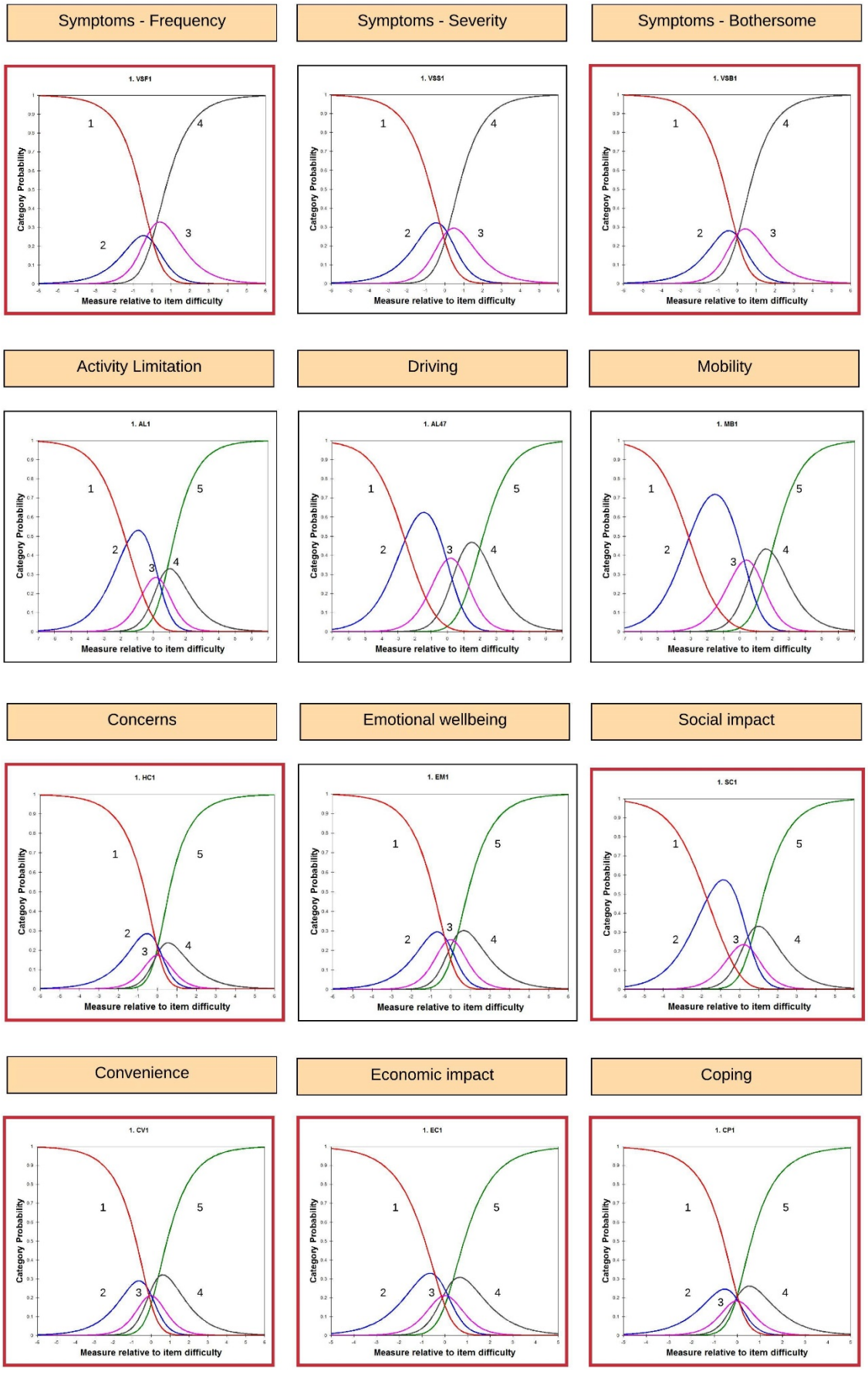


Figure 6-2 Category probability curves of the 12 original item banks.
CPCs highlighted in red boxes show disordered thresholds.

Two out of the three symptom item banks namely the frequency and bothersome exhibited disordered category thresholds. In both item banks, categories two and three were disordered; from the respective CPCs it is evident that the second category in frequency item bank and both the second and third categories in the bothersome item bank never had the highest probability of being endorsed along the entire continuum of the latent trait. Although the symptom-severity item bank exhibited ordered thresholds, the distance between the threshold calibrations corresponding to categories 3 and 4 was very narrow (0.04).

Out of the other nine item banks, four, namely the activity limitation, driving, mobility and emotional well-being had ordered thresholds, while concerns, social impact, convenience, economic impact and coping had disordered thresholds. Disordered category thresholds could be due to presence of underused response categories. Alternate explanation could be that the number of categories is more than what the respondent could distinguish. Disordered thresholds are usually repaired by combining adjacent categories.

6.5.2.5 Category functioning: English versus Indian languages

However, before venturing into any such initiative, the functioning of the categories was tested independently for English and Indian languages. This was done to rule out if the disordering was due to translational flaws (categories not understood correctly in the translated version). If the categories function optimally in the English version and not in the translated versions, it might indicate categorical inequivalence between languages. Due to a small number of respondents who answered the Tamil item banks, both Indian languages- Hindi and Tamil were assessed together and their category functioning was compared with English and the combined analysis. The Table 6-6 reports the threshold calibrations assessed by language.

Table 6-6 Category thresholds: Comparison between combined analysis and independent analysis of English and Indian languages

Item banks	Category thresholds		
	Combined analysis	English	Indian languages
Symptoms - frequency	Disordered (None, 0.04, -0.28, 0.24)	Disordered (None, -0.03, -0.21, 0.24)	Disordered (None, 0.13, -0.38, 0.25)
Symptoms - severity	Ordered (None, -0.26, 0.11, 0.15)	Ordered (None, -0.37, 0.18, 0.19)	Ordered (None, -0.14, 0.01, 0.13)
Symptoms - bothersome	Disordered (None, -0.04, -0.04, 0.07)	Ordered (None, -0.15, 0.02, 0.12)	Disordered (None, 0.08, -0.12, 0.04)
Activity limitation	Ordered (None, -1.60, 0.32, 0.43, 0.85)	Ordered (None, -1.63, 0.31, 0.51, 0.82)	Ordered (-1.62, 0.31, 0.33, 0.98)
Driving	Ordered (None, -2.57, -0.04, 0.63, 1.97)	Ordered (None, -2.74, 0.02, 0.79, 1.94)	Ordered (None, -2.27, -0.17, 0.40, 2.04)
Mobility	Ordered (None, -3.08, 0.27, 0.86, 1.95)	Ordered (-2.76, 0.16, 0.91, 1.69)	Ordered (None, -3.77, 0.46, 0.89, 2.42)
Concerns	Disordered (None, -0.07, 0.25, -0.04 and -0.15)	Disordered (None, 0.05, 0.16, 0.03, -0.24)	Disordered (None, -0.31, 0.39, -0.12, 0.04)
Emotional impact	Ordered (None, -0.32, -0.18, 0.15, 0.35)	Ordered (None, -0.59, -0.24, 0.36, 0.47)	Disordered (None, -0.06, -0.08, -0.13, 0.27)
Social impact	Disordered (None, -1.70, 0.64, 0.24 and 0.82)	Disordered (-1.57, 0.57, 0.36, 0.65)	Disordered (None, -1.92, 0.73, 0.12, 1.07)
Convenience	Disordered (None, -0.24, 0.1, -0.14 and 0.37)	Disordered (None, -0.11, -0.12, -0.01, 0.24)	Disordered (None, -0.47, 0.18, -0.30, 0.58)
Economic impact	Disordered (None, -0.43, 0.15, -0.06 and 0.34)	Disordered (None, -0.27, 0.07, -0.12, 0.32)	Disordered (None, -0.62, 0.21, 0.02, 0.40)
Coping	Disordered (None, 0.11, 0.03, -0.11, -0.03)	Disordered (None, 0.19, -0.04, -0.06, -0.09)	Disordered (None, -0.02, 0.12, -0.18, 0.08)

Grey: disordered categories

Similar pattern of ordering and disordering of category thresholds was observed in the independent and combined analysis for most of the item banks (except symptoms - bothersome and emotional impact), indicating that the categories were functioning mostly similarly across translations. A possible explanation for the disordered thresholds in just the Indian languages version of the symptom- bothersome and emotional item banks could be the non-monotonic increase of the category frequencies (underuse of middle categories) as compared to the monotonic pattern in

the English version. Having ruled out the differential categorical function with respect to languages, collapsing of categories was pursued for repairing category thresholds.

When category 3 is disordered, it can either be combined with 2 or 4. Decision on which two categories should be combined was made based on the effect of collapsing on other psychometric properties such as measurement precision and the distance between the threshold calibrations. Before collapsing the categories, the person responses for the misfitting items in each item bank were examined for z-residuals >+/-3 and these were muted to see if the category functioning improved. However, there was no effect.

6.5.2.6 Optimising category thresholds

Although only two of the three symptoms item banks, exhibited explicit disordering, considering the narrow distance between the category thresholds in the barely ordered symptoms-severity scale, the middle categories 2 and 3 of all three item banks were combined. This increased the measurement precision of all three (frequency, severity and bothersome item banks) from 2.35, 2.25 and 2.13 to 2.44, 2.43 and 2.41 respectively. Also, the measurement range improved from 2.10, 1.98 and 1.98 to 2.92, 2.78 and 2.75 respectively. The category and item fit statistics were satisfactory. The Figure 6-3 displays the CPCs of the optimised symptom item banks in comparison with the original. Distinct peaks and acceptable distance between thresholds were evident upon optimisation.

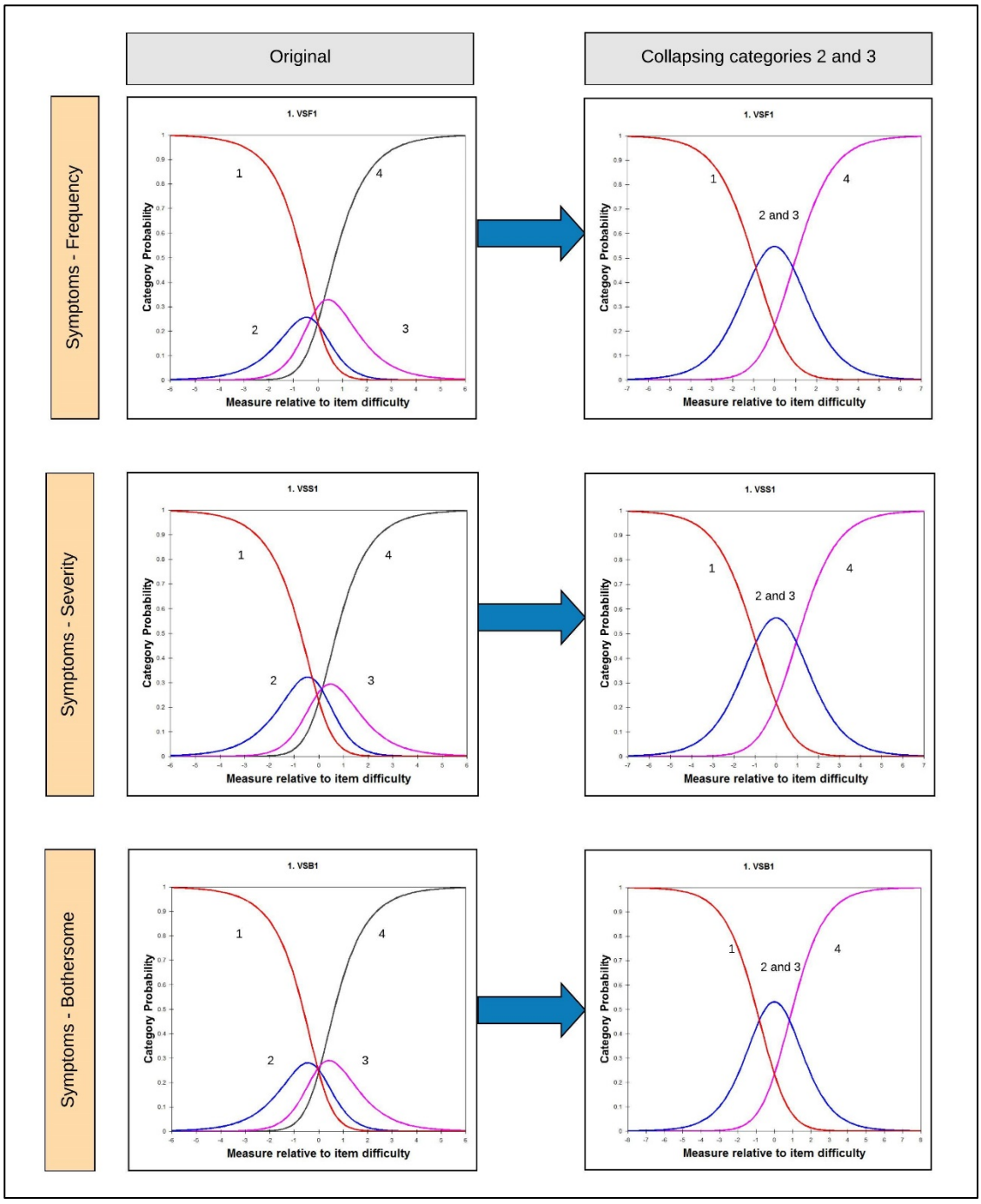


Figure 6-3 Category probability curves of the Symptom item banks.

On collapsing the middle categories 2 and 3, the thresholds are ordered and functioning optimised (right) as compared to the original iteration (left).

The highly disordered category thresholds of the concerns item banks underwent several iterations. First, the categories 1 and 2 were combined resulting in a total of 4 response categories; however, this did not result in threshold ordering. Similarly combining categories 2 and 3 (second iteration) and 3 and 4 (third iteration) did not optimise thresholds. Finally, the categories '1 and 2' (extremely and a lot) and categories '3 and 4' (moderate and a little) were combined, resulting in a total of 3

response categories. This resulted in ordered thresholds; the measurement precision and range of the concerns item bank improved from 3.09 and 1.59 to 3.6 and 2.61 respectively. The category and item fit statistics were also optimal.

Similar to the concerns item bank, the response categories of the economic impact and the coping item banks were reduced from 5 to 3. On combining categories '1 and 2' (extremely and a lot) and '3 and 4' (moderate and a little) of the economic impact item bank, the measurement precision and range improved from 1.56 and 0.89 to 1.81 and 1.57 respectively. However, the measurement precision at this point was sub-optimal and the scale required further optimisation; this is described in section 6.6.9. In the coping item bank, the categories '2 and 3' (a little and moderate) and '4 and 5' (a lot and extremely) were combined. This improved the measurement precision and range from 2.06 and 1.42 to 2.11 and 2.54 respectively. The category and item fit statistics were optimal. The CPCs of the original and the optimised concerns, economic impact and coping item banks are displayed in the Figure 6-4.

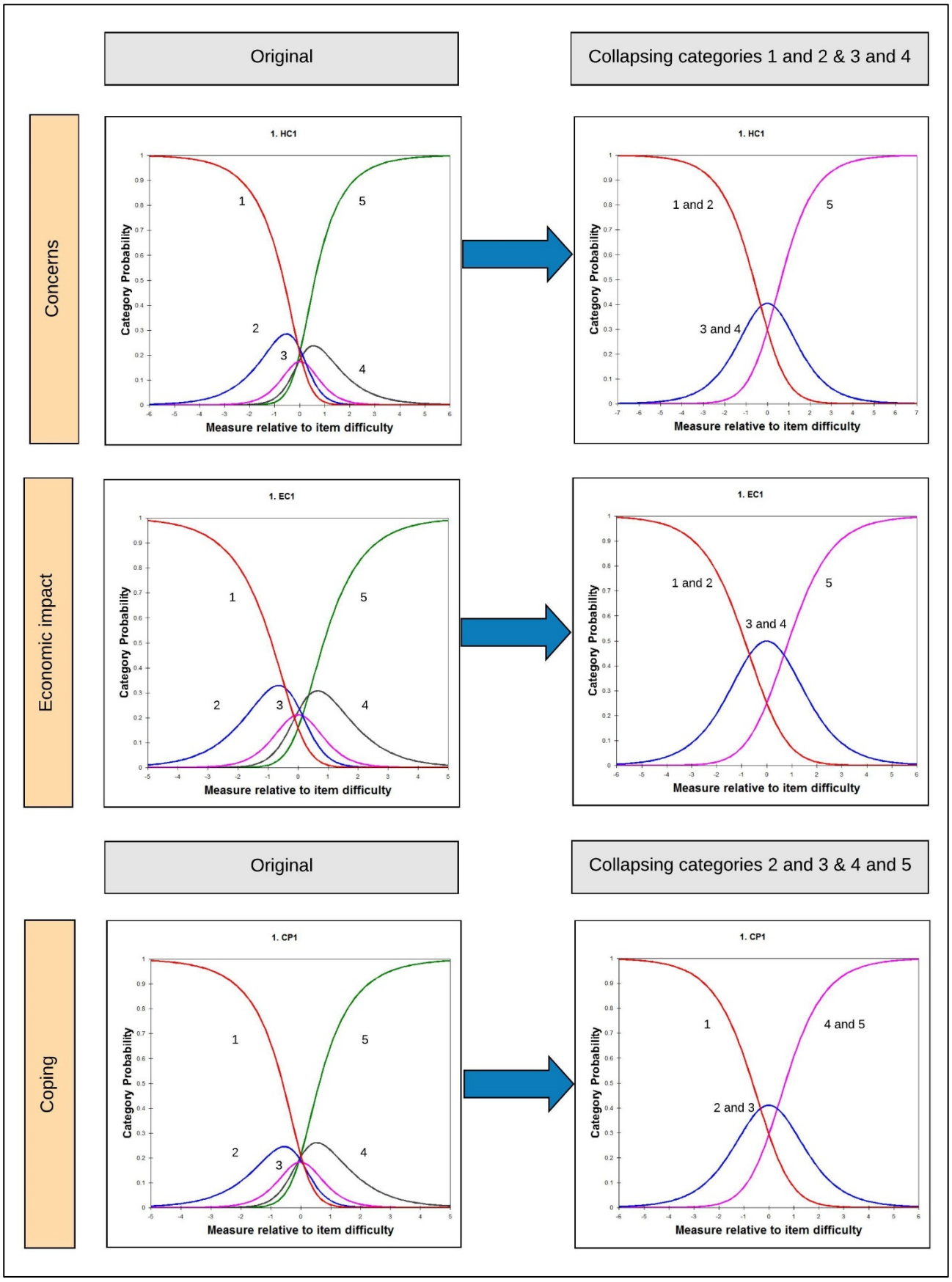


Figure 6-4 Category probability curves of the concerns, economic impact and coping item banks.

On collapsing the categories, the thresholds were ordered, and functioning was optimal (right) compared to the original iteration (left).

The social impact and the convenience item banks required combining 2 categories that resulted in a total of 4 response categories. In the social impact item bank, the categories 3 and 4 (quite a bit and a little) were combined. This resulted in wider distance between category thresholds than combining categories 2 and 3 (a lot and quite a bit). The measurement precision and range improved from 1.49 and 0.77 to 1.71 and 1.26 respectively; these were low, and therefore, the scale underwent further optimisation which is described in section 6.6.7. The thresholds in convenience item bank were ordered only on combining categories 2 and 3 (quite a lot and a moderate amount). This improved the measurement precision and range from 2.05 and 1.02 to 2.25 and 1.45 respectively. The CPCs of the original and the optimised social impact and convenience item banks are shown in the Figure 6-5.

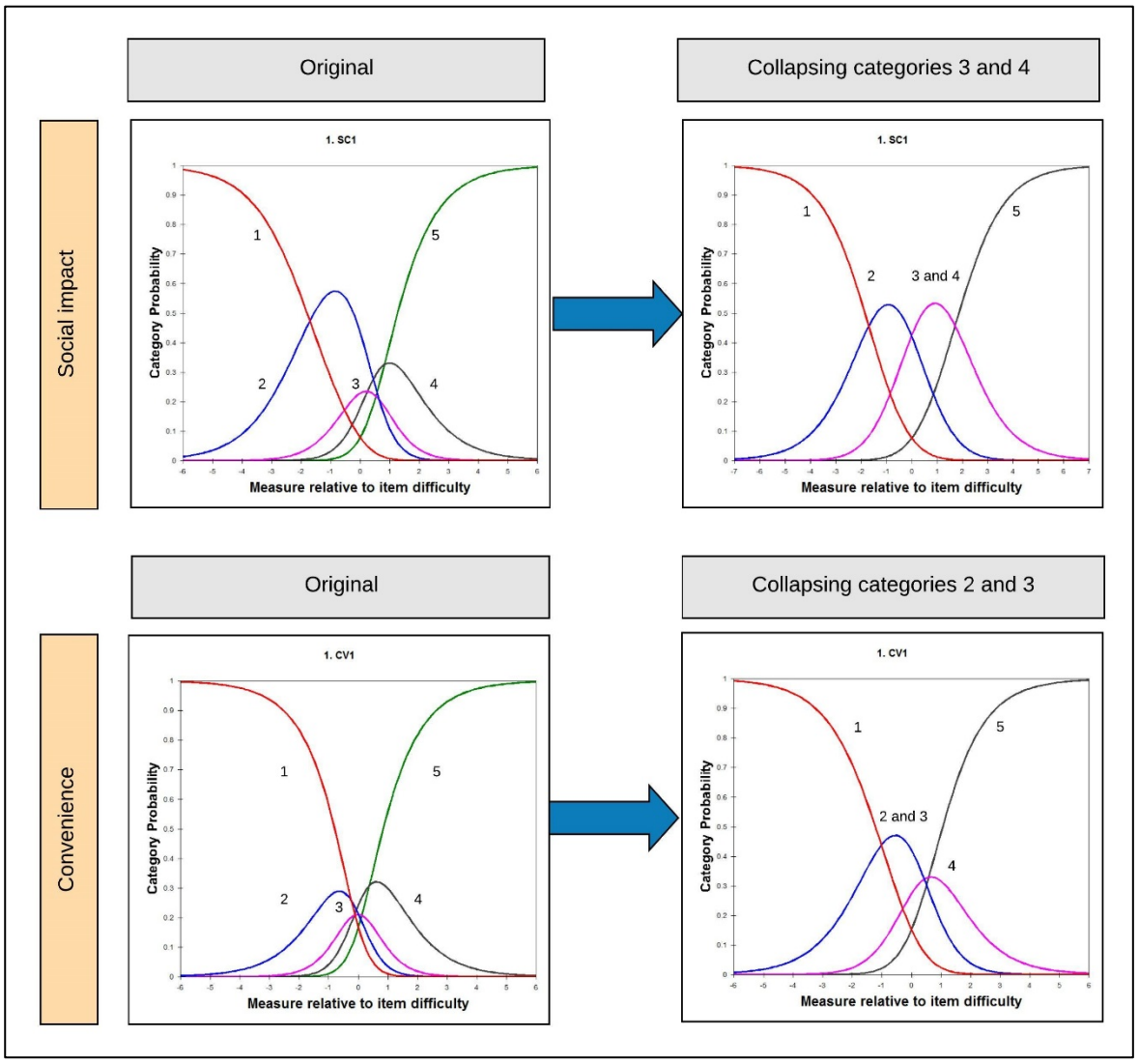


Figure 6-5 Category probability curves of the social impact and convenience item banks.

Upon collapsing the categories, the thresholds were ordered.

6.5.2.7 Category functioning: India versus Australia

As the long-term aim of the Eye-tem bank project is to have universal scales with common items validated across populations, threshold ordering and the best action taken to repair disordered thresholds was compared between the Australian and Indian item banks (Table 6-7). This exercise was done to see if the category functioning was similar across populations. Despite small sample size (n=55) in Australia, the minimum frequency for stable calibrations (n=10) was obtained in almost all response categories. The psychometric properties and preliminary results of the Australian item banks are presented in section 6.8.

Ten out of the twelve item banks exhibited similar category threshold ordering across Indian and Australian data analysis: the item banks, symptoms-severity, activity limitation, driving, mobility and emotional impact had ordered thresholds in both analysis while the item banks, symptoms- frequency, concerns, convenience, economic impact and coping had disordered thresholds. The item banks with disordered thresholds functioned similarly in both Indian and Australian data and were optimised by combining the same categories; for example, the concerns item bank was optimised only on combining categories '1 and 2' and '3 and 4' resulting in a total of 3 response categories and the convenience item bank required combination of categories 2 and 3, resulting in a total of 4 response categories in both Indian and Australian item banks. Difference in category threshold ordering were observed in symptoms- bothersome and social impact item banks in which the thresholds were ordered in the Australian version; however, the distance was narrow between middle thresholds.

Table 6-7 Comparison of category threshold ordering and optimisation: India versus Australia

Item banks	Original no. of RC	Indian item banks			Australian item banks		
		Category thresholds	Repaired by collapsing (Ordered category thresholds)	Final no. of RC	Category thresholds	Repaired by collapsing (Ordered category thresholds)	Final no. of RC
Symptoms – Frequency	4	Disordered (None, 0.04, -0.28, 0.24)	Categories 2 and 3 (None, -0.88, 0.88)	3	Disordered (None, -0.25, -0.50, 0.76)	Categories 2 and 3 (None, -1.30, 1.30)	3
Symptoms - Severity	4	Ordered* (None, -0.26, 0.11, 0.15)			Ordered (None, -0.97, -0.18, 1.15)		
Symptoms - Bothersome	4	Disordered (None, -0.04, -0.04, 0.07)	Categories 2 and 3 (None, -0.82, 0.82)	3	Ordered* (None, -0.52, -0.39, 0.91)		
Activity limitations	5	Ordered (None, -1.60, 0.32, 0.43, 0.85)			Ordered (None, -1.63, -0.25, 0.51, 1.37)		
Driving	5	Ordered (None, -2.57, -0.04, 0.63, 1.97)			Ordered (None, none -1.46, -0.28, 1.74)		
Mobility	5	Ordered (None, -3.08, 0.27, 0.86, 1.95)			Ordered (None, -1.26, -0.55, 1.81)		

Concerns	5	Disordered (None, -0.07, 0.25, -0.04 and -0.15)	Categories 1 and 2 & 3 and 4 (None, -0.31, 0.31)	3	Disordered (None, 0.09, -0.32, 0.08, 0.16)	Categories 1 and 2 & 3 and 4 (None, -0.67, 0.67)	3
Emotional impact	5	Ordered (None, -0.32, -0.18, 0.15, 0.35)			Ordered (None, -0.64, -0.16, -0.09, 0.89)		
Social impact	5	Disordered (None, -1.70, 0.64, 0.24 and 0.82)	Categories 3 and 4 (None, -1.70, -0.01, 1.71)	4	Ordered* (None, -1.65, 0.00, 0.32, 1.33)		
Convenience	5	Disordered (None, -0.24, 0.1, -0.14 and 0.37)	Categories 2 and 3 (None, -1.02, 0.43, 0.58)	4	Disordered (None, -0.11, -0.34, 0.04, 0.41)	Categories 2 and 3 (None, -1.10, 0.47, 0.63)	4
Economic impact	5	Disordered (None, -0.43, 0.15, -0.06 and 0.34)	Categories 1 and 2 & 3 and 4 (None, -0.69, 0.69)	3	Disordered (None, 0.03, -0.43, 0.15, 0.25)	Categories 1 and 2 & 3 and 4 (None, -0.87, 0.87)	3
Coping	5	Disordered (None, 0.11, 0.03, -0.11, -0.03)	Categories 4 and 5 & 3 and 2 (None, -0.33, 0.33)	3	Disordered (None, 0.12, -0.10, 0.03, -0.05)	Categories 4 and 5 & 3 and 2 (None, -0.45, 0.45)	3

Ordered thresholds are highlighted in green and disordered thresholds are highlighted in grey. RC: Response categories; *narrow distance between thresholds

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6.6 Psychometric properties of the Indian item banks

This section describes the psychometric properties of the twelve item banks: measurement precision and reliability, item fit statistics, dimensionality and targeting. The performance of the original item bank (initial iteration), optimisations that were necessary and the psychometric properties of the final item banks (final iteration) are reported.

6.6.1 Symptom - item banks

6.6.1.1 Symptoms – Frequency

The symptoms-frequency item bank had a total of 32 items. It assessed the frequency of symptoms faced by participants. Each item preceded with the item stem 'How often do you experience' and was followed by four response categories: never, occasionally, quite often and very often. These were coded 4, 3 2 and 1 respectively so that higher scores indicate lesser frequency of symptoms (more able persons) and *vice versa*. The psychometric properties of the original scale are shown in the Table 6-8.

Table 6-8 Psychometric properties of the original and final Symptoms- frequency item bank

Parameters	Psychometric properties - Original Symptoms – frequency scale	Psychometric properties - Final iteration
No of items / persons	32 / 304	32 / 304
No of categories	4	3
Category functioning		
Average measures	Ordered	Ordered
Threshold calibration	Disordered	Ordered
Category misfit	None	None
Separation and reliability statistics		
PSI (person reliability)	2.33 (0.84)	2.44 (0.86)
ISI (item reliability)	6.55 (0.98)	6.54 (0.98)
Item misfit		
Infit MNSQ > 1.5	3 (VSF4, VSF3, OSF13i)	1 (VSF 4)
Outfit MNSQ > 1.5	3 (VSF4, VSF3, OSF13i)	1 (VSF 4)
Targeting		
Difference between person and item means	0.86	1.19
Dimensionality (PCA of residuals)		
Variance explained by the Rasch dimension (observed / expected)	34.5% / 35.6%	32.4% / 32.7%
Variance explained by the items	20.40%	18.30%
Eigen value of the first contrast	3.37	3.27
Unexplained variance in first contrast	6.90%	6.90%

Items loading on first contrast (number, item IDs)	15 (OSF 1-7, 9-10, GSF 1-6)	15 (OSF 1-7, 9-10, GSF 1-6)
Disattenuated correlation between the first and second item clusters	0.70	0.69
Measurement range	2.08 (1.15 to -0.93)	2.92 (1.65 to -1.27)

The rating scale functioning of the original symptoms-frequency item bank was described earlier (section 6.5.2); while the average measures were ordered, category thresholds were not. There was no category misfit observed. The person and item separation, reliability indices and targeting of the scale were optimal. However, three items (VSF4, VSF3 and OSF13i) exhibited misfit.

The item misfit was addressed by muting the errant person responses (z-residuals > +/-3). The disordered thresholds were ordered on combining categories 2 and 3 (quite often and occasionally). The category statistics indicated ordered thresholds in addition to optimal fit statistics and monotonicity of the average measures (Table 6-9).

Table 6-9 Category statistics of the final Symptoms-frequency scale

Category code	Response category	Category count	Category %	Average measure	Infit MNSQ	Outfit MNSQ	Threshold calibration
1	Very often	1076	11	-0.13	1.02	1.03	None
2 and 3	Quite often & Occasionally	3474	36	0.73	0.97	0.92	-0.88
4	Never	5045	53	1.77	1.02	1.02	0.88

Upon collapsing, the measurement precision and range of the scale improved (Table 6-8). One item (VSF4 Poor vision in one eye) was still misfitting with infit and outfit MNSQs 1.55 and 1.54 respectively. Considering the clinical importance of this item and that the misfit was only marginal (not degrading), this item was retained and not deleted. The bubble chart with infit MNSQs and size of standard errors of the items along the measurement continuum is presented in Appendix 10.

The PCA of residuals revealed that the variance explained by the measure (32.4%) was close to the Rasch model expectations (32.7%). The ratio of the raw variance explained by the items (18.3%) to the unexplained variance in the first contrast (6.9%) was about 3. However, the eigenvalue of the first contrast was 3.27 which is slightly more than the acceptable value for item banks. 15 items loaded on the first contrast; these were mainly the general and ocular symptoms such as headaches, neck pain, eye strain and dry eyes. As these items were conceptually different to an extent from the other items which mainly assessed visual symptoms such as blurred

vision, double vision and glare, the possibility of a secondary dimension was investigated.

First the disattenuated correlation between the two clusters of items was examined. This was 0.69, which indicated that about 48% of the variance is shared by the two sets of items. Although this value is not too low, considering that not even 50% of the variance was shared by the dimensions, splitting the scale into two (17-item visual symptoms scale and the 15-item ocular and general symptoms scale) was considered (Table 6-10).

Table 6-10 17 and 15 item clusters

17 items	15 items
VS1 Blurred vision for distance	OS1 Eye strain
VS2 Blurred vision for near	OS2 Tired eyes
VS3 Poor vision in both eyes	OS3 Heavy eyes
VS4 Poor vision in one eye	OS4 Dry eyes
VS5 Poor peripheral vision (side vision) in the affected eye	OS5 Red eyes
VS6 Difficulty in focussing your eyes	OS6 Watery eyes
VS7 Difficulty in judging distances /perceiving depth between two objects	OS7 Pain in your eyes
VS9 Double vision	OS9 Burning sensation in your eyes
VS10 Double vision when tired	OS10 Irritation in your eyes
VS11 Ghost images or shadows around objects you see	GS1 Headaches
VS13 Glare from lights e.g. sunlight, car headlights	GS2 Back pain
OS11 Misalignment of your eyes (Squint eyes)	GS3 Neck pain
OS12 Misalignment of your eyes (Squint) when tired	GS4 Tiredness
OS13i Difference in the size of right and left eyes	GS5 Dizziness
GS8 Loss of balance	GS6 Sleepiness
GS9 Abnormal head posture (e.g. head turn, head tilt)	
GS10 Difficulty in concentrating	

The psychometric properties of the two scales are shown in Table 6-11. Both the 17 and 15 item scales had poor measurement precision (PSI <2) and the measurement range was slightly lower than the combined scale. The 15-item scale displayed poor targeting (2.05 logits). The eigenvalues of the first contrast was less than 3. The Bland and Altman agreement analysis (refer Figure 6-6 for B&A plot) between the two scales revealed moderate agreement [B&A Mean = -0.99 (-1.14 to -0.85); LOA = -3.49 to 1.50].

Table 6-11 Psychometric properties of the 17 item and 15 item symptoms-frequency scale

Parameters	17-item scale	15-item scale
No of items / persons	17 / 304	15 / 304
No of categories	3	3
Category functioning		
Average measures	Ordered	Ordered
Threshold calibration	Ordered	Ordered
Category misfit	None	None
Separation and reliability statistics		
PSI (person reliability)	1.8 (0.76)	1.97 (0.8)
ISI (item reliability)	7.34 (0.98)	5.78 (0.97)
Item misfit		
Infit MNSQ > 1.5	None	None
Outfit MNSQ > 1.5	None	1 (OSF 4)
Targeting		
Difference between person and item means	0.95	2.05
Dimensionality (PCA of residuals)		
Variance explained by the Rasch dimension (observed / expected)	36.50% / 37.1%	38.60% / 38.4%
Variance explained by the items	19.80%	17.60%
Eigen value of the first contrast	2.56	1.93
Unexplained variance in first contrast	9.60%	7.90%
Items loading on first contrast (number, item IDs)	2 (OSF 11, 12)	-
Disattenuated correlation between the first and second item clusters	1.00	-
Measurement range	2.70 (1.37 to -1.33)	2.71 (1.52 to -1.19)

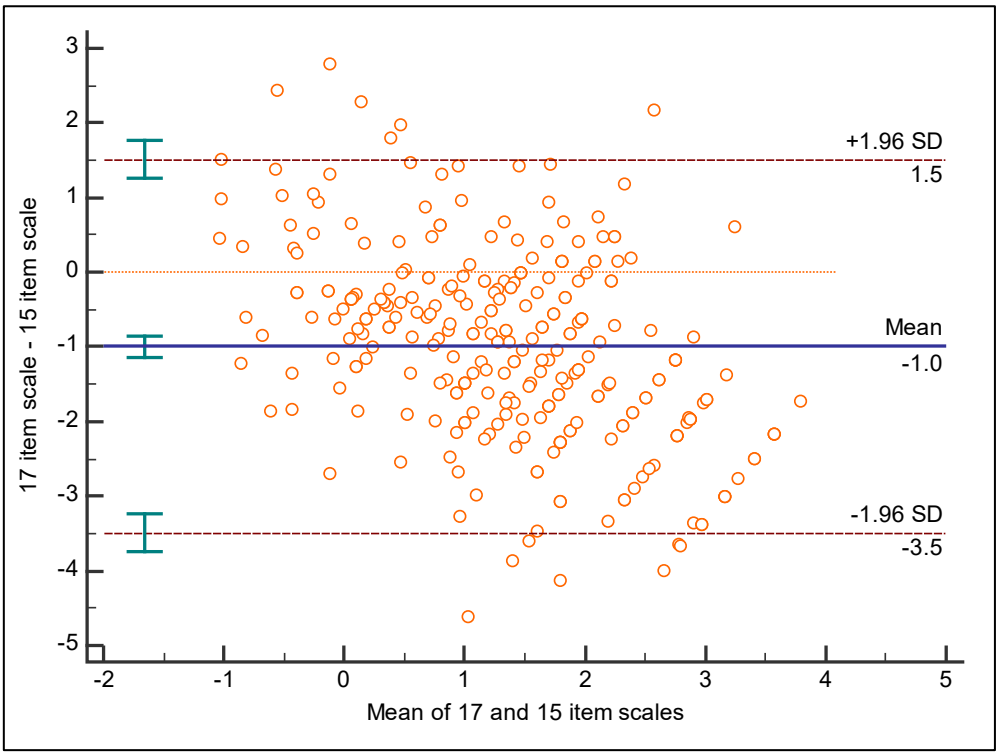

Figure 6-6 Bland and Altman plot of the 17 and 15 item Symptoms frequency scale

Owing to the degradation in the discriminatory ability of the scales, no significant improvement in measurement properties and the presence of only moderate correlation and agreement, splitting of the scale was abandoned at this stage. For most practical purposes, the two dimensions can be considered as one. Investigations with wider range of sample abilities in the future is recommended to decide the usefulness of having two separate scales versus one.

The psychometric properties of the final symptom-frequency scale are shown in Table 6-8. The measurement precision of the final scale was good (PSI =2.44) indicating that it can distinguish between persons with three strata of abilities. The response categories functioned optimally. The targeting of the scale was slightly over the acceptable value of 1 logit. Inspection of the person-item map (Figure 6-7) indicated the lack of items to measure persons with higher ability (on the top left side of the measurement continuum) reliably. The measurement range of the scale was 2.98 logits. As the measurement range and targeting are sample dependent, these are expected to improve in a more symptomatic sample (persons with low abilities).

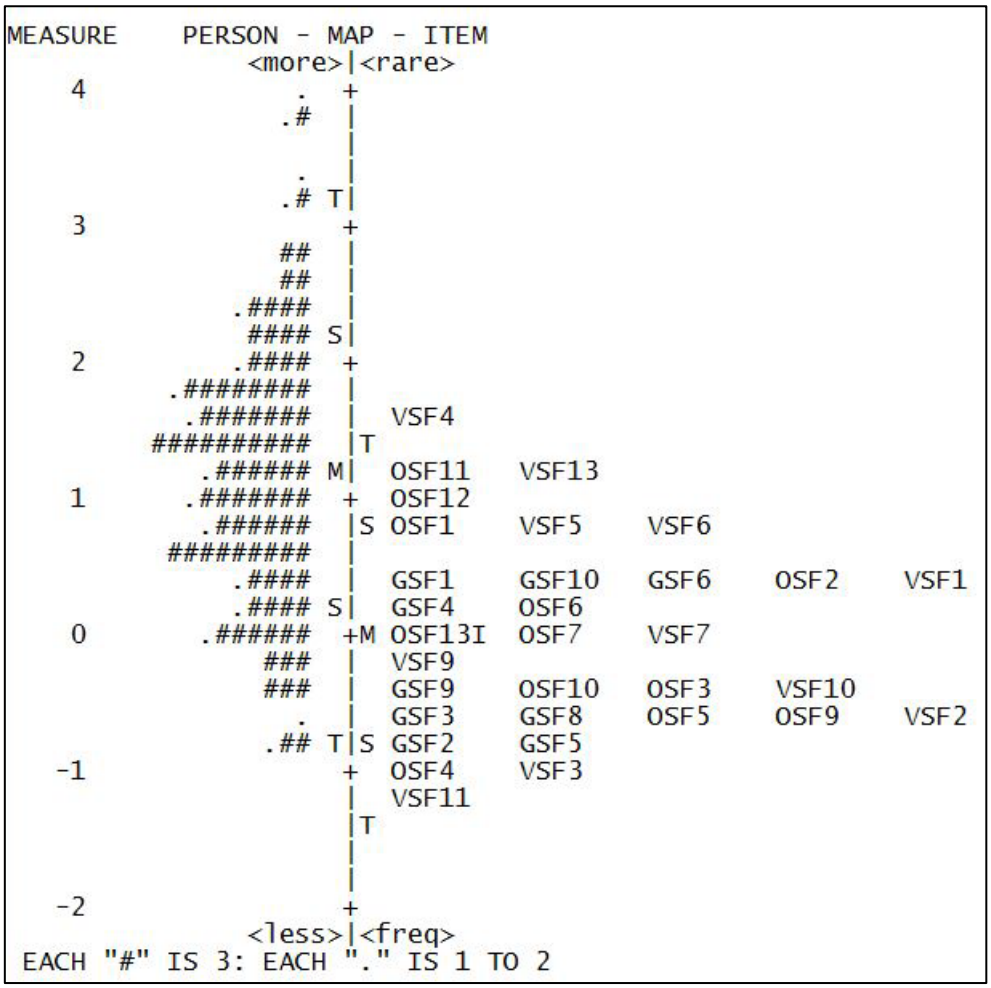

Figure 6-7 Person-Item map: Final Symptoms-frequency scale

The psychometric properties of the symptoms- severity and bothersome item banks were similar to the frequency item bank and are described briefly in subsequent sections.

6.6.1.2 Symptoms – Severity

The symptoms-severity item bank had a total of 32 items. It assessed the severity of symptoms faced by participants. Each item preceded with the item stem 'how severe is the' and was followed by four response categories: not at all, mild, moderate and severe. These were coded 4, 3 2 and 1 respectively so that higher scores indicate lesser severity of symptoms (more able persons) and *vice versa*. The psychometric properties of the original scale are shown in Table 6-12.

Table 6-12 Psychometric properties of the original and final Symptoms-severity item bank

Parameters	Psychometric properties - Original Symptoms – severity scale	Psychometric properties - Final iteration
No of items / persons	32 / 304	32 / 304
No of categories	4	3
Category functioning		
Average measures	Ordered	Ordered
Threshold calibration	Ordered*	Ordered
Category misfit	None	None
Separation and reliability statistics		
PSI (person reliability)	2.25 (0.84)	2.43 (0.86)
ISI (item reliability)	6.18 (0.97)	6.09 (0.97)
Item misfit		
Infit MNSQ > 1.5	None	None
Outfit MNSQ > 1.5	None	None
Targeting		
Difference between person and item means	0.99	1.38
Dimensionality		
Variance explained by the Rasch dimension (observed / expected)	35.5% / 36.4%	33.2% / 33.4%
Variance explained by the items	20.0%	17.4%
Eigen value of the first contrast	3.22	3.08
Unexplained variance in first contrast	6.5%	6.4%
Items loading on first contrast (number, item IDs)	12 (OSS 1-4, 7, 9-10, GSS 1-5)	15 (OSS 1-7, 9-10, GSS 1-6)
Disattenuated correlation between the first and second item clusters	1.0	0.67
Measurement range	1.98 (1.03 to -0.95)	2.78 (1.46 to -1.32)

The category statistics of the original symptoms-severity scale was described earlier (section 6.5.2). Although the category thresholds were ordered, considering the very narrow distance between the threshold calibrations, the middle categories 2 and 3 were combined, similar to symptoms- frequency and bothersome item banks. Upon combining, the category statistics were optimal (Table 6-13).

Table 6-13 Category statistics of the final Symptoms-severity scale

Category code	Response category	Category count	Category %	Average measure	Infit MNSQ	Outfit MNSQ	Threshold calibration
1	Severe	918	10	-0.10	1.04	1.04	None
2 and 3	Moderate & Mild	3340	35	0.81	0.98	0.94	-0.95
4	Not at all	5198	55	1.93	0.99	0.99	0.95

The measurement precision and range of the item bank improved (Table 6-12) and there were no misfitting items. The bubble chart is presented in Appendix 10.

The PCA of residuals indicated the variance explained by the measure (33.2%) was close to the Rasch expectations (33.4%). The eigenvalue was slightly over 3 and 15 items loaded on the first contrast; these were the same items that loaded on the first contrast of the symptom-frequency item bank. The disattenuated correlation between the first and second item clusters was 0.67, indicating that about 45% of the variance was shared by these dimensions. Analysis on splitting the scale into two, indicated that both the scales had less than optimal measurement precision (PSI of 17-item scale was 1.89 and 15-item scale was 1.79). Furthermore, the 15-item scale displayed poor targeting (2.04); the targeting of the 17-item scale was 1.2. The Bland and Altman agreement analysis (refer Figure 6-8 for B&A plot) between the two scales revealed moderate agreement [B&A Mean = -0.69 (-0.84 to -0.55); LOA =-3.09 to 1.71].

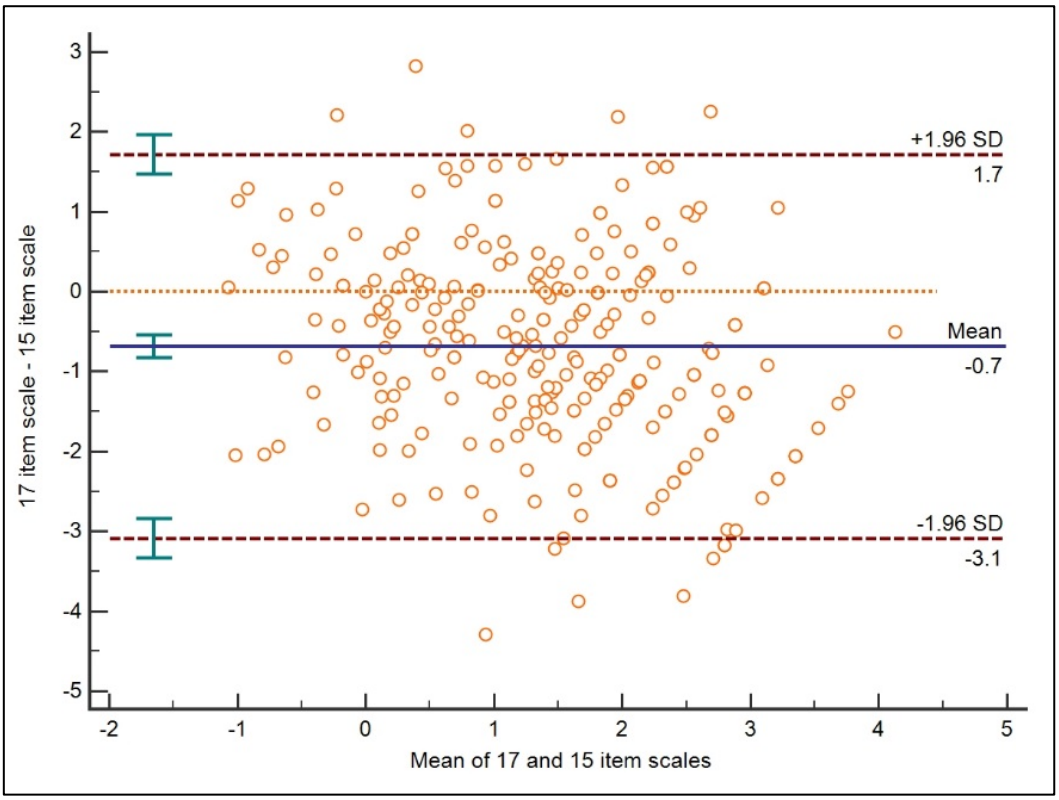

Figure 6-8 Bland and Altman plot of the 17 and 15 item Symptoms severity scale

These statistical evidences are identical to that of the symptoms-frequency item bank and hence similar decision was made. As the discriminatory ability of the scales was poor upon splitting, to preserve the usability of the scale, the scale was retained as such at this stage. Further testing in the future is warranted.

The psychometric properties of the final symptom-severity scale are shown in Table 6-12. The measurement precision of the final scale was good (PSI =2.43) indicating that it can distinguish between persons with three strata of abilities. The response categories functioned optimally. The targeting of the scale was 1.38 logit; inspection of the person-item map (Figure 6-9) indicated the lack of items to measure persons with higher ability (on the top left side of the measurement continuum) reliably. The measurement range of the scale was 2.78 logits.

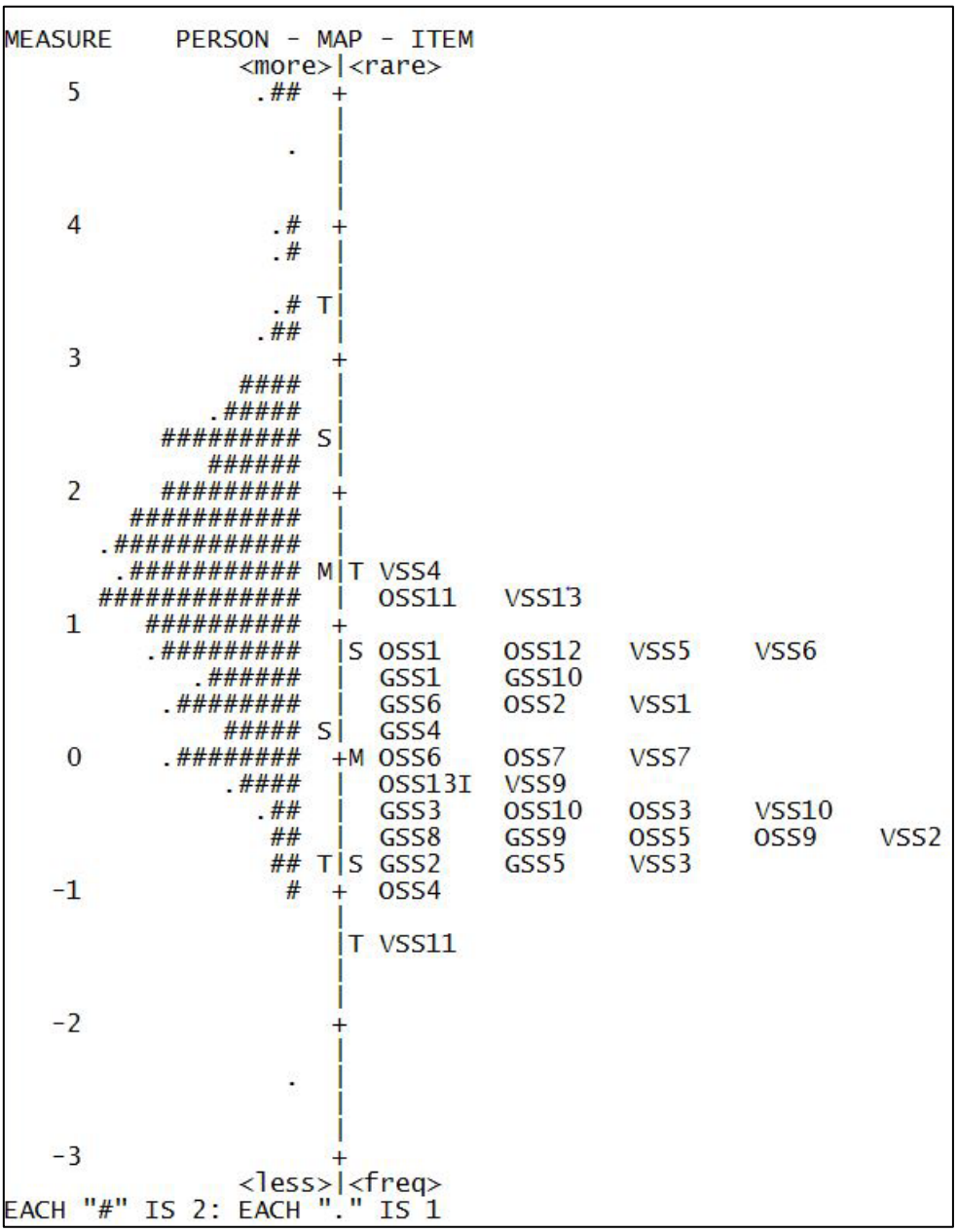

Figure 6-9 Person-Item map: Final Symptoms-severity scale

6.6.1.3 Symptoms – Bothersome

The symptoms-bothersome item bank had a total of 32 items. It assessed the degree to which the symptoms faced by the person was bothersome. Each item preceded with the item stem 'how much of a problem is the' and was followed by four response categories: none, a little, quite a lot and a lot. These were coded 4, 3, 2 and 1 respectively so that higher scores indicated symptoms were less problematic (more able persons) and *vice versa*. The psychometric properties of the original scale are shown in Table 6-14.

Table 6-14 Psychometric properties of the original and final Symptoms- bothersome item bank

Parameters	Psychometric properties - Original Symptom – bothersome scale	Psychometric properties - Final iteration
No of items / persons	32 / 303	32 / 303
No of categories	4	3
Category functioning		
Average measures	Ordered	Ordered
Threshold calibration	Disordered	Ordered
Category misfit	None	None
Separation and reliability statistics		
PSI (person reliability)	2.13 (0.82)	2.41 (0.85)
ISI (item reliability)	5.91 (0.97)	5.91 (0.97)
Item misfit		
Infit MNSQ > 1.5	None	None
Outfit MNSQ > 1.5	None	None
Targeting		
Difference between person and item means	1.13	1.54
Dimensionality (PCA of residuals)		
Variance explained by the Rasch dimension (observed / expected)	37.4% / 38.4%	35.6% / 35.9%
Variance explained by the items	19.6%	17.3%
Eigen value of the first contrast	3.34	3.31
Unexplained variance in first contrast	6.5%	6.7%
Items loading on first contrast (number, item IDs)	15 (OSB 1-7, 9-10, GSB 1-6)	15 (OSB 1-7, 9-10, GSB 1-6)
Disattenuated correlation between the first and second item clusters	0.78	0.71
Measurement range	1.98 (0.90 to -1.08)	2.75 (1.24 to -1.51)

The category statistics of the original symptoms-severity scale was described earlier (section 6.5.2). The disordered thresholds were optimised by combining the middle categories 2 and 3; optimal fit statistics and monotonicity of the average measures

was observed (Table 6-15). The measurement precision and range of the item bank improved (Table 6-14) and there was no misfitting items. The bubble chart is presented in Appendix 10.

Table 6-15 Category statistics of the final Symptoms-bothersome scale

Category code	Response category	Category count	Category %	Average measure	Infit MNSQ	Outfit MNSQ	Threshold calibration
1	A lot	922	10	-0.13	1.04	1.08	None
2 and 3	Quite a bit & a little	2919	31	0.81	0.97	0.91	-0.82
4	None	5574	59	2.07	0.99	0.99	0.82

The PCA of residuals indicated the variance explained by the measure (35.6%) was close to the Rasch expectations (35.9%). The eigenvalue was 3.31 and the same 15 items which loaded on the first contrast of frequency and severity item banks clustered. The disattenuated correlation between the first and second item clusters was 0.71, indicating that more than 50% of the variance was shared by these dimensions. Similar to the other two symptom item banks, splitting up the scale resulted in low measurement precision of both the 17 and 15 item scales (PSI was 1.89 and 1.75). The Bland and Altman agreement analysis (refer Figure 6-10 for B&A plot) between the two scales revealed moderate agreement [B&A Mean = -0.72 (-0.88 to -0.56); LOA =-3.25 to 1.81]. Considering these evidences, splitting up of the scale was not pursued further as before.

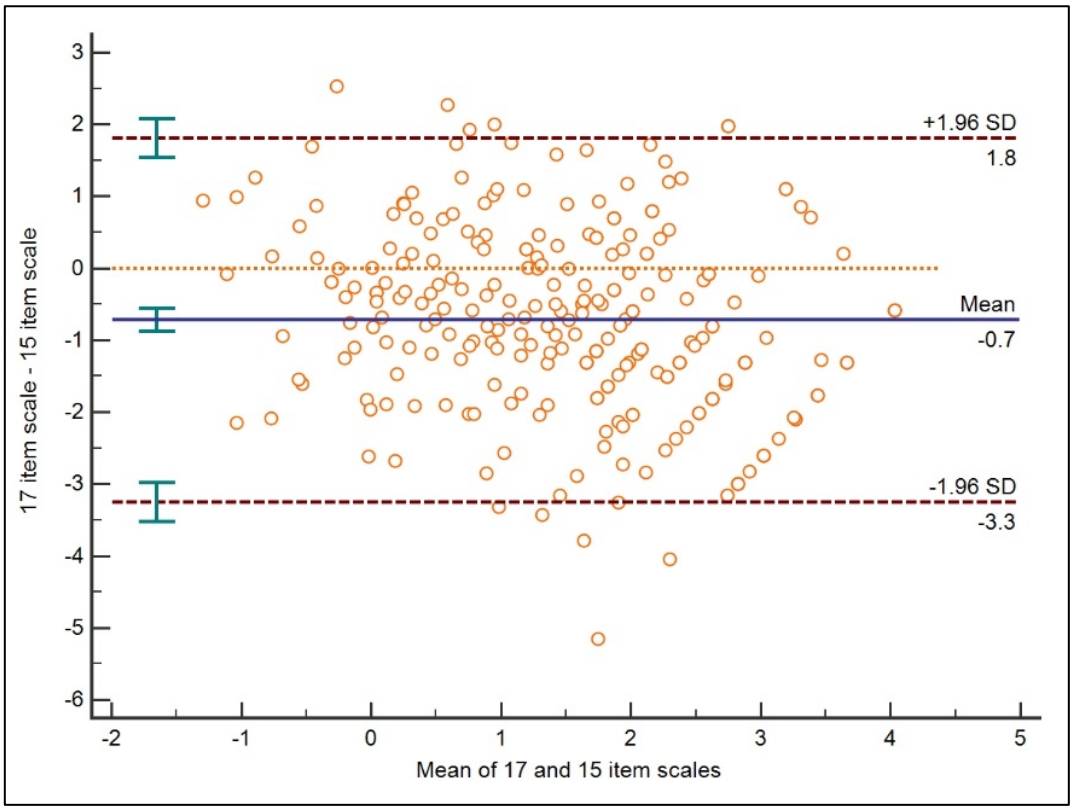

Figure 6-10 Bland and Altman plot of the 17 and 15 item Symptoms bothersome scale

The psychometric properties of the final symptom-bothersome scale are shown in Table 6-14. The measurement precision of the final scale was good (PSI =2.41) indicating that it can distinguish between persons with three strata of abilities. The response categories functioned optimally. The targeting of the scale was 1.54 logit; inspection of the person-item map (Figure 6-11) indicated the lack of items to measure persons with higher ability (on the top left side of the measurement continuum) reliably. The measurement range of the scale was 2.75 logits.

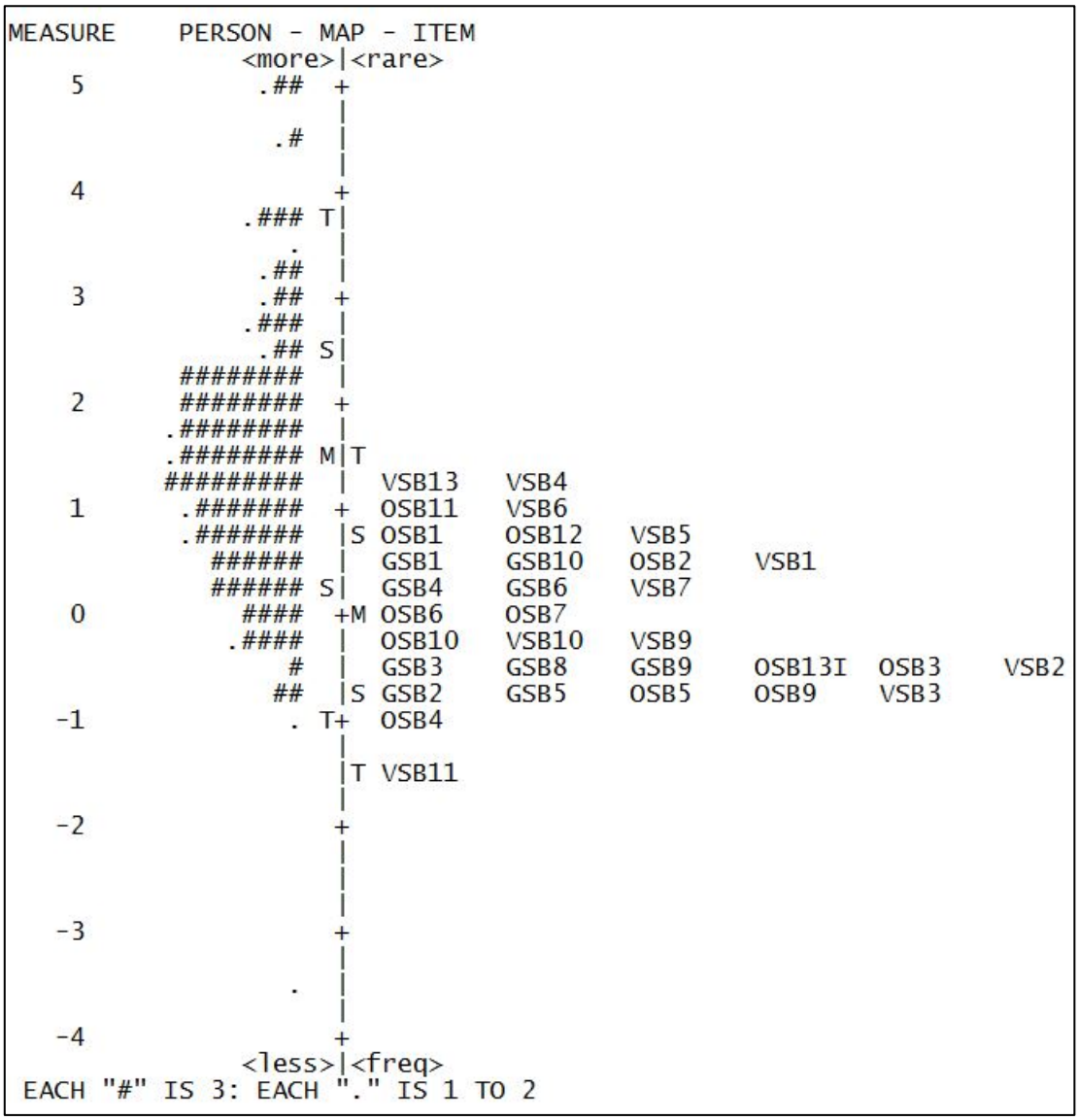

Figure 6-11 Person-Item map: Final Symptoms-bothersome scale

6.6.1.4 Symptoms item banks – summary

All three symptom item banks showed identical psychometric properties. They functioned optimally with three response categories. All three had similar person discriminatory abilities and reliabilities. Their item separation indices were >3, indicating that the sample is large enough to confirm the item difficulty hierarchy. Identical order of item hierarchy observed across the three item banks further substantiates the construct validity of the scales (Figure 6-12). Poor vision in one eye (VS4) was the most difficult item (highest item measure) and ghost images or shadows around objects you see (VS11) was the easiest item (least item measure) consistently in all three item banks.

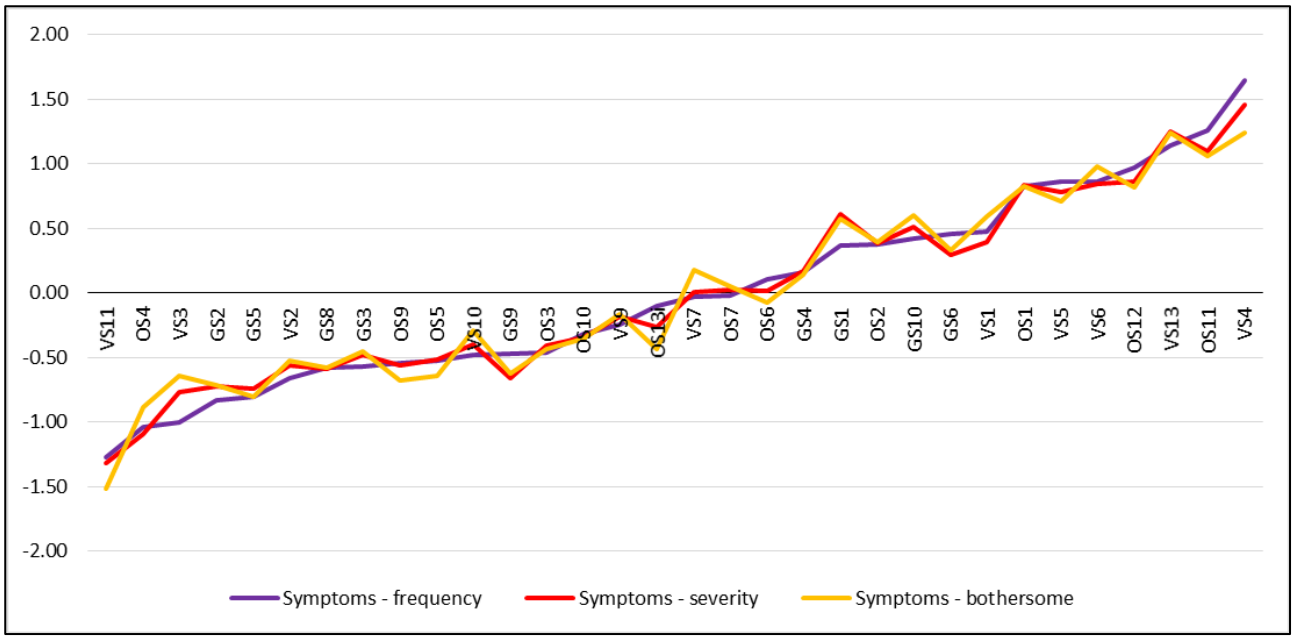

Figure 6-12 Line chart comparing item measures and hierarchy across the three symptoms item banks.

Comparable Item hierarchy can be observed across the three symptom item banks. Poor vision in one eye (VS4) was the most difficult item (highest item measure) and ghost images or shadows around objects you see (VS11) was the easiest item (least item measure) consistently in all three item banks.

Although the item fit statistics in all three item banks was satisfactory, the PCA of residuals indicated the possibility of a secondary dimension. It was interesting to note that the same fifteen items loaded on the first contrast in each item bank. However, due to the degradation of measurement properties (low measurement precision and reliability) and the lack of strong evidence supporting the splitting up of the item banks, it was not pursued at this stage. For most practical purposes, the symptom item banks can be considered unidimensional. The targeting and measurement range of the item banks are expected to improve in samples with higher variances in person ability.

6.6.2 Activity limitations

The activity limitations item bank had a total of 43 items. It assessed the level of difficulty persons had in performing activities in everyday life. Each item preceded with the item stem 'how much difficulty do you have...?' and was followed by five response categories: none, a little, quite a bit, a lot and unable to do because of my eye condition. These were coded 5, 4, 3 2 and 1 respectively so that higher scores indicated lesser difficulty (more able persons) and *vice versa*. The psychometric properties of the original scale are shown in Table 6-16.

Table 6-16 Psychometric properties of the original and final Activity limitation item bank

Parameters	Psychometric properties – Activity limitations Original scale	Psychometric properties - Final iteration
No of items / persons	43 / 304	43 / 304
No of categories	5	5
Category functioning		
Average measures	Ordered	Ordered
Threshold calibration	Ordered	Ordered
Category misfit	Category 1 (outfit MNSQ = 2.37)	None
Separation and reliability statistics		
PSI (person reliability)	2.52 (0.86)	2.42 (0.85)
ISI (item reliability)	4.69 (0.96)	5.03 (0.96)
Item misfit		
Infit MNSQ > 1.5	AL10, AL27, AL7, AL8	AL27
Outfit MNSQ > 1.5	AL10, AL27, AL6, AL1, AL7, AL8, AL68i, AL11	AL27
Targeting		
Difference between person and item means	1.78	1.97
Dimensionality (PCA of residuals)		
Variance explained by the Rasch dimension (observed / expected)	46.3% / 47.6%	47.1% / 48.6%
Variance explained by the items	9.2%	9.7%
Eigen value of the first contrast	5.08	5.16
Unexplained variance in first contrast	6.3%	6.3%
Items loading on first contrast (number, item IDs)	7 (AL 4, 18, 19, 20, 22, 67i, 69i)	7 (AL 4, 18, 19, 20, 22, 67i, 69i)
Disattenuated correlation between the first and second item clusters	1.0	0.99
Measurement range	1.74 (0.75 to -0.99)	1.97 (0.79 to -1.18)

The rating scale functioning of the original activity limitations item bank was described earlier (section 6.5.2). The average measures and the threshold calibrations were ordered; however, the category 1 (unable to do) showed misfit (outfit MNSQ = 2.37). The person and item separation indices and reliabilities were optimal (Table 6-16). Eight items exhibited misfit. The person responses for the misfitting items were examined and responses with z-residuals >+3 or <-3 were muted iteratively. After several iterations, all items fit the model except item AL27 (using binocular instruments). However, the infit and outfit MNSQs of AL27 were only slightly over 1.5 (infit MNSQ: 1.51, outfit MNSQ: 1.55). Considering the importance of this item and its relevance to amblyopia and strabismus, as substantiated by the qualitative research,

the item was retained. The bubble chart is presented in Appendix 10.

Muting errant person responses not only improved the item fit statistics but also the category fit statistics. The infit and outfit MNSQs of all categories were optimal (Table 6-17). However, the distance between the thresholds corresponding to categories 3 and 4 was still narrow (0.14) like before (0.11).

Table 6-17 Category statistics of the final Activity limitations scale

Category code	Response category	Category count	Category %	Average measure	Infit MNSQ	Outfit MNSQ	Threshold calibration
1	Unable to do	196	2	-0.07	1.21	1.42	None
2	A lot	1077	10	0.26	1.04	1.17	-1.70
3	Quite a bit	1279	11	0.73	0.98	0.88	0.30
4	A little	2342	21	1.32	0.94	0.80	0.44
5	None	6343	56	2.36	1.03	1.02	0.96

The PCA of residuals indicated that the variance explained by the measure (47.1%) was close to the Rasch expectations (48.6%). The ratio of the variance explained by the items to the unexplained variance in first contrast was low (1.5). The eigenvalue of the first contrast was 5.16 and 7 items loaded on the first contrast. Out of the 7 items, 6 items (AL 18, 19, 20, 22, 67i, 69i) measured limitations related to sport activities and one item (AL4) measured limitation in pouring water without spilling.

Although the items that grouped together forms a meaningful construct (limitations in sports), it could be thought of as a strand of the broader activity limitations item bank. To confirm this, the disattenuated correlation between the first and second item clusters was examined. This was 0.99, indicating that 98% of the variance was shared by these dimensions. Further the Bland and Altman agreement analysis (see Figure 6-13 for B&A plot) between the 37 item main scale and the 6 item sports scale revealed excellent agreement [B&A Mean = -0.35 (-0.64 to -0.06); LOA =-3.96 to 3.26]. The spearman correlation coefficient between the person measures estimated by these two scales was 0.60 (0.49 to 0.69).

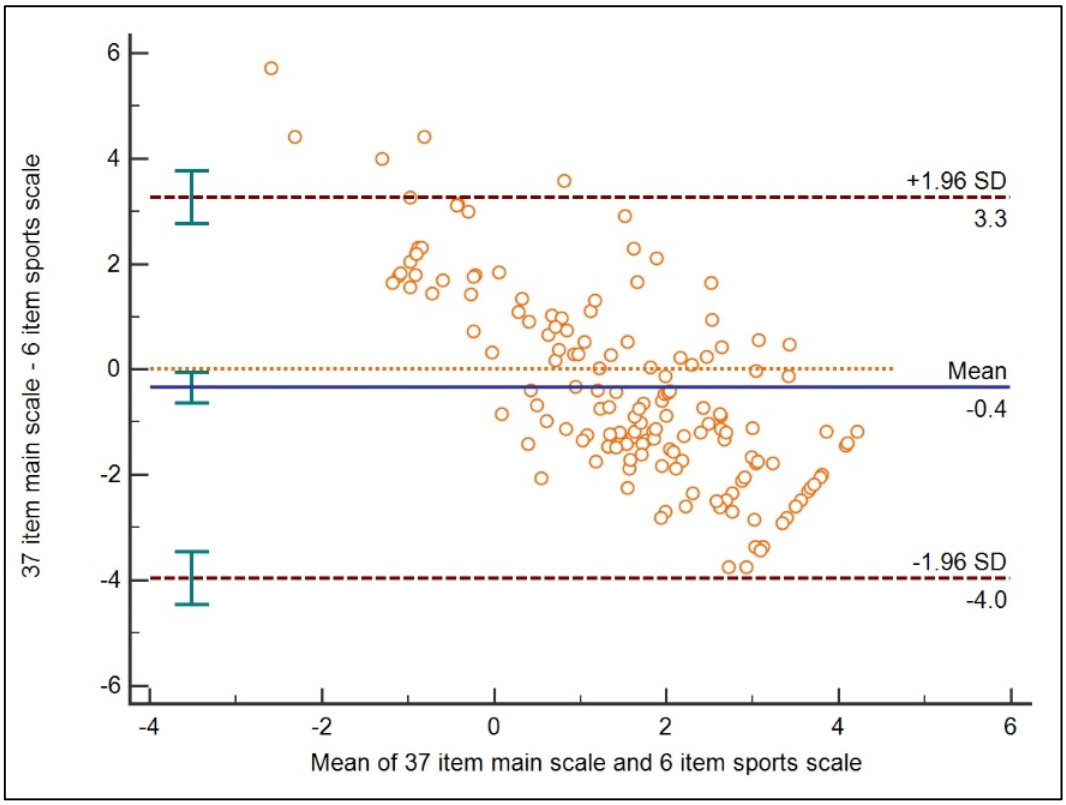

Figure 6-13 Bland and Altman plot of the 37 and 6 item Activity limitations scale

Assessment of the psychometric properties of the six-item sports scale indicated poor measurement precision (1.88) and targeting (3.17), in addition to narrow measurement range (1.31). Upon removing the sports items from the main scale, the measurement precision of the main scale dropped from 2.42 to 2.35. Although the eigenvalue improved, it was still over 3 (3.86) and 7 items (5 items measuring limitations in using electronic gadgets – screen items namely AL28, AL29, AL30, AL32, AL70i and 2 items measuring reading difficulties namely AL35 and AL71i) loaded on the first contrast. However, the disattenuated correlation between these two item clusters was 1.0 indicating that 100% of the variance was shared by these dimensions.

The psychometric assessment of the five screen items indicated poor measurement precision (1.51), targeting (4.33) and narrow measurement range (1.15). On removing the screen items, the measurement precision of the main scale (32 items) further dropped to 2.26 and the eigenvalue was still over 3 (3.34). Now, nine items measuring limitations in reading (AL35, AL37, AL39, AL40, AL41, AL43, AL44 AL45 and AL71i) loaded on the first contrast. The disattenuated correlation between the two item clusters was again 1.0. Removing the reading items from the main scale

significantly dropped measurement precision of the main scale (23 items) to 1.81, although eigenvalue improved to less than 3 (2.34). The psychometric assessment of the reading scale indicated acceptable PSI (2.01), suboptimal targeting (2.6) and narrow measurement range (1.79).

It is likely that items measuring similar concepts group together in large questionnaires such as item banks. This may not necessarily indicate a unique secondary dimension and could just be a strand of the primary dimension. In this case, the three cluster of items identified by the iterative analysis formed meaningful constructs namely limitations in sports, using electronic screen gadgets and reading. However, these are conceptually part of the broader primary construct 'activity limitation'. This was statistically substantiated by the decrease in measurement precision noted upon splitting the scale, indicating that these items contribute to the measurement of the primary construct. The high disattenuated correlations between the item clusters in each iteration adds validity to the claim that these are mere strands and not truly unique secondary dimensions. Further, these strands of items, exhibited unsatisfactory psychometric properties when tested independently and could not form meaningful measurement scales by themselves (except reading). For most practical purposes, it would be useful to measure the range of activity limitations using a single scale. Therefore, it was decided to ignore the large eigenvalue and retain the scale as such.

The psychometric properties of the final activity limitations item bank are displayed in Table 6-16. The response categories functioned optimally. The measurement precision of the final scale was good (PSI =2.42) indicating that it can distinguish between persons with three strata of abilities. The large ISI (5.03) indicates that the sample size is sufficient to confirm the item difficulty hierarchy. The targeting of the scale was sub-optimal (1.97 logit). Inspection of the person-item map (Figure 6-14) indicated the lack of items to measure persons with higher ability (on the top left side of the measurement continuum) reliably. The measurement range of the scale was narrow (1.97). Seeing in glare conditions (AL11) was the most difficult item to endorse (item measure = 0.79) and difficulty in cooking (AL1) was the easiest item to endorse (item measure = -1.18). In general, the reading items calibrated at a higher level than the sports and screen items along the measurement continuum.

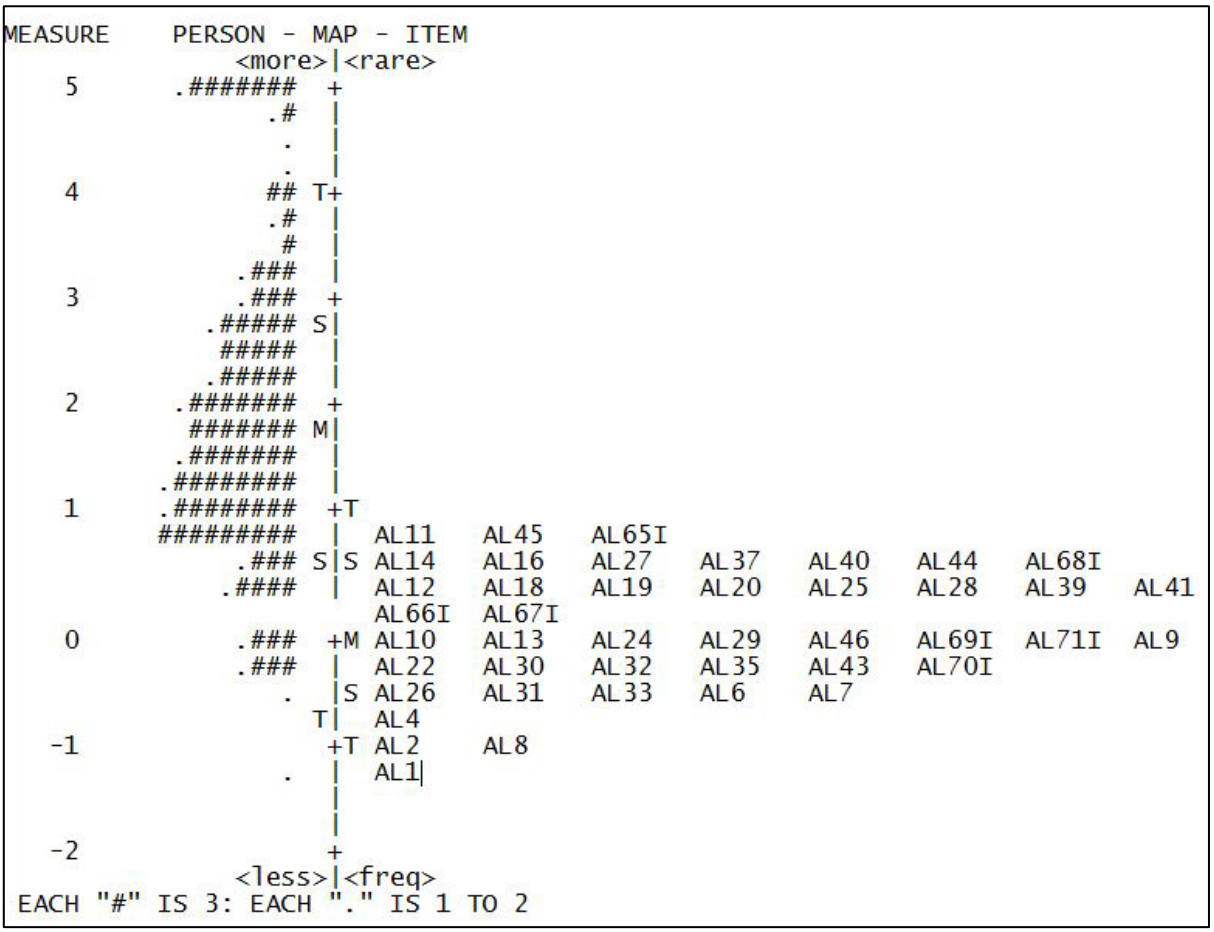

Figure 6-14 Person-Item map: Final Activity limitations scale

6.6.3 Driving

The driving item bank had a total of 18 items. It assessed the level of difficulty persons had in driving a car and riding a motor bike. Each item preceded with the item stem 'how much difficulty do you have...?' and was followed by five response categories: none, a little, quite a bit, a lot and unable to do because of my eye condition. These were coded 5, 4, 3 2 and 1 respectively so that higher scores indicated lesser difficulty in driving (more able persons) and *vice versa*. The psychometric properties of the original scale are shown in Table 6-18.

Table 6-18 Psychometric properties of the original and final Driving item bank

Parameters	Psychometric properties - Original Driving scale	Psychometric properties - Final iteration
No of items / persons	18 / 232	18 / 232
No of categories	5	5
Category functioning		
Average measures	Ordered	Ordered
Threshold calibration	Ordered	Ordered
Category misfit	Category 1 (outfit MNSQ = 1.55)	None
Separation and reliability statistics		
PSI (person reliability)	2.44 (0.86)	2.52 (0.86)
ISI (item reliability)	4.24 (0.95)	4.35 (0.95)
Item misfit		
Infit MNSQ > 1.5	AL61	None
Outfit MNSQ > 1.5	AL61	None
Targeting		
Difference between person and item means	2.3	2.51
Dimensionality (PCA of residuals)		
Variance explained by the Rasch dimension (observed / expected)	62.1% / 63.1%	64.0% / 64.9%
Variance explained by the items	22.8%	23%
Eigen value of the first contrast	2.93	2.98
Unexplained variance in first contrast	6.2%	6.0%
Items loading on first contrast (number, item IDs)	6 (AL 47, 48, 49, 50, 55, 56)	6 (AL 47, 48, 49, 50, 55, 56)
Disattenuated correlation between the first and second item clusters	1.0	1.0
Measurement range	2.26 (1.34 to -0.92)	2.47 (1.48 to -0.99)

The rating scale functioning of the original driving item bank was described earlier (section 6.5.2). The category statistics indicated ordered average measures and thresholds; however, the category 1 exhibited marginal misfit (outfit MNSQ = 1.55). The measurement precision of the original item bank was 2.44. One item (AL61) exhibited misfit. Muting the errant person responses for this item improved its fit to acceptable standards (infit MNSQ = 1.11 and outfit MNSQ = 1.10); however, this worsened the fit of another item, AL 60 (outfit MNSQ = 1.51). Upon muting the errant responses for this item, no further misfit was observed (bubble chart is presented in Appendix 10). Through the iterations, the measurement precision improved to 2.52 and the category fit statistics improved to acceptable standards (Table 6-19).

Table 6-19 Category statistics of the final Driving scale

Category code	Response category	Category count	Category %	Average measure	Infit MNSQ	Outfit MNSQ	Threshold calibration
1	Unable to do	108	3	-1.82	1.35	1.21	None
2	A lot	306	9	-0.35	1.06	1.14	-2.86
3	Quite a bit	407	12	0.74	0.90	0.87	-0.05
4	A little	781	24	1.96	0.87	0.80	0.71
5	None	1697	51	3.54	1.15	1.14	2.20

The PCA of residuals indicated that the variance explained by the measure (64%) was close to the Rasch expectations (64.9%). The eigenvalue of the first contrast was 2.98 and the ratio of the variance explained by the items to the unexplained variance in first contrast was high (3.8). Six items (AL47, AL48, AL49, AL59, AL55, AL56) measuring difficulties in driving a car loaded on the first contrast. The disattenuated correlation between the two item clusters was 1.0 indicating that 100% of the variance was shared by the two dimensions. Also, conceptually items targeting difficulties in driving a car can be thought of as a strand of the broader dimension 'difficulties in driving'. Hence the scale was retained as such.

The psychometric properties of the final driving item bank are shown in Table 6-18. The response categories functioned optimally. The measurement precision of the final scale was good (PSI =2.52) indicating that it can distinguish between persons with three strata of abilities. The large ISI (4.35) indicates that the sample size is sufficient to confirm the item difficulty hierarchy. The targeting of the scale was sub-optimal (2.51 logit) with more able persons than difficult items. Inspection of the person-item map (Figure 6-15) confirmed the gap in the top right side of the measurement continuum. The measurement range of the scale was 2.47 logits. Item AL54 (driving towards oncoming headlights of other vehicles) was the most difficult item (item measure = 1.48) and item AL64 (riding a motorbike during the day) was the easiest item (item measure = -0.99). Construct validity of the scale was substantiated by examining the item hierarchy; items such as driving a car and riding a motorbike during the day (Al47 and AL64) calibrated at a lower level on the measurement continuum (easy to endorse) in comparison to driving a car and motorbike at night (AL48 and AL72i) which were difficult to endorse.

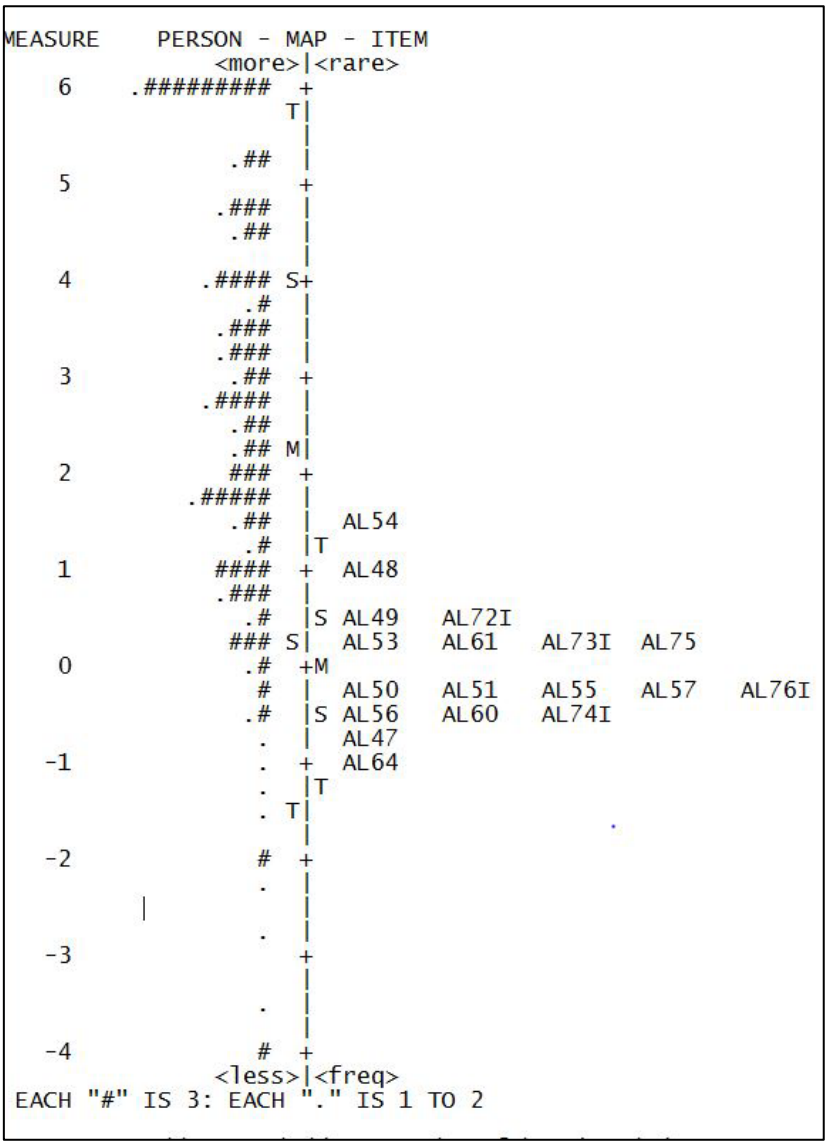

Figure 6-15 Person-Item map: Final Driving scale

6.6.4 Mobility

The mobility item bank had a total of 12 items. It assessed the level of difficulty persons had in mobility. Similar to the activity limitations and driving item banks, each item preceded with the item stem 'how much difficulty do you have..?' and was followed by five response categories: none, a little, quite a bit, a lot and unable to do because of my eye condition. These were coded 5, 4, 3 2 and 1 respectively so that higher scores indicated lesser difficulty in mobility (more able persons) and *vice versa*. The psychometric properties of the original scale are shown in Table 6-20.

Table 6-20 Psychometric properties of the original and final Mobility item bank

Parameters	Psychometric properties - Original Mobility scale	Psychometric properties - Final iteration
No of items / persons	12 / 300	12 / 277
No of categories	5	5
Category functioning		
Average measures	Disordered	Disordered
Threshold calibration	Ordered	Ordered
Category misfit	Category 1 (infit MNSQ = 2.41; outfit MNSQ = 1.89) Category 2 (outfit MNSQ = 1.58)	None
Separation and reliability statistics		
PSI (person reliability)	1.39 (0.63)	1.47 (0.69)
ISI (item reliability)	5.91 (0.97)	5.35 (0.97)
Item misfit		
Infit MNSQ > 1.5	MB14 (2.00), MB12 (1.57)	MB14 (1.87), MB12 (1.55)
Outfit MNSQ > 1.5	MB14 (1.97), MB12 (1.51)	MB14 (1.84)
Targeting		
Difference between person and item means	3.42	4.12
Extreme responses (maximum scores), n (%)		73 (26.4%)
Non-extreme PSI (person reliability)		**2.07 (0.81)**
Targeting		**3.26**
Dimensionality (PCA of residuals)		
Variance explained by the Rasch dimension (observed / expected)	52.4% / 55.3%	58.7% / 60.9%
Variance explained by the items	18.7%	19.4%
Eigen value of the first contrast	2.23	2.14
Unexplained variance in first contrast	8.8%	7.4%
Items loading on first contrast (number, item IDs)	3 (MB1-3)	3 (MB1-3)
Disattenuated correlation between the first and second item clusters	1	1
Measurement range	2.11 (-1.00 to 1.11)	2.67 (-1.24 to 1.43)

PSI and targeting for non-extreme respondents in final iteration are highlighted in bold font.

The rating scale functioning of the original mobility item bank was described earlier (section 6.5.2). High ceiling effect was observed with about 70% of the responses in the highest category (category 5: none) and the lowest category (category 1: unable to do) had a bare minimum number of responses required for stable calibration (n=10). Although the threshold calibrations were ordered, the average measures of the two lowest categories were disordered and the two categories exhibited misfit. The measurement precision was poor (PSI<2). Two items exhibited misfit; the infit and outfit MNSQs of item MB14 was close to 2 (significant measurement noise) and

that of MB12 was slightly over 1.50 (marginal misfit).

As an initiative to fix these misfitting items, the errant person responses corresponding to each item were muted iteratively. This improved the fit of item MB12 close to acceptable standards (infit MNSQ=1.52; outfit MNSQ=1.47) and the fit of item MB14 to <2.0 (infit MNSQ=1.97; outfit MNSQ=1.92). However, the PSI of the scale was still low (1.31) and the category misfits remained. As a next step, the most misfitting item MB14 was deleted from the analysis and the psychometric properties of the 11-item mobility item bank was assessed. This, however, did not improve measurement precision (PSI =1.31); in addition, it worsened the fit of item MB12 (infit MNSQ=1.74; outfit MNSQ=1.64). Thus, the item MB14 was reinstated in the analysis.

Next, the persons who were underfitting (person MNSQ >1.5, n=23) were eliminated from the analysis. This caused a slight improvement in PSI (which improved from 1.31 to 1.47); however, the two items were still misfitting (refer bubble chart in Appendix 10) and the targeting of the scale dropped from 3.49 to 4.12 logits.

The category statistics upon deleting misfitting persons are shown in Table 6-21. The number of responses in category 1 was less than 10 and the average measures of categories 1 and 2 were disordered as before. For category 1 the observed average (0.32) was notably different from the expected average (-1.40). In addition, the category 1 exhibited significant misfit (infit MNSQ >2).

Table 6-21 Category statistics of the final Mobility scale

Category code	Response category	Category count	Category %	Average measure	Infit MNSQ	Outfit MNSQ	Threshold calibration
1	Unable to do	6	0	0.32*	2.59	1.60	None
2	A lot	138	4	0.20	1.34	1.37	-3.82
3	Quite a bit	259	8	1.17	0.92	0.82	0.04
4	A little	597	19	2.59	0.92	0.70	1.13
5	None	2221	69	4.29	1.04	1.04	2.65

As none of the optimisation attempts improved the measurement precision of the scale to satisfactory level, as a last resort, the respondents with maximum extreme scores [n=73 (26.4%)] were omitted from the analysis and the PSI was recomputed. For non-extreme respondents the PSI (2.07) and person reliability (0.81) were acceptable. Although the targeting improved to 3.26, it was still sub-optimal.

The PCA of residuals indicated that the variance explained by the measure (58.7%)

was close to Rasch expectations (60.9%). The eigenvalue of the first contrast was slightly over 2 and the ratio of the variance explained by the items to the unexplained variance in first contrast was 2.62. Although the eigenvalue was less than 3, considering the small number of items in the mobility item bank, the items that loaded on the first contrast was examined. These items assessed difficulty in crossing a road and using stairs. This clearly is a strand of the mobility construct which was further confirmed by the perfect disattenuated correlation. Therefore, the scale was retained as such.

The psychometric properties of the final mobility item bank are shown in Table 6-20. The response categories functioned optimally except category 1, which was significantly underused by the sample tested resulting in misfit and disordered average measure. The measurement precision of the final scale for non-extreme respondents was good (PSI=2.07) indicating that the scale has satisfactory discriminatory ability for respondents whose scores are estimable by the scale. The large ISI (5.35) indicates that the sample size is large enough to confirm the item difficulty hierarchy. The targeting of the scale was sub-optimal (3.26 logits for non-extreme sample and 4.12 logits, overall). Inspection of the person-item map (Figure 6-16) confirmed that the sample had more able persons. However, the measurement range of the scale was not narrow (2.67 logits). Item MB12 (noticing things on the side of the affected eye while moving around) was the most difficult item (item measure = 1.43) and item MB5 (using escalators) was the easiest item (item measure = -1.24). Construct validity of the scale was substantiated by examining the item hierarchy; item MB3 (going down steps or stairs) calibrated at a higher level (difficult to endorse) on the measurement continuum than item MB2 (going up steps or stairs) as noted by the qualitative exploration with patients.

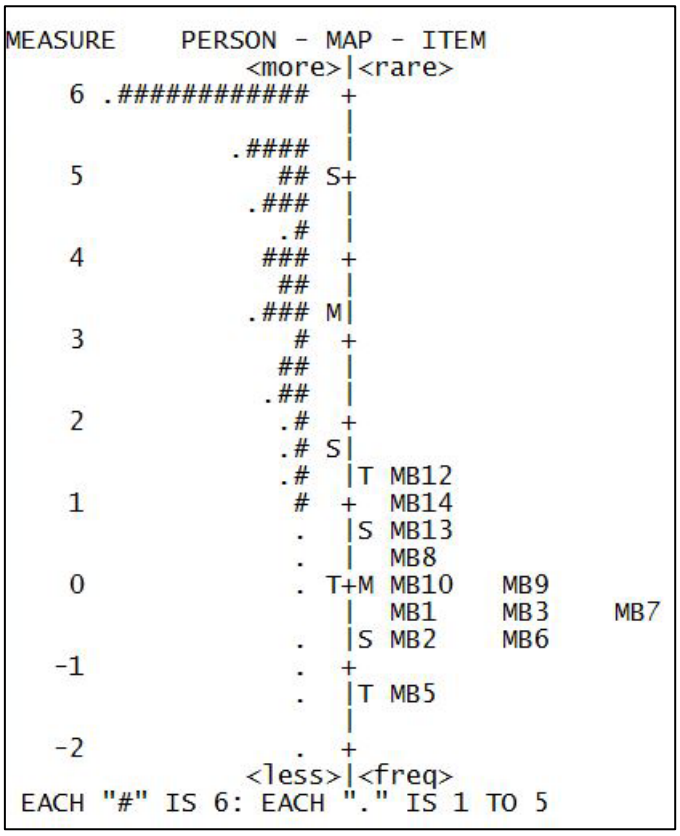

Figure 6-16 Person-Item map: Final Mobility scale

To summarise, the mobility item bank has limitations in category functioning, measurement precision and targeting. The limitations can be mostly accounted to the high ability of the current sample used for calibration. These limitations could be overcome by testing the scale on a sample with more individuals with lower abilities. Excluding those with perfect scores in the current sample improved measurement precision to acceptable standards, which indicates that the scale's discriminatory ability is optimal for persons whose scores are estimable (about 74% of the current sample). Although two items were under-fitting the model, they were retained as they measured important aspects of mobility which were identified by the qualitative exploration with patients and their misfits were not high enough to degrade measurement. However, these items should be examined for any DIF and might need group-specific calibrations if notable DIF was evident. Despite limitations, the mobility item bank has scope for optimisations in future testing.

6.6.5 Concerns

The concerns item bank had a total of 58 items. It assessed the level of concerns persons had in relation to their eye condition. Each item preceded with the item stem 'how concerned are you about...?' and was followed by five response categories: not

at all, a little bit, a moderate amount, a lot and extremely. These were coded 5, 4, 3 2 and 1 respectively so that higher scores indicated lesser concerns (more able persons) and *vice versa*. The psychometric properties of the original scale are shown in Table 6-22.

Table 6-22 Psychometric properties of the original and final Concerns item bank

Parameters	Psychometric properties - Original Concerns scale	Psychometric properties - Final iteration
No of items / persons	58 / 301	58 / 301
No of categories	5	3
Category functioning		
Average measures	Ordered	Ordered
Threshold calibration	Disordered	Ordered
Category misfit	None	None
Separation and reliability statistics		
PSI (person reliability)	3.09 (0.91)	3.60 (0.93)
ISI (item reliability)	5.82 (0.97)	5.69 (0.97)
Item misfit		
Infit MNSQ > 1.5	HC12 (1.58)	None
Outfit MNSQ > 1.5	HC20 (1.55)	None
Targeting		
Difference between person and item means	0.71	0.67
Dimensionality (PCA of residuals)		
Variance explained by the Rasch dimension (observed / expected)	45.10% / 45.9%	42% / 42.4%
Variance explained by the items	12.1%	12.0%
Eigen value of the first contrast	5.89	5.92
Unexplained variance in first contrast	5.6%	5.9%
Items loading on first contrast (number, item IDs)	13 (HC 17, 18, 19, 20, 21, 22, 23, 24, 25, 27, 28, 29, 52)	13 (HC 17, 18, 19, 20, 21, 22, 23, 24, 25, 27, 28, 29, 52)
Disattenuated correlation between the first and second item clusters	0.81	0.79
Measurement range	1.59 (0.85 to -0.74)	2.61 (1.48 to -1.13)

The rating scale functioning of the original concerns item bank was described earlier (section 6.5.2). The average measures were ordered, and no category misfit was observed; however, the thresholds were disordered. The person and item separation, reliability indices and targeting of the scale were optimal. Two items (HC12 and HC20) exhibited marginal misfit.

The item misfit was addressed by muting the errant person responses. The disordered thresholds were optimised by combining categories 1 and 2 (extremely and a lot) and 3 and 4 (a moderate amount and a little bit). Upon threshold optimisation, the

category statistics were optimal (Table 6-23) and no item misfit was observed (Refer bubble chart in Appendix 10).

Table 6-23 Category statistics of the final Concerns scale

Category code	Response category	Category count	Category %	Average measure	Infit MNSQ	Outfit MNSQ	Threshold calibration
1 and 2	Extremely and A lot	3603	24	-0.73	0.98	0.96	None
3 and 4	A moderate amount and A little bit	4145	27	0.39	0.98	0.94	-0.31
5	Not at all	7495	49	1.40	1.05	1.09	0.31

Upon optimisation, the measurement precision of the scale improved from 3.09 to 3.60, the targeting improved from 0.71 to 0.67 and the measurement range improved from 1.59 to 2.61. These improvements substantiated the benefits of collapsing categories.

The PCA of residuals indicated that the variance explained by the Rasch dimension (42%) was close to the Rasch expectations (42.4%). However, the eigenvalue of the first contrast was high (5.92) and the ratio of the variance explained by the items to the unexplained variance in first contrast was about 2. Thirteen items (Table 6-24) loaded on the first contrast. These items specifically measured the psychosocial concerns associated with the eye condition.

Table 6-24 13 items measuring psychosocial concerns

Item ID	Item
HC17	Your looks
HC18	Being in photographs
HC19	Having eye contact with people while talking
HC20	What other people think of you
HC21	The way people behave with you
HC22	People not understanding your eye condition
HC23	People judging you wrongly
HC24	People passing comments about your eye condition
HC25	Being bullied or teased
HC27	Being treated differently
HC28	Being left out or rejected
HC29	Not being able to earn the respect of others
HC52	The impact of appearance on work

The disattenuated correlation between the two clusters of items was 0.79, indicating that about 62% of the variance was shared by the dimensions. Although these items measure psychosocial aspects specifically, these can be thought of as a strand of the broader construct - concerns. On removing these 13 items from the main scale, the

measurement precision of the main scale dropped from 3.60 to 3.24, indicating that these items are contributing to the measurement of the primary construct. In addition, the agreement between the person measures obtained from the 13-item psychosocial scale and the 45 item concern scale was good (refer Figure 6-17 for B&A plot). Therefore, the concerns scale was retained as such to measure the wide range of concerns over a single continuum.

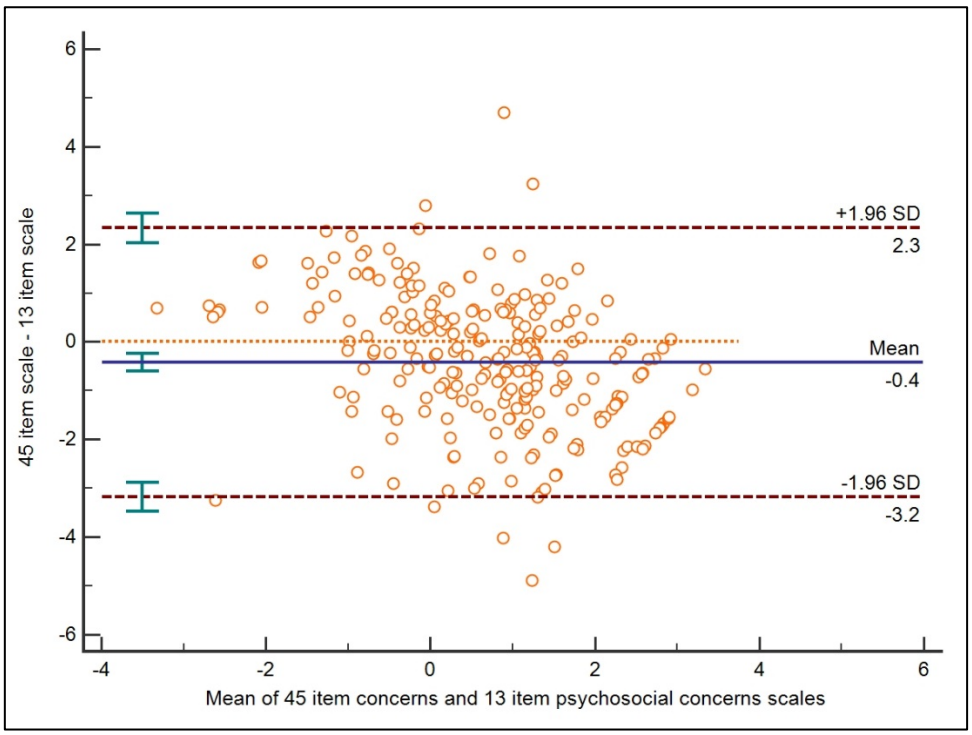

Figure 6-17 Bland and Altman plot of the 45 and 13 item Concerns scale

However, in clinical practice and research, it might sometimes be useful to solely measure the psychosocial concerns associated with amblyopia and strabismus. Therefore, the psychometric properties of the 13-item psychosocial concerns scale were assessed (Table 6-25). The category statistics were optimal with ordered average measures, thresholds and no category misfits. The measurement precision was optimal, and no item misfit was observed. The targeting of the scale was close to acceptable standards and the measurement range of the scale was 2.32 logits. The PCA of residuals indicated that the variance explained by the Rasch dimension was close to the Rasch expectations. The eigenvalue was 2.73; although this is less than 3, which is the cut-off for item banks, given the small number of items in this scale, the items loading on the first contrast were examined. 5 items loaded on the first contrast (HC 24, 25, 27, 28, 29) and the disattenuated correlation between the two clusters was 1, indicating that the items were just a strand of the primary construct. Overall, the 13-items forms a valid measurement scale to measure the psychosocial

concerns associated with amblyopia and strabismus.

Table 6-25 Psychometric properties of the 13 item psychosocial concerns scale

Parameters	Psychometric properties - Original Psychological scale
No of items / persons	13/ 300
No of categories	3
Category functioning	
Average measures	Ordered
Threshold calibration	Ordered
Category misfit	None
Separation and reliability statistics	
PSI (person reliability)	2.14 (0.82)
ISI (item reliability)	6.04 (0.97)
Item misfit	
Infit MNSQ > 1.5	None
Outfit MNSQ > 1.5	None
Targeting	
Difference between person and item means	1.17
Dimensionality (PCA of residuals)	
Variance explained by the Rasch dimension (observed / expected)	52.4% / 52.6%
Variance explained by the items	20.6%
Eigen value of the first contrast	2.73
Unexplained variance in first contrast	10%
Items loading on first contrast (number, item IDs)	5 (HC 24, 25, 27, 28, 29)
Disattenuated correlation between the first and second item clusters	1.0
Measurement range	2.32 (1.10 to -1.22)

The psychometric properties of the final concerns item bank are shown in Table 6-22. The response categories functioned optimally. The measurement precision of the final scale was excellent (3.60) indicating that the scale can distinguish four strata of person abilities. The large ISI (5.69) indicates that the sample size is enough to confirm the item difficulty hierarchy. The targeting of the scale was optimal (0.67 logit); the large range of items and persons along the measurement continuum can be visualised in the person-item map (Figure 6-18). The measurement range of the scale was 2.61 logits; the item HC8 (How concerned are you about the safety of your eyes?) was the most difficult item to endorse (item measure = 1.48) and the item HC39 (How concerned are you about having non-motor vehicle related accidents?) was the easiest item to endorse (item measure = -1.13).

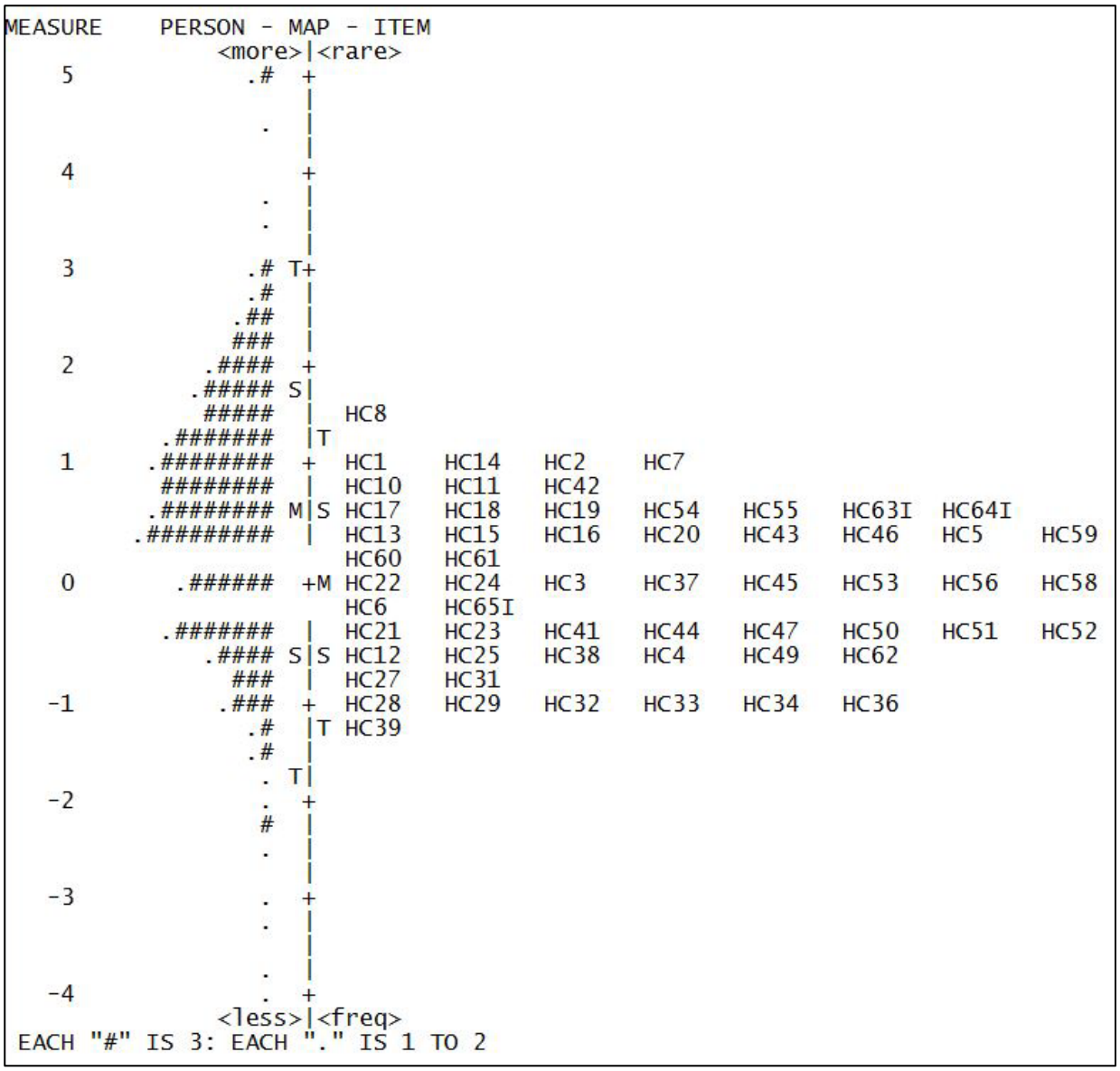

Figure 6-18 Person-Item map: Final Concerns scale

6.6.6 Emotional impact

The emotional impact item bank had a total of 37 items. It assessed the level of emotional impact persons had in relation to their eye condition. Each item preceded with the item stem 'during the past four weeks, how often did you..?' and was followed by five response categories: none of the time, a little of the time, some of the time, most of the time and all the time. These were coded 5, 4, 3 2 and 1 respectively so that higher scores indicated lesser emotional impact (more able persons) and *vice versa*. The psychometric properties of the original scale are shown in Table 6-26.

Table 6-26 Psychometric properties of the original and final Emotional impact item bank

Parameters	Psychometric properties - Original Emotional impact scale	Psychometric properties - Final iteration
No of items / persons	37 / 299	35 / 298
No of categories	5	5
Category functioning		
Average measures	Ordered	Ordered
Threshold calibration	Ordered	Ordered
Category misfit	None	None
Separation and reliability statistics		
PSI (person reliability)	2.5 (0.86)	2.51 (0.86)
ISI (item reliability)	6.3 (0.98)	6.44 (0.98)
Item misfit		
Infit MNSQ > 1.5	EM43, EM42, EM47	EM42
Outfit MNSQ > 1.5	EM43, EM42, EM47, EM41, EM20, EM49	EM42
Targeting		
Difference between person and item means	1.38	1.51
Dimensionality (PCA of residuals)		
Variance explained by the Rasch dimension (observed / expected)	55.3% / 57.1%	57.5% / 59.3%
Variance explained by the items	23.0%	23.3%
Eigen value of the first contrast	4.78	4.81
Unexplained variance in first contrast	5.8%	5.8%
Items loading on first contrast (number, item IDs)	10 (EM 25, 27, 28, 29, 30, 33, 35, 38, 39, 40)	10 (EM 25, 27, 28, 29, 30, 33, 35, 38, 39, 40)
Disattenuated correlation between the first and second item clusters	1.0	1.0
Measurement range	2.34 (1.47 to -0.87)	2.54 (1.61 to -0.93)

The rating scale functioning of the original emotional item bank was described earlier (section 6.5.2). The category statistics indicated ordered average measures and thresholds and no category misfits. The measurement precision of the original item bank was optimal, and six items exhibited misfit.

The errant person responses were muted iteratively in order to fix the misfitting items. After several iterations, the items EM43 (infit MNSQ = 1.66; outfit MNSQ = 1.64) and EM47 (infit MNSQ = 1.60) were still misfitting with no z-residuals >3 or <-3. The content of these items was examined to see if these measure aspects different to other items in the emotional item bank. It was then realised that the item EM43 (How often did you feel overprotective about your eyes) was quite different than other items; it measured concern associated with the eye condition and better suits the concerns item bank which already had items measuring concerns related to safety of

the good eye. Hence, this item was removed, and the analysis was repeated. On deleting the item, the measurement precision of the scale improved from 2.47 to 2.50 indicating that the item did not contribute to the measurement of the primary construct. However, the item EM47 was still misfitting (infit MNSQ = 1.62) along with two other items which exhibited marginal misfits (EM42: infit MNSQ = 1.56; outfit MNSQ = 1.59 and EM49: outfit MNSQ = 1.54). On muting errant person responses, the item EM49 showed fit to the model. Another careful examination of the content indicated that the item EM47 (feel envious about others with good vision) is a sensitive question and the social desirability could have affected the responses. This was confirmed by examining the frequency of responses for this item which revealed that the category 5 (none of the time) was endorsed 76% of the time. Hence the item was removed. Removal of the item did not affect measurement precision or any other psychometric properties of the scale, again indicating that it did not contribute to the measurement. The item EM42 which was still misfitting (infit MNSQ = 1.57; outfit MNSQ = 1.61) measured the fear of losing vision in good eye. Although this can also be thought of a concern, the component of fear is an emotion. Removal of the item affected measurement precision and targeting of the scale which deteriorated from 2.51 and 1.51 to 2.49 and 1.56 respectively. Although the deterioration was minimal, the trend suggests that the item is contributing to the measurement; also considering that the item measures an important concept that arose from the qualitative exploration, the item was reinstated. The infit MNSQs of the items and size of the standard errors can be visualised in the bubble chart (Appendix 10). The category statistics of the scale was acceptable and are shown in Table 6-27.

Table 6-27 Category statistics of the final Emotional impact scale

Category code	Response category	Category count	Category %	Average measure	Infit MNSQ	Outfit MNSQ	Threshold calibration
1	All of the time	794	8	-0.78	1.24	1.35	None
2	Most of the time	737	7	-0.19	0.91	0.84	-0.42
3	Some of the time	1048	10	0.36	0.89	0.73	-0.23
4	A little of the time	1847	18	1.04	1.03	0.90	0.17
5	None of the time	5784	57	1.96	1.06	1.09	0.48

The PCA of residuals indicated that the variance explained by the measure (57.5%) was close to the Rasch expectations (59.3%). Although the eigenvalue of the first contrast was high (4.81) and the ratio of the variance explained by the items to the unexplained variance in first contrast was also high (4.02). Ten items (EM 25, 27, 28,

29, 30, 33, 35, 38, 39 and 40) measuring emotions related to psychosocial impacts loaded on the first contrast. For example, items EM25, EM27 and EM28 were 'feel embarrassed because of your appearance', 'feel ashamed' and 'feel humiliated'. However, the disattenuated correlation between the two item clusters was perfect indicating that 100% of the variance was shared by the dimensions. Although these items measured emotions related to psychosocial impacts, they are still part of the broader emotional construct and it would be useful to measure the holistic emotional impact on a single scale. Moreover, removing the ten items from the main scale affected the measurement precision of the main scale which dropped to 2.40. In addition, the 10-item scale displayed poor psychometric properties such as sub-optimal measurement precision (PSI = 1.42) and targeting (2.62 logits). Therefore, the 35-item emotional scale was retained as such.

The psychometric properties of the final emotional impact item bank are shown in Table 6-26. The measurement precision of the final scale was optimal (2.51) to discriminate between three strata of person abilities. The ISI was high enough (6.44) to confirm the item difficulty hierarchy. The targeting of the scale was slightly sub-optimal (1.51 logits) and lack of items to measure persons with high ability was evident on inspecting the person-item map (Figure 6-19). The measurement range of the scale was 2.54; the item EM49 (wish things were normal) was the most difficult item to endorse (item measure = 1.61) and the item EM28 (feel humiliated) was the easiest item to endorse (item measure = -0.93). In general, the items tapping into the psychosocial aspects of emotional impact calibrated at a lower level (easy to endorse) than other items on the scale.

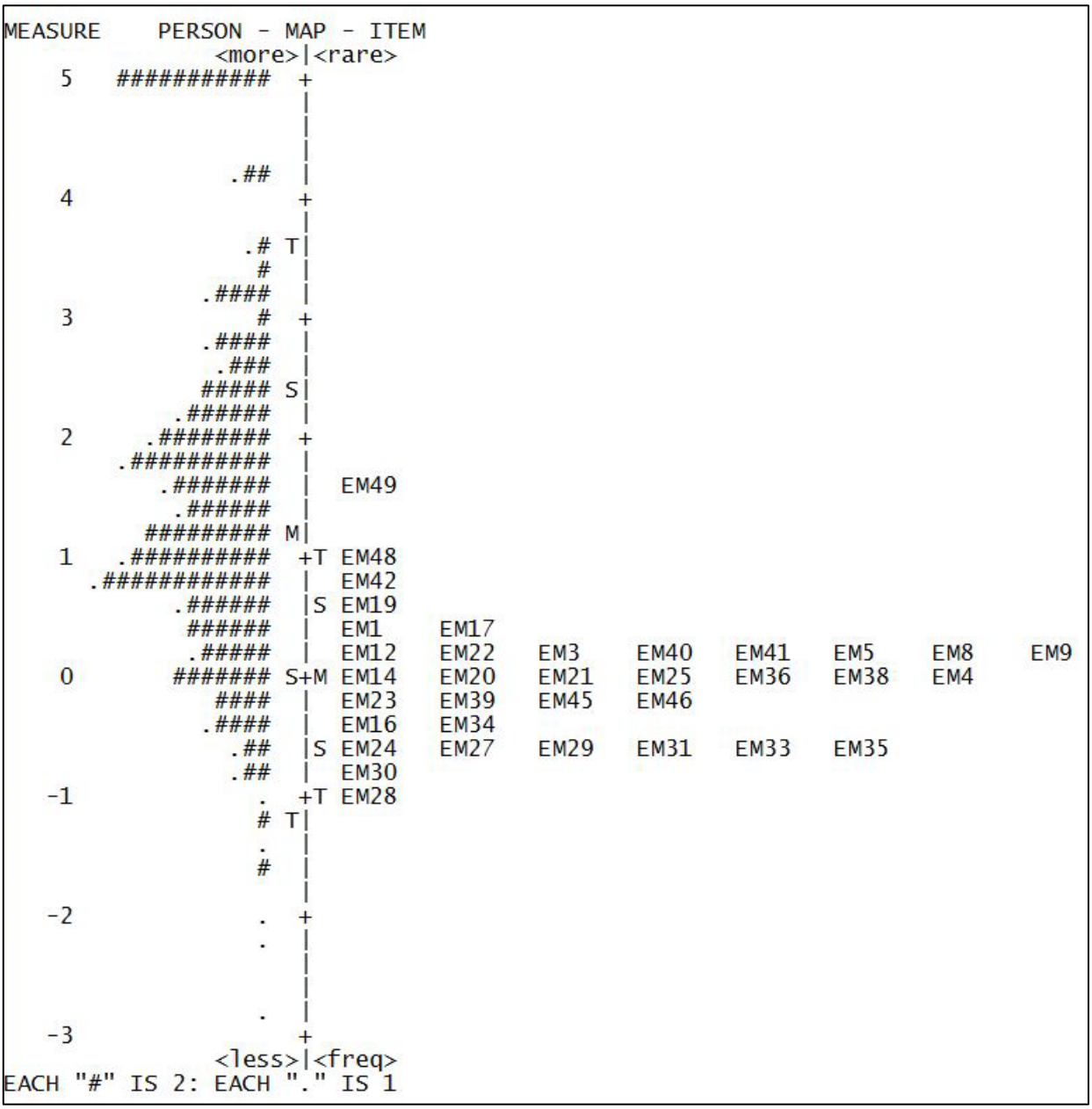

Figure 6-19 Person-Item map: Final Emotional impact scale

6.6.7 Social impact

The social impact item bank had a total of 20 items. It assessed the level of impact persons had in social life and participation. Each item preceded with the item stem 'how much of a problem do you have...?' and was followed by five response categories: none, a little, quite a bit, a lot and unable to do because of my eye condition. These were coded 5, 4, 3 2 and 1 respectively so that higher scores indicated lesser social impact (more able persons) and *vice versa*. The psychometric properties of the original scale are shown in Table 6-28.

Table 6-28 Psychometric properties of the original and final Social impact item bank

Parameters	Psychometric properties - Original Social impact scale	Psychometric properties - Final iteration
No of items / persons	20 / 299	19 / 299
No of categories	5	4
Category functioning		
Average measures	Ordered	Ordered
Threshold calibration	Disordered	Ordered
Category misfit	None	None
Separation and reliability statistics		
PSI (person reliability)	1.49 (0.69)	1.72 (0.75)
ISI (item reliability)	2.43 (0.86)	2.85 (0.89)
Item misfit		
Infit MNSQ > 1.5	SC22	None
Outfit MNSQ > 1.5	SC22, SC6, SC20	None
Targeting		
Difference between person and item means	2.41	3.2
Extreme responses (maximum scores), n (%)		85 (28.4%)
Non-extreme PSI (person reliability)		**2.50 (0.86)**
Targeting		**2.10**
Dimensionality (PCA of residuals)		
Variance explained by the Rasch dimension (observed / expected)	48.2% / 48.6%	46.6% / 46.7%
Variance explained by the items	20.5%	17.8%
Eigen value of the first contrast	2.51	2.64
Unexplained variance in first contrast	6.5%	7.4%
Items loading on first contrast (number, item IDs)	5 (SC 13-17)	4 (SC14-17)
Disattenuated correlation between the first and second item clusters	1.0	1.0
Measurement range	0.77 (0.36 to -0.41)	1.31 (0.63 to -0.68)

PSI and targeting for non-extreme respondents in final iteration are highlighted in bold font.

The rating scale functioning of the original social item bank was described earlier (section 6.5.2). The category statistics indicated ordered average measures and no category misfit; however high ceiling effects was observed with about 66% of the responses corresponding to category 5 and the thresholds were disordered. The measurement precision of the original item bank was sub-optimal, and three items exhibited misfit.

The item misfits were addressed by muting errant person responses iteratively and the disordered thresholds were optimised by combining categories 3 and 4 (Quite a bit and a little). Upon category optimisation, the PSI improved (1.71) but was still sub-

optimal. All items fit the model, except item SC22 (infit MNSQ = 1.70; outfit MNSQ = 1.59). Examining the content of this item indicated that this item measured a slightly different dimension of social impact; it assessed problems in getting social support (How much of a problem do you have in getting help and support from friends?) while other items on the scale measured impacts on social participation (SC10 Engaging in social activities) and interpersonal relationships (e.g. SC4 Making new friends). Therefore, this item was considered for deletion. Deleting this item did not affect measurement precision or range and there was no further item misfit observed (refer bubble chart in Appendix 10). The category statistics were optimal (Table 6-29).

Table 6-29 Category statistics of the final Social impact scale

Category code	Response category	Category count	Category %	Average measure	Infit MNSQ	Outfit MNSQ	Threshold calibration
1	Unable to do	95	2	-0.96	1.15	1.29	None
2	A lot	447	8	0.41	0.92	0.92	-1.79
3 and 4	Quite a bit and A little	1318	24	1.63	0.94	0.97	-0.03
5	None	3546	66	2.94	1.06	1.07	1.83

However, the measurement precision of the scale was not satisfactory (1.72) and the targeting was sub-optimal (3.2 logits). Considering the high ceiling effects observed, persons with maximum extreme scores were eliminated from the analysis and the PSI and targeting was recomputed. Upon eliminating 85 (28.4%) persons with perfect scores, the PSI and person reliability were 2.50 and 0.86 respectively. Although the targeting of the scale improved to 2.10 logits, it was still sub-optimal.

The PCA of residuals indicated that the variance explained by the measure (46.6%) was close to the Rasch expectations (46.7%). The eigenvalue of the first contrast was less than 3 (2.64) and the ratio of the variance explained by the items to the unexplained variance in first contrast was 2.41. Considering the small number of items in the social item bank, the items loaded on the first contrast was examined as eigenvalue was greater than 2. Four items measuring impacts on socialising (SC 14, 15, 16 and 17) loaded on the first contrast. However, the disattenuated correlation between the two clusters of items was perfect and hence the scale was retained as such.

The psychometric properties of the final social impact item bank are shown in Table 6-28. The measurement precision of the final scale was optimal (2.50) for respondents with non-extreme scores. The ISI was 2.85; as this value is less than 3 it indicates that more sample size is needed to confirm the item hierarchy. The targeting

of the scale was sub-optimal for entire sample (3.2 logits) as well as for the respondents with non-extreme scores (2.1 logits). A large number of able persons along the top-left side of the measurement continuum and corresponding gap on the top-right side can be visualised in the person-item map (Figure 6-20). The measurement range of the scale was narrow (1.31 logits); the item SC16 (socialising because people are unsure about which eye to look at) was the most difficult item to endorse (item measure =0.63) and the item SC5 (maintaining your friendships) was the easiest item to endorse (item measure = -0.68). Despite limitations, the social impact scale shows potential for optimisation in future testing.

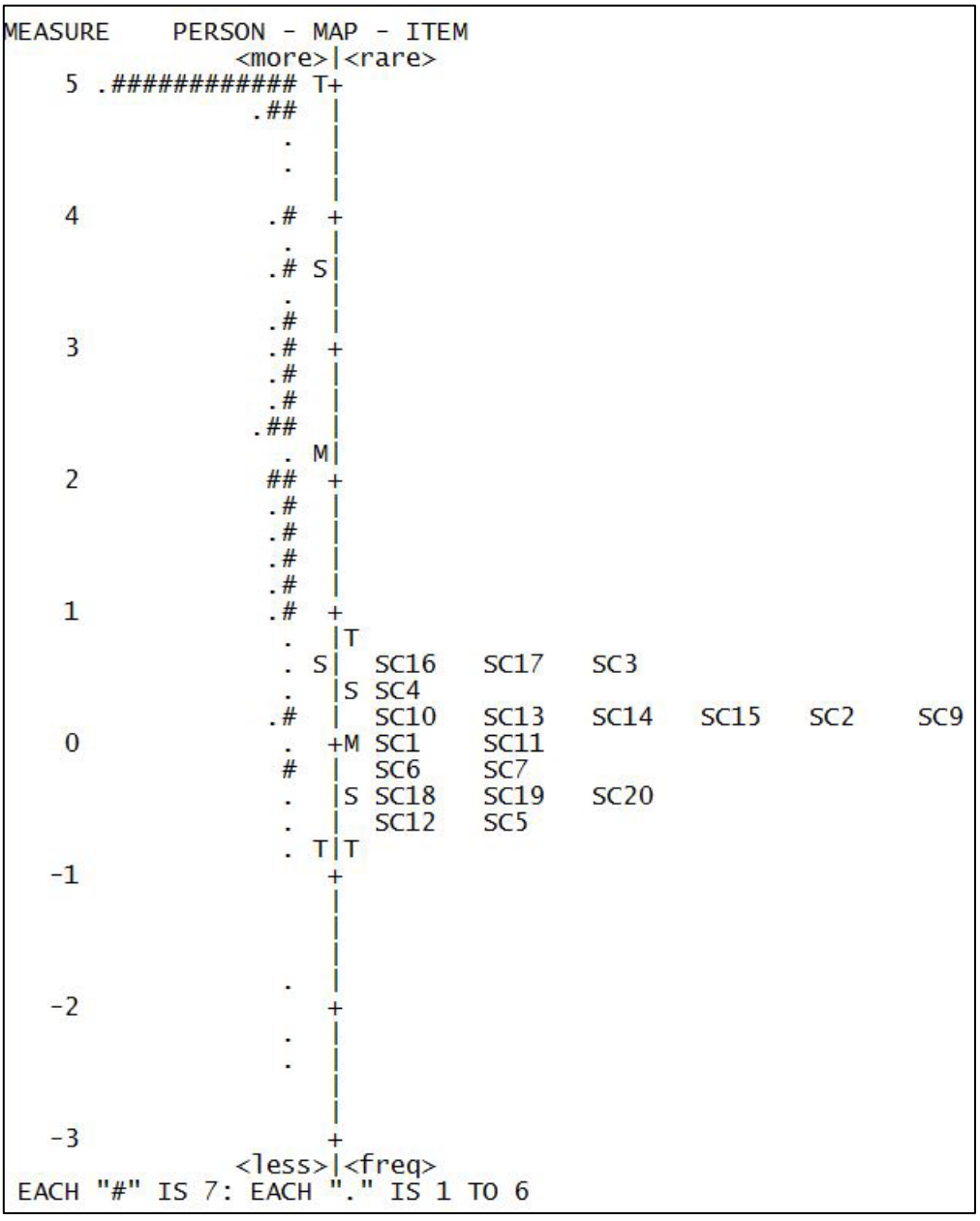

Figure 6-20 Person-Item map: Final Social impact scale

6.6.8 Convenience

The convenience item bank had a total of 24 items. It assessed the level of inconveniences persons had in relation to their eye condition. Each item preceded with the item stem 'how much trouble is...?' and was followed by five response categories: none, a little bit, a moderate amount, quite a lot and extremely. These were coded 5, 4, 3 2 and 1 respectively so that higher scores indicated lesser inconvenience (more able persons) and *vice versa*. The psychometric properties of the original scale are shown in Table 6-30.

Table 6-30 Psychometric properties of the original and final Convenience item bank

Parameters	Psychometric properties - Original Convenience scale	Psychometric properties - Final iteration
No of items / persons	24 / 299	24 / 299
No of categories	5	4
Category functioning		
Average measures	Ordered	Ordered
Threshold calibration	Disordered	Ordered
Category misfit	None	None
Separation and reliability statistics		
PSI (person reliability)	2.05 (0.81)	2.25 (0.85)
ISI (item reliability)	3.1 (0.91)	3.45 (0.92)
Item misfit		
Infit MNSQ > 1.5	CV19	None
Outfit MNSQ > 1.5	CV18, CV15	None
Targeting		
Difference between person and item means	1.04	1.23
Dimensionality (PCA of residuals)		
Variance explained by the Rasch dimension (observed / expected)	43.50% / 44.5%	43.20% / 43.9%
Variance explained by the items	7.3%	6.3%
Eigen value of the first contrast	2.66	2.69
Unexplained variance in first contrast	6.3%	6.4%
Items loading on first contrast (number, item IDs)	5 (CV 1, 4, 5, 6, 7)	6 (CV 1, 4, 5, 6, 7, 9)
Disattenuated correlation between the first and second item clusters	1.0	1.0
Measurement range	1.02 (0.51 to -0.51)	1.45 (0.73 to -0.72)

The rating scale functioning of the original convenience item bank was described earlier (section 6.5.2). The category statistics indicated ordered average measures and no category misfit; however, the thresholds were disordered. The measurement precision of the original item bank was optimal. Three items exhibited misfit.

The misfitting items were fixed by muting errant person responses and the thresholds were optimised by combining categories 2 and 3 (quite a lot and a moderate amount). Upon threshold optimisation, the measurement precision improved to 2.25 and there was no further item misfit (refer bubble chart in Appendix 10). The category statistics were optimal (Table 6-31).

Table 6-31 Category statistics of the final Convenience scale

Category code	Response category	Category count	Category %	Average measure	Infit MNSQ	Outfit MNSQ	Threshold calibration
1	Extremely	458	8	-0.39	1.15	1.20	None
2 and 3	Quite a lot and a moderate amount	1145	19	0.22	0.94	0.92	-1.02
4	A little bit	1337	23	0.91	0.91	0.87	0.43
5	None	2970	50	1.76	1.02	1.03	0.58

The PCA of residuals indicated that the variance explained by the measure (43.2%) was close to the Rasch expectations (43.9%). The eigenvalue of the first contrast was less than 3 (2.65). However, the ratio of the variance explained by the items to the unexplained variance in first contrast was very low (about 1). Six items (CV 1, 4, 5, 6, 7 and 9) loaded on the first contrast. These measured physical inconveniences associated with executing tasks; for example, items CV 1, 4 and 5 were 'having to be slower and careful', 'needing longer to do things' and 'having limitations on how long you can do things for'. These items were slightly different from other items that measured a range of inconveniences associated with their eye condition; for example, item CV10 was 'having to cover one eye to see clearly' and CV14 was 'having to wear glasses or contact lens most of the time'. However, the disattenuated correlation between the two clusters was 1 indicating that 100% of the variance was shared by the two dimensions. Moreover, removing the six items decreased the measurement precision of the main scale to sub-optimal level (PSI = 1.85). As the six items are clearly a part of the broader convenience construct and due to the lack of evidence to split the scale into two, the scale was retained as such.

The psychometric properties of the final convenience item bank are shown in Table 6-30. The measurement precision of the final scale was optimal (2.25) to distinguish at least three strata of person abilities. The ISI (3.45) indicates that the sample size is sufficient to confirm the item hierarchy. The targeting of the scale was slightly sub-standard (1.23 logits). Inspection of the person-item map (Figure 6-21) revealed the presence of a high number of more able persons in the sample tested. The

measurement range of the scale was narrow (1.45 logits); the item CV22 (when a dirt gets into your good eye) was the most difficult item to endorse (item measure = 0.73) and the item CV16 (having to use prism glasses) was the easiest item to endorse (item measure = -0.72). It is expected that the targeting and measurement range would increase in a sample with lower abilities.

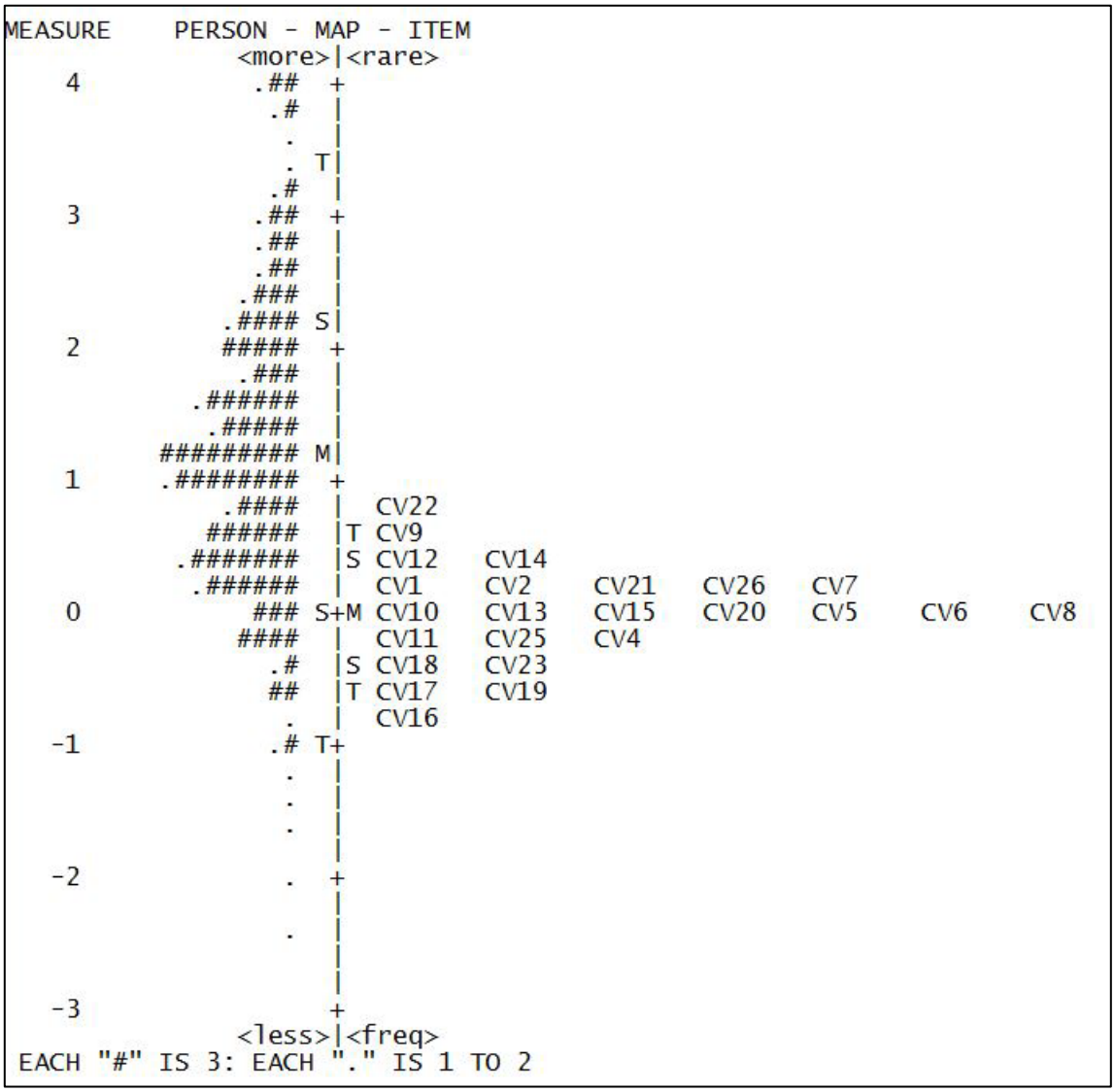

Figure 6-21 Person-Item map: Final Convenience scale

6.6.9 Economic impact

The economic impact item bank had a total of 13 items. It assessed the level of economic and financial concerns persons had in relation to their eye condition. Each item preceded with the item stem 'how concerned are you about...?' and was followed by five response categories: not at all, a little bit, a moderate amount, quite a bit and extremely. These were coded 5, 4, 3 2 and 1 respectively so that higher scores indicated lesser economic impact (more able persons) and *vice versa*. The

psychometric properties of the original scale are shown in Table 6-32.

Table 6-32 Psychometric properties of the original and final Economic impact item bank

Parameters	Psychometric properties - Original Economic impact scale	Psychometric properties - Final iteration
No of items / persons	13 / 295	13 / 281
No of categories	5	3
Category functioning		
Average measures	Ordered	Ordered
Threshold calibration	Disordered	Ordered
Category misfit	None	None
Separation and reliability statistics		
PSI (person reliability)	1.56 (0.71)	1.9 (0.78)
ISI (item reliability)	3.5 (0.92)	4.26 (0.95)
Item misfit		
Infit MNSQ > 1.5	None	None
Outfit MNSQ > 1.5	None	None
Targeting		
Difference between person and item means	0.98	0.93
Extreme responses (maximum scores), n (%)		39 (28.4%)
Non-extreme PSI (person reliability)		**2.02 (0.80)**
Targeting		**0.37**
Dimensionality (PCA of residuals)		
Variance explained by the Rasch dimension (observed / expected)	52.7% / 53.3%	48.7% / 48.6%
Variance explained by the items	26.2%	8.8%
Eigen value of the first contrast	2.93	2.65
Unexplained variance in first contrast	10.7%	10.5%
Items loading on first contrast (number, item IDs)	5 (EC1-5)	5 (EC1-5)
Disattenuated correlation between the first and second item clusters	1.0	1.0
Measurement range	0.89 (0.38 to -0.51)	1.96 (0.86 to -1.10)

PSI and targeting for non-extreme respondents in final iteration are highlighted in bold font.

The rating scale functioning of the original economic impact item bank was described earlier (section 6.5.2). The category statistics indicated ordered average measures and no category misfit; however, the thresholds were disordered. The measurement precision of the original item bank was sub-optimal. There were no item misfits observed.

The disordered thresholds were optimised by combining categories 1 and 2 (extremely and quite a bit) and 3 and 4 (a moderate amount and a little bit). Upon threshold

optimisation, the category statistics were optimal (Table 6-33) and no item misfit were observed (refer bubble chart in Appendix 10).

Table 6-33 Category statistics of the final Economic impact scale

Category code	Response category	Category count	Category %	Average measure	Infit MNSQ	Outfit MNSQ	Threshold calibration
1 and 2	Extremely and Quite a bit	699	23	-0.96	0.97	0.94	None
3 and 4	A moderate amount and A little bit	844	28	0.34	0.97	0.98	-0.69
5	Not at all	1458	49	1.54	1.04	1.09	0.69

Upon threshold optimisation, the PSI, targeting and measurement range of the scale improved from 1.56, 0.98 and 0.89 to 1.81, 0.82 and 1.57 respectively and there were no item misfits. Although the measurement precision (PSI) improved, it was still sub-optimal. Eliminating the persons with perfect scores [n= 39 (13.2%)] at this stage did not improve measurement precision (PSI = 1.82) and therefore they were reinstated. As a next attempt, the persons who were under-fitting the model [n=14 (4.75%)] were deleted and the analysis was repeated. This improved the measurement precision close to satisfactory level (PSI = 1.90). Further, eliminating the persons with perfect scores at this stage, improved the PSI to 2.02.

The PCA of residuals indicated that the variance explained by the measure (48.7%) matched the Rasch expectations (48.6%). The eigenvalue of the first contrast was less than 3 (2.65). The variance explained by the items (8.8%) was lower than the unexplained variance in first contrast (10.5%). Five items (EC 1-5) loaded on the first contrast. These items measured the direct financial costs associated with treating the eye condition; for example the item EC2 was 'how concerned are you about the cost of treating your lazy eye?' and item EC5 was 'how concerned are you about the cost of having surgery to correct you turned eye?' These items were slightly different from other items that assessed indirect forms of economic impact; for example, lost job opportunities because of not meeting occupational vision standards (EC7) and economic impact associated with limitations in performing work tasks (EC11). However, the disattenuated correlation between the two clusters of items was perfect. Removing the five items from the main scale decreased the PSI of the main scale to 1.50 and the PSI of the five-item scale was 1.42. These evidences indicate that the five items are contributing to the measurement of the broader 'economic' construct. As it would be useful to measure the holistic economic impact on a single scale, the

scale was retained as such.

The psychometric properties of the final economic impact item bank are shown in Table 6-32. The measurement precision of the final scale was optimal (2.02) for non-extreme respondents who fit the model. The high ISI (4.26) indicates that the sample size is sufficient to confirm the item hierarchy. The targeting of the scale was optimal (0.93). The person-item map (Figure 6-22) helps in visualising the spread of items and persons along the measurement continuum. The measurement range of the scale was 1.96 logits; the item EC3 (having to take time off work to go to the hospital in order to undergo treatment…) was the most difficult item to endorse (item measure = 0.86) and the item EC10 (losing your job) was the easiest item to endorse (item measure = -1.10). In general, the items measuring direct financial costs calibrated at a higher level than other items on the scale. Despite limitations in the scale's discriminatory ability for the current sample, the scale is valid for discriminating persons without perfect scores and those who fit the model.

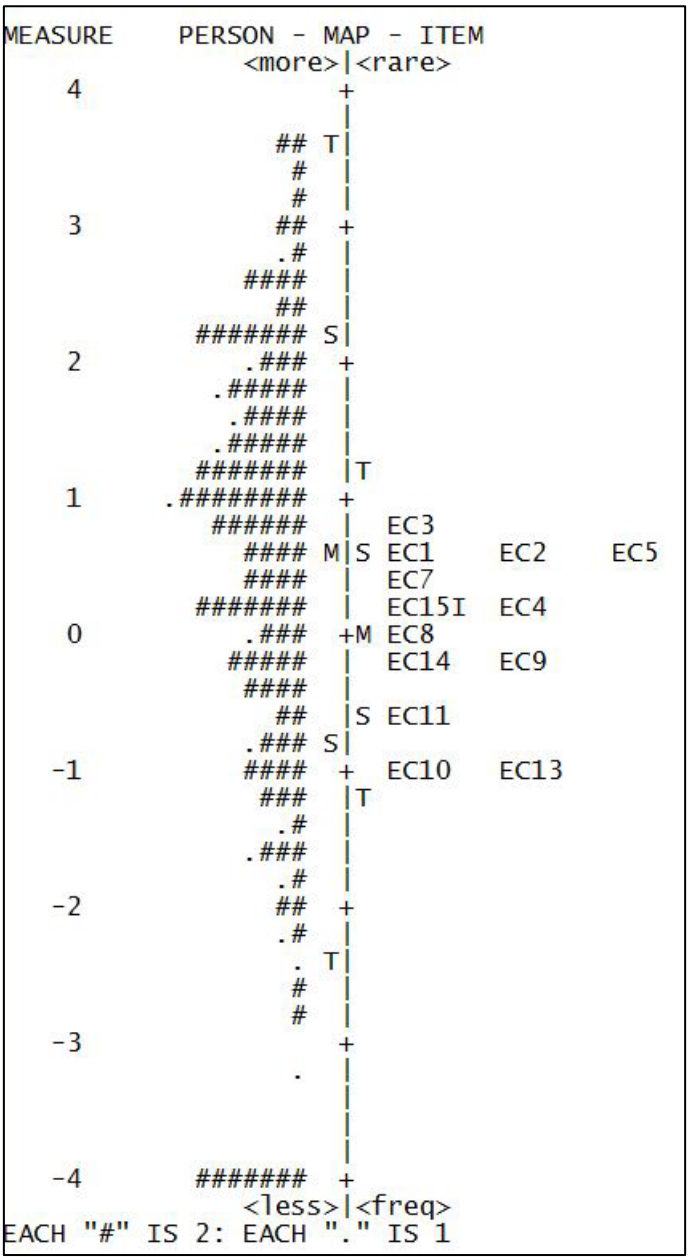

Figure 6-22 Person-Item map: Final Economic impact scale

6.6.10 Coping

The coping item bank had a total of 20 items. It assessed the level to which persons used coping strategies to combat the issues associated with their eye condition. Each item preceded with the item stem 'how much do you cope by...?' and was followed by five response categories: not at all, a little bit, a moderate amount, a lot and extremely. These were coded 1, 2, 3, 4 and 5 respectively so that higher scores indicated higher level of coping (higher use of the coping strategies) and *vice versa*. The psychometric properties of the original scale are shown in Table 6-34.

Table 6-34 Psychometric properties of the original and final Coping item bank

Parameters	Psychometric properties - Original Coping scale	Psychometric properties - Final iteration
No of items / persons	20 / 299	20 / 299
No of categories	5	3
Category functioning		
Average measures	Ordered	Ordered
Threshold calibration	Disordered	Ordered
Category misfit	None	None
Separation and reliability statistics		
PSI (person reliability)	2.06 (0.81)	2.11 (0.82)
ISI (item reliability)	7.42 (0.98)	7.62 (0.98)
Item misfit		
Infit MNSQ > 1.5	None	None
Outfit MNSQ > 1.5	None	None
Targeting		
Difference between person and item means	-0.4	-0.24
Dimensionality (PCA of residuals)		
Variance explained by the Rasch dimension (observed / expected)	38.5% / 38.8%	37.6% / 37.4%
Variance explained by the items	16.0%	16.7%
Eigen value of the first contrast	3.11	2.82
Unexplained variance in first contrast	9.6%	8.8%
Items loading on first contrast (number, item IDs)	6 (CP 14, 19, 20, 21, 23, 24)	6 (CP 14, 19, 20, 21, 23, 24)
Disattenuated correlation between the first and second item clusters	0.94	0.85
Measurement range	1.42 (0.79 to -0.63)	2.54 (1.38 to -1.16)

The rating scale functioning of the original coping impact item bank was described earlier (section 6.5.2). The category statistics indicated ordered average measures and no category misfit; however, the thresholds were disordered. The measurement precision of the original item bank was optimal and there were no item misfits observed.

The disordered thresholds were optimised by combining categories 1 and 2 (extremely and a lot) and 3 and 4 (a moderate amount and a little bit). Upon threshold optimisation, the category statistics were optimal (Table 6-35) and no item misfit were observed (refer bubble chart in Appendix 10). The PSI, targeting and measurement precision of the scale improved from 2.06, -0.4 and 1.42 to 2.11, -0.24 and 2.54 respectively.

Table 6-35 Category statistics of the final Coping scale

Category code	Response category	Category count	Category %	Average measure	Infit MNSQ	Outfit MNSQ	Threshold calibration
1	Not at all	2172	38	-1.05	0.95	0.97	None
2 and 3	A little bit and A moderate amount	1767	31	-0.02	1.02	1.09	-0.33
4 and 5	A lot and Extremely	1729	31	0.67	1.04	1.03	0.33

The PCA of residuals indicated that the variance explained by the measure (37.6%) was close to the Rasch expectations (37.4%). The eigenvalue of the first contrast was less than 3 (2.82) and the ratio of the variance explained by the items to the unexplained variance in first contrast was about 2 (1.9). Six items (CP 14, 19, 20, 21, 23 and 24) loaded on the first contrast. These items measured coping strategies that were cognitive; for example, item CP14 was 'being strong' and CP19 was 'trying not to think about your eye condition'. These are slightly different from other items that tapped into physical coping strategies and adaptations; for example, item CP1 was 'being careful' and CP8 was 'using glasses or contact lenses'. However, the disattenuated correlation between the two item clusters was 0.85 indicating that 72% of the variance was shared by the two dimensions. Moreover, removing the six items from the main scale decreased affected the measurement precision (PSI =1.8); in addition, the 6 items did not form a valid measurement scale due to low PSI (1.31). Like other item banks, as it would be useful to measure the level of coping along a single continuum, the scale was retained as such.

The psychometric properties of the final coping item bank are shown in Table 6-34. The measurement precision of the final scale was optimal (2.11) to discriminate people with atleast three levels of coping behaviour. The high ISI (7.62) indicates that the sample size is sufficient to confirm the item hierarchy. The targeting of the scale was optimal (-0.24). The person-item map (Figure 6-23) helps in visualising the spread of items and persons along the measurement continuum. The persons with a high level of coping (those who used a lot of coping strategies) can be seen along the top of the measurement continuum while those with lesser level of coping (who used the coping strategies less often) can be seen along the bottom of the measurement continuum. The measurement range of the scale was 2.54 logits; the item CP12 (withdrawing yourself from others) was the most difficult item to endorse, that is the least commonly used coping strategy (item measure = 1.38) and the item CP20 (trying to be positive) was the easiest item to endorse, that is the most commonly used coping strategy (item measure = -1.16).

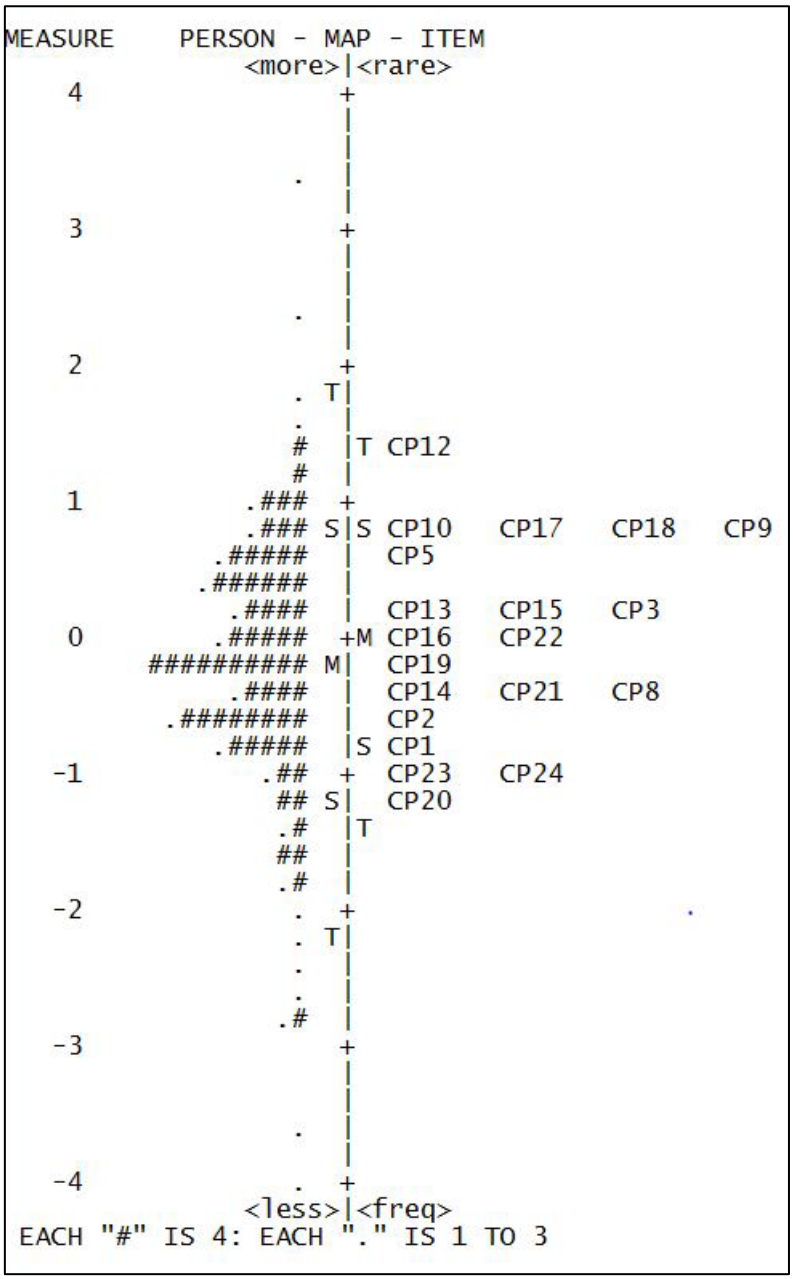

Figure 6-23 Person-Item map: Final Coping scale

6.7 Differential item functioning (DIF)

The sub-groups of sample were tested for DIF by 1) gender (male vs female) 2) age (less than 40 years vs 40 years and above) (3) education (degree or higher qualification vs diploma, certificate or lower qualification) 4) occupation (employed vs unemployed) 5) language of questionnaire (English vs Indian languages – Hindi and Tamil) 6) presence of amblyopia (amblyopia vs isolated strabismus) 7) presence of strabismus (strabismus vs isolated amblyopia) and 8) visual acuity (6/19 or better vs worse than 6/19). The results are elaborated below. The supporting person DIF plots for each variable are provided in Appendix 11.

6.7.1.1 DIF: Gender

DIF was assessed by gender: male (n=192) and female (112). Out of the 12 scales validated in this study, 9 scales namely symptoms - frequency, symptoms-severity, mobility, concerns, emotional impact, social impact, convenience, economic impact and coping did not exhibit any item bias when tested by gender. 3 items (0.9% of the total 338 items) from the other three scales namely symptoms-bothersome, activity limitation and driving exhibited notable DIF that was statistically significant (Table 6-36).

Table 6-36 Items exhibiting DIF by gender

Scale (No. of items showing DIF)	Items exhibiting DIF		DIF contrast	p-value
	Easier to endorse by males	Easier to endorse by females		
Symptoms – bothersome (n=1)	-	VSB11 Ghost images or shadows around objects you see	1.22	0.0034
Activity limitation (n=1)	AL7 Putting on eye make-up)	-	-1.7	<0.001
Driving (n=1)	-	AL55 Reversing your car	1.73	0.0059

Closer examination of the content revealed that the item AL7 (Putting on eye-make up), being an irrelevant question for males was calibrated at a higher difficulty level for females than males, indicating gender bias. The item AL55 (reversing the car) in the driving scale, on the other hand, was easy for females than males. However, on examining the response frequencies, it was found that the sample had very few female car drivers. As a result, this question was answered by very few females (n=20) compared to males (n=90); for more stable and reliable calibration, administering the questionnaire to more female drivers is recommended. The DIF plots for all scales in which the item measures for both genders as well as the baseline (measures in the absence of DIF) were plotted are shown in Appendix 11.

6.7.1.2 DIF: Age

DIF for all scales were assessed by age – less than 40 years (n=255) and 40 years and above (n=49). The cut-off of 40 years was chosen taking into consideration that persons over 40 years may have presbyopia and may perceive items differently compared to younger group. Out of the 12 scales, six scales namely symptoms (severity), activity limitation, driving, mobility, concerns, emotional impact, convenience and coping lacked evidence of any item bias. 14 items (4.1%) showed notable DIF that was statistically significant (Table 6-37).

Table 6-37 Items exhibiting DIF by age

Scale (No. of items showing DIF)	Items exhibiting DIF		DIF contrast	p-value
	Easier to endorse by younger group (less than 40 years)	Easier to endorse by older group (40 years and above)		
Symptoms-frequency (n=1)	VSF10 Double vision when tired)		-1	0.0004
Symptoms-bothersome (n=2)	VSB10 Double vision when tired		-1.06	0.0003
		GSB6 Sleepiness while reading	1.41	0.0001
Mobility (n=2)	MB2 Going up steps or stairs		-1.05	0.0021
		MB12 Noticing things to the side of the affected eye while moving around	1.24	0.0002
Concerns (n=7)		HC23 People judging you wrongly	1.14	0.0036
		HC24 People passing comments about your eye condition	1.18	0.0013
		HC25 Being bullied or teased	1.29	0.0032
		HC27 Being treated differently	1.02	0.0173
	HC33 Tripping		-1.04	0.0005
	HC34 Falling		-1.08	0.0003
	HC37 Experiencing double vision		-1.01	0.0008
Social impact (n=1)		SC14 Socialising because people comment on your eyes	1.00	0.0152
Economic impact (n=1)		EC7 Not meeting vision requirements for certain jobs	1.17	0.0416

The item ‘double vision when tired’ showed significant DIF on two out of the three scales of symptoms namely frequency and bothersome; although notable DIF was not observed in the symptoms- severity scale, moderate DIF was evident (DIF contrast = -0.88; p-value = 0.0022). On examining the content, it was evident that the older group were more symptomatic of double vision when tired, had more difficulty in using stairs and were more concerned about experiencing double vision, tripping and falling. In contrast, the younger group were more concerned about psychosocial issues (e.g. being bullied, socialising) and about not meet occupational vision standards. However, these findings should be substantiated with larger sample size as this study sample had fewer older people compared to younger. The DIF plots by age

for all scales are presented in Appendix 15.

6.7.1.3 DIF: Education

The sample was classified into two sub-groups based on education – persons who had completed degree or higher qualification (n= 176) and those who had diploma, certificate or lower qualifications (n=116). These groups were assessed for DIF based on their level of education. None of the items across the 12 scales exhibited any notable DIF. The DIF plot by education for all the scales are presented in Appendix 11.

6.7.1.4 DIF: Occupation

The sample was classified into two sub-groups based on their employment status. The first group comprised of all those who were currently employed (n=149) and the second group included students, unemployed and personnel who had retired from work (n=113). None of the items across the 12 scales exhibited any notable DIF. The DIF plot by occupation status for all the scales are presented in Appendix 11.

6.7.1.5 DIF: Questionnaire language

To examine the presence of any item bias based on translation, the sample was assessed for DIF based on the language of questionnaire they had answered. Due to the small number of persons who had answered the Tamil version (n=45) in comparison to Hindi (n=74) and English versions (n=185), the sample was classified into two groups – those who answered in English (n=185) and in either Hindi or Tamil (Indian languages, n=119) and DIF was assessed for these two groups. None of the items across the 12 scales exhibited any notable DIF which substantiates cross validation across the languages. The DIF plots by questionnaire language for all the scales are presented in Appendix 11.

6.7.1.6 DIF: Presence of amblyopia

As the study sample had respondents with a range of amblyopia and strabismus diagnosis, the presence of DIF was assessed based on the presence and absence of amblyopia. The first group comprised of those with amblyopia, irrespective of type (n=156) and the second group comprised of those with isolated strabismus (without amblyopia, n=133). Out of the 12 scales, eight scales namely activity limitation, driving, mobility, concerns, emotional impact, convenience, economic impact and coping had no notable DIF. 15 items (4.4% of the total 338 items) from the other 4 scales displayed notable DIF that was statistically significant (Table 6-38).

Table 6-38 Items exhibiting DIF by the presence of amblyopia

Scale (No. of items showing DIF)	Items exhibiting DIF		DIF contrast	p-value
	Easier to endorse by amblyopia group	Easier to endorse by isolated strabismus group		
Symptoms-frequency (n=6)		VSF4 Poor vision in one eye	2.38	<0.0001
		VSF5 Poor peripheral vision (side vision) in the affected eye	1.17	<0.0001
	VSF9 Double vision		-1.16	<0.0001
	VSF10 Double vision when tired		-1.22	<0.0001
	OSF11 Misalignment of your eyes (Squint eyes)		-1.5	<0.0001
	OSF12 Misalignment of your eyes (Squint) when tired		-1.15	<0.0001
Symptoms – Severity (n=4)		VSS4 Poor vision in one eye	2.37	<0.0001
	VSS9 Double vision		-1.16	<0.0001
	VSS10 Double vision when tired		-1.05	<0.0001
	OSS11 Misalignment of your eyes (Squint eyes)		-1.23	<0.0001
Symptoms – Bothersome (n=4)		VSB4 Poor vision in one eye	1.68	<0.0001
	VSB9 Double vision		-1.14	<0.0001
	VSB10 Double vision when tired		-1.1	<0.0001
	OSS11 Misalignment of your eyes (Squint eyes)		-1.26	<0.0001
Social impact (n=1)	SC18 Socialising because you experience double vision		-1.23	0.0001

Out of the 15 items that showed significant DIF, 14 were from the symptom scales. As expected, the DIF investigation pointed out the symptoms that calibrated at a higher level (harder) for those with amblyopia (e.g. poor vision in one eye) and those with isolated strabismus (e.g. double vision). The DIF plot by the presence of amblyopia for all scales are presented in Appendix 11.

6.7.1.7 DIF: Presence of strabismus

The DIF was also assessed based on the presence and absence of strabismus. The sample was classified into two groups – those with strabismus which included persons with strabismic, combined-mechanism amblyopia and isolated strabismus (n=236)

and those with isolated amblyopia (without strabismus, n=63). Out of the 12 scales, 4 scales namely activity limitation, driving, emotional impact and coping did not exhibit any DIF. 21 items (6.21%) from the other 8 scales showed notable DIF that was statistically significant (Table 6-39).

Table 6-39 Items exhibiting DIF by the presence of strabismus

Scale (No. of items showing DIF)	Items exhibiting DIF		DIF contrast	p-value
	Easier to endorse by strabismus group	Easier to endorse by isolated amblyopia group		
Symptoms-frequency (n=4)	VSF4 Poor vision in one eye		-1.79	<0.0001
		VSF10 Double vision when tired	1.06	0.0027
		OSF11 Misalignment of your eyes (Squint eyes)	2.88	<0.0001
		OSF12 Misalignment of your eyes (Squint) when tired	2.52	<0.0001
Symptoms – Severity (n=4)	VSS4 Poor vision in one eye		-1.59	<0.0001
		VSS9 Double vision	1.16	0.001
		OSS11 Misalignment of your eyes (Squint eyes)	2.7	<0.0001
		OSS12 Misalignment of your eyes (Squint) when tired	2.21	<0.0001
Symptoms – Bothersome (n=3)		VSB9 Double vision	1.47	0.0003
		OSB11 Misalignment of your eyes (Squint eyes)	2.41	<0.0001
		OSB12 Misalignment of your eyes (Squint) when tired	2.01	<0.0001
Mobility (n=1)		MB14 Walking when you experience double vision	1.18	0.0016
Concerns (n=5)	HC12 Becoming blind		-1.25	<0.0001
		HC14 Having a misaligned or turned eye (squint)	1.27	<0.0001
		HC19 Having eye contact with people while talking	1.1	<0.0001
		HC60 The outcome of strabismus (squint) surgery	1.45	0.0008
		HC61 Recurrence of strabismus even after treatment	1.46	0.0003

Social impact (n=2)		SC16 Socialising because people are unsure about which eye to look at	1.8	0.0004
		SC17 Socialising because of not being able to maintain eye contact	1.03	0.0001
Convenience (n=1)		CV18 Having to undergo multiple eye operations to correct the turned eye (squint)	1.78	0.0042
Economic impact (n=1)		EC5 The cost of having surgery to correct your turned eye (squint)	1.39	0.0072

18 out of the 21 items calibrated at a higher level (harder) for the strabismus group and were easier to endorse by those with isolated amblyopia. On examining the content, it is clear that these items are irrelevant to those with isolated amblyopia (e.g. misalignment of eyes) and hence the DIF. The DIF plots by the presence of strabismus are presented in Appendix 11.

6.7.1.8 DIF: Visual acuity

The study sample with amblyopia was classified into two groups based on the visual acuity in their amblyopic eye (unilateral amblyopia) and worse eye (bilateral amblyopia) – the first group comprised of persons with visual acuity 6/19 or better (n=87) and the second group comprised of persons with visual acuity worse than 6/19 (n=68). The cut-off 6/19 was chosen as it denotes low vision in one eye.[419] Nine out of the 12 scales did not show any notable DIF. 4 items (1.2% of the total 338 items) from the other 3 scales exhibited notable DIF that was statistically significant (Table 6-40). The DIF plots by visual acuity are presented in Appendix 11.

Table 6-40 Items exhibiting DIF by visual acuity

Scale (No. of items showing DIF)	Items exhibiting DIF		DIF contrast	p-value
	Easier to endorse by those with VA 6/19 or better	Easier to endorse by those with VA worse than 6/19		
Symptoms-frequency (n=1)	VSF4 Poor vision in one eye		-1.42	0.0002
Symptoms – Severity (n=2)	VSS4 Poor vision in one eye		-1.25	0.0002
	VSS5 Poor peripheral vision (side vision) in the affected eye		-1.05	0.0002
Social impact (n=1)		SC18 Socialising because you experience double vision	1.19	0.0203

6.7.1.9 DIF Summary

The number of items that exhibited DIF with respect to each variable and the total number of unique items showing DIF in each scale are summarised in Table 6-41. No DIF was observed in the emotional impact and coping item banks. Minimal DIF (n=1) was observed in the activity limitation, driving and convenience item banks and highest DIF (n=12) was observed in the concerns item bank.

Table 6-41 Summary of the number of items showing DIF in each item bank

Scales	No. of items exhibiting notable and statistically significant DIF by								No. of unique items*
	Gender	Age	Education	Occupation	Questionnaire language	Presence of amblyopia	Presence of strabismus	Visual acuity	
Symptoms - frequency	0	1	0	0	0	6	4	1	6
Symptoms - Severity	0	0	0	0	0	4	4	2	6
Symptoms - Bothersome	1	2	0	0	0	4	3	0	7
Activity limitation	1	0	0	0	0	0	0	0	1
Driving	1	0	0	0	0	0	0	0	1
Mobility	0	2	0	0	0	0	1	0	3
Concerns	0	7	0	0	0	0	5	0	12
Emotional impact	0	0	0	0	0	0	0	0	0
Social impact	0	1	0	0	0	1	2	1	4
Convenience	0	0	0	0	0	0	1	0	1
Economic impact	0	1	0	0	0	0	1	0	2
Coping	0	0	0	0	0	0	0	0	0

*Total number of unique items exhibiting DIF across all variables tested in each item bank

6.8 Preliminary results: Australian item bank

A preliminary analysis of the data collected in Australia was carried out with a sample size, n=55. 39 (70.9%) participants completed the online survey and 16 (29.1%) filled the paper questionnaire. The demographics and clinical characteristics of the participants is provided in Appendix 12 and the psychometric properties resulted from the preliminary evaluation is summarised in the table in Appendix 13.

The response category function of the item banks was detailed in section 6.6.2.7. All item banks except, the mobility, social impact, convenience and economic impact had optimal measurement precision. The PSI ranged from 4.04 (concerns) to 1.0 (social impact) and the ISI ranged from 4.02 (activity limitations) to 0.52 (social impact). Except symptoms-frequency, concerns and coping, all item banks had sub-optimal targeting with person-item mean difference >1. Misfitting items and large eigenvalues (>3) were evident in all item banks.

6.9 Discussion

This chapter presented the psychometric validation of the twelve item banks developed for adults with amblyopia and/or strabismus using Rasch analysis. Following initial evaluations, the Indian item banks were optimised to produce valid psychometric measurement of all important QoL dimensions recognised by adults with amblyopia and strabismus in Chapter 4. This is the first set of item banks developed for this disease group and has great potential for further development and application via a CAT system.

In the preliminary analysis, seven out of the twelve item banks exhibited disordered thresholds and the pattern of disordering was consistent across questionnaire languages (English vs Indian languages) and population (India vs Australia). Although disordered thresholds do not violate the Rasch model, it is an indication that the probability of endorsing categories from easy to hard is not progressing with increasing person measures.[387] This precludes item-category level inferences.

It was interesting to note that item banks that used difficulty type rating scale (activity limitations, driving and mobility) and frequency type rating scale (emotional, except symptoms) had ordered thresholds. This means that these response categories were interpreted and used as intended.[387] In contrast, the other rating scales had

underutilised response categories representing narrow intervals on the latent variable. This suggests that these were difficult for participants of this disease group to discriminate.[243] Similar findings were observed in general function subscale of the adult strabismus questionnaire[212] and the amblyopia and strabismus questionnaire.[75] Following these examples, the disordered thresholds were remediated by combining adjacent categories. Improvement in person reliability, separation index and measurement range further substantiated this decision. The final item banks had ordered thresholds and optimal category functioning. In future, it is recommended to test the optimised item banks with new set of data to see if the exploratory manipulation of these categories holds up upon replication.

In the final iteration, all except the mobility, social and economic impact item banks exhibited optimal measurement precision. Out of those with optimal precision, the PSI was highest for the concerns item bank (3.6) and lowest for the coping item bank (2.11). The measurement precision of the three item banks with sub-optimal PSI improved to acceptable standards when estimated for non-extreme respondents. This indicates that the discriminatory ability of the scale is satisfactory for respondents whose abilities are estimable by the scales. Extreme scores correspond to zero and perfect scores (ceiling effect); these do not contribute to the construction of measurement[355] and are dropped for estimating parameters.[365] They are then reinstated and imputed with reasonable measures. Thus, omitting them improved measurement precision. Maximum benefit was observed for the social impact scale whose PSI improved from 1.72 to 2.50. It would be interesting to examine the measurement precision by administering these item banks to a sample with wider range of abilities in the future.

The difference between person and item means was more than 1 logit for nine out of the twelve item banks. Targeting is sample dependent; [219, 243, 404] large positive mean differences observed in the item banks indicates that the sample used for validation has more able persons than the range of item difficulties.[396] This is substantiated by the ceiling effect observed in the frequencies of response categories; interestingly, the item banks with the highest ceiling effects (mobility and social impact) had the worst targeting. Mistargeting in these cases can be addressed by adding more difficult items or by administering the item banks to people with lower abilities.[243, 253] As the development of the item banks followed an extensive item identification and selection process, it is less likely that any relevant item is left out. However, addition of new items and recalibration is possible with item banking; this can be done in later stages

when the item banks are implemented via a CAT system. Despite the sample being more able, targeting was optimal for the concerns, economic impact and coping item banks. This indicates that these QoL domains are important and relevant even to those with higher abilities and who were less impacted across traditionally assessed functional domains (i.e. activity limitation, mobility). This reinforces the importance of selecting QoL domains that are important and relevant to the disease population as an outcome measure for clinical trials.

Unidimensionality is a fundamental property of measurement.[89] If a scale measures more than one construct, the results and scores are more ambiguous due to noise and it would be difficult to discern how much of what is measured. However, in reality achieving absolute unidimensionality is challenging due to differences in cognition, personality and experiences of test-takers.[371] Moreover it is likely for items measuring similar content to group together in large questionnaires such as item banks. This may not indicate multidimensionality but instead strands of the primary dimension. Such scales may not be statistically unidimensional but can be thought of as unidimensional for practical purposes. This was true for all the twelve item banks validated in this chapter. After thorough investigations of misfit, unexplained variance, eigenvalue, disattenuated correlation and agreement[2], the scales were considered adequately unidimensional for meaningful measurement.

For instance, in the activity limitations item bank validated in this chapter, items measuring limitations in sports, using electronic gadgets and reading clustered together resulting in large eigenvalues. Similarly, the items measuring psychosocial concerns in the concerns item bank grouped together. However, on further evaluation, the item banks were deemed practically unidimensional. Using several sub-scales to measure strands of primary construct would be tiresome and difficult to implement in routine clinical practices. Nevertheless, this can be useful when the objective is specific (e.g. measuring reading ability) rather than comprehensive (e.g. measuring activity limitation). As the aim of this doctoral research was to develop item banks, deriving short forms of subscales was not a priority, although this can be easily constructed from the item banks.

Differential item functioning indicates item bias,[372] the presence of which distorts measurement and precludes meaningful comparison between sub-groups of the sample, different populations and settings.[411] Therefore, the chapter investigated DIF with respect to major demographic and clinical variables. The absence of DIF by

questionnaire language indicates that there are no significant systematic differences in the pattern of responses given by the group of participants who answered the questionnaire in English and Indian languages. This demonstrates cross linguistic validation. However, due to limited sample size, DIF evaluations between groups of respondents who answered the Tamil and Hindi versions was not possible at this stage and is recommended in future to establish equivalence between the two translations.

The evaluations with respect to the presence of amblyopia (amblyopia versus isolated strabismus and the presence of strabismus (strabismus versus isolated amblyopia) identified 15 (4.4%) and 21 (6.2%) items exhibiting DIF. Majority of these items were from the three symptom item banks; this finding is not surprising due to inherent differences in disease characteristics. The overall small percentage of items showing DIF by diagnosis substantiates the decision made in Chapter 4 to develop common item banks for both amblyopia and strabismus. In future stages, these items would receive disease-specific calibrations to set up CAT.

Despite small sample size, the preliminary analysis of the data from Australia showed promising results; in particular, the activity limitations and concerns item banks had excellent measurement precision. As expected, the item separation indices were generally low suggesting that the sample size is inadequate to confirm item hierarchy. For the given sample, targeting was optimal for the symptoms-frequency and concerns item banks. The large positive person-item mean difference in other item banks indicates that the sample is more able. Thus, care should be taken to include those with potentially lesser ability in future data collection. On comparing the results of the Australian and Indian item banks, it was obvious that the Australian item banks had wider measurement range. This is surprising given the relatively smaller sample size used for validating the item banks in Australia. Although it is early to comment, this finding substantiates the qualitative inference (Chapter 4) that the individuals in Australia more readily related their QoL issues with their eye condition than those in India. If this holds true, the final Australian item banks would have greater precision and better targeting inherently.

The strengths of this study were the use of a psychometric model that conforms to the principles of measurement[89] and an evidence-based systematic methodological approach.[2] Collaborating with a renowned tertiary eye care hospital was advantageous as it was possible to recruit participants from diverse cultural background across India.

Selection bias may be present in the current sample used for validation as majority was recruited from a hospital set up which may not represent the entire population. QoL parameters estimated in a hospital-based sample could be different to those who do not seek care. However, the aim of this research was not to evaluate or compare the level of impact but rather to validate the item banks. The distinguishing property of Rasch analysis is invariance; that is, the ability to provide sample-free estimates of item difficulties.[381] Hence the presence of selection bias is not expected to influence the item calibrations largely.

The current sample was considerably younger with more than 80% under 40 years of age. As comorbidities such as cataract are common in older people, it is likely that they were excluded from the study. This sample, however represented the amblyopia and strabismus population that visited the hospital. The qualitative study in Chapter 4 recognised that as participants aged, they learnt to live with their eye condition. This could be the reason for the smaller number of older individuals that visited the hospital for this eye condition. Typically, this should not affect the validation and item calibrations and should be confirmed by DIF analysis with a greater number of older individuals.

Although much care was taken to recruit participants with a range of abilities as measured by clinical parameters such as visual acuity and ocular deviation, the sample had a greater number of able persons. As the level of impact or ability depends not only on the clinical characteristics but also on other factors such as need and perception, it is not easy to predict the individual ability based on the severity of the disease alone. Therefore, it is recommended to iteratively analyse the data with increasing sample size. This dynamic calibration is possible via CAT system and is the future scope of this research project.[157]

The guidelines used for the psychometric evaluation of the item banks validated in this chapter are quite lenient than the quality assessment criteria proposed for fixed short form questionnaires.[92, 131, 152, 253, 254] This is however acceptable as revalidation and constant upgradation are possible with item banking.[3, 157] Moreover, the goal in the construction of item banks is to accommodate as much relevant items as possible, in contrast to the selection of the best items in short forms. It is expected that the measurement properties of the item banks will improve in future stages. Implementing the item banks via a CAT system would enable customised administration of items with maximum information for each respondent, thereby

facilitating more valid and precise measurement.[164] In the next phase, more data would be collected on the item banks and other measures of validity and reliability would be assessed.

CHAPTER 7 COMPUTER ADAPTIVE TESTING SIMULATION OF THE INDIAN ITEM BANKS

7.1 Introduction

The scope of CAT in health care is being explored by several studies. According to Jensen et al, 2015, clinical application of PROMs could be used for needs assessment, clinical decision making, management of symptoms, assessment of outcomes and quality improvement.[420] Although not widely used yet, several initiatives are being taken to develop and implement the CAT systems. For instance, the PROMIS group (Patient-Reported Outcomes Measurement Information System) has developed several web-based CAT applications to measure constructs such as pain and fatigue.[150, 155] These applications could also be downloaded as an app in electronic devices. The PEDI-CAT and the kids-CAT are other examples.[421, 422]

Chapter 6 presented the psychometric evaluation and validation of the twelve Indian item banks developed for measuring the QoL impacts of amblyopia and strabismus. This chapter presents the CAT simulations that were carried out to test the efficiency of these item banks. These simulations help in estimating the number of items that would be required for precise measurement of the QoL constructs and provide preliminary evidence about the usefulness of developing CAT platforms for these item banks in future.

7.1.1 Computer adaptive testing

Irrespective of whether an item is relevant to a person or not, traditional tests requires all respondents to answer all items, posing unnecessary respondent burden.[423] The burden is particularly great when the test is long. Such tests take more time to complete and therefore cannot be easily implemented in busy clinical practices.[154] A CAT system overcomes these disadvantages by enabling selection of items that are most appropriate (most informative) for each individual.[154] Customisation of the test is possible through an algorithm which is driven by a set of item selection and stopping rules.[151, 164]

Based on clinical, demographic or other characteristics, item selection rules can be applied to avoid presentation of items that are irrelevant to an individual (e.g. driving items to those who do not drive).[2, 424] Likewise, CAT could be programmed to include one or two items from each sub-dimension so the whole range of construct would be

covered in the test (via item usage/ exposure control rules).[425] For instance, an algorithm can be written such that the CAT includes items on both reading and sports when administering the activity limitations item bank developed in this doctoral work. Although different individuals may answer different sets of items on a CAT, comparison of scores is meaningful as the items are drawn from the same calibrated item bank.[164]

7.1.2 CAT logic

A typical CAT logic[151] is presented in the Figure 7-1. The test starts with a preliminary estimate of a person (person ability measure or theta).[151] The first item presented is usually the item with average difficulty.[93] The participant's response to that item is scored and the interim theta and confidence interval is estimated. Based on this estimate, the next informative item (item whose measure matches the estimated interim theta) is presented. The test is repeated until the stopping rule is satisfied. Stopping rule can be a fixed length of items (e.g. abort test after administering 5 items) or standard error (SE).[151, 423] Being able to set the standard error allow the investigators to control the level of precision required. For instance, a low standard error (SE = 0.387) can be set for high precision (reliability = 0.85) which is a priority in clinical trials.[93] In contrast, a high standard error (SE = 0.521) can be set for moderate precision (reliability = 0.72) which can be used in busy clinical practices.[93]

A battery of tests, for instance the twelve QoL item banks developed in this research can be administered consecutively using CAT. Once the person ability is estimated on a scale (e.g. symptoms), the CAT system proceeds with assessment of the next scale (e.g. activity limitations) until the entire battery of tests are exhausted (Figure 7-1).

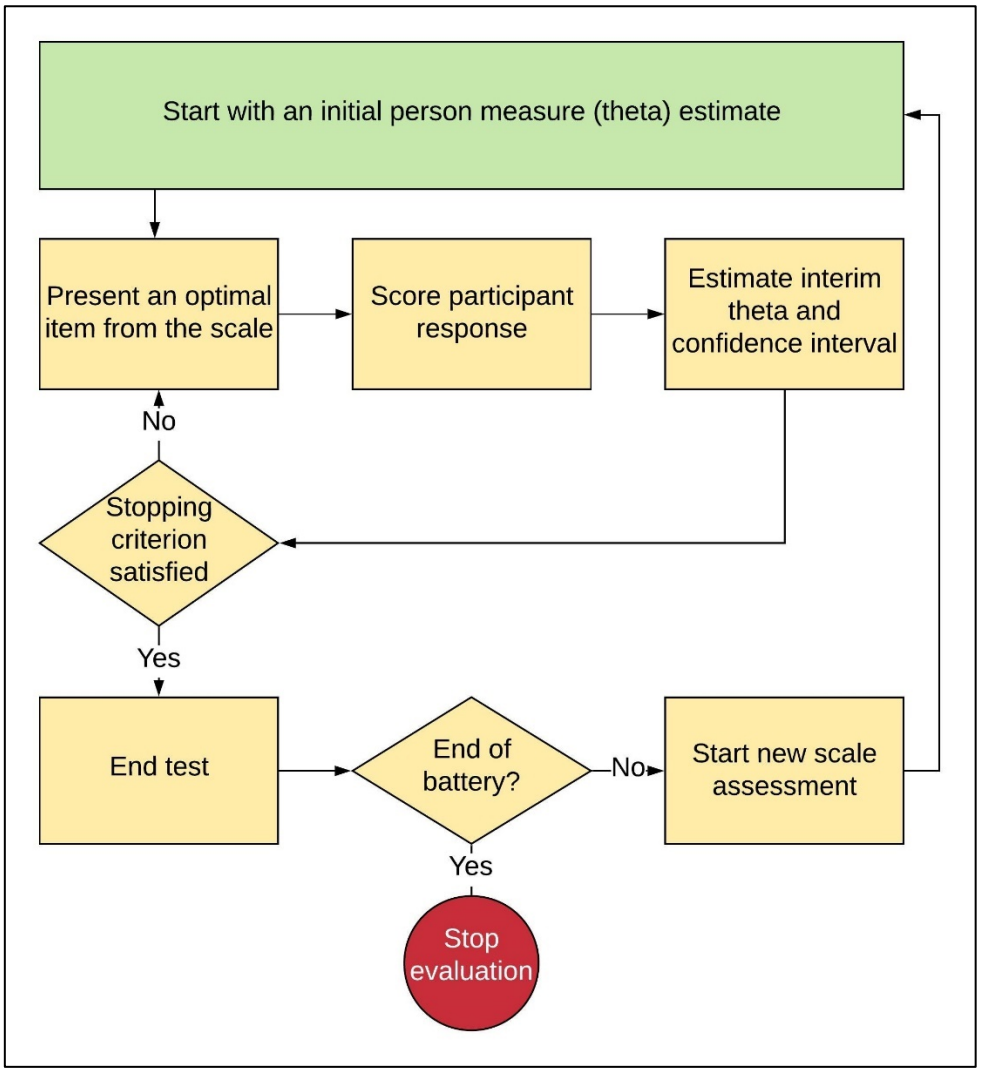

Figure 7-1 CAT logic (adapted from Bjorner *et al*., 2005)[151]

7.1.3 CAT illustration

Below is an illustration of CAT from the activity limitations item bank simulation carried out in this chapter. The Figure 7-2 shows the CAT theta audit trail for examinee (respondent) 998. The sequence of items presented, the corresponding responses, interim theta (person measure) estimates with 95% confidence intervals and the final theta can be visualised.

The test started with the item 31 (How much difficulty do you have in writing in a straight line? Options: none - 5, a little – 4, quite a bit – 3, a lot – 2 and unable to do because of my eye condition – 1). The participant's response to that item was 1 and the interim theta estimated was about -1.00 logit. As the estimated theta indicates that the person is less able, easier items targeting that level of participant ability were presented; item 31 was followed by items 1 (cooking), 6 (cutting fingernails and toenails safely) and item 2 (cutting or chopping vegetable or food) for which the

participant responses were 2, 2 and 3. As the set standard error of 0.527 (moderate precision) was reached, the test aborted with the item 2. The test length for this examinee was 4 items and the estimated person ability (theta) was -1.44 (SE =0.49).

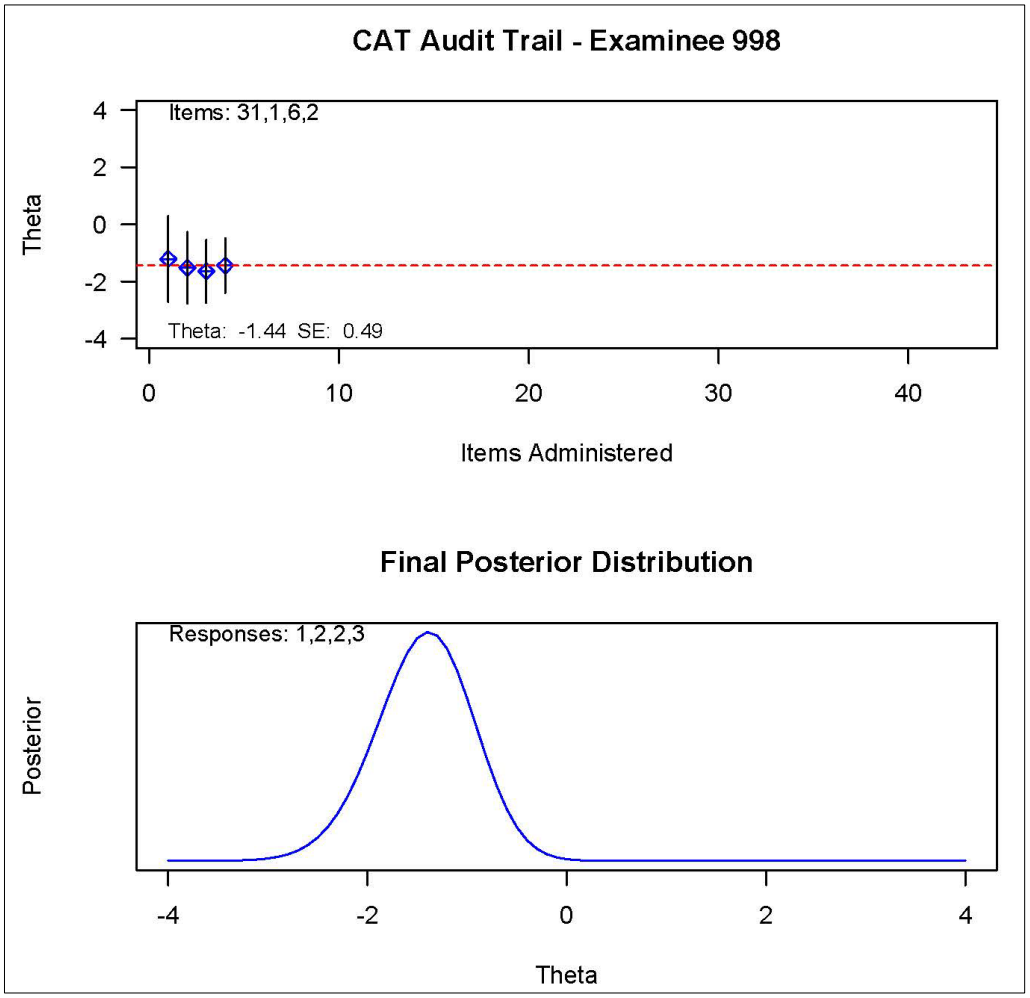

Figure 7-2 Theta audit trail for examinee 998 (CAT simulation of activity limitations item bank) from Firestar CAT simulation software

Items presented and the corresponding participant responses are displayed in the top and bottom figures respectively. The interim theta estimates and confidence interval are given by the blue dots and whiskers and the final theta is given by the red dotted line in the top figure. A total of 4 items were required to obtain moderate precision. The item 31 was the first item administered, followed by items 1, 6 and 2. The final theta estimated was -1.44 (standard error = 0.49).

The length of CAT depends on the desired precision and the measurement range of the item bank.[93] More items would be required to achieve higher precision than that required for moderate precision[93] (Figure 7-3) and fewer items would be required when the person ability (final theta) is well targeted by the range of item difficulties in the item bank (Figure 7-4).[426] These figures are also from the activity limitation item bank CAT simulation performed in this chapter.

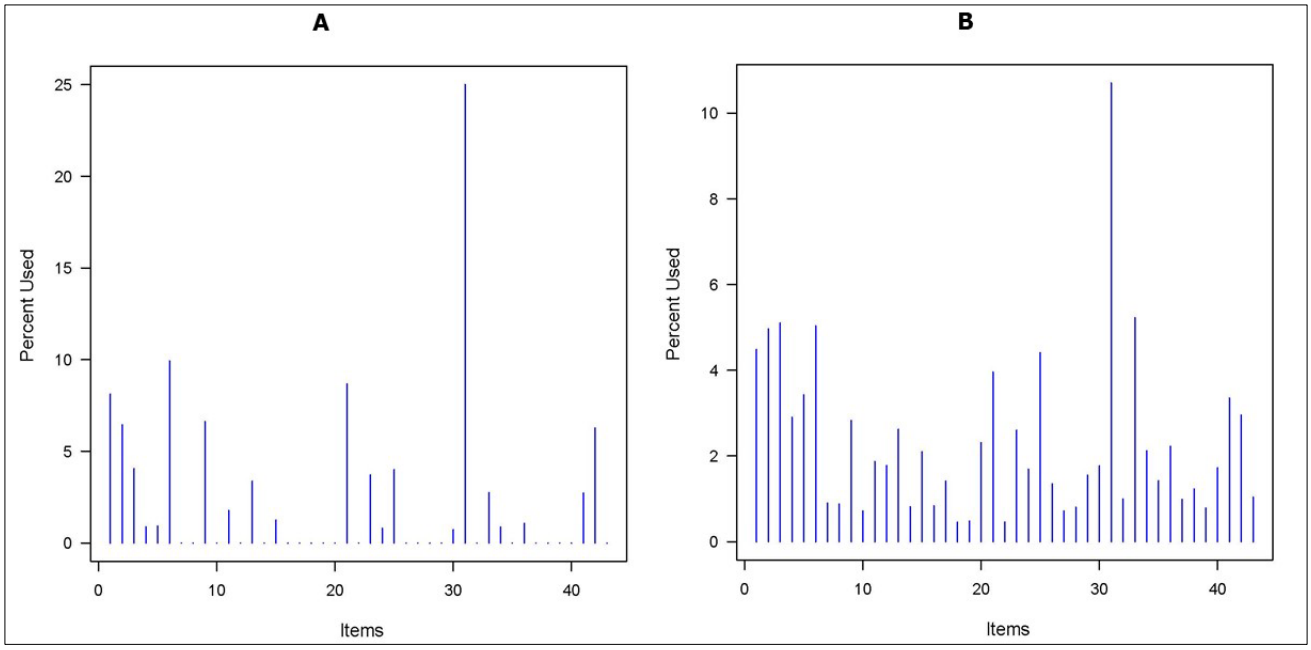

Figure 7-3 Item usage for activity limitations item bank: moderate vs high precision

The percentage of items used is calculated by dividing the total number of times each item is used by the total number of items administered across all respondents. Comparing A (moderate precision) and B (high precision), it is evident that fewer items are required for moderate precision and some items were never used. In both cases, item 31 was the most commonly administered item.

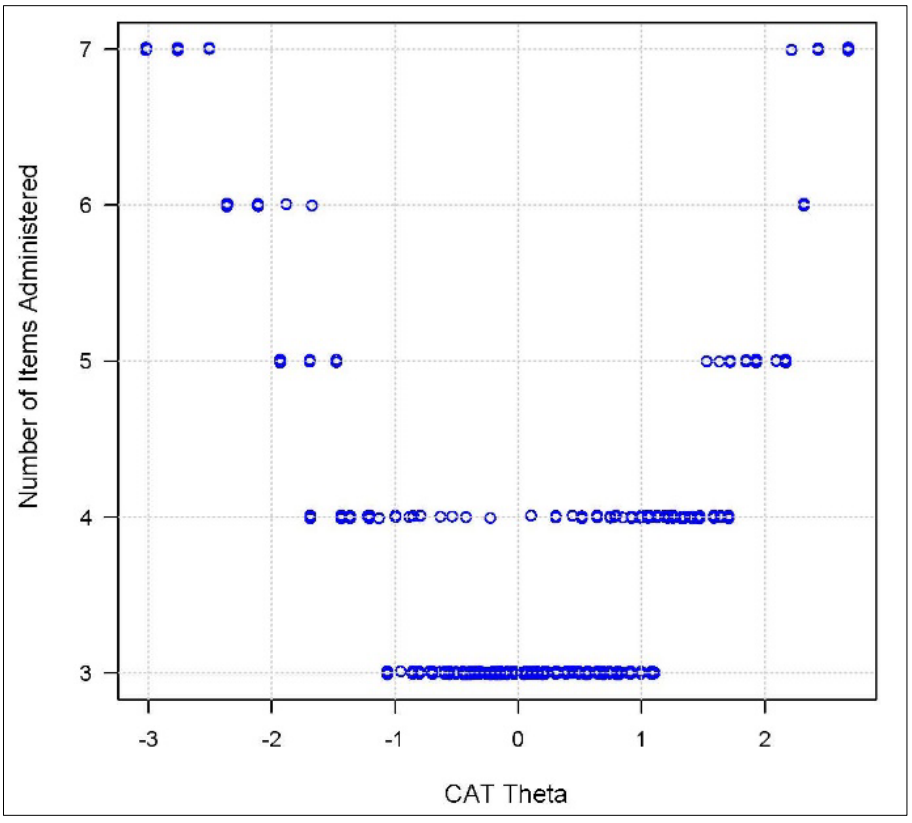

Figure 7-4 Number of items administered as a function of CAT theta for standard error = 0.521 (moderate precision): Activity limitations item bank

The number of items required ranged from 3 to 7 and were minimal at the centre where the theta (person measures) are well targeted by the items.

7.1.4 Importance of CAT simulations

Conducting simulations is an integral part of developing CAT systems[427] and is recommended before real testing.[428] CAT simulation software such as Firestar[426] offers several choices for item selection, content balancing, exposure control and theta estimators.[427] These options could be varied to test the efficacy of the CAT system before live implementation,[164, 426-428] and based on the results from the simulation studies, the real CAT engine could be optimised.[157] In addition to these benefits, CAT simulations are useful in selecting the best items when short forms are created from item banks.[158]

7.1.5 Obtaining LID-free item calibrations for CAT

Local item dependency (LID) was described in Chapter 5 (section 5.7.6). The items in a scale should not have anything in common other than the primary dimension (main construct). The presence of other relationships between items (LID) can be identified by examining their residual correlations.[93] Items that exhibit LID do not make unique contribution to the assessment and are detrimental to measurement.[409] Hence, it is important to test the items in the item bank for LID and obtain item calibrations that are free from the effects of LID (described in Methods section 7.3) before proceeding with the development of the CAT system.

7.2 Aim

The aim of the work described in this chapter is to test the efficiency of the twelve Indian item banks using a CAT simulation programme. Efficiency was determined by assessing the reduction in test length of the item banks.

The objectives are to

i. Test the twelve Indian item banks for LID and obtain item calibrations that are free from the effects of LID
ii. Run CAT simulations of the twelve item banks to determine the average number of items required to measure each QoL construct with moderate and high precisions.

7.3 Methods

The final Winsteps control file of the twelve item banks validated in chapter 6 were

used for further analysis in this chapter. LID-free item calibrations were obtained and were used to generate a CAT simulation command (R script), that was processed to determine the average number of items required to measure the QoL constructs with high and moderate precision. The entire process is described below.

a) The presence of local item dependency was detected by running the analysis with the command PRCOMP=R in the Winsteps control file. The command produces raw score residuals which is the difference between the expected and observed values.
b) The inter-item residual correlations were then obtained by retrieving the ICORFILE= from the Winsteps output files menu. The item pairs with correlations >0.3 were reviewed and one item from each pair was chosen for deletion. The item which correlated significantly with multiple items was prioritised for deletion.
c) The item chosen from each pair was deleted from the control file along with persons with extreme scores as they do not contribute to measurement (using the commands IDFILE=* and PDFILE=*). This new control file was run in Winsteps to produce person measures that are free from the effects of locally dependent items.
d) Next, the LID-free person measures obtained from step c was pasted along with respective IDs in the control file (person measures for those with extreme scores was left blank) using the PAFILE=* command. This anchors the person measures so that the new item difficulty estimates and rating scale structures are free from the effects of LID.
e) The deleted items and persons were reinstated in the control file in step d, and the analysis was run with the anchored person measures. Winsteps output tables 6, 17 or 18 was reviewed to verify if anchoring has been correctly applied in the analysis.
f) Next, the summary statistics and item fit statistics were reviewed. Misfitting items were fixed by muting erroneous participant responses as before (Chapter 6) and corresponding changes in summary statistics were noted.
g) The item threshold values (I+THRESH) were then obtained from the Winsteps output file 'ISFILE='. A CSV file was prepared with the first column containing the item discrimination value, which is 1, followed by the threshold values and the number of response categories corresponding to each item.
h) The CSV file was imported into a Firestar computer program, version 1.5.1,

developed by Choi S for polytomous IRT models[426] to generate the CAT simulation command in the form of an R script.

i) The Expected A Posteriori Estimator (EAP) and Maximum Posterior Weighted Information (MPWI) was chosen as the item selection method[93] and the standard error (SE) was specified as the stopping criteria. For moderate precision, SE of 0.521 (reliability coefficient = 0.72) was chosen and for high precision, SE was 0.387 (reliability coefficient = 0.85) was chosen.[93]
j) The Generalised Partial Credit Model (GPCM) which supports the rating scale model was selected.[426] The item with the average difficulty (item measure closer to zero) was opted as the first test item; items best targeting the participants' estimated person measure at any given point during the test was administered subsequently until the maximum standard error criteria (stopping criteria) was achieved.[426]
k) The sample size for simulation was specified as 1000. With these specifications, the R script were generated.[426]
l) The generated R script was run in the R program (a language and environment for statistical computing, version 3.5.2 developed by the R Foundation for Statistical Computing, Vienna, Austria)[429] and the average number of items required for moderate and high and precision was determined.
m) The correlations between the person measures estimated by the CAT and the full item banks were calculated.

7.4 Results

7.4.1 Local item dependency

The number of pairs with residual correlations >0.3 in each item bank and the number of items that were deleted temporarily to obtain LID-free calibrations are displayed in Table 7-1. The driving item bank had the highest percentage of locally dependent pairs (7.8%), followed by the emotional impact (5.2%), social impact (4.7%) and activity limitation item banks (4.7%). The LID-free item calibrations (item measures) for all item banks are provided in the Appendix 14.

Table 7-1 Number (%) of locally dependent pairs of items in each item bank

Item bank	Total no. of item pairs assessed for LID	No. (%) of locally dependent pairs (Correlation >0.30)	No of items selected for deletion
Symptoms - frequency	496	6 (1.2)	6
Symptoms - severity	496	8 (1.6)	6
Symptoms - bothersome	496	6 (1.2)	5
Activity limitation	903	42 (4.7)	18
Driving	153	12 (7.8)	8
Mobility	66	2 (3.0)	2
Concerns	1653	59 (3.6)	26
Emotional impact	595	31 (5.2)	13
Social impact	171	8 (4.7)	7
Convenience	276	5 (1.8)	4
Economic impact	78	1 (1.3)	1
Coping	190	3 (1.6)	2

7.4.2 CAT simulation results

The average number of items in each item bank that was required to measure the respective QoL construct with moderate and high precisions are displayed in Table 7-2. The Table 7-2 also presents the correlations between the CAT system and the full item bank.

Table 7-2 CAT simulation: Average number of items required for moderate and high precisions, and the correlations between the CAT simulation and the full item bank

Item bank	No. of items in the item bank	Moderate precision		High precision	
		Average no. of items	Correlation between CAT and full item bank	Average no. of items	Correlation between CAT and full item bank
Symptoms - frequency	32	7.7	0.97	18.4	0.99
Symptoms - severity	32	7.8	0.97	18.7	0.99
Symptoms - bothersome	32	7.8	0.96	18.4	0.99
Activity limitation	43	3.9	0.96	9.5	0.99
Driving	18	5.5	0.97	11.6	0.99
Mobility	12	5.9	0.98	10.7	1.0
Concerns	58	6.9	0.96	18.7	0.98
Emotional impact	35	4.4	0.96	12.6	0.99
Social impact	19	6.4	0.97	14	0.99
Convenience	24	5.6	0.96	13.2	0.99
Economic impact	13	8.4	0.98	13	1.0
Coping	20	7.8	0.98	15.1	1.0

The total number of items required to measure all the twelve item banks with moderate and high precisions was 78 (23%) and 174 (51.4%) respectively. On an average, 6.5 +/- 1.5 items (range = 3.9 items for activity limitations and 8.4 items

for economic impact item banks) and 14.5 +/- 3.3 items (range = 9.5 for activity limitations and 18.7 for concerns item banks) were required for estimating person measures with moderate and high precisions respectively. High correlations (>0.95) was observed between the CAT and the full item bank estimates (Table 7-2).

All item banks, except economic impact, had substantial reduction in test length (>50%) when tested for moderate precision (Table 7-3). The larger item banks namely activity limitations, concerns and emotional impact, benefitted the highest reduction in test length and the smaller item banks namely, economic impact and mobility benefitted the least (Table 7-3).

Table 7-3 Reduction in test length estimated by CAT simulation for moderate and high precision

Item bank	Test length reduction (%)	
	Moderate precision	High precision
Symptoms - frequency	76.0	42.4
Symptoms - severity	75.7	41.5
Symptoms - bothersome	75.8	42.7
Activity limitation	90.9	78.0
Driving	69.6	35.6
Mobility	51.3	10.9
Concerns	88.2	67.8
Emotional impact	87.4	64.0
Social impact	66.3	26.6
Convenience	76.9	44.9
Economic impact	35.1	0.0
Coping	61.2	24.5

The activity limitations, concerns and emotional impact item banks benefitted substantially as the total number of items reduced by 78%, 68% and 64% respectively for high precision. The economic impact item bank benefitted the least with 0% reduction in test length for high precision.

7.5 Discussion

This chapter described the efficiency of the item banks validated in Chapter 6 by simulating computer adaptive testing. The number of items required to estimate person measures without significant loss of precision was determined. For moderate precision, the test length reduced by more than 50% for all item banks except economic impact precision. For high precision, the test length reduced by more than 30% for all item banks except economic impact, mobility, coping and social impact. The activity limitations item bank benefitted most from CAT as the items reduced from 43 to about 4 for moderate precision and 10 for high precision.

High correlations (0.96-1) between the CAT estimated person measures and the full item bank observed in this chapter are comparable to other studies.[93, 157, 430] However, the average number of items required for moderate and high precision in this study was slightly higher than other studies.[93, 430] The minimal reduction in test length observed for the economic impact, mobility, coping and social impact item banks could be explained by the low measurement precision these item banks exhibited during validation phase (Chapter 6). More data collected on these item banks should be evaluated before proceeding with CAT development.

Three kinds of CAT simulations are undertaken in health measurement – post-hoc, hybrid and Monte-Carlo.[428] Post-hoc simulations are based on real patient data. Data collected on the full item bank are imported into the CAT system; however, the CAT only reads the responses to those items that would have been presented in a real CAT.[151] A complete data set with no missing values is required to carry out this simulation, which is a significant disadvantage.[428] This disadvantage is overcome by the hybrid simulation. The hybrid simulation utilises available patient responses to impute values to missing data, thereby completing the data matrix, so post-hoc simulation can be implemented.[428] While the post-hoc and hybrid simulations uses patient data, the Monte-Carlo simulation uses computer- generated responses based on the Rasch or IRT model.[428] This method is used when little or no data is available. The advantage of using hypothetical test-takers is that different CAT options can be evaluated.[428, 431]

The simulations performed in this chapter used computer-generated responses. Although simulations with real data would have been more ideal to study reduction in test length,[157, 428] considering the limited sample size at this stage, the Monte-Carlo was opted. This way, the required sample size of 1000 could be obtained.[151] In future stages, more data would be collected from the population, and post-hoc simulations would be carried out.[423] These results would then be validated against the results from administering the entire item banks.[431] In addition to LID, the effects of differential item functioning would be tested and incorporated in the actual CAT platform.[431] Content balancing for item banks with sub-dimensions/ strands (e.g. activity limitations item bank) would also be explored.[151]

The simulations performed in this chapter used the expected a posteriori (EAP) method for theta estimation. The EAP method is considered more efficient than other computational methods such as maximum fisher information and maximum likelihood

weighted information as it provides more accurate estimates.[426] Nevertheless, it would be interesting to compare the results using different methods of parameter estimation and having fixed test length as stopping criteria. These possibilities would be explored in future.

Item banking and CAT have several advantages.[424] Together with rapid, precise and accurate measurement, CAT offers the scope for seeding in new items for the expansion of item banks.[164] Furthermore, immediate data entry, real-time scoring and instant CAT results provides the opportunity for focussed communication between patients and clinicians, enabling better care.[155, 164] However, these advantages should be weighed against the cost involved in developing and maintaining CAT platforms.[151] This is particularly important in relation to smaller item banks (e.g. mobility and economic impact item banks developed in this doctoral work).

One might argue that these item banks would be better off as short forms as the entire item bank had to be administered by CAT for high precision. Yet this might restrict the utility of the scale, its application and expansion in future. As the long-term aim of the Eye-tem bank project is to develop universal item banks with common items calibrated across various eye diseases, all item banks developed would undergo further evaluations and appropriate CAT simulations.[2] Overall, the results of the CAT simulations in this chapter offers scope for advancing measurement of amblyopia and strabismic specific QoL using item banking and CAT.

Computer adaptive tests could be implemented in clinical practice via a web-based computer application that could be installed in mobile phones, i-pad or laptops.[421, 422, 432] This can also be integrated into the electronic medical records so instantaneous results about the patient's wellbeing could be obtained. These are emerging and has the potential to revolutionise care in clinical settings based on patient's perspectives. For example, the current amblyopia and strabismus bank could be used by practitioners to monitor the impact of any adult amblyopia treatment from patient's perspectives.

The application of CAT is novel in the field of eye care and the eye-tem bank project are pioneering research in this area.[3] As most of the modules are still under construction or validation phase, the clinical uptake is uncertain and future research is warranted. However, given the benefits, it is hoped that it would be well received.

CHAPTER 8 OVERALL DISCUSSION AND CONCLUSIONS

Despite several extant PROMs, QoL measurement in relation to amblyopia and strabismus is limited and there are gaps in our understanding of the multidimensional impacts caused by these conditions (Chapter 1). Having recognised the need for developing PROMs that precisely measure all disease specific, patient derived constructs of QoL (Chapter 2), this research ventured into the development of technologically advanced PROMs for amblyopia and strabismus and capitalises on the advantages of item banking and CAT (Chapters 3-7). This chapter broadly discusses the findings of this research and its implications, describes the major strengths and limitations of the study, recommends future directions and documents the challenges in implementing item banking and CAT systems.

8.1 Summary of the findings and its implications

The systematic review in chapter 2 examined the content and measurement quality of the extant disease-specific PROMs developed for amblyopia and strabismus.[115] By reviewing 108 articles, 32 amblyopia and/or strabismus specific PROMs were identified. Out of them, 18 had been developed for adults, particularly for those in high or middle-income country settings (Table 2-2). Although all adult PROMs were patient-reported, not all were not patient-derived; that is, they did not include patients' perspectives in the initial stages of development which is crucial for content validity. They had gaps in content to measure the impacts across the whole spectrum of QoL (Table 2-7) and had issues in their psychometric properties and methods used for validation (Table 2-9,Table 2-10,Table 2-11 and Table 2-12). Moreover, all extant PROMs were paper-and-pencil based (static in content), requiring all participants to answer all items whether relevant or not, with little scope for customisation. As PROMs have become indispensable in evaluating disease impacts and effectiveness of interventions, the limitations underlined by the systematic review established the rationale of this research to develop technologically advanced and psychometrically sound, patient derived QoL item banks for amblyopia and strabismus.

Two independent studies in Australia and India following a systematic rigorous protocol were carried out to develop country-specific item banks. This thesis presented the results of the phases 1 and 2 of the Indian study and the results of phase 1 and preliminary results of phase 2 of the Australian study.

High quality qualitative studies with patients are crucial for the development of PROMs that are patient-centered[287] and have been recommended by regulatory bodies such as the FDA.[293-296] Such studies enable deeper understanding of the QoL issues from the perspectives of those experiencing a particular phenomenon, which would never be known otherwise.[288] Therefore, as a first step, extensive qualitative explorations were conducted in Australia and India to identify the QoL constructs that were important (affected) to adults experiencing amblyopia and strabismus (Chapter 3). Eight themes emerged from the qualitative analysis of Australian and Indian data (Table 3-2). They represented the multifaceted impacts caused by amblyopia and strabismus in day to day life which encompassed symptoms, impacts on everyday tasks, concerns posed by the eye condition, impacts on social life and participation, impacts on emotional wellbeing, impacts on study, work and finance, inconveniences associated with the eye condition and coping strategies used by participants to combat the impacts. The QoL issues articulated by participants under each theme formed the foundation of the item banks.

While the extant qualitative investigations focus on the impact of amblyopia treatment on children[82-84] and the psychosocial impacts of strabismus,[85, 86] the qualitative studies conducted as part of this research expands our understanding about the wide range of impacts that should be considered for comprehensive QoL evaluation. For instance, the chapter identified several limitations in day to day activities such as driving, reading, sports, mobility and work tasks. This knowledge complements our current understanding about the functional impairments associated with amblyopia and strabismus identified by clinical and experimental studies and is novel because the limitations were recognised by individuals themselves in normal everyday situations.[162] In addition, the studies addressed the gap in literature by providing insights about the unique impacts caused by different types of amblyopia and strabismus (Table 3-3) and the differences in QoL experiences and perspectives of individuals living in economically and culturally different country-settings.

Following the qualitative exploration, a systematic process of item extraction, evaluation and construction was adopted to develop two sets of country-specific item pools for Australia and India (Chapter 4). Items from extant PROMs, qualitative literature and those that emerged from the qualitative research from least to most frequent occurrence were incorporated into the item pools to cover the broad range of impacts noted by individuals in their day to day life. These item pools underwent a rigorous process of binning and winnowing (item reduction and classification, Figure

4-1) by which optimal sets of representative items addressing nine important QoL constructs were devised. The final item pools for Australia and India had 386 and 341 items respectively (Table 4-25). The item banks for Australia was developed in English and that for India was developed in English and two common Indian languages, Hindi and Tamil using a robust translation protocol (Figure 4-4).

In the process of deriving item banks, it was discovered that about 67% of the items were common to both amblyopia and isolated strabismus (Table 4-14); that is, they were articulated by both disease groups during the qualitative exploration. While it was unclear in the literature if amblyopia and strabismus needed separate measurement systems, this evidence suggested that one set of calibrated item banks would be sufficient for both disease groups. The decision to develop common item banks for both amblyopia and strabismus in Chapter 4 was later substantiated by the DIF analysis of the Indian data in Phase 2 (Chapter 6) which indicated that only a small number of items (15 items, 4.4%) exhibited DIF (Table 6-38), when tested by the presence of amblyopia (amblyopia vs isolated strabismus). Unlike static PROMs, the presence of unique items is not problematic in item banking as these items could be given group-specific item calibrations during CAT development.

As a result of the systematic process, twelve item pools measuring the 1) frequency 2) severity and 3) bothersome of symptoms associated with amblyopia and strabismus, 4) limitations in performing activities, 5) limitations in driving, 6) difficulties in mobility, 7) concerns associated with the eye condition, 8) impacts on emotional wellbeing, 9) impacts on social life and participation, 10) inconveniences associated with the eye condition, 11) financial and economic implications, and 12) strategies used by participants to cope with their eye condition were developed. These item pools were validated using Rasch analysis, a modern psychometric technique which has its foundation in Rasch measurement theory (RMT). The RMT, as described in Chapter 5, is a model that conforms to the principles of measurement.[252] Unlike classical test theory (CTT), the RMT can be tested empirically,[161] and unlike item response theory, it prioritises the model over data.[380] It provides important insights about the measurement properties of a scale such as unidimensionality, measurement precision and targeting.[131, 152]

Chapter 6 presented the validation of the Indian item banks using Rasch analysis. It tested the hypothesis that the items in each item bank co-operate to measure a single QoL construct by examining the functioning of the response categories, response

patterns to items that are inconsistent with the model expectation (item fit statistics), patterns of residual correlations that indicate secondary dimensions (principal component analysis of residuals) and systematic differences in item responses by sub-groups of participants (differential item functioning). The discriminatory ability of the scale (measurement precision) was evaluated by examining the person separation index and the reproducibility of the measures was evaluated by the person and item reliability indices. The targeting of the items to the respondents was assessed by difference between item and person means. Upon initial evaluation of the Indian item banks, category dysfunction and sub-optimal psychometric properties (data inconsistent with model expectations) identified were fixed whenever possible.

The final Indian item banks exhibited satisfactory psychometric properties. All twelve item banks had ordered thresholds and optimal category functioning. None of them had misfitting items that could damage measurement. Despite signs of multidimensionality in principal component analysis of residuals, all scales were deemed as unidimensional for practical purposes based on *post-hoc* analysis and qualitative judgement. All item banks had optimal measurement precision except mobility, social and economic impact; however, the measurement precision of these three item banks improved to satisfactory level when evaluated for non-extreme respondents. Increase in measurement precision for those without perfect scores indicated that these item banks in the current state can discriminate between those with moderate or high impacts. Due to the high number of able participants in the sample, targeting of items difficulties to person abilities was sub-optimal in most item banks, except concerns, economic impact and coping. Measurement precision and targeting can be improved in later stages by administering the item banks to samples with wider range of abilities or by adding new items to the item bank (e.g. including difficult items to target highly able individuals). Moreover, as CAT customises tests by selecting items that closely matches the person's ability, targeting is not as much an issue as it is for short form questionnaires. The small number of items (43 out of 338 items, 12.7%) that exhibited statistically significant, notable DIF would undergo further evaluation and receive group-specific calibrations in future.

Finally, Chapter 7 tested the efficiency of the Indian item banks using a CAT simulation. The results of the simulation demonstrated that all item banks, except mobility, social impact, economic impact and coping benefitted substantially, as the test length reduced by more than 30% for high precision and more than 60% for moderate precision (Table 7-3). This presents the scope for quick and precise

measurement of QoL impacts in busy clinical practices where the item banks can be incorporated alongside electronic patient records for constant QoL monitoring and evaluation. The clinician or researcher can choose which of the item banks they would like to administer based on their research question (for example, the activity limitations, mobility and driving item banks can be administered to study the functional limitations), although administration of all item banks is recommended for comprehensive evaluation of QoL, for example in clinical trials.

Item banks administered via a CAT system overcomes the disadvantages of static questionnaires. Presenting patients with long questionnaires with the same set of items (whether relevant or not) at every clinical visit may be bothersome.[423] In contrast, fewer items used by CAT reduces respondent burden and thereby is expected to increase participation rate. Moreover, as the items presented in CAT depends on the participant's current level of ability and responses to previous questions, it is unlikely that the same set of questions will be presented each time. This would reduce recall bias and enable more targeted evaluation. In addition, immediate feedback from CAT could be incorporated into patient care for focussed communication; this in turn would save the clinician chair time and at the same time, enable prompt service and satisfaction.[155, 164]

Overall, the twelve item banks developed in this research show promising potential to revolutionise QoL measurement in relation to amblyopia and strabismus. To the best of my knowledge, this is the first set of item banks developed for adults with amblyopia and strabismus. With hardly any valid amblyopia and strabismus specific PROM for the large Indian population, the development of technologically advanced item banks is a big leap forward. The item banks developed in three languages - English, Hindi and Tamil would serve most of the Indian population.

This doctoral study has several research and clinical implications. Using the item banks developed in this research, the impacts of the conditions across the whole spectrum of QoL can be measured reliably. This would clarify the discrepant findings regarding the long-term impact of amblyopia in the literature[6, 79, 80, 138, 139] and in turn benefit the cost-effective analysis of amblyopia screening programs.[69-71, 433] The item banks can also be used for comprehensive evaluations of the efficacy of adult amblyopia and strabismus interventions[25, 26, 73, 434] and support claims of novel interventions as recommended by the FDA and EMEA.[61, 110-112] Incorporation of these in routine clinical practices is the way forward in providing evidence-based, patient-

centered care and rehabilitation. In short, these item banks would enable quick and efficient measurement of the multidimensional impact of the disease condition from patient's perspectives, aid in testing and development of interventions that improve well-being, facilitate communication between eye care providers and patients, guide clinical decisions, allocation of resources and support formulation of health care policies in relation to amblyopia and strabismus.[435]

8.2 Strengths and limitations

This doctoral study has several strengths. Most importantly, it created item banks that are patient-centered by incorporating patient's perspectives and their lived experiences into their construction and did not solely rely on the literature or the researcher's a priori. The qualitative studies adopted a phenomenological approach and grounded theory-based analysis, which were recommended by subject experts for accurately incorporating the voice of patients into the development of PROMs.[287, 300, 302, 303] Rigour of the qualitative research was established by the triangulation of the data, collected using different methods (focus groups and interviews), from different countries (Australia and India) and sources (community, optometry practices and hospital set-up).

The systematic, rigorous protocol followed to derive amblyopia and strabismus specific QoL item banks in this research is similar to that followed in the development of other eye-tem bank disease modules[2] such as glaucoma,[153] diabetic retinopathy.[246] This is also similar to that followed by the Patient Reported Outcome Measurement Information System (PROMIS) group, which is developing item banks and CAT systems to assess physical, mental and social health in children and adults.[338, 395, 436] Following an established item bank development process substantiates the validity of the methodology used in this doctoral study. As the quality of the CAT system largely depends on the item bank from which it draws its items, it is crucial that the item banks are comprehensive, containing items that measures the whole range of the latent construct from low to high.[158] Having included all relevant items from three different sources (extant PROMs, qualitative literature and qualitative research) increases the content validity of the item banks and the likelihood that they are comprehensive.

The multistep translation process adopted to translate the Indian item banks from English to Hindi and Tamil languages are methodologically sound and reproducible. It

conforms to the translation guidelines recommended by the regulatory bodies such as the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Task Force for translation and the cultural adaptation.[348, 350-352] The lack of DIF by questionnaire language in Phase 2 analysis substantiates the translational validity of the questionnaire. This means that the items were understood and interpreted similarly by participants who answered the item banks in English and Indian languages. This finding suggests successful implementation of the translation protocol and its robustness. India being a diverse country with many regional languages, the protocol followed in this study could be replicated in future to develop item banks in other languages to cater to the entire Indian population.

The use of advanced psychometric analysis for the validation of the item banks developed in this research overcomes the limitations of the traditional CTT used for validating most extant amblyopia and strabismus specific PROMs.[115, 131] The thorough psychometric evaluation ranging from the appraisal of rating scale functioning to differential item functioning provides a detailed description of the performance of the item banks and its ability to produce valid and reliable measurement. By recognising the inherent limitations of psychological measurement, the results of Rasch analysis were interpreted using both statistical guidelines adopted by the Eye-tem bank project group and qualitative judgement, so scales worthy of productive measurement could be developed.[365] The use of diverse sample (in terms of diagnosis, clinical characteristics and demographics) for validation is another notable strength.

By pretesting the efficiency of the item banks by CAT simulation, the study provided preliminary evidence about the potential usefulness of the item banks before real testing. This evidence is particularly important before venturing into the development of CAT systems and live testing which are expensive.[428]

QoL is a multidimensional concept.[119, 120] The twelve item banks developed in this research measures twelve unique QoL constructs important to those with amblyopia and strabismus. Therefore, comprehensive QoL evaluation should ideally involve administration of all twelve item banks which would yield 12 unique scores. While a single composite QoL score may be easy to interpret and communicate, it cannot discriminate the level, or the kind of impact faced by individuals. For example, a person with strabismic amblyopia may face several activity limitations (high impact), cope well in their social life (minimal social impact) and have good financial support (nil economic impact). This information would be lost if the person was given a single

composite score. Moreover, having individual item banks for each QoL construct offers stakeholders the choice of outcomes they might want to study. For instance, regulatory bodies may be interested in symptoms and activity limitations while policy makers may be interested in other QoL constructs such as emotional and social impacts.[435] These benefits outweigh the ease of having one composite QoL score advocated by generic QoL PROMs.[245]

Despite several strengths, the study has some limitations. This study focussed on the long-term impacts of amblyopia and strabismus on adults and devised item banks to measure these impacts. However, amblyopia and strabismus are common childhood conditions, which have major impacts on children. The item banks developed for adults cannot be administered to children as some item banks may be totally irrelevant to them (e.g. economic impact, driving). Even if an item bank is relevant (e.g. activity limitation), all items may not be appropriate (e.g. cooking). In addition, item banks for children may warrant different item stems and response options for easy comprehension.[437] Moreover, child specific validation and item calibration is necessary for reliable measurement. It is recommended that researchers follow a similar protocol to develop QoL item banks specifically for children with amblyopia and strabismus, so treatment benefits could be evaluated, and cost-effective analysis of school screening programs be complemented.

There are some limitations in the sample used in the Phase 1. The Indian sample did not have participants with isolated strabismus, although the sample consisted of those with strabismic and mixed amblyopia. Hence, care was taken to include those with isolated strabismus in Phase 2, to test the validity of the item bank in this disease sub-group. Similarly, the Phase 1 Australian sample did not include indigenous population. Therefore, Phase 2, which is ongoing in Australia, will aim to include them to evaluate the performance of the item banks. If DIF was noted between indigenous population and others, the items would receive group-specific calibrations during CAT development.

Although care was taken to recruit persons with a range of visual impairments in Phase 2, the Indian sample had a greater number of able individuals. This was evident by the ceiling effects observed in the item banks. As a result, measurement range and targeting of the item banks was sub-optimal. It is possible that this population may have inherently high ability. However, this is not certain at this stage and is early to comment. Future evaluations with large data sets would enable deeper understanding

of the disease characteristics and impact range. Such evaluations may result in more stable item calibrations than those resulted from this study.

Amblyopia in the current research was defined as 'best corrected visual acuity of 6/9 or worse in at least one eye without any underlying organic cause'. Although this was diagnosed by an eye care provider, it is possible that some adults diagnosed with mild amblyopia had undetectable pathology such as early cataract or neurological disorder. It is therefore recommended to include the history of an amblyogenic factor such as strabismus or anisometropia in childhood to confirm amblyopia diagnosis in future investigations.

Another limitation of the current research is that the aim, which was to develop item banks for both Australian and Indian population, was not completely achieved. As noted in the previous chapters, the Phase 2 of the study in Australia is ongoing as required sample for psychometric validation has not yet been achieved. Despite best efforts (collaboration with multiple eye practitioners, advertisements, media releases, development of online surveys), identification and recruitment of participants were challenging. This has slowed the progression of the Australia QoL item banks to the next stages. Future directions would be collaborating with more eye practices, strabismus surgeons and eye hospitals in Australia. The possibility of collaborating with other high-income countries will also be explored. The quality appraisal of the PROMs reviewed in the systematic review described in this thesis used the quality assessment criteria adapted by the eye-tem bank project group.[131, 152] These guidelines are similar to the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) checklist developed for assessing the quality of PROMs.[438] However, the COSMIN checklists have more exhaustive qualitative indicators and are graded differently. More recently, the COSMIN risk of bias tool (2018) for systematic reviews of PROMs was derived from the original COSMIN checklist.[439] This tool is more specific than the original checklist as it focusses on methodological standards that are crucial to obtain unbiased results. Nevertheless, this was published in 2018 after the systematic review in Chapter 2 was conducted and hence could not be utilised.

8.3 Future directions

More data will be collected as part of Phase 2 in India to confirm the item calibrations resulted out of this research. Care will be taken to recruit individuals with severe

forms of amblyopia and/or strabismus with an intent to balance the distribution of the current study sample which had a greater number of able individuals. Similarly, as the majority of the current study sample were less than 40 years of age, individuals over 40 years of age would be recruited to test the suitability of scales for older individuals through DIF evaluations and to further establish the long-term impact of the eye conditions.

Phase 2 in Australia will follow the same methodology used for the validation of the Indian item banks. As about 79% of the items were common to both Australian and Indian item banks, the possibility of merging the two country-specific item banks by common item linking will be explored upon validation of the Australian item banks. A pooled analysis with data from both countries will be carried out. The rating scale functioning and other psychometric properties will be re-evaluated and DIF will be examined to investigate the possibility of having common item banks for both high- and low-income countries. CAT simulations will be carried out to pre-test the efficiency of the item banks.

Phase 3 will involve the development of CAT algorithms for the CAT system through which the item banks would be administered. The algorithm would include a set of rules on item selection and test termination. The CAT system will be validated by administering the item banks to a different study sample in Australia and India. The feasibility of the CAT system will be evaluated by calculating the average test time and test length. The convergent validity, discriminant validity and known-group validity would be assessed by relating the scores to clinical characteristics and comparing it with currently available PROMs such as adult strabismus questionnaire (AS-20) and amblyopia and strabismus questionnaire (A&SQ). Cross-cultural validity will be assessed by comparing the results of the Indian and Australian CAT systems. Reliability would be assessed by test precision and repeat administration (test-retest reliability).

The validated CAT systems in phase 3, would be implemented in research settings and routine clinical practices in Phase 4. In Phase 4, the CAT systems would be used to comprehensively evaluate the QoL impacts of amblyopia and strabismus. The data collected would be used to determine threshold values using which individuals could be classified according to their level of impact. Responsiveness of the CAT system to change in impacts over time and sensitivity to detect clinically significant changes will also be evaluated.

Finally, the item banks developed in this research would be collaborated with other item banks developed by the Eye-tem bank project to form universal scales that offer measurement of impacts caused by different eye diseases along the same continuum, so impacts can be compared. Although health measurement using CAT systems are becoming popular, most of them are still in research phase. Little is known about the real-time application of CAT systems in clinical settings. Despite potential benefits, there are several challenges in successful implementation of CAT (section 8-4). Thus, future research in the field of amblyopia and strabismus is warranted to test the usefulness of CAT and its uptake in clinical settings.

8.4 Challenges in implementation

There are several differences between using PROMs (both static, paper-based and dynamic, electronic PROMs) for research purposes and implementing it in routine clinical practices.[440] Most importantly, in research, PROMs are used to study a representative sample (e.g. measure disease burden in a group), while in clinical practices, the aim of using PROMs is to study individual characteristics (e.g. impact on an individual), so customised patient care can be provided.[440] Second, the person using the PROMs in research is a trained researcher; in contrast, many clinicians lack expertise in administering PROMs and interpreting their results.[441] Moreover, the benefits of PROMs are not fully realised by some clinicians and healthcare providers who are hesitant about using them.[435] These professionals believe PROMs are burdensome and consider it to be a waste of time. Third, the cost involved in using PROM for research purposes is mostly a one-time investment, while routine collection, storage and maintenance of data in clinical practices requires incessant funding and resources. Finally, data privacy and security are ethical concerns for routine collection of data in clinical practices.[441] Patients may be apprehensive about who will be accessing their data, where is will be stored and how it may be used. This is particularly predominant when data is collected electronically via smart phones, tablet or computer.

Although CAT systems minimise respondent burden of answering long paper-based questionnaires, perform targeted evaluation of person ability by test customisation, provide instantaneous feedback for immediate incorporation in patient care and permit real time monitoring of impacts (e.g. symptoms), the above challenges remain. In addition, the implementation of CAT systems is challenged by high costs involved in creating and maintaining a functional CAT system, the need for technology (electronic

devices) and expertise in using it.[441] These barriers may restrain implementation of item banks and CAT systems in low resource and low-income country settings.

Several guidelines have been proposed to overcome these barriers and successfully incorporate PROMs into health systems.[442] Notably, the user guides created by the international society for quality of life research[443] and patient-centered outcomes research institute[444] provide useful information regarding the implementation of PROMs. Developing user-friendly data collection interfaces and providing training and technical support, especially in the early stages of CAT implementation are recommended to minimise technological barriers.[441] Data privacy concerns can be addressed by following robust protocols and establishing good practices.[435] The information obtained via PROMs should be optimally integrated into patient care to encourage patient participation.[445] The efficiency of the systems should be regularly evaluated and improved.[435] When the benefits of incorporating PROM data into patient care are fully embraced, the cost involved in building CAT systems could be justified.[441]

Although computer literacy is currently low in India, the government is taking several initiatives to increase it.[446] Moreover, the use of electronic health records is becoming common in hospital set-ups. For example, the Sankara Nethralaya eye hospital in Chennai, from which the Indian data in this research was collected and the LV Prasad eye institute in Hyderabad, another renowned eye hospital in southern India, uses ophthalmic electronic medical records, hospital management and clinical decision support systems.[447, 448] Thus, there is huge potential for integrating computerised PROMs into existing systems. Such integration would result in more patient-centred care and satisfaction.

8.5 Conclusion

Using an evidence-based, patient-centered methodology and sound psychometric methods, this research developed item banks to measure the long-term QoL impacts caused by amblyopia and strabismus on adults. Upon further development and validation described in section 8.3, the item banks will be ready for clinical and research applications.

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Appendix 1

Extant amblyopia and strabismus specific PROMs

Original language, population and country income classification (World Bank Country and Lending Groups. The World Bank; 2018. Available at: https://datahelpdesk.worldbank.org/knowledgebase/articles/906519; Accessed: 11th April 2018.)

Extant amblyopia and strabismus specific PROMs	Language	Population	Country income group
Amblyopia Survey	English	USA	High income
Patching success questionnaire	English	Netherlands	High income
Amblyopia treatment index	English	USA	High income
Child amblyopia treatment index	English	USA	High income
Perceived psychosocial questionnaire	English	UK	High income
Emotional impact of amblyopia treatment questionnaire	English	UK	High income
Occlusion patch comfort questionnaire	English	Netherlands	High income
Child amblyopia treatment questionnaire	English	UK	High income
Children's vision for living scale	Arabic	Saudi Arabia	High income
46 item QoL questionnaire	Romanian	Romania	Upper middle income
QoL questionnaire for children with anisometropic amblyopia	Chinese	China	Upper middle income
Socio professional integration questionnaire	Not reported	Romania	Upper middle income
Adult strabismus quality of life questionnaire	English	USA	High income
Intermittent exotropia questionnaire	English	USA	High income

Vision function scale	English	USA	High income
Perceived visibility of strabismus	English	UK	High income
Strabismus survey	English	USA	High income
8 item QoL instrument	Native	India	Lower middle income
Disability questionnaire	English	USA	High income
Repertory grid	English	UK	High income
Psychosocial experience questionnaire	English	USA	High income
Expectations of strabismus surgery questionnaire	English	UK	High income
Effect of diplopia questionnaire	Chinese	China	Upper middle income
Perspectives questionnaire	English	USA	High income
Post strabismus surgery symptom questionnaire	Not reported	South Korea	High income
Psychosocial effects of strabismus pre and post-operative questionnaire	English	China	Upper middle income
Exotropia symptom questionnaire	English	South Korea	High income
Satisfaction of surgical outcome	English	Australia	High income
Visual analog scale	English	UK	High income
Modified RAND health insurance study QoL instrument	English	USA	High income
Amblyopia and strabismus questionnaire	Dutch	Netherlands	High income
Psychological impact questionnaire	English	UK	High income

Appendix 2

Ethics approval documents and amendments – Australia

Office for Research

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SA Health
Southern Adelaide Local Health Network

Amendment to ethics application approved

You are reminded that this letter constitutes ethical approval only for this amendment. If you are waiting on Site Specific Assessment (SSA) authorisation for your study, you must not commence this research project at any public Health site until separate authorisation from the Chief Executive or delegate of that site has been obtained.

06 July 2016
27 October 2016

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Flinders University
BEDFORD PARK SA 5042

Dear Professor Pesudovs

The Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC EC00188) have reviewed and provided ethical approval for this amendment which appears to meet the requirements of the *National Statement on Ethical Conduct in Human Research.*

Application Number: OFR # 469.11

Title: A system for measurement of vision-specific quality of life using item banking and computer adaptive testing (Eye-tem Bank)

Chief Investigator: Professor Konrad Pesudovs

Approval date: 06 July 2016

This amendment approval does not alter the current SAC HREC approval period for the study: 20 January 2016 to 20 January 2017

The below documents have been reviewed and approved:

- Cover Letter dated 17 June 2016
- Project Amendment Application form – addition of Ms Sheela Evangeline Kumaran as Professional Research Personnel to the study dated 17 June 2016
- General Research Application form v11 dated 17 June 2016

TERMS AND CONDITIONS OF ETHICAL APPROVAL
As part of the Institution's responsibilities in monitoring research and complying with audit requirements, it is essential that researchers adhere to the conditions below and with the *National Statement chapter 5.5.*

Final ethical approval is granted subject to the researcher agreeing to meet the following terms and conditions:

1. The approval covers the ethics component of the application. Please submit a copy of the approved amendment to the local RGO for acknowledgement
2. If University personnel are involved in this project, the Principal Investigator should notify the University before commencing their research to ensure compliance with University requirements including any insurance and indemnification requirements.
3. Compliance with the *National Statement on Ethical Conduct in Human Research* (2007) & the *Australian Code for the Responsible Conduct of Research* (2007).
4. To immediately report to SAC HREC anything that may change the ethical or scientific integrity of the project.
5. Report Significant Adverse events (SAE's) as per SAE requirements available at our website.
6. Submit an annual report on each anniversary of the date of final approval and in the correct template from the SAC HREC website.
7. Confidentiality of research participants MUST be maintained at all times.
8. A copy of the signed consent form must be given to the participant unless the project is an audit.
9. Any reports or publications derived from the research should be submitted to the Committee at the completion of the project.
10. All requests for access to medical records at any SALHN site must be accompanied by this approval email.
11. To regularly review the SAC HREC website and comply with all submission requirements, as they change from time to time.
12. Once your research project has concluded, any new product/procedure/intervention cannot be conducted in the SALHN as standard practice without the approval of the SALHN New Medical Products and Standardisation Committee or the SALHN New Health Technology and Clinical Practice Innovation Committee (as applicable) Please refer to the relevant committee link on the SALHN intranet for further information.
13. Researchers are reminded that all advertisements/flyers need to be approved by the committee, and that no promotion of a study can commence until final ethics and executive approval has been obtained. In addition, all media contact should be coordinated through the FMC media unit.

Yours sincerely

A/Professor Bernadette Richards
Chair, SAC HREC

Office for Research

Flinders Medical Centre
Ward 6C, Room 6A219
Flinders Drive, Bedford Park SA 5042
Tel: (08) 8204 6453
E: Health.SALHNOfficeforResearch@sa.gov.au

Government of South Australia
SA Health
Southern Adelaide Local Health Network

Amendment to ethics application approved

You are reminded that this letter constitutes ethical approval only for this amendment. If you are waiting on Site Specific Assessment (SSA) authorisation for your study, you must not commence this research project at any public Health site until separate authorisation from the Chief Executive or delegate of that site has been obtained.

08 November 2016

Professor Konrad Pesudovs
Optometry and Vision Science
Flinders Medical Centre
BEDFORD PARK SA 5042

Dear Professor Pesudovs

The Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC EC00188) have reviewed and provided ethical approval for this amendment which appears to meet the requirements of the *National Statement on Ethical Conduct in Human Research.*

Application Number: OFR # 469.11

Title: A system of measurement of vision-specific quality of life using item banking and computer adaptive testing (Eye-tem bank)

Chief Investigator: Professor Konrad Pesudovs

This amendment approval does not alter the current SAC HREC approval period for the study: 20 January 2016 to 20 January 2017

Public health sites approved under this application:

- NH&MRC Centre for Clinical Eye Research at the Discipline of Optometry and Vision Science, FUSA
- Flinders Medical Centre

Sites Noted:

- Optometry Sunbury, VIC
- Vision for Children, VIC
- OPSM, Broken Hill, NSW
- Burnside Hospital, SA
- Eyemedics Ophthalmologists, Bagot House, SA
- Adelaide Eye and Retina Centre, SA
- Royal Victorian Eye and Ear Hospital VIC,
- Ashford Advanced Eye Care, SA
- Tilganga Institute of Ophthalmology, Kathmandu, Nepal
- Dhulikhel Hospital, Kavre, Nepal
- Elite School of Optometry, Sankara Nethralaya, India

The below documents have been reviewed and approved:

- Cover Letter dated 25 October 2016
- Project Amendment form – Addition of New Study Sites in VIC, NSW and India dated 17 June 2016
- General Research Application v13 dated 09 September 2016
- Approval letter from Vision Research Foundation, India dated 10 October 2016
- Letter of Support from Dr R Krishna Kumar, Principal, Elite School of Optometry, Sankara Nethralaya, India dated 26 March 2016

- Letter of Support from Rod Baker, Director Optometry Sunbury and Vision for Children, Victoria dated 15 July 2016
- Letter of Support from Senthil Murugappa, Optometrist Principal, OPSM, Broken Hill, NSW dated 29 August 2016
- Participant Information Sheet and Consent forms - Phase I and II - for Amblyopia and Strabismus v2 dated 09 September 2016 (English)
- Participant Information Sheet and Consent forms – Phase I and II – for Amblyopia and Stabismus v2 dated 09 September 2016 (Tamil)
- Validation of Tamil Consent Form and Information Sheets dated 13 and 14 April 2016

TERMS AND CONDITIONS OF ETHICAL APPROVAL
As part of the Institution's responsibilities in monitoring research and complying with audit requirements, it is essential that researchers adhere to the conditions below and with the *National Statement chapter 5.5.*

Final ethical approval is granted subject to the researcher agreeing to meet the following terms and conditions:

1. The approval covers the ethics component of the application. Please submit a copy of the approved amendment to the local RGO for acknowledgement
2. If University personnel are involved in this project, the Principal Investigator should notify the University before commencing their research to ensure compliance with University requirements including any insurance and indemnification requirements.
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6. Submit an annual report on each anniversary of the date of final approval and in the correct template from the SAC HREC website.
7. Confidentiality of research participants MUST be maintained at all times.
8. A copy of the signed consent form must be given to the participant unless the project is an audit.
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12. Once your research project has concluded, any new product/procedure/intervention cannot be conducted in the SALHN as standard practice without the approval of the SALHN New Medical Products and Standardisation Committee or the SALHN New Health Technology and Clinical Practice Innovation Committee (as applicable) Please refer to the relevant committee link on the SALHN intranet for further information.
13. Researchers are reminded that all advertisements/flyers need to be approved by the committee, and that no promotion of a study can commence until final ethics and executive approval has been obtained. In addition, all media contact should be coordinated through the FMC media unit.

Yours sincerely

A/Professor Bernadette Richards
Chair, SAC HREC

Office for Research

Flinders Medical Centre
Ward 6C, Room 6A219
Flinders Drive, Bedford Park SA 5042
Tel: (08) 8204 6453
E: Health.SALHNOfficeforResearch@sa.gov.au

Government of South Australia

SA Health

Southern Adelaide Local Health Network

Amendment: Ethics Approval

21 August 2017

Konrad Pesudovs

Dear Konrad Pesudovs

OFR Number: 469.11

Project title: A system of measurement of vision-specific quality of life using item banking and computer adaptive testing (Eye-tem bank)

Chief Investigator: Konrad Pesudovs

Ethics and Governance Approval Period: 20 January 2017 to 20 January 2018

The Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC EC00188) has reviewed and provided ethics approval for this amendment which appears to meet the requirements of the *National Statement on Ethical Conduct in Human Research (2007)*.

This amendment approval does not alter the current SAC HREC approval period.

The below documents have been reviewed and approved by the SAC HREC:

- Cover letter dated 21 June, 2017
- Project amendment application form – addition of pilot questionnaire – dated 21 June, 2017
- General research application form v14 dated June 2017
- Amblyopia and Strabismus 'Quality of Life' Survey dated 21 June 2017
- Refractive error item bank questionnaire dated 21 June 2017

TERMS AND CONDITIONS OF ETHICS APPROVAL
As part of the Institution's responsibilities in monitoring research and complying with audit requirements, it is essential that researchers adhere to the conditions below and with the *National Statement Chapter 5.5.*

Final ethics approval is granted subject to the researcher agreeing to meet the following terms and conditions:

1. The approval covers the ethics component of the application. Please submit a copy of the approved amendment to the local RGO for acknowledgement
2. If University personnel are involved in this project, the Principal Investigator should notify the University before commencing their research to ensure compliance with University requirements including any insurance and indemnification requirements.
3. Compliance with the *National Statement on Ethical Conduct in Human Research* (2007) & the *Australian Code for the Responsible Conduct of Research* (2007).
4. To immediately report to SAC HREC anything that may change the ethics or scientific integrity of the project.
5. Report Significant Adverse events (SAE's) as per SAE requirements available at our website.
6. Submit an annual report on each anniversary of the date of final approval and in the correct template from the SAC HREC website.
7. Confidentiality of research participants MUST be maintained at all times.

8. A copy of the signed consent form must be given to the participant unless the project is an audit.
9. Any reports or publications derived from the research should be submitted to the Committee at the completion of the project.
10. All requests for access to medical records at any SALHN site must be accompanied by this approval email.
11. To regularly review the SAC HREC website and comply with all submission requirements, as they change from time to time.
12. Once your research project has concluded, any new product/procedure/intervention cannot be conducted in the SALHN as standard practice without the approval of the SALHN New Medical Products and Standardisation Committee or the SALHN New Health Technology and Clinical Practice Innovation Committee (as applicable) Please refer to the relevant committee link on the SALHN intranet for further information.
13. Researchers are reminded that all advertisements/flyers need to be approved by the committee, and that no promotion of a study can commence until final ethics and executive approval has been obtained. In addition, all media contact should be coordinated through the FMC media unit.

For any queries about this matter, please contact the Office for Research on (08) 8204 7433 or via email to Health.SALHNOfficeforResearch@sa.gov.au.

Yours sincerely

A/Professor Bernadette Richards
Chair, SAC HREC

Office for Research

Flinders Medical Centre
Ward 6C, Room 6A219
Flinders Drive, Bedford Park SA 5042
Tel: (08) 8204 6453
E: Health.SALHNOfficeforResearch@sa.gov.au

Government of South Australia
SA Health
Southern Adelaide Local Health Network

Amendment: Ethics Approval

15 March 2018

Associate Professor Ecosse Lamoureux
Department of Ophthalmology
University of Melbourne
Locked Bag 8
East Melbourne VIC 8002

Dear Associate Professor Lamoureux

OFR Number: 469.11
Project title: A system for measurement of vision-specific quality of life using item banking and computer adaptive testing (Eye-tem Bank)
Chief Investigator: Associate Professor Ecosse Lamoureux

Ethics and Governance Approval Period: 20 January 2018 - 20 January 2019

The Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC EC00188) has reviewed and provided ethics approval for this amendment which meets the requirements of the *National Statement on Ethical Conduct in Human Research (2007)*.

This amendment approval does not alter the current SAC HREC approval period.

Public health sites approved under this Ethics amendment application:
- Flinders Medical Centre
- Royal Adelaide Hospital
- the Queen Elizabeth Hospital

The below documents have been reviewed and approved by the SAC HREC:
- Project amendment form - staff changes - dated 02 February 2018
- General research application form v15 dated 05 March 2018

Terms and Conditions Of Ethics Approval:
It is essential that researchers adhere to the conditions below and with the *National Statement Chapter 5.5.*

Final ethics approval is granted subject to the researcher agreeing to meet the following terms and conditions:

1. The approval covers the ethics component of the application. Please submit a copy of the approved amendment to the local RGO for acknowledgement
2. If University personnel are involved in this project, the Principal Investigator should notify the University before commencing their research to ensure compliance with University requirements including any insurance and indemnification requirements.
3. Compliance with the *National Statement on Ethical Conduct in Human Research* (2007) & the *Australian Code for the Responsible Conduct of Research* (2007).

4. To immediately report to SAC HREC anything that may change the ethics or scientific integrity of the project.
5. Report Significant Adverse events (SAE's) as per SAE requirements available at our website.
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7. Confidentiality of research participants MUST be maintained at all times.
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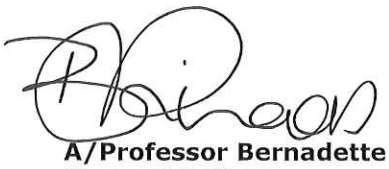
13. Researchers are reminded that all advertisements/flyers need to be approved by the committee, and that no promotion of a study can commence until final ethics and executive approval has been obtained. In addition, all media contact should be coordinated through the FMC media unit.

For any queries about this matter, please contact the Executive Officer on (08) 8204 6453 or via email to Health.SALHNOfficeforResearch@sa.gov.au.

Yours sincerely



A/Professor Bernadette Richards
Chair, SAC HREC

Appendix 3

Ethics approval document - India

VISION RESEARCH FOUNDATION

[Regd. Under Act XXI of 1860]
New No.41, Old No.18, College Road, Chennai - 600 006

Dr. LINGAM GOPAL, MS., DNBE., FRCS Ed. President
Dr. TARUN SHARMA, MD., FRCS Ed., MBA Hony. Secretary
R.S. FALOR Hony. Treasurer
Dr. RONNIE JACOB GEORGE, D.O., D.N.B., M.S Director – Research

Name and Address of Research Cell Committee :	Research Cell Committee Vision Research Foundation New No.41, Old No.18 College Road Chennai 600 006.

Research Cell Committee Decision

Study Protocol Title :	A system for measurement of amblyopia and strabismus – specific quality of life using item banking and computer adaptive testing (Eye-tem Bank)
Principal Investigator(s) :	**Ms. Jameel Rizwana,** Vision Research Foundation Sankara Nethralaya, New No.41, Old No.18 College Road Chennai 600 006.
Name of Trial Site(s)	Vision Research Foundation, Sankara Nethralaya New No.41, Old No.18 College Road Chennai 600 006.

The Research Cell Committee has reviewed the following documents related to the above study :

A system for measurement of amblyopia and strabismus – specific quality of life using item banking and computer adaptive testing (Eye-tem Bank)

Review and Approval

29.09.2016 & Chennai
Date and Place of Decision

The study / Study documents
- ✓ are approved
- are not approved
- Require modification prior to approval

An explanation / Comments are provided in comments
- ✓ Yes
- No

18.10.2016
Date of Issue

Dr. S. Krishnakumar
Member, Research Cell Committee

Phone : 91 - 44 - 2827 1616, 4227 1500 Fax : 91 - 44 - 2825 4180
INTERNET e-mail : drrg@snmail.org, nanu@snmail.org
WEB : http://www.sankaranethralaya.org

Appendix 4

Reasons for excluding full text articles from the systematic review

Reference	Construct(s) measured
Costello, P. A., et al. (2001)[1]	Measured the perception of parents of children undergoing treatment for acquired esotropia
Eustis, S. and D. R. Smith (1987)[2]	Assessed parental understanding of strabismus and treatment by surgery
Holmes, J. M., et al. (2005)[3]	Measured the frequency of diplopia in several positions of gaze
Tonge, B. J., et al. (1984)[4]	Evaluated the educational performance of children by a questionnaire filled by the teacher
Escardo-Paton, J. A. and R. A. Harrad (2009)[5]	Assessed the severity and duration of conjunctival redness post strabismus surgery
Horwood, J., et al. (2005)[6]	Assessed bullying behaviour of children
Mruthyunjaya, P., et al. (1996)[7]	Assessed parent's perception of pre-operative, surgical, and post-operative experiences
Norman, P., et al. (2003)[8]	Assessed parent's protection motivation for their children and adherence to eye patching recommendations

References

1. Costello PA, Simon JW, Jia YM, Lininger LL. Acquired Esotropia: Subjective and Objective Outcomes. J AAPOS 2001;5:193-7.
2. Eustis S, Smith DR. Parental Understanding of Strabismus. J Pediatr Ophthalmol Strabismus 1987;24:232-6.
3. Holmes JM, Leske DA, Kupersmith MJ. New Methods for Quantifying Diplopia. Ophthalmology 2005;112:2035-9.
4. Tonge BJ, Lipton GL, Crawford G. Psychological and Educational Correlates of Strabismus in School Children. Aust N Z J Psychiatry 1984;18:71-7.
5. Escardo-Paton JA, Harrad RA. Duration of Conjunctival Redness Following Adult Strabismus Surgery. J AAPOS 2009;13:583-6.
6. Horwood J, Waylen A, Herrick D, et al. Common Visual Defects and Peer Victimization in Children. Invest Ophthalmol Vis Sci 2005;46:1177-81.
7. Mruthyunjaya P, Simon JW, Pickering JD, Lininger LL. Subjective and Objective Outcomes of Strabismus Surgery in Children. J Pediatr Ophthalmol Strabismus 1996;33:167-70.
8. Norman P, Searle A, Harrad R, Vedhara K. Predicting Adherence to Eye Patching in Children with Amblyopia: An Application of Protection Motivation Theory. Br J Health Psychol 2003;8:67-82.

Appendix 5

Phase 1 Participant information sheets and consent forms
English and Tamil

Government of South Australia
SA Health

Flinders UNIVERSITY

PARTICIPANT INFORMATION SHEET

Title of the project: Questionnaire Study – Phase I
A system for measurement of amblyopia (lazy eye) and strabismus (turned eye) - specific quality of life using item banking and computer adaptive testing (Eye-tem Bank): Phase I- Item identification

Name of organizations:
This is a collaborative study carried out at Flinders University as a lead organization and four centres: The Queen Elizabeth Hospital, SA, The Royal Adelaide Hospital, SA, the Royal Victorian Eye and Ear Hospital, VIC, Optometry Sunbury and Vision for Children, Victoria and OPSM, Broken Hill, NSW and Elite School of Optometry, Sankara Nethralaya, India.

This is a research project and you do not have to be involved. If you do not wish to participate, your medical care will not be affected in any way.

You are invited to take part in Phase I of a research study conducted by the Discipline of Optometry and Vision Science at Flinders University. This study is being conducted to explore how amblyopia (lazy eye) / strabismus (turned eye) and its correction affect people's lives. The information obtained will be used to develop a comprehensive bank of items (questions) for the assessment of quality of life. This item bank will assist eye doctors and researchers to better evaluate the impact of an eye problem on each patient and determine the appropriate course for treatment.

If you choose to participate, you may be invited to attend a focus group discussion or one-on-one interview (face-to-face or telephone), in which you will be asked to talk about how your eye problem is affecting you and your life. The focus group/ face-to-face interviews will take place in one of four settings (Flinders University, Bedford Park, SA, The Queen Elizabeth Hospital, Woodville West, SA, the Royal Adelaide Hospital, Adelaide, SA, and the Royal Victorian Eye and Ear Hospital, East Melbourne, VIC), wherever is most convenient for you. Similarly, in India, the focus groups or interviews will take place in the Elite school of optometry, Sankara Nethralaya eye Hospital, Chennai. A facilitator will be present to guide the discussion/interviews, which will last around 1-2 hours. If you instead prefer a telephone interview, one of our staff will contact you at your preferred time and will guide the telephone interview. The focus group discussion and interviews will be audiotaped, but your identity and what you say will remain confidential, anonymity cannot be maintained in a focus group. Apart from attending a discussion group /interview you will not be asked to attend any special visits. You will receive a flat rate of AUD 20 to assist with transportation costs.

You will need to fill out the demographic form and sign the consent (attached) before participating in the study, this should only take few minutes. If you agree to participate, we will acquire measurements of your vision and diagnosis from your clinical file. If you do not consent, we will not access your clinical file.

There are no direct benefits to you from being associated with this study. However, your input may help eye doctors and researchers in being better able to assess how these eye problems affect quality of life in future patients.

Your involvement in this study will not affect your treatment in any way. Your participation in the study is entirely voluntary and you have the right to withdraw at any time. If you decide not to participate in this study or if you withdraw, you may do this freely without prejudice to any treatment.

You may feel some distress from participation in this study. If this occurs you may withdraw from this study if you wish and your care will not be affected in any way. By participating in this study you do not give up any of your legal rights.

If you suffer injury as a result of participation in this research or study, compensation might be paid without litigation. However, such compensation is not automatic and you may have to take legal action to determine whether you should be paid.

All records containing personal information will remain confidential and no information that could lead to your identification will be released. Records will be kept in a securely locked filing cabinet and in a password protected computer located in room S171, Sturt West, Flinders University. The audio recording of the focus groups and interviews will be transcribed for analytic purposes only. Data will be deleted and destroyed 5 years after the study is completed. We expect that once the study is completed, the results will be published in a scientific journal. All patient responses will be de-identified and then collated, so that your identity and any personal information will remain completely confidential.

Please note, if you do not want to be identified by name during the focus group session, you can use a different name. In order to respect the privacy of other participants, we request that you do not share what has been discussed in the focus group or divulge the identity of fellow participants to anybody outside the group.

Should you require further details about the project, either before, during or after the study, you may contact the research personnel (PhD Candidate), Ms Sheela Kumaran, Mobile No +61 448 326 022 (Australia)/ +91 98401 84001 (India) (Discipline of Optometry and Vision Science, Flinders University).

This study has been reviewed by the Southern Adelaide Clinical Human Research Ethics Committee. If you wish to discuss the study with someone not directly involved, in particular in relation to policies, your rights as a participant, or should you wish to make a confidential complaint, you may contact Prof Villis Marshall on 8204 6453 or email SALHNOfficeforResearch@sa.gov.au

Government of South Australia
SA Health

Flinders UNIVERSITY

SOUTHERN ADELAIDE CLINICAL HUMAN RESEARCH ETHICS COMMITTEE / FLINDERS UNIVERSITY

CONSENT TO PARTICIPATION IN RESEARCH

I, ... request and give
(first or given names) *(last name)*

consent to my involvement in the research project: Questionnaire Study – Phase I
A system for measurement of Amblyopia & Strabismus - specific quality of life using item banking and computer adaptive testing (Eye-tem Bank) Phase I: Item identification

I acknowledge the nature, purpose and contemplated effects of the research project, especially as far as they affect me, have been fully explained to my satisfaction by..... and my consent is given voluntarily
(first or given names) *(last name)*.

I acknowledge that the detail(s) of the following has/have been explained to me, including indications of risks, any discomfort involved, anticipation of length of time, and the frequency with which they will be performed.

Joining a focus group/one-on-one interviews (which may last for 1-2 hours) to talk about how Amblyopia & Strabismus affects me:

I have understood and am satisfied with the explanations that I have been given.

I have been provided with a written information sheet.

I understand that my involvement in this research project may not be of any direct benefit to me and that I may withdraw my consent at any stage without affecting my rights or the responsibilities of the researchers in any respect.

I understand that my medical records may be accessed to confirm my diagnosis.

I declare that I am over the age of 18 years.

I also consent to extracting my clinical details (measurements of vision and diagnosis) from my clinical file for this research *(please tick)* ☐ Yes ☐ No

I acknowledge that I have been informed that should I receive an injury as a result of taking part in this study, I may need to start legal action to determine whether I should be paid.

Signature of Research Participant : ..... Date: .....

I, ... have described to ..... the research project and nature and effects of procedure(s) involved. In my opinion he/she understands the explanation and has freely given his/her consent.

Signature: ..... Date: .....

Status in Project: .....

பங்கேற்பாளர் தகவல் தாள்

ஆய்வுத் தலைப்பு: வினாப்பட்டியல் ஆராய்ச்சி **– கட்டம் I**

வினா (உருப்படி) **வங்கி (Item Bank) மற்றும்** கணினிவழி சோதனை **மூலமாக சோம்பல் கண் மற்றும் மாறு கண் (ஓரக்கண்) நோயால் பாதிக்கப்பட்டவரின்** வாழ்க்கை தரத்தை **அறிய ஒரு** அளவீடு முறை**. கட்டம் I :** உருப்படி **கண்டறிதல்.**

நிறுவனங்களின் பெயர்:

இந்த ஆய்வு ஃபிலின்டர்ஸ் பல்கலைக்கழகம் (முன்னணி மையம்) மற்றும் நான்கு பிற மையங்களின் (தி குஈன் எலிசபெத் மருத்துவமனை, தெ.ஆ , தி ராயல் அடிலெயிட் மருத்துவமனை, தெ.ஆ, தி ராயல் விக்டோரியன் கண் மற்றும் காது மருத்துவமனை, விக்டோரியா, ஆப்டோமெட்ரி சன்பரி அண்ட் விஷன் பார் சில்ட்ரன், விக்டோரியா, ஓ பி எஸ் ம், ப்ரோகென் ஹில் மற்றும் தி எலைட் ஸ்கூல் ஒப் ஆப்டோமெட்ரி, சங்கர நேத்ராலயா, இந்தியா) கூட்டு முயற்சி.

இது ஒரு ஆராய்ச்சி ஆய்வு. இதில் நீங்கள் கலந்து கொள்வது கட்டாயம் இல்லை. நீங்கள் இதில் கலந்துக்கொள்ள விரும்பவில்லையென்றாலும் உங்களது மருத்துவ கவனிப்பு பாதிக்கப்படாது.

ஃபிலின்டர்ஸ் பல்கலைகழகத்தின் ஆப்டோமெட்ரி மற்றும் பார்வை அறிவியல் துறை நடத்தும் ஆய்வின் கட்டம் I யில் பங்கேற்க உங்களை அழைக்கிறோம். சோம்பல் கண் / மாறு கண் (ஓரக்கண்) எவ்வாறு மக்களின் வாழ்க்கையை பாதிக்கின்றது என்பதை ஆராய இந்த ஆய்வு மேற்கொள்ளப்படுகிறது. இந்த ஆய்வின் மூலம் சேகரிக்கப்படும் தகவல், வாழ்க்கை தரத்தை அளக்க ஒரு விரிவான வினா (உருப்படி) வங்கி (Item Bank) தயாரிக்க உபயோகிக்கப்படும். இந்த வினா வங்கி கண் மருத்துவர்களுக்கும் ஆராய்ச்சியாளர்களுக்கும் ஒருவர் மீது உள்ள கண் நோய் தாக்கத்தை மதிபீடவும், சிறந்த சிகிச்சை முறையை தேர்ந்தெடுக்கவும் துணை புரியும்.

இந்த ஆராய்ச்சியில் பங்கேற்க நீங்கள் விரும்பினால், ஒரு நேர்முக தேர்வில் (அல்லது தொலைபேசி தேர்வு) / விவாத குழுவில் பங்கேற்க அழைக்கப்படுவீர்கள். இந்த நேர்முக தேர்வு/ விவாத குழு சங்கர நேத்ராலயா கண் மருத்துவமனையில் நடத்தப்படும். ஒன்றிலிருந்து இரண்டு மணி நேரம் நடக்கும் இந்த உரையாடலை ஒரு பேட்டியாளர் வழி நடத்துவார். நீங்கள் ஒரு வேளை தொலைப்பேசி தேர்வை விரும்பினால், எங்கள் ஊழியர்களில் ஒருவர், நீங்கள் விரும்பும் நேரத்தில் உங்களை அழைத்து தொலைப்பேசி தேர்வை நடத்துவார். இந்த உரையாடல்கள் ஒலிப்பதிவு செய்யப்படும். உங்கள் அடையாளம் மற்றும் நீங்கள் தெரிவிக்கும் தகவல்கள் ரகசியமாக காக்கப்படும். எனினும் விவாத குழுவில் நீங்கள் பங்கேற்றால், உங்களது அடையாளம் சக பங்கேற்ப்பாளர்களுக்கு மறைவாக இருக்காது. இதை தவிர, வேறொன்றிற்கும்

உங்களை மீண்டும் அழைக்க மாட்டோம். உங்களது போக்குவரத்து செலவுக்காக உங்களுக்கு ரூபாய் முன்னூறு வழங்கப்படும்.

உங்களை குறித்த தனிப்பட்ட தகவல்கள் நேர்முக தேர்வுக்கு முன்பு பெறப்படும். நீங்கள் பின் வரும் ஒப்புதல் படிவத்தில் கை ஒப்பம் இட வேண்டும். இதற்கு அதிக நேரம் தேவைப்படாது. நீங்கள் பங்கேற்க சம்மதித்தால், உங்களது மருத்துவ பதிவேட்டிலிருந்து உங்கள் மருத்துவ விவரங்கள் (பார்வை அளவீடுகள் மற்றும் வியாதி நிர்ணயம்) சேகரிக்கப்படும். நீங்கள் ஒப்புதல் அளிக்கவில்லையென்றால் உங்களது மருத்துவ பதிவேடு எங்களால் அனுகப்படாது.

இந்த ஆய்வில் ஈடுபடுவதால் உங்களுக்கு நேரடியாக எந்த பயனும் இருக்காது. எனினும். நீங்கள் அளிக்கும் தகவல் எதிர்காலத்தில் கண் மருத்துவர்களுக்கும், ஆராய்ச்சியாளர்களுக்கும், கண் நோயால் பாதிக்கப்பட்டவரின் வாழ்க்கைத்தரத்தில் ஏற்படும் தாக்கத்தை மதிப்பிட உதவும்.(patients missing)

உங்களது பங்கேற்ப்பு உங்களது சிகிச்சையை எந்த விதத்திலும் பாதிக்காது. உங்களது பங்கேற்பு முழுமையாக உங்களது விருப்பம். இந்த ஆய்விலிருந்து எந்த நேரத்திலும் நீங்கள் விலகிக்கொள்ளலாம். நீங்கள் இந்த ஆய்வில் பங்கேற்காமல் போனாலும் அல்லது விலகினாலும், அது உங்கள் சிகிச்சையை பாதிக்காது.

நீங்கள் பங்கேற்கும் பொது உங்களுக்கு ஒருவேளை சிறிது விசனம் ஏற்ப்படலாம். இது நடந்தால், நீங்கள் இந்த ஆய்விலிருந்து விலகிக்கொள்ளலாம். அது உங்கள் சிகிச்சையை பாதிக்காது. இந்த ஆய்வில் பங்கேர்ப்பதினால் நீங்கள் உங்கள் சட்ட உரிமைகளை விட்டுக்கொடுக்கவில்லை.

இந்த ஆய்வில் பங்கேர்ப்பதினால் ஏதேனும் கெடுதி ஏற்பட்டால் வழக்கு இல்லாமல் இழப்பீடு கிடைக்ககூடும். ஆகினும் அந்த இழப்பீடு கிடைக்குமா என்பதை உறுதி செய்ய சட்டரீதியான நடவடிக்கை எடுக்க வேண்டும்.

உங்களது தனிப்பட்ட தகவல்கள் ரகசியமாக வைக்கப்படும். உங்கள் அடையாளத்தை தெரிவிக்கும் எந்த தகவலும் வெளியிடப்படாது. ஆவணங்கள் அனைத்தும், ஃபிலின்டர்ஸ் பல்கலைக்கழகத்தில் உள்ள ஸ்டுர்ட் வளாகத்தில் அறை எண் S171யில் பூட்டுடை நிலைப் பெட்டியில் வைக்கப்பட்டு மற்றும் கடவுச்சொல்லால் பாதுக்காக்கப்பட்ட கணினியில் சேமிக்கப்படும். நேர்முக தேர்வு / விவாத குழுவின் ஒலிப்பதிவுகள் பகுப்பாய்வுக்காக மாத்திரம் படியாக்கம் செய்யப்படும். ஆய்வு முடிந்த ஐந்து வருடங்களுக்கு பிறகு, சேகரிக்கப்பட்ட தரவு முற்றிலும் அழிக்கப்படும். இந்த ஆராய்ச்சி முழுமையடைந்தவுடன், ஆய்வுவின் முடிவுகள் அறிவியல் பத்திரிக்கையில் வெளியாகும் என்று எதிர்பார்க்கிறோம். அணைத்து பங்கேற்ப்பாளரின் அடையாளம் மறைக்கப்பட்டு, தொகுக்கப்பட்ட தகவல்கள் மட்டுமே வெளியாகும். தனிப்பட்ட தகவல்கள் அனைத்தும் ரகசியமாக காக்கப்படும்.

குறிப்பு: ஒருவேளை உங்களது பெயரை விவாத குழுவில் நீங்கள் தெரிவிக்க விரும்பவில்லையென்றால், நீங்கள் வேறொரு பெயரை உபயோகப்படுத்தலாம். சக பங்கேற்பாளரின் தனியுரிமையை மதித்து, யாருடைய தனி அடையாளங்களை வெளிப்படுத்தாமலும், இங்கே தெரிவிக்கப்படும் எந்த தகவல்களையும் யாரிடமும் பகிராமலும் இருக்க கோருகிறோம்.

இந்த ஆராய்ச்சிக்கு முன்பாகவோ, இறுதியிலோ அல்லது ஆராய்ச்சியின் பொழுதோ நீங்கள் இந்த ஆராய்ச்சிக்கு தொடர்பாக மேலும் விவரங்கள் தெரிந்துக்கொள்ள விரும்பினால், நீங்கள் PhD வேட்பாளர், ஷீலா குமரன் அவர்களை +61 448 326 022 (ஆஸ்திரேலியா) / +91 98401 84001 (இந்தியா) என்ற தொலைப்பேசி எண்ணில் அழைக்கலாம்.

இந்த ஆராய்ச்சி தெற்கு அடிலெயிட் மருத்துவ ஆராய்ச்சி நெறிமுறைகள் குழுவால் மதிப்பாய்வுரை செய்யப்பட்டது. இந்த ஆய்வைப்பற்றி, குறிப்பாக ஆராய்ச்சி பங்கேற்பாளராகிய உங்களுடைய உரிமைகளை பற்றி அல்லது ஆராய்ச்சி கொள்கை பற்றி, இதில் நேரடியாக தொடர்பில்லாதவர்களிடம் பேச விரும்பினால், அல்லது இந்த ஆய்வின் நடத்தைக்குறித்து புகார் தர விரும்பினால், பேராசிரியர் வில்லிஸ் மார்ஷல் அவர்களை +61 8204 6453 என்ற தொலைப்பேசி எண்ணில் அல்லது SALHNOfficeforResearch@sa.gov.au என்ற மின்னஞ்சலில் தொடர்புக்கொள்ளலாம்.

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(தெற்கு அடிலெய்ட் சுகாதார சேவை / ஃபிலின்டர்ஸ் பல்கலைக்கழகம்)
ஆராய்ச்சியில் பங்கேற்பதற்கு இணக்கம்

ஆய்வுத் தலைப்பு: **வினா** (உருப்படி) **வங்கி** (Item Bank) **மற்றும்** கணினிவழி சோதனை **மூலமாக சோம்பல் கண்** (lazy eye) **மற்றும் மாறு கண்** (**ஓரக்கண்**) **நோயால் பாதிக்கப்பட்டவரின்** வாழ்க்கை தரத்தை **அறிய ஒரு** அளவீடு முறை. **கட்டம்** I : உருப்படி **கண்டறிதல்**

நான், ..., மேலே சொல்லப்பட்டு இருக்கும் வினாப்பட்டியல் ஆராய்ச்சி ஆய்வில் பங்கேற்பதற்கு என் ஒப்புதலை தெரிவித்துக்கொள்கிறேன்.

இந்த ஆய்வுடைய இயல்பு, நோக்கம், சாத்தியமான விளைவுகள், குறிப்பாக, இந்த ஆய்வு என்னை எவ்வாறு பாதிக்ககூடும் என்பதை பற்றி முழுமையாக, திருப்திகரமாக, ... விளக்கினார். என் சுய விருப்பத்தின் அடிப்படையில் என் ஒப்புதல் அளிக்கப்படுகிறது.

பின் வரும் விவரங்கள், குறிப்பாக, இந்த ஆய்வால் ஏற்படக்கூடிய ஆபத்துக்கான அறிகுறிகள், அசௌகரியம், தோராயமான அவகாசம் பற்றி எனக்கு விவரிக்கப்பட்டது என்று ஒப்புக்கொள்கிறேன்

சோம்பல் கண் / ஓரக்கண், என்னையும் என் வாழ்க்கையும் எவ்வாறு பாதிக்கின்றது என்பதை பற்றி தெரிவிக்க, நான் ஒரு நேர்முக தேர்வில் / விவாத குழுவில் பங்கேற்க இருக்கிறேன். இதற்க்கு ஒன்றிலிருந்து இரண்டு மணி நேரம் தேவைப்படும்.

எனக்கு கொடுக்கப்பட்ட விளக்கங்களை நான் புரிந்து கொண்டேன். அவைகள் எனக்கு திருப்திகரமாக உள்ளது.

எழுதப்பட்ட ஒப்புதல் வடிவம் எனக்கு வழங்கப்பட்டுள்ளது.

இந்த ஆய்வில் என்னுடைய ஈடுபாட்டால் எனக்கு நேரடியாக எந்த பயனும் இருக்காது என்றும், நான் என் ஒப்புதலை என் உரிமையும், ஆராய்ச்சியாளரின் பொறுப்புகளும் எந்த விதத்திலும் பாதிக்கபாடாமல் எந்த நேரத்தில்லும் வாபஸ் பெற இயலும் என்று அறிந்திருக்கிறேன்.

என்னுடைய மருத்துவ பதிவேடுகள் என் மருத்துவ நிர்ணயத்தை உறுதிபடுத்திக்கொள்ள அணுகப்பட கூடும்.

நான் பதினெட்டு வயதுக்கு மேற்பட்டவர் என்று தெரிவித்துக்கொள்கிறேன்.

இந்த ஆய்வுக்காக, என் மருத்துவ பதிவேட்டிலிருந்து என் மருத்துவ விவரங்கள் (பார்வை அளவீடுகள் மற்றும் மருத்துவ நிர்ணயம்) சேகரிக்கப்பட என் ஒப்புதல் அளிக்கிறேன்.
(தயவு செய்து குறிப்பிடவும்) ஆம் ☐ இல்லை ☐

இந்த ஆய்வில் பங்கேர்ப்பதினால் எனக்கு ஏதேனும் கெடுதி ஏற்பட்டால், எனக்கு இழப்பீடு கிடைக்குமா என்பதை உறுதி செய்ய நான் சட்டரீதியான நடவடிக்கை எடுக்க வேண்டும் என்று எனக்கு தெரிவிக்கப்பட்டுள்ளது என்று ஒப்புக்கொள்கிறேன்.

....

ஆராய்ச்சி பங்கேற்பாளரின் கையொப்பம் தேதி

நான் ....., ஆராய்ச்சி பங்கேற்பாளர், ...க்கு இந்த ஆய்வை பற்றியும், அதன் இயல்பு, வழிமுறை, மற்றும் பாதிப்பு பற்றியும் விளக்கியுள்ளேன். என்னுடைய பார்வையில், இவர் கொடுக்கப்பட்ட விளக்கங்களை புரிந்து கொண்டதின் அடிப்படையில் தன்னுடைய ஒப்புதலை அளித்துள்ளார்.

....

கையொப்பம் தேதி

ஆராய்ச்சி நிலை .....

Appendix 6
Interview guide

Introduction

Thank you for taking part in the study. We are interested to know how your eye condition has affected your day to day life – your quality of life. Your responses will be used to understand the impact of lazy eye – amblyopia and cross eye-strabismus on one's life.

About the eye condition

What bothers you most about your eyes?
Can you brief about your eye condition?
How and when was it diagnosed?

Treatment and impact

Have you had any sort of treatment?
What was your experience undergoing treatment?

Symptoms

Can you describe your eyesight/vision?
What are the visual, ocular sensation or symptoms you experience? (e.g. blurred vision, double vision)
What about any general bodily symptoms associated with your eye condition? (e.g. headaches, tiredness)
How does these symptoms affect your life?

Activity limitation

What sort of difficulties do you experience in your day-to-day life because of your eye condition and its treatment/s?
Are you aware of any tasks that you can't perform or avoid doing?
Have there been any instances in which you need to change the way you complete day-to-day tasks?

Work and finance

How does your eye condition affect your work life?
Do you feel your eye condition has affected any job opportunities? Can you explain?
Did you notice any hindrances caused by the eye condition at work?
What things have cost you money because of your eye problems and its treatment or care?

Social impact

How does your eye condition affect your social life and family life?
Have you ever been treated differently for having your eye problem?
Can you describe any problems you might have in interpersonal relationships or communicating with others?
What was the attitude of your family and friends about your eye condition?

Emotional impact
How does having this eye condition make you feel emotionally?
Does the treatment or anything associated with it affect you emotionally?
Do you worry about anything?

Concerns
What are the concerns you have because of your eye condition?
Were you concerned about your treatment outcome/s?
Are you concerned about what people think about your eye condition?

Mobility
Can you describe how your eye problems have affected your ability to travel or navigate?
Do you have any problem getting around? e.g. using stairs, crossing roads
Do you have any problems in travelling outside or in crowded places?

Inconvenience
From your experiences what are the major inconveniences associated with having a lazy eye and their treatment/s?

Coping
We've talked a lot about the impact of your eye condition. So how did you manage or cope up?
What sort of techniques did you use?

Closure
Is there anything else you want to add about the impact of your eye condition on your life?

Thank you very much for participating.

Interview guide – Tamil

அறிமுகம்
இந்த ஆய்வில் பங்கேற்றதற்கு நன்றி. உங்கள் கண் நோயானது உங்கள் அன்றாட வாழ்க்கையை எவ்வாறு பாதித்துள்ளது என்பதை அறிய விரும்புகிறோம். உங்கள் பதில்கள் சோம்பல் கண் மற்றும் மாறு கண்ணால் ஏற்படும் தாக்கத்தை புரிந்துகொள்ள உதவும்

கண் பிரச்சனை பற்றி
உங்கள் கண்களைபற்றி நினைக்கும் போது எது மிகுந்த வருத்தத்தை அளிக்கிறது?
உங்கள் கண் பிரச்சனையைப்பற்றி சொல்லுங்கள்.
அது எப்படி, எப்போது கண்டறியப்பட்டது?

சிகிச்சை மற்றும் தாக்கம்
உங்கள் கண் பிரச்சனைக்கு, எதாவது சிகிச்சைப்பெற்றிருக்கிறீர்களா?
சிகிச்சைப்பெற்ற அனுபவத்தை பற்றி சொல்லுங்கள்.

அறிகுறிகள்
உங்கள் கண் பார்வை எவ்வாறு உள்ளது?
நீங்கள்அனுபவிக்கும் கண் பிரச்சனை சார்ந்த அறிகுறிகள் என்ன? (உ.தா. மங்கலான பார்வை, இரட்டை பார்வை)
உங்கள் கண் பிரச்சனையினால் உடலில் ஏற்படும் கஷ்டம்என்ன?
இந்த அறிகுறிகள் எவ்வாறு உங்கள் வாழ்க்கையை எவ்வாறு பாதிக்கின்றன?

தினசரி வாழ்க்கையில் உள்ள கஷ்டங்கள்
உங்களுடைய கண் பிரச்சனை மற்றும் சிகிச்சை காரணமாக உங்கள் தினசரி வாழ்க்கையில் எந்த வகையான கஷ்டங்களை அனுபவிக்கிறீர்கள்?
உங்கள் கண் பிரச்சனை காரணமாக ஒரு சில வேலைகளை செய்ய முடியாமல் போனதுண்டா?
உங்கள் தினசரி பணிகளை முடிக்க வித்தியாசமான முறைகளை பயன்படுத்த வேண்டியிருந்ததா?

பொருளாதார தாக்கம்
உங்கள் கண் பிரச்சனை உங்கள் வேலையை/ பணியை எவ்வாறு பாதிக்கின்றது?
உங்கள் கண் பிரச்சனையினால் ஏதேனும் வேலை வாய்ப்புகளை இழந்ததாக நினைக்கின்றீர்களா?

உங்கள் கண் பிரச்சனையால் வேலை ஸ்தலத்தில் ஏதேனும் தாக்கம் ஏற்பட்டதுண்டா?
உங்கள் கண் பிரச்சினைகள் மற்றும் அதன் சிகிச்சையால் ஏற்படும் பொருளாதார தாக்கத்தை பற்றி சொல்லுங்கள்

சமூக வாழ்க்கையில் உள்ள கஷ்டங்கள்
உங்கள் கண் பிரச்சனை உங்கள் சமூக வாழ்க்கையையும் குடும்ப வாழ்க்கையையும் எப்படி பாதிக்கின்றது?
உங்கள் கண் பிரச்சனையினால், பிறர் உங்களை வித்தியாசமாக நடத்துவதுண்டா?
நெருக்கமான உறவுகள், மற்றவரோடு பேசி பழகுதல் போன்றவற்றில் ஏதேனும் பிரச்சனை உண்டா?
உங்கள் கண் பிரச்சனை பற்றி உங்கள் குடும்பம் மற்றும் நண்பர்களின் மனப்பான்மை என்ன?

மன நலம்
இந்த கண் பிரச்சனை உள்ளதால், உணர்ச்சி ரீதியாக எப்படி உணர்கிறீர்கள்?
உங்கள் கண் பிரச்சனைக்கு அளிக்கப்பட்ட சிகிச்சை அல்லது அதை தொடர்புடைய ஏதேனும் உங்கள் மனதை பாதித்துள்ளதா?
நீங்கள் எதை பற்றியாகிலும் கவலைப்படுகிறீர்களா?

கண் பிரச்சனை சார்ந்த கவலைகள்
உங்கள் கண் பிரச்சினையினால் நீங்கள் எதைக்குறித்து கவலைப்படுகிறீர்கள்?
உங்களுக்கு அளிக்கப்பட்ட சிகிச்சை/ அதன் பலன் பற்றி நீங்கள் கவலைப்பட் டீர்களா?
உங்கள் கண் பிரச்சினையைப் பற்றி மற்றவர்கள் என்ன நினைப்பார்கள் என்று கவலைப்படுகிறீர்களா?

நடமாடுதல்
உங்கள் கண் பிரச்சனைகள் உங்கள் நடமாடுதலை எவ்வாறு பாதிக்கின்றது?
மாடி படிக்கட்டுகள் பயன்படுத்துவதில் அல்லது சாலைகளை கடப்பதில் ஏதேனும் பிரச்சனை இருக்கிறதா?
கூட் ட நெரிசலான இடங்களில் பயணிப்பதில் ஏதேனும் சிக்கல் இருக்கிறதா?

அசௌகரியங்கள்
உங்கள் அனுபவங்களிலிருந்து, இந்த கண் பிரச்சனை மற்றும் சிகிச்சை காரணமாக ஏற்படும் சிரமங்கள் / அசௌகரியகளை விவரியுங்கள்.

சமாளிக்கும் முறை
உங்கள் கண் பிரச்சினையினால் உண்டான பாதிப்பைகுறித்து சொன்னீர்கள். அந்த பாதிப்பை எவ்வாறு சமாளிக்கின்றீர்கள்? நீங்கள் எந்த விதமான வழிகளை/ முறைகளை பயன்படுத்தி சமாளித்தீர்கள்?

முடிவுரை
உங்கள் கண் பிரச்சனை உங்கள் வாழ்க்கையை வேறு எவ்வாறு பாதிக்கின்றது? வேறு ஏதாவது பகிர்ந்துகொள்ள விரும்புகிறீர்களா? இந்த ஆய்வில் கலந்த கொண்டமைக்கு மிக்க நன்றி.

Appendix 7

Background questionnaire and Item banks - Australia

Thank you for taking part in this research survey.

All of the following questions are about **the impact of amblyopia (lazy eye), strabismus (crossed eye) and its treatment on your quality of life**.

This questionnaire is a long one. We have included a wide range of questions to comprehensively cover all issues that arise with the condition (mild to severe). Therefore, some issues may not be relevant to you. It is very important that we validate this long questionnaire (which we address as 'item bank'), which will enable us to develop an advanced measurement system (next phase of this research) that will use very few questions to measure quality of life precisely. The advanced measurement system will be useful for clinical and research purposes, especially to evaluate the effectiveness of new treatment for amblyopia and strabismus.

This questionnaire is divided into several sections addressing different aspects of quality of life (like limitations in performing daily activities, emotional well-being, convenience etc.). Each question is followed by a list of all possible answers. You may choose the answer that best applies to you (if they don't apply to you, please select 'this task is not relevant to me / don't do the task'). As your response to each of the questions is very important to us, please take as much time as you need to answer. All your answers and the information you provide will be regarded as strictly confidential.

Please consider ONLY your <u>amblyopia and/or strabismus</u> and its <u>current treatment</u> (e.g. patching therapy, action video game therapy, vision therapy) when you answer these questions. If you usually use glasses, contact lenses or low vision devices, please answer according to how you can see when using them.

Date: Time started: Time finished:	**For office use** Name: Participant ID:

Background Questionnaire

Please answer the following questions about yourself and your eye condition. This will help us analyse the results of this survey.

Name	
Address	
	Post Code:
Contact telephone no	
E-mail	
Date of Birth (DD/MM/YYYY)	
Country of birth	Australia / Other If other, please specify:
Gender	Male / Female / Other / Refuse to answer
Main language spoken at home	English / Other If other, please specify:
Highest educational qualification	Degree or higher/ Diploma/ Certificate/ No post school qualification/ Other If other, please specify:
Current employment status	Retired / Unemployed/ Employed/ Volunteer work/ Student / Other, please specify:
Do you currently have amblyopia (lazy eye)?	Yes / No / Not sure Eye involved: Right/ Left/ Both/ Not sure
Do you currently have strabismus (crossed eyes / misaligned eyes)?	Yes / No / Not sure Eye involved: Right/ Left / Not sure
Is your strabismus (eye misalignment) noticeable by others?	Yes / No / I don't have strabismus / I am not sure
Do you have refractive error in either of your eyes (e.g. short sight, long sight, astigmatism)	Yes/ No Eye involved: Right/ Left/ Both

Background questionnaire - continued

Have you had any treatment for amblyopia or strabismus? **Please circle all responses that apply**	Glasses / Contact lenses / Patching therapy / Drops / Vision therapy / Video game therapy / Surgery / Other If other, please specify:
Do you have any other eye disease?	Yes / No If yes, please specify:
Do you have any other medical condition or diagnosis?	Yes / No If yes, please specify:
Please specify the name of your eye care provider if you give us approval to contact them to obtain some clinical details about your eye condition (e.g. visual acuity)	

VISUAL SYMPTOMS														
		Because of your eye condition or its treatment												
		How often do you experience…?					**How severe is/are the…?**				**How much of a problem is/are the…?**			
		Never	Occasionally	Quite often	Very often		Not at all	Mild	Moderate	Severe		None	A little	Quite a bit	A lot
Example	**Tired eyes**	4	(3)	2	1		4	3	(2)	1		4	3	2	(1)
VS1	Blurred vision for distance	4	3	2	1		4	3	2	1		4	3	2	1
VS2	Blurred vision for near	4	3	2	1		4	3	2	1		4	3	2	1
VS3	Poor vision	4	3	2	1		4	3	2	1		4	3	2	1
VS4	Poor vision in one eye	4	3	2	1		4	3	2	1		4	3	2	1
VS5	Poor peripheral vision (side vision) in the affected eye	4	3	2	1		4	3	2	1		4	3	2	1
VS6	Difficulty in focussing your eyes	4	3	2	1		4	3	2	1		4	3	2	1
VS7	Difficulty in judging distances / perceiving depth	4	3	2	1		4	3	2	1		4	3	2	1
VS8	Difficulty shifting focus between near and far distances	4	3	2	1		4	3	2	1		4	3	2	1
VS9	Double vision	4	3	2	1		4	3	2	1		4	3	2	1
VS10	Double vision when tired	4	3	2	1		4	3	2	1		4	3	2	1
VS11	Ghost images or shadows around objects you see	4	3	2	1		4	3	2	1		4	3	2	1

VISUAL SYMPTOMS - continued															
		Because of your eye condition or its treatment													
		How often do you experience…?					**How severe is/are the…?**					**How much of a problem is/are the…?**			
		Never	Occasionally	Quite often	Very often		Not at all	Mild	Moderate	Severe		None	A little	Quite a bit	A lot
VS12	Objects that you are looking at move or jump around	4	3	2	1		4	3	2	1		4	3	2	1
VS13	Glare from lights e.g. sunlight, car headlights	4	3	2	1		4	3	2	1		4	3	2	1
VS14	Sensitivity to light	4	3	2	1		4	3	2	1		4	3	2	1
VS15	Difficulty in adapting to changes in light [bright to dark or dark to bright]	4	3	2	1		4	3	2	1		4	3	2	1

OCULAR SYMPTOMS														
		Because of your eye condition or its treatment												
		How often do you experience…?					**How severe is/are the…?**					**How much of a problem is/are the…?**			
		Never	Occasionally	Quite often	Very often		Not at all	Mild	Moderate	Severe		None	A little	Quite a bit	A lot
OS1	Eye strain	4	3	2	1		4	3	2	1		4	3	2	1
OS2	Tired eyes	4	3	2	1		4	3	2	1		4	3	2	1
OS3	Heavy eyes	4	3	2	1		4	3	2	1		4	3	2	1
OS4	Dry eyes	4	3	2	1		4	3	2	1		4	3	2	1
OS5	Red eyes	4	3	2	1		4	3	2	1		4	3	2	1
OS6	Watery eyes	4	3	2	1		4	3	2	1		4	3	2	1
OS7	Pain in your eyes	4	3	2	1		4	3	2	1		4	3	2	1
OS8	Discomfort in your eyes	4	3	2	1		4	3	2	1		4	3	2	1
OS9	Burning sensation in your eyes	4	3	2	1		4	3	2	1		4	3	2	1
OS10	Irritation in your eyes	4	3	2	1		4	3	2	1		4	3	2	1
OS11	Misalignment of your eyes	4	3	2	1		4	3	2	1		4	3	2	1
OS12	Misalignment of your eyes when tired	4	3	2	1		4	3	2	1		4	3	2	1

GENERAL SYMPTOMS															
		Because of your eye condition or its treatment													
		How often do you experience …?					**How severe is/are the…?**					**How much of a problem is/are the…?**			
		Never	Occasionally	Quite often	Very often		Not at all	Mild	Moderate	Severe		None	A little	Quite a bit	A lot
GS1	Headaches	4	3	2	1		4	3	2	1		4	3	2	1
GS2	Back pain	4	3	2	1		4	3	2	1		4	3	2	1
GS3	Neck pain	4	3	2	1		4	3	2	1		4	3	2	1
GS4	Tiredness	4	3	2	1		4	3	2	1		4	3	2	1
GS5	Dizziness	4	3	2	1		4	3	2	1		4	3	2	1
GS6	Sleepiness (e.g. while reading, in low light conditions)	4	3	2	1		4	3	2	1		4	3	2	1
GS7	Feeling of confusion and disorientation	4	3	2	1		4	3	2	1		4	3	2	1
GS8	Loss of balance	4	3	2	1		4	3	2	1		4	3	2	1
GS9	Abnormal head posture (e.g. head turn, head tilt)	4	3	2	1		4	3	2	1		4	3	2	1
GS10	Difficulty in concentrating	4	3	2	1		4	3	2	1		4	3	2	1

ACTIVITY LIMITATION								
Because of your eye condition or its treatment, how much difficulty do you have…?		**None**	**A little**	**Quite a bit**	**A lot**	**Unable to do because of my eye condition**	**This task is not relevant to me / don't do the task**	**Refuse to answer**
AL1	Cooking	5	4	3	2	1	9	8
AL2	Cutting or chopping food	5	4	3	2	1	9	8
AL3	Getting things out of the oven	5	4	3	2	1	9	8
AL4	Pouring a drink	5	4	3	2	1	9	8
AL5	Picking up or putting cups back on the table	5	4	3	2	1	9	8
AL6	Looking after your appearance, e.g. your face, hair, shaving	5	4	3	2	1	9	8
AL7	Putting on eye make-up	5	4	3	2	1	9	8
AL8	Cutting your fingernails or toenails safely	5	4	3	2	1	9	8
AL9	Judging how close or far things are from you	5	4	3	2	1	9	8
AL10	Seeing 3D movies or 3D pictures	5	4	3	2	1	9	8
AL11	Seeing in glare conditions	5	4	3	2	1	9	8
AL12	Seeing well at night	5	4	3	2	1	9	8
AL13	Seeing well when you are tired	5	4	3	2	1	9	8
AL14	Seeing what people are pointing at in the distance	5	4	3	2	1	9	8
AL15	Sewing	5	4	3	2	1	9	8
AL16	Threading a needle	5	4	3	2	1	9	8
AL17	Crocheting or knitting	5	4	3	2	1	9	8
AL18	Judging the ball when playing sports	5	4	3	2	1	9	8
AL19	Catching a ball	5	4	3	2	1	9	8
AL20	Hitting a ball	5	4	3	2	1	9	8
AL21	Playing fast ball games e.g. tennis, cricket	5	4	3	2	1	9	8
AL22	Playing basketball, netball or football	5	4	3	2	1	9	8
AL23	Swimming	5	4	3	2	1	9	8

ACTIVITY LIMITATION - continued								
Because of your eye condition or its treatment, how much difficulty do you have…?		**None**	**A little**	**Quite a bit**	**A lot**	**Unable to do because of my eye condition**	**This task is not relevant to me / don't do the task**	**Refuse to answer**
AL24	Performing work related tasks	5	4	3	2	1	9	8
AL25	Doing any small, fiddly tasks	5	4	3	2	1	9	8
AL26	Using hand tools, e.g. a screwdriver	5	4	3	2	1	9	8
AL27	Using instruments that require using both eyes together e.g. binoculars, stereoscopes	5	4	3	2	1	9	8
AL28	Using a computer	5	4	3	2	1	9	8
AL29	Using a mobile phone	5	4	3	2	1	9	8
AL30	Using an IPad or tablet	5	4	3	2	1	9	8
AL31	Writing in a straight line	5	4	3	2	1	9	8
AL32	Watching television	5	4	3	2	1	9	8
AL33	Engaging in a hobby or leisure activity, e.g. reading, crafts, photography	5	4	3	2	1	9	8
AL34	Taking care of the garden, e.g. weeding, pruning, mowing the lawn	5	4	3	2	1	9	8
AL35	Reading the newspaper	5	4	3	2	1	9	8
AL36	Reading glossy and colourful prints, e.g. cook books, magazines	5	4	3	2	1	9	8
AL37	Reading small print, e.g. the phone book, yellow pages	5	4	3	2	1	9	8
AL38	Reading menu boards e.g. in fast food restaurants	5	4	3	2	1	9	8
AL39	Reading text on television	5	4	3	2	1	9	8
AL40	Reading from a board or overhead screen	5	4	3	2	1	9	8
AL41	Reading the numbers on the front of a bus	5	4	3	2	1	9	8
AL42	Reading the printed timetable in a railway station or a bus station	5	4	3	2	1	9	8
AL43	Reading street signs	5	4	3	2	1	9	8
AL44	Reading in dim light conditions	5	4	3	2	1	9	8

ACTIVITY LIMITATION - continued								
Because of your eye condition or its treatment, how much difficulty do you have…?		**None**	**A little**	**Quite a bit**	**A lot**	**Unable to do because of my eye condition**	**This task is not relevant to me / don't do the task**	**Refuse to answer**
AL45	Reading for a prolonged period of time	5	4	3	2	1	9	8
AL46	Reading at a fast pace	5	4	3	2	1	9	8

DRIVING								
Because of your eye condition or its treatment, how much difficulty do you have…?		**None**	**A little**	**Quite a bit**	**A lot**	**Unable to do because of my eye condition**	**Don't drive for other reasons**	**Refuse to answer**
AL47	Driving during the day	5	4	3	2	1	9	8
AL48	Driving at night	5	4	3	2	1	9	8
AL49	Driving in bad weather	5	4	3	2	1	9	8
AL50	Driving in heavy traffic	5	4	3	2	1	9	8
AL51	Driving in unfamiliar places	5	4	3	2	1	9	8
AL52	Driving at high speed, e.g. on highways	5	4	3	2	1	9	8
AL53	Driving for long periods of time	5	4	3	2	1	9	8
AL54	Driving towards oncoming headlights	5	4	3	2	1	9	8
AL55	Reversing your car	5	4	3	2	1	9	8
AL56	Parking	5	4	3	2	1	9	8
AL57	Judging distances while driving and parking	5	4	3	2	1	9	8
AL58	Judging the lane of the oncoming traffic while waiting at intersections	5	4	3	2	1	9	8
AL59	Changing lanes in traffic	5	4	3	2	1	9	8
AL60	Noticing when the car in front of you is speeding up or slowing down	5	4	3	2	1	9	8
AL61	Seeing objects on the side of the affected eye while driving e.g. other cars, bikes or pedestrians	5	4	3	2	1	9	8
AL62	Seeing road markings clearly when driving	5	4	3	2	1	9	8
AL63	Seeing at your car's dashboard clearly, e.g. speedometer, fuel gauge	5	4	3	2	1	9	8
AL64	Riding a motorcycle or moped	5	4	3	2	1	9	8

MOBILITY								
Because of your eye condition or its treatment, how much difficulty do you have…?		**None**	**A little**	**Quite a bit**	**A lot**	**Unable to do because of my eye condition**	**This task is not relevant to me / don't do the task**	**Refuse to answer**
MB1	Crossing a street or road	5	4	3	2	1	9	8
MB2	Going up steps or stairs	5	4	3	2	1	9	8
MB3	Going down steps or stairs	5	4	3	2	1	9	8
MB4	Using unmarked steps or curbs, e.g. concrete curbs or steps that do not have a coloured strip	5	4	3	2	1	9	8
MB5	Using escalators	5	4	3	2	1	9	8
MB6	Walking steadily with normal posture/ gait	5	4	3	2	1	9	8
MB7	Walking in unfamiliar areas	5	4	3	2	1	9	8
MB8	Walking on uneven ground and negotiating bumps or cracks in your path	5	4	3	2	1	9	8
MB9	Walking in crowded situations	5	4	3	2	1	9	8
MB10	Negotiating obstacles while walking, e.g. table, people	5	4	3	2	1	9	8
MB11	Judging doorways	5	4	3	2	1	9	8
MB12	Noticing things to the side of the affected eye while moving around	5	4	3	2	1	9	8
MB13	Navigating in dim light	5	4	3	2	1	9	8
MB14	Navigating when you experience double vision	5	4	3	2	1	9	8

CONCERNS								
Because of your eye condition or its treatment, how concerned are you about…?		**Not at all**	**A little bit**	**A moderate amount**	**A lot**	**Extremely**	**This issue is not relevant to me**	**Refuse to answer**
HC1	Having just one good eye	5	4	3	2	1	9	8
HC2	Being dependent on the good eye	5	4	3	2	1	9	8
HC3	Getting other eye diseases in your good eye	5	4	3	2	1	9	8
HC4	Undergoing treatment for other eye disease in your good eye e.g. cataract surgery	5	4	3	2	1	9	8
HC5	Straining or overloading your good eye	5	4	3	2	1	9	8
HC6	Your good eye getting injured	5	4	3	2	1	9	8
HC7	Your bad eye	5	4	3	2	1	9	8
HC8	Safety of your eyes	5	4	3	2	1		8
HC9	Letting other people touch your eyes	5	4	3	2	1		8
HC10	Problems associated with your eye condition becoming worse with age	5	4	3	2	1		8
HC11	Your eyesight or eye problems getting worse	5	4	3	2	1		8
HC12	Going blind	5	4	3	2	1		8
HC13	Passing the eye condition onto your children	5	4	3	2	1	9	8
HC14	Having a misaligned or turned eye	5	4	3	2	1	9	8
HC15	Having to wear thick glasses	5	4	3	2	1	9	8
HC16	The cosmetic appearance of your eyes	5	4	3	2	1	9	8
HC17	Your looks	5	4	3	2	1	9	8
HC18	Being in photographs	5	4	3	2	1		8
HC19	Having eye contact with people	5	4	3	2	1		8
HC20	What other people think of you	5	4	3	2	1		8
HC21	The way people react to you	5	4	3	2	1	9	8
HC22	People not understanding your eye condition	5	4	3	2	1	9	8

CONCERNS - continued								
Because of your eye condition or its treatment, how concerned are you about…?		**Not at all**	**A little bit**	**A moderate amount**	**A lot**	**Extremely**	**This issue is not relevant**	**Refuse to answer**
HC23	People judging you	5	4	3	2	1	9	8
HC24	People passing comments about your eye condition	5	4	3	2	1	9	8
HC25	Being bullied or teased	5	4	3	2	1	9	8
HC26	Being laughed at	5	4	3	2	1	9	8
HC27	Being treated differently	5	4	3	2	1	9	8
HC28	Being left out, e.g. not selected for sports team	5	4	3	2	1	9	8
HC29	Not being able to earn the respect of others	5	4	3	2	1	9	8
HC30	Being clumsy	5	4	3	2	1	9	8
HC31	Bumping into people or objects	5	4	3	2	1	9	8
HC32	Dropping things or spilling liquids	5	4	3	2	1	9	8
HC33	Tripping	5	4	3	2	1		8
HC34	Falling	5	4	3	2	1		8
HC35	Getting injured while cutting food	5	4	3	2	1	9	8
HC36	Getting injured while playing sports	5	4	3	2	1	9	8
HC37	Experiencing double vision	5	4	3	2	1	9	8
HC38	Having accidents (motor vehicle related) e.g. scratching car while parking	5	4	3	2	1	9	8
HC39	Having accidents (non-motor vehicle related) e.g. while using tools like a hammer	5	4	3	2	1	9	8
HC40	Missing out on things	5	4	3	2	1		8
HC41	Not being able to enjoy 3D pictures or movies	5	4	3	2	1	9	8
HC42	Not being able to use both eyes together	5	4	3	2	1	9	8
HC43	Not being able to do things you like in the future	5	4	3	2	1		8
HC44	Not being able to do well academically	5	4	3	2	1	9	8

CONCERNS - continued								
Because of your eye condition or its treatment, how concerned are you about…?		**Not at all**	**A little bit**	**A moderate amount**	**A lot**	**Extremely**	**This issue is not relevant**	**Refuse to answer**
HC45	Not being able to pursue the sports, hobbies or leisure activities that you like	5	4	3	2	1	9	8
HC46	Not being able to concentrate for a long period of time	5	4	3	2	1	9	8
HC47	Not being successful	5	4	3	2	1	9	8
HC48	Losing your driver's licence in the future	5	4	3	2	1	9	8
HC49	Putting other people in danger by driving	5	4	3	2	1	9	8
HC50	Having to alter your career choice	5	4	3	2	1	9	8
HC51	Your ability to obtain or keep a job	5	4	3	2	1	9	8
HC52	The impact of your appearance on work	5	4	3	2	1	9	8
HC53	The impact your eye condition or disability has on your family members	5	4	3	2	1	9	8
HC54	Not being diagnosed or treated early	5	4	3	2	1	9	8
HC55	Knowing that there is no or limited treatment options available for your eye condition	5	4	3	2	1	9	8
HC56	Your doctor being unsure about treatment modality and outcome	5	4	3	2	1	9	8
HC57	The type of treatment you received	5	4	3	2	1	9	8
HC58	Ineffective treatment in the past	5	4	3	2	1	9	8
HC59	Long duration of amblyopia (lazy eye) treatment	5	4	3	2	1	9	8
HC60	The outcome of strabismus surgery e.g. over or under-corrected squint	5	4	3	2	1	9	8
HC61	Recurrence of strabismus even after treatment	5	4	3	2	1	9	8
HC62	Not getting enough information or explanation from the medical staff	5	4	3	2	1	9	8

EMOTIONAL							
(Because of your eye condition or its treatment) **During the past four weeks, how often did you…?**		**None of the time**	**A little of the time**	**Some of the time**	**Most of the time**	**All of the time**	**Refuse to answer**
EM1	Feel unhappy	5	4	3	2	1	8
EM2	Feel annoyed	5	4	3	2	1	8
EM3	Feel depressed	5	4	3	2	1	8
EM4	Feel anxious	5	4	3	2	1	8
EM5	Feel frustrated	5	4	3	2	1	8
EM6	Feel disconcerted	5	4	3	2	1	8
EM7	Feel nervous	5	4	3	2	1	8
EM8	Feel stressed	5	4	3	2	1	8
EM9	Feel upset	5	4	3	2	1	8
EM10	Feel awful	5	4	3	2	1	8
EM11	Feel terrible	5	4	3	2	1	8
EM12	Feel troubled	5	4	3	2	1	8
EM13	Feel miserable	5	4	3	2	1	8
EM14	Feel irritable	5	4	3	2	1	8
EM15	Feel demoralized	5	4	3	2	1	8
EM16	Feel like crying	5	4	3	2	1	8
EM17	Feel like you are struggling	5	4	3	2	1	8
EM18	Feel life is hard	5	4	3	2	1	8
EM19	Feel regretful or guilty about your eye care in the past	5	4	3	2	1	8
EM20	Feel bad about your treatment outcome	5	4	3	2	1	8
EM21	Feel shocked by what your eye specialists have told you about your eyes	5	4	3	2	1	8
EM22	Feel disappointed	5	4	3	2	1	8
EM23	Feel hopeless	5	4	3	2	1	8
EM24	Feel discriminated against	5	4	3	2	1	8
EM25	Feel embarrassed because of your appearance	5	4	3	2	1	8
EM26	Feel embarrassed when you make a mistake	5	4	3	2	1	8
EM27	Feel ashamed	5	4	3	2	1	8
EM28	Feel humiliated	5	4	3	2	1	8

EMOTIONAL - continued							
(Because of your eye condition or its treatment) **During the past four weeks, how often did you…?**		**None of the time**	**A little of the time**	**Some of the time**	**Most of the time**	**All of the time**	**Refuse to answer**
EM29	Feel inferior	5	4	3	2	1	8
EM30	Feel left out	5	4	3	2	1	8
EM31	Feel lonely or isolated	5	4	3	2	1	8
EM32	Feel not appreciated	5	4	3	2	1	8
EM33	Feel reluctant to socialise	5	4	3	2	1	8
EM34	Feel like you have low self-confidence	5	4	3	2	1	8
EM35	Feel like you have low self-esteem	5	4	3	2	1	8
EM36	Feel self-conscious	5	4	3	2	1	8
EM37	Feel shy	5	4	3	2	1	8
EM38	Feel that you are different from everyone else	5	4	3	2	1	8
EM39	Feel uncomfortable in public	5	4	3	2	1	8
EM40	Feel uneasy when people stare at you	5	4	3	2	1	8
EM41	Feel reluctant to talk about your eye problem	5	4	3	2	1	8
EM42	Fear losing vision in your good eye	5	4	3	2	1	8
EM43	Feel overprotective about your eyes	5	4	3	2	1	8
EM44	Feel scared when you experience double vision	5	4	3	2	1	8
EM45	Feel unfortunate	5	4	3	2	1	8
EM46	Feel sorry for yourself	5	4	3	2	1	8
EM47	Feel envious about others with good vision	5	4	3	2	1	8
EM48	Worry about your eye condition	5	4	3	2	1	8
EM49	Wish things were normal	5	4	3	2	1	8

SOCIAL								
Because of your eye condition or its treatment, how much of a problem do you have…?		**None**	**A little**	**Quite a bit**	**A lot**	**Unable to do because of my eye condition**	**This task is not relevant to me / don't do the task**	**Refuse to answer**
SC1	Chatting with people	5	4	3	2	1		8
SC2	Interacting socially with people	5	4	3	2	1		8
SC3	Meeting people for the first time	5	4	3	2	1		8
SC4	Making new friends	5	4	3	2	1		8
SC5	Maintaining your friendships	5	4	3	2	1		8
SC6	Maintaining your roles and responsibilities at work	5	4	3	2	1		8
SC7	Maintaining your close personal relationships, e.g. marriage, partner, living companion, family members	5	4	3	2	1		8
SC8	Engaging with your children or grandchildren in playing, e.g. ball games	5	4	3	2	1	9	8
SC9	Talking to the opposite gender	5	4	3	2	1		8
SC10	Engaging in social activities	5	4	3	2	1		8
SC11	Participating in social activities at night	5	4	3	2	1		8
SC12	Socialising in peer groups	5	4	3	2	1		8
SC13	Socialising with people or groups you don't know that well	5	4	3	2	1		8
SC14	Socialising because people comment on your eyes	5	4	3	2	1	9	8
SC15	Socialising because of the way people look at you	5	4	3	2	1	9	8
SC16	Socialising because people become uncomfortable e.g. people unsure about which eye to look at	5	4	3	2	1	9	8
SC17	Socialising because of not being able to maintain eye contact	5	4	3	2	1	9	8
SC18	Socialising because you experience double vision	5	4	3	2	1	9	8
SC19	With family members or friends getting annoyed at you when you can't do something	5	4	3	2	1	9	8
SC20	With family members or friends getting annoyed at you when you make a mistake	5	4	3	2	1	9	8

SOCIAL - continued								
Because of your eye condition or its treatment, how much of a problem do you have…?		**None**	**A little**	**Quite a bit**	**A lot**	**Unable to do because of my eye condition**	**This task is not relevant to me / don't do the task**	**Refuse to answer**
SC21	With family members or friends making an issue of your eye problem	5	4	3	2	1		8
SC22	Getting help and support from your family and friends	5	4	3	2	1		8

CONVENIENCE								
Because of your eye condition or its treatment, how much trouble is…?		**None**	**A little bit**	**A moderate amount**	**Quite a lot**	**Extremely**	**This is not relevant to me**	**Refuse to answer**
CV1	Having to be slower or more careful	5	4	3	2	1	9	8
CV2	Having to drive slowly and more carefully	5	4	3	2	1	9	8
CV3	Having to allow a bit of extra leeway while driving	5	4	3	2	1	9	8
CV4	Needing longer to do things	5	4	3	2	1	9	8
CV5	Having limitations on how long you can do things for, e.g. reading for prolonged time or going for a long drive	5	4	3	2	1	9	8
CV6	Having to put in more effort in order to do certain things, e.g. reading, driving	5	4	3	2	1	9	8
CV7	Having to concentrate harder on things	5	4	3	2	1	9	8
CV8	Having to take rest periods or frequent breaks while doing certain tasks	5	4	3	2	1	9	8
CV9	Having to squint or shut one eye in bright sunlight	5	4	3	2	1	9	8
CV10	Having to cover one eye to focus or see clearly	5	4	3	2	1	9	8
CV11	Having to adopt unusual head or body posture	5	4	3	2	1	9	8
CV12	Having to travel a long way to attend your eye appointments	5	4	3	2	1	9	8
CV13	Having to wait to get the right glasses	5	4	3	2	1	9	8
CV14	Having to wear glasses or contact lenses most of the time	5	4	3	2	1	9	8
CV15	Having to remove glasses when doing some tasks, e.g. swimming, sports	5	4	3	2	1	9	8
CV16	Having to use prism glasses	5	4	3	2	1	9	8
CV17	Having to wear sunglasses most of the time	5	4	3	2	1	9	8
CV18	Having to undergo multiple eye operations to correct the turned eye	5	4	3	2	1	9	8
CV19	Not being able to use contact lenses	5	4	3	2	1	9	8

CONVENIENCE - continued								
Because of your eye condition or its treatment, how much trouble is…?		**None**	**A little bit**	**A moderate amount**	**Quite a lot**	**Extremely**	**This is not relevant to me**	**Refuse to answer**
CV20	Not being able to do what you want to do	5	4	3	2	1	9	8
CV21	Turning your head in order to see what is on the side of the affected eye	5	4	3	2	1	9	8
CV22	It when an eye lash or dirt gets into your good eye	5	4	3	2	1	9	8
CV23	It when you knock things over or break things	5	4	3	2	1	9	8
CV24	It when you make a mistake or do the wrong thing	5	4	3	2	1	9	8
CV25	It when you suddenly experience double vision while driving	5	4	3	2	1	9	8
CV26	Trying to focus when you experience double vision	5	4	3	2	1	9	8

ECONOMIC								
Because of your eye condition or its treatment, how concerned are you about...?		**Not at all**	**A little bit**	**A moderate amount**	**Quite a bit**	**Extremely**	**This issue is not relevant to me**	**Refuse to answer**
EC1	The cost associated with seeing your eye care practitioner or eye specialist	5	4	3	2	1	9	8
EC2	The cost of treating your lazy eye, e.g. undergoing vision therapy	5	4	3	2	1	9	8
EC3	Having to take time off work to undergo treatment (e.g. vision therapy, exercises) for your eye condition	5	4	3	2	1	9	8
EC4	The initial and ongoing cost of buying your glasses	5	4	3	2	1	9	8
EC5	The cost of having surgery to correct your turned eye	5	4	3	2	1	9	8
EC6	The cost of private health insurance	5	4	3	2	1	9	8
EC7	Not meeting vision requirements for certain jobs e.g. pilot, police	5	4	3	2	1	9	8
EC8	Your ability to find employment or get a new job	5	4	3	2	1	9	8
EC9	Limitation on the types of jobs you can do e.g. driving heavy vehicles	5	4	3	2	1	9	8
EC10	Losing your job	5	4	3	2	1	9	8
EC11	Your work tasks being affected	5	4	3	2	1	9	8
EC12	Keeping up with things at work, e.g. feeling like you have to catch up all the time, taking longer to complete tasks	5	4	3	2	1	9	8
EC13	Strain on your work relationships, e.g. because of time off or overall performance	5	4	3	2	1	9	8
EC14	Your career being compromised	5	4	3	2	1	9	8

COPING							
Given that you know about your eye condition, how much do you cope by...?		**Not at all**	**A little bit**	**A moderate amount**	**A lot**	**Extremely**	**Refuse to answer/ not relevant**
CP1	Being organised and careful	1	2	3	4	5	8
CP2	Paying more attention while doing tasks that are difficult	1	2	3	4	5	8
CP3	Avoiding tasks that are difficult, e.g. driving, going out at night time	1	2	3	4	5	8
CP4	Adopting a compensatory body or head posture like a head turn or tilt	1	2	3	4	5	8
CP5	Closing one eye e.g. to focus clearly, to avoid double vision	1	2	3	4	5	8
CP6	Using magnifying devices or low vision aids e.g. magnifying glass, magnification in computers, large print books	1	2	3	4	5	8
CP7	Using peripheral vision of worse eye to see things to its side	1	2	3	4	5	8
CP8	Using visual aids, e.g. glasses, prism glasses, prescription sunglasses	1	2	3	4	5	8
CP9	Hiding your eye defect. e.g. by avoiding eye contact or wearing sunglasses	1	2	3	4	5	8
CP10	Using humour	1	2	3	4	5	8
CP11	Improving appearance, e.g. applying eye make up	1	2	3	4	5	8
CP12	Withdrawing into yourself	1	2	3	4	5	8
CP13	Being with people with whom you are comfortable	1	2	3	4	5	8
CP14	Being strong, e.g. ignoring comments from others, ignoring that you have an eye problem	1	2	3	4	5	8
CP15	Communicating with people about your eye condition	1	2	3	4	5	8
CP16	Getting support from others	1	2	3	4	5	8
CP17	Not relating the problems you face to your eye condition	1	2	3	4	5	8
CP18	Attributing your eye problems to ageing	1	2	3	4	5	8
CP19	Trying not to think about it	1	2	3	4	5	8
CP20	Trying to be positive	1	2	3	4	5	8
CP21	Thinking that people have much worse problems than you	1	2	3	4	5	8
CP22	Thinking that your eye condition is not progressive	1	2	3	4	5	8

COPING - continued							
Given that you know your eye condition, do you cope by...?		**Not at all**	**A little bit**	**A moderate amount**	**A lot**	**Extremely**	**Refuse to answer/ not relevant**
CP23	Learning to live with your eye condition	1	2	3	4	5	8
CP24	Accepting your eye condition	1	2	3	4	5	8

Appendix 8

Background questionnaire and Item banks – India

English, Hindi & Tamil

All of the following questions are about the impact of **amblyopia (lazy eye), strabismus (Squint / turned eye) and its treatment on your quality of life.**

Please consider ONLY your amblyopia, strabismus and its current treatment (e.g. patching therapy, vision therapy) when you answer these questions.

If you usually use glasses, contact lenses or low vision devices, please answer according to how you can see when using them.

For office use	
Participant's name:	Participant ID:
MRD Number:	Date:
Time started:	Time finished:

Background Questionnaire

Please fill in the following questions about yourself and your eye condition.

Name	
MRD Number	
Address	
Phone Number	
E-mail	
Date of Birth (DD/MM/YYYY)	
Age	
Place of birth	
Gender	Male / Female
Mother tongue	
Educational qualification	
Occupation	
Please circle your answer for the following questions	
Your eye condition	Amblyopia (Lazy eye) / Strabismus (Squint)/ Both
Affected eye	Right / Left / Both
Is your strabismus (squint) noticeable by others?	Yes / No / I don't know / I don't have squint
Do you wear glass or contact lenses?	Yes/ No
What treatment(s) did you undergo for your eye condition?	Glasses / Contact lenses / Patching therapy / Drops / Vision therapy / Video game therapy / Surgery / Other, please mention
Do you have any other eye disease?	Yes / No; If yes, please specify:
Do you have any other general health problem?	Yes / No; If yes, please specify:

VISUAL SYMPTOMS

		Because of your eye condition or its treatment											
		How often do you experience…?				How severe is/are the…?				How much of a problem is/are the…?			
		Never	Occasionally	Quite often	Very often	Not at all	Mild	Moderate	Severe	None	A little	Quite a bit	A lot
Example	**Tired eyes**	4	(3)	2	1	4	3	(2)	1	4	3	2	(1)
VS1	Blurred vision for distance	4	3	2	1	4	3	2	1	4	3	2	1
VS2	Blurred vision for near	4	3	2	1	4	3	2	1	4	3	2	1
VS3	Poor vision in both eyes	4	3	2	1	4	3	2	1	4	3	2	1
VS4	Poor vision in one eye	4	3	2	1	4	3	2	1	4	3	2	1
VS5	Poor peripheral vision (side vision) in the affected eye	4	3	2	1	4	3	2	1	4	3	2	1
VS6	Difficulty in focussing your eyes	4	3	2	1	4	3	2	1	4	3	2	1
VS7	Difficulty in judging distances /perceiving depth between two objects	4	3	2	1	4	3	2	1	4	3	2	1
VS9	Double vision	4	3	2	1	4	3	2	1	4	3	2	1
VS10	Double vision when tired	4	3	2	1	4	3	2	1	4	3	2	1
VS11	Ghost images or shadows around objects you see	4	3	2	1	4	3	2	1	4	3	2	1
VS13	Glare from lights e.g. sunlight, car headlights	4	3	2	1	4	3	2	1	4	3	2	1

OCULAR SYMPTOMS														
		Because of your eye condition or its treatment												
		How often do you experience…?					**How severe is/are the…?**					**How much of a problem is/are the…?**			
		Never	Occasionally	Quite often	Very often		Not at all	Mild	Moderate	Severe		None	A little	Quite a bit	A lot
OS1	Eye strain	4	3	2	1		4	3	2	1		4	3	2	1
OS2	Tired eyes	4	3	2	1		4	3	2	1		4	3	2	1
OS3	Heavy eyes	4	3	2	1		4	3	2	1		4	3	2	1
OS4	Dry eyes	4	3	2	1		4	3	2	1		4	3	2	1
OS5	Red eyes	4	3	2	1		4	3	2	1		4	3	2	1
OS6	Watery eyes	4	3	2	1		4	3	2	1		4	3	2	1
OS7	Pain in your eyes	4	3	2	1		4	3	2	1		4	3	2	1
OS9	Burning sensation in your eyes	4	3	2	1		4	3	2	1		4	3	2	1
OS10	Irritation in your eyes	4	3	2	1		4	3	2	1		4	3	2	1
OS11	Misalignment of your eyes (Squint eyes)	4	3	2	1		4	3	2	1		4	3	2	1
OS12	Misalignment of your eyes (Squint) when tired	4	3	2	1		4	3	2	1		4	3	2	1
OS13i	Difference in the size of right and left eyes	4	3	2	1		4	3	2	1		4	3	2	1

GENERAL SYMPTOMS															
		Because of your eye condition or its treatment													
		How often do you experience …?					**How severe is/are the…?**					**How much of a problem is/are the…?**			
		Never	Occasionally	Quite often	Very often		Not at all	Mild	Moderate	Severe		None	A little	Quite a bit	A lot
GS1	Headaches	4	3	2	1		4	3	2	1		4	3	2	1
GS2	Back pain	4	3	2	1		4	3	2	1		4	3	2	1
GS3	Neck pain	4	3	2	1		4	3	2	1		4	3	2	1
GS4	Tiredness	4	3	2	1		4	3	2	1		4	3	2	1
GS5	Dizziness	4	3	2	1		4	3	2	1		4	3	2	1
GS6	Sleepiness (e.g. while reading)	4	3	2	1		4	3	2	1		4	3	2	1
GS8	Loss of balance	4	3	2	1		4	3	2	1		4	3	2	1
GS9	Abnormal head posture (e.g. head turn, head tilt)	4	3	2	1		4	3	2	1		4	3	2	1
GS10	Difficulty in concentrating	4	3	2	1		4	3	2	1		4	3	2	1

ACTIVITY LIMITATION								
Because of your eye condition or its treatment, how much difficulty do you have…?		**None**	**A little**	**Quite a bit**	**A lot**	**Unable to do because of my eye condition**	**This task is not relevant to me / don't do the task**	**Refuse to answer**
AL1	Cooking	5	4	3	2	1	9	8
AL2	Cutting or chopping vegetables or food	5	4	3	2	1	9	8
AL4	Pouring water/ drink without spilling	5	4	3	2	1	9	8
AL6	Looking after your appearance, e.g. your face, hair, shaving	5	4	3	2	1	9	8
AL7	Putting on eye make-up	5	4	3	2	1	9	8
AL8	Cutting your fingernails or toenails safely	5	4	3	2	1	9	8
AL9	Judging how close or far things are from you	5	4	3	2	1	9	8
AL10	Seeing 3D movies or 3D pictures	5	4	3	2	1	9	8
AL11	Seeing in glare conditions	5	4	3	2	1	9	8
AL12	Seeing well at night	5	4	3	2	1	9	8
AL13	Seeing well when you are tired	5	4	3	2	1	9	8
AL14	Seeing what people are pointing at in the distance	5	4	3	2	1	9	8
AL65i	Seeing fine details	5	4	3	2	1	9	8
AL66i	Seeing facial reactions and gestures at a distance	5	4	3	2	1	9	8
AL16	Threading a needle	5	4	3	2	1	9	8
AL18	Judging the direction of the ball when playing sports	5	4	3	2	1	9	8
AL19	Catching a ball	5	4	3	2	1	9	8
AL20	Hitting a ball	5	4	3	2	1	9	8
AL67i	Playing cricket	5	4	3	2	1	9	8
AL22	Playing basketball or football	5	4	3	2	1	9	8
AL68i	Playing in bright sunlight	5	4	3	2	1	9	8
AL69i	Playing shuttle cock or badminton	5	4	3	2	1	9	8
AL24	Performing work related tasks	5	4	3	2	1	9	8

ACTIVITY LIMITATION - continued								
Because of your eye condition or its treatment, how much difficulty do you have…?		**None**	**A little**	**Quite a bit**	**A lot**	**Unable to do because of my eye condition**	**This task is not relevant to me / don't do the task**	**Refuse to answer**
AL25	Doing any small, fine tasks	5	4	3	2	1	9	8
AL26	Using hand tools, e.g. a screwdriver, a hammer	5	4	3	2	1	9	8
AL27	Using instruments that require using both eyes together e.g. binoculars	5	4	3	2	1	9	8
AL28	Using a computer	5	4	3	2	1	9	8
AL29	Using a mobile phone	5	4	3	2	1	9	8
AL30	Using an IPad or Tab	5	4	3	2	1	9	8
AL70i	Playing videogames	5	4	3	2	1	9	8
AL31	Writing in a straight line	5	4	3	2	1	9	8
AL32	Watching television	5	4	3	2	1	9	8
AL33	Engaging in a hobby or leisure activity, e.g. crafts	5	4	3	2	1	9	8
AL35	Reading the newspaper	5	4	3	2	1	9	8
AL71i	Reading a book	5	4	3	2	1	9	8
AL37	Reading small print, e.g. the yellow pages	5	4	3	2	1	9	8
AL39	Reading text on television e.g. flash news	5	4	3	2	1	9	8
AL40	Reading from a board	5	4	3	2	1	9	8
AL41	Reading the bus numbers	5	4	3	2	1	9	8
AL43	Reading street signs	5	4	3	2	1	9	8
AL44	Reading in dim light conditions	5	4	3	2	1	9	8
AL45	Reading for a prolonged period of time	5	4	3	2	1	9	8
AL46	Reading at a fast pace	5	4	3	2	1	9	8

DRIVING								
Because of your eye condition or its treatment, how much difficulty do you have…?		**None**	**A little**	**Quite a bit**	**A lot**	**Unable to do because of my eye condition**	**Don't drive for other reasons**	**Refuse to answer**
AL47	Driving a car during the day	5	4	3	2	1	9	8
AL48	Driving a car at night	5	4	3	2	1	9	8
AL49	Driving a car in bad weather	5	4	3	2	1	9	8
AL50	Driving a car in heavy traffic	5	4	3	2	1	9	8
AL55	Reversing your car	5	4	3	2	1	9	8
AL56	Parking	5	4	3	2	1	9	8
AL64	Riding a motor bike during the day	5	4	3	2	1	9	8
AL72i	Riding a motor bike at night	5	4	3	2	1	9	8
AL73i	Riding a motor bike in bad weather	5	4	3	2	1	9	8
AL74i	Riding a motor bike in heavy traffic	5	4	3	2	1	9	8
AL75i	Riding a motor bike in bright sunlight	5	4	3	2	1	9	8
AL51	Driving a car or riding bike in unfamiliar places	5	4	3	2	1	9	8
AL53	Driving a car or riding bike for long periods of time	5	4	3	2	1	9	8
AL54	Driving towards oncoming headlights of other vehicles	5	4	3	2	1	9	8
AL57	Judging distances between your vehicle and others while driving and parking	5	4	3	2	1	9	8
AL60	Noticing when the car in front of you is speeding up or slowing down	5	4	3	2	1	9	8
AL61	Seeing objects on the side of the affected eye while driving e.g. other cars, bikes or pedestrians	5	4	3	2	1	9	8
AL76i	Seeing speed breakers on the road while driving	5	4	3	2	1	9	8

MOBILITY								
Because of your eye condition or its treatment, how much difficulty do you have…?		**None**	**A little**	**Quite a bit**	**A lot**	**Unable to do because of my eye condition**	**This task is not relevant to me / don't do the task**	**Refuse to answer**
MB1	Crossing a street or road	5	4	3	2	1	9	8
MB2	Going up steps or stairs	5	4	3	2	1	9	8
MB3	Going down steps or stairs	5	4	3	2	1	9	8
MB5	Using escalators	5	4	3	2	1	9	8
MB6	Walking steadily with normal posture	5	4	3	2	1	9	8
MB7	Walking in unfamiliar areas	5	4	3	2	1	9	8
MB8	Walking on a bumpy / uneven road	5	4	3	2	1	9	8
MB9	Walking in crowded situations	5	4	3	2	1	9	8
MB10	Negotiating obstacles while walking, e.g. table, people	5	4	3	2	1	9	8
MB12	Noticing things to the side of the affected eye while moving around	5	4	3	2	1	9	8
MB13	Walking in dim light	5	4	3	2	1	9	8
MB14	Walking when you experience double vision	5	4	3	2	1	9	8

CONCERNS								
Because of your eye condition or its treatment, how concerned are you about…?		**Not at all**	**A little bit**	**A moderate amount**	**A lot**	**Extremely**	**This issue is not relevant to me**	**Refuse to answer**
HC1	Having just one good eye	5	4	3	2	1	9	8
HC2	Being dependent on the good eye	5	4	3	2	1	9	8
HC3	Getting other eye diseases in your good eye	5	4	3	2	1	9	8
HC4	Undergoing treatment for other eye disease in your good eye e.g. cataract surgery	5	4	3	2	1	9	8
HC5	Straining or overloading your good eye	5	4	3	2	1	9	8
HC6	Your good eye getting injured	5	4	3	2	1	9	8
HC7	Your affected eye (weak eye)	5	4	3	2	1	9	8
HC8	Safety of your eyes	5	4	3	2	1		8
HC10	Problems associated with your eye condition becoming worse with age	5	4	3	2	1		8
HC11	Your eyesight or eye problems getting worse	5	4	3	2	1		8
HC12	Becoming blind	5	4	3	2	1		8
HC13	Passing the eye condition onto your children	5	4	3	2	1	9	8
HC14	Having a misaligned or turned eye (squint)	5	4	3	2	1	9	8
HC15	Having to wear thick glasses	5	4	3	2	1	9	8
HC63i	Being dependent on glasses or contact lenses	5	4	3	2	1	9	8
HC64i	Vision not improving with glasses	5	4	3	2	1	9	8
HC16	The cosmetic appearance of your eyes	5	4	3	2	1	9	8
HC17	Your looks	5	4	3	2	1	9	8
HC18	Being in photographs	5	4	3	2	1		8
HC19	Having eye contact with people while talking	5	4	3	2	1		8
HC20	What other people think of you	5	4	3	2	1		8
HC21	The way people behave with you	5	4	3	2	1	9	8

CONCERNS - continued								
Because of your eye condition or its treatment, how concerned are you about…?		**Not at all**	**A little bit**	**A moderate amount**	**A lot**	**Extremely**	**This issue is not relevant**	**Refuse to answer**
HC22	People not understanding your eye condition	5	4	3	2	1	9	8
HC23	People judging you wrongly	5	4	3	2	1	9	8
HC24	People passing comments about your eye condition	5	4	3	2	1	9	8
HC25	Being bullied or teased	5	4	3	2	1	9	8
HC27	Being treated differently	5	4	3	2	1	9	8
HC28	Being left out or rejected	5	4	3	2	1	9	8
HC29	Not being able to earn the respect of others	5	4	3	2	1	9	8
HC31	Bumping into people or objects while walking	5	4	3	2	1	9	8
HC32	Dropping things or spilling liquids	5	4	3	2	1	9	8
HC33	Tripping	5	4	3	2	1		8
HC34	Falling	5	4	3	2	1		8
HC36	Getting injured while playing sports	5	4	3	2	1	9	8
HC37	Experiencing double vision	5	4	3	2	1	9	8
HC38	Having motor vehicle related accidents e.g. hitting a post or wall while parking a car	5	4	3	2	1	9	8
HC39	Having non-motor vehicle related accidents e.g. while using tools like hammer	5	4	3	2	1	9	8
HC65i	Not being able to recognise people from a far distance	5	4	3	2	1		8
HC41	Not being able to enjoy 3D movies	5	4	3	2	1	9	8
HC42	Not being able to use both eyes together	5	4	3	2	1	9	8
HC43	Not being able to do things you like in the future	5	4	3	2	1		8
HC44	Not being able to do well academically	5	4	3	2	1	9	8
HC45	Not being able to pursue the sports, hobbies or leisure activities that you like	5	4	3	2	1	9	8

CONCERNS - continued								
Because of your eye condition or its treatment, how concerned are you about…?		**Not at all**	**A little bit**	**A moderate amount**	**A lot**	**Extremely**	**This issue is not relevant**	**Refuse to answer**
HC46	Not being able to concentrate for a long period of time	5	4	3	2	1	9	8
HC47	Not being successful in life	5	4	3	2	1	9	8
HC49	Putting other people in danger by driving	5	4	3	2	1	9	8
HC50	Having to alter your career choice	5	4	3	2	1	9	8
HC51	Your ability to obtain or keep a job	5	4	3	2	1	9	8
HC52	The impact of your appearance on work	5	4	3	2	1	9	8
HC53	The impact your eye condition has on your family members	5	4	3	2	1	9	8
HC54	Not being diagnosed or treated early	5	4	3	2	1	9	8
HC55	Knowing that there is no or limited treatment options available for your eye condition	5	4	3	2	1	9	8
HC56	Your doctor being unsure about treatment modality and outcome	5	4	3	2	1	9	8
HC58	Ineffective treatment in the past	5	4	3	2	1	9	8
HC59	Long duration of amblyopia (lazy eye) treatment	5	4	3	2	1	9	8
HC60	The outcome of strabismus (squint) surgery	5	4	3	2	1	9	8
HC61	Recurrence of strabismus even after treatment	5	4	3	2	1	9	8
HC62	Not getting enough information or explanation from the medical staff	5	4	3	2	1	9	8

EMOTIONAL							
(Because of your eye condition or its treatment) **During the past four weeks, how often did you…?**		**None of the time**	**A little of the time**	**Some of the time**	**Most of the time**	**All of the time**	**Refuse to answer**
EM1	Feel unhappy	5	4	3	2	1	8
EM3	Feel depressed	5	4	3	2	1	8
EM4	Feel anxious	5	4	3	2	1	8
EM5	Feel frustrated	5	4	3	2	1	8
EM8	Feel stressed	5	4	3	2	1	8
EM9	Feel upset	5	4	3	2	1	8
EM12	Feel troubled	5	4	3	2	1	8
EM14	Feel irritable	5	4	3	2	1	8
EM16	Feel like crying	5	4	3	2	1	8
EM17	Feel like you are struggling	5	4	3	2	1	8
EM19	Feel regretful or guilty about your eye care in the past	5	4	3	2	1	8
EM20	Feel bad about your treatment outcome	5	4	3	2	1	8
EM21	Feel shocked by what your eye specialists have told you about your eyes	5	4	3	2	1	8
EM22	Feel disappointed	5	4	3	2	1	8
EM23	Feel hopeless	5	4	3	2	1	8
EM24	Feel discriminated against by others	5	4	3	2	1	8
EM25	Feel embarrassed because of your appearance	5	4	3	2	1	8
EM27	Feel ashamed	5	4	3	2	1	8
EM28	Feel humiliated	5	4	3	2	1	8
EM29	Feel inferior	5	4	3	2	1	8
EM30	Feel rejected	5	4	3	2	1	8
EM31	Feel lonely or isolated	5	4	3	2	1	8
EM33	Feel reluctant to socialise	5	4	3	2	1	8
EM34	Feel like you have low self-confidence	5	4	3	2	1	8
EM35	Feel like you have low self-esteem	5	4	3	2	1	8
EM36	Feel self-conscious	5	4	3	2	1	8

EMOTIONAL - continued							
(Because of your eye condition or its treatment) **During the past four weeks, how often did you…?**		**None of the time**	**A little of the time**	**Some of the time**	**Most of the time**	**All of the time**	**Refuse to answer**
EM38	Feel that you are different from everyone else	5	4	3	2	1	8
EM39	Feel uncomfortable in public	5	4	3	2	1	8
EM40	Feel uneasy when people stare at you	5	4	3	2	1	8
EM41	Feel reluctant to talk about your eye problem	5	4	3	2	1	8
EM42	Fear losing vision in your good eye	5	4	3	2	1	8
EM43	Feel overprotective about your eyes	5	4	3	2	1	8
EM45	Feel unfortunate	5	4	3	2	1	8
EM46	Feel sorry for yourself	5	4	3	2	1	8
EM47	Feel envious about others with good vision	5	4	3	2	1	8
EM48	Worry about your eye condition	5	4	3	2	1	8
EM49	Wish things were normal	5	4	3	2	1	8

SOCIAL								
Because of your eye condition or its treatment, how much of a problem do you have…?		**None**	**A little**	**Quite a bit**	**A lot**	**Unable to do because of my eye condition**	**This task is not relevant to me / don't do the task**	**Refuse to answer**
SC1	Chatting with people	5	4	3	2	1		8
SC2	Interacting socially with people	5	4	3	2	1		8
SC3	Meeting people for the first time	5	4	3	2	1		8
SC4	Making new friends	5	4	3	2	1		8
SC5	Maintaining your friendships	5	4	3	2	1		8
SC6	Maintaining your roles and responsibilities at work	5	4	3	2	1		8
SC7	Maintaining your close personal relationships, e.g. marriage partner, family members	5	4	3	2	1		8
SC9	Talking to the opposite gender	5	4	3	2	1		8
SC10	Engaging in social activities	5	4	3	2	1		8
SC11	Participating in social activities at night	5	4	3	2	1		8
SC12	Socialising in peer groups	5	4	3	2	1		8
SC13	Socialising with people or groups you don't know that well	5	4	3	2	1		8
SC14	Socialising because people comment on your eyes	5	4	3	2	1	9	8
SC15	Socialising because of the way people look at you	5	4	3	2	1	9	8
SC16	Socialising because people are unsure about which eye to look at	5	4	3	2	1	9	8
SC17	Socialising because of not being able to maintain eye contact	5	4	3	2	1	9	8
SC18	Socialising because you experience double vision	5	4	3	2	1	9	8
SC19	With family members or friends getting annoyed / irritated at you when you can't do something	5	4	3	2	1	9	8
SC20	With family members or friends getting annoyed / irritated at you when you make a mistake	5	4	3	2	1	9	8
SC22	Getting help and support from your family and friends	5	4	3	2	1		8

INCONVENIENCES								
Because of your eye condition or its treatment, how much trouble is…?		**None**	**A little bit**	**A moderate amount**	**Quite a lot**	**Extremely**	**This is not relevant to me**	**Refuse to answer**
CV1	Having to be slower or more careful	5	4	3	2	1	9	8
CV2	Having to drive slowly and more carefully	5	4	3	2	1	9	8
CV4	Needing longer to do things	5	4	3	2	1	9	8
CV5	Having limitations on how long you can do things for, e.g. reading for prolonged time or going for a long drive	5	4	3	2	1	9	8
CV6	Having to put in more effort in order to do certain things, e.g. reading, driving	5	4	3	2	1	9	8
CV7	Having to concentrate harder on things	5	4	3	2	1	9	8
CV8	Having to take rest periods or frequent breaks while doing certain tasks	5	4	3	2	1	9	8
CV9	Having to squint or shut one eye in bright sunlight	5	4	3	2	1	9	8
CV10	Having to cover one eye to see clearly	5	4	3	2	1	9	8
CV11	Having to adopt unusual head or body posture (e.g. head turn)	5	4	3	2	1	9	8
CV12	Having to travel a long way to attend your eye appointments	5	4	3	2	1	9	8
CV13	Having to wait to get the right glasses	5	4	3	2	1	9	8
CV14	Having to wear glasses or contact lens most of the time	5	4	3	2	1	9	8
CV15	Having to remove glasses when doing some tasks, e.g. sports	5	4	3	2	1	9	8
CV16	Having to use prism glasses	5	4	3	2	1	9	8
CV17	Having to wear sunglasses most of the time	5	4	3	2	1	9	8
CV18	Having to undergo multiple eye operations to correct the turned eye (squint)	5	4	3	2	1	9	8
CV19	Not being able to use contact lenses	5	4	3	2	1	9	8
CV20	Not being able to do what you want to do	5	4	3	2	1	9	8

INCONVENIENCES								
Because of your eye condition or its treatment, how much trouble is…?		**None**	**A little bit**	**A moderate amount**	**Quite a lot**	**Extremely**	**This is not relevant to me**	**Refuse to answer**
CV21	Turning your head in order to see what is on the side of the affected eye	5	4	3	2	1	9	8
CV22	When a dirt gets into your good eye	5	4	3	2	1	9	8
CV23	When you knock things over or break things by mistake	5	4	3	2	1	9	8
CV25	When you suddenly experience double vision while driving	5	4	3	2	1	9	8
CV26	Trying to focus when you experience double vision	5	4	3	2	1	9	8

ECONOMIC								
Because of your eye condition or its treatment, how concerned are you about...?		**Not at all**	**A little bit**	**A moderate amount**	**Quite a bit**	**Extremely**	**This issue is not relevant to me**	**Refuse to answer**
EC1	The cost associated with seeing your eye care practitioner or eye specialist	5	4	3	2	1	9	8
EC2	The cost of treating your lazy eye, e.g. undergoing vision therapy	5	4	3	2	1	9	8
EC3	Having to take time off work to go to hospital in order to undergo treatment (e.g. vision therapy, exercises) for your eye condition	5	4	3	2	1	9	8
EC4	The initial and ongoing cost of buying your glasses or contact lenses	5	4	3	2	1	9	8
EC5	The cost of having surgery to correct your turned eye (squint)	5	4	3	2	1	9	8
EC7	Not meeting vision requirements for certain jobs e.g. pilot, police	5	4	3	2	1	9	8
EC8	Your ability to find employment or get a new job	5	4	3	2	1	9	8
EC9	Limitation on the types of jobs you can do e.g. driving heavy vehicles	5	4	3	2	1	9	8
EC10	Losing your job	5	4	3	2	1	9	8
EC11	Your work tasks being affected	5	4	3	2	1	9	8
EC13	Strain on your work relationships, e.g. taking longer to complete tasks	5	4	3	2	1	9	8
EC14	Not being able to pursue the career of your choice	5	4	3	2	1	9	8
EC15i	The cost of travel to access eye care	5	4	3	2	1	9	8

COPING							
Given that you know about your eye condition, how much do you cope by...?		**Not at all**	**A little bit**	**A moderate amount**	**A lot**	**Extremely**	**Refuse to answer/ not relevant**
CP1	Being careful	1	2	3	4	5	8
CP2	Paying more attention while doing tasks that are difficult	1	2	3	4	5	8
CP3	Avoiding tasks that are difficult, e.g. driving at night time	1	2	3	4	5	8
CP5	Closing one eye e.g. to see clearly, to avoid double vision	1	2	3	4	5	8
CP8	Using glasses or contact lenses	1	2	3	4	5	8
CP9	Hiding your eye defect. e.g. by avoiding eye contact or wearing sunglasses	1	2	3	4	5	8
CP10	Using humour	1	2	3	4	5	8
CP12	Withdrawing yourself from others	1	2	3	4	5	8
CP13	Being with people with whom you are comfortable	1	2	3	4	5	8
CP14	Being strong, e.g. ignoring comments from others	1	2	3	4	5	8
CP15	Sharing with people about your eye condition	1	2	3	4	5	8
CP16	Getting support from others	1	2	3	4	5	8
CP17	Not relating the problems you face to your eye condition	1	2	3	4	5	8
CP18	Attributing your eye problems to ageing	1	2	3	4	5	8
CP19	Trying not to think about your eye condition	1	2	3	4	5	8
CP20	Trying to be positive	1	2	3	4	5	8
CP21	Thinking that people have much worse problems than you	1	2	3	4	5	8
CP22	Thinking that your eye condition is not progressive	1	2	3	4	5	8
CP23	Learning to live with your eye condition	1	2	3	4	5	8
CP24	Accepting your eye condition	1	2	3	4	5	8

For office use

Eye hospital/ practice name		
MRD Number		
Participant ID		
Participant's name		
Ocular diagnosis		
Type of amblyopia		
Type of strabismus		
Refractive error	OD: OS:	
Best corrected visual acuity	OD:	OS:
Cover test	Distance:	Near:
Magnitude of deviation	Distance:	Near:
Co-existing ocular diagnosis		
General health		

निम्नलिखित सभी प्रश्न आपके जीवन की गुणवत्ता पर एम्बीलोपिया *(*आलसी आंख*)* या स्ट्रैबिस्मस *(*भेंगापन/टेढ़ापन*)* और इसका उपचार के प्रभाव के बारे में हैं

जब आप इन सवालों के जवाब देते हैं, तो कृपया केवल अपने एम्बीलोपिया *(*आलसी आंख*)*, स्ट्रैबिस्मस *(*भेंगापन/टेढ़ापन*)* और इसके वर्तमान उपचार *(*जैसे की पैचिंग थेरेपी, विज़न थेरेपी *)*को ध्यान में रख कर करें

यदि आप आमतौर में चश्मा, कॉन्टेक्ट लेंस या दृष्टि वर्धक उपकरणों का उपयोग करते हैं, तो कृपया इसका जवाब दें कि उनका उपयोग करते समय आप कैसे देख सकते हैं

For office use	
Participant's name:	Participant ID:
MRD Number:	Date:
Time started:	Time finished:

अपने और आपकी आंख की स्थिति के बारे में निम्नलिखित विवरण भरें

नाम	
एम.आर.डी. नम्बर	
पता	
फ़ोन नंबर	
ईमेल	
उम्र	
जन्म तारीख	
जन्म स्थान	
लिंग	पुरुष / महिला
मातृ भाषा	
शिक्षा	
काम	
कृपया निम्नलिखित प्रश्नों के लिए अपना जवाब पर गोल कीजिए	
आपकी आंख की स्थिति	आलसी आंख (एम्बलोपिया) / स्ट्रैबिस्म (टेढ़ेपन)/ दोनों
कौन सा आंख प्रभावित है?	दाहिना आँख / बायीं आँख / दोनों आँख
क्या आपके आँखों का भेंगापन (टेढ़ापन) दूसरों के ध्यान में आता है	हाँ / नहीं/ पता नहीं / मुझे टेढ़ापन नहीं है
क्या आप चश्मा या कॉन्टैक्ट लेन्स का इस्तेमाल करते हैं	हाँ / नहीं
अपनी आंख की स्थिति के लिए किए गए सभी उपचार का उल्लेख करें	चश्मा / कॉन्टेक्ट लेंस / पैचिंग थेरेपी / आँख की दवा / विज़न थेरेपी / वीडियो गेम चिकित्सा / सर्जरी / अन्य, कृपया उल्लेख करें_____
क्या आपके पास कोई अन्य नेत्र रोग है?	हाँ / नहीं; यदि हां, तो कृपया उल्लेख करें _____
क्या आपके पास कोई अन्य सामान्य स्वास्थ्य समस्या है?	हाँ / नहीं; यदि हां, तो कृपया उल्लेख करें _____

आंख की स्थिति से संबंधित लक्षण													
		आपके आँखों की स्थिति या इलाज के वजह से इनमे से किन चीज़ो को अक्सर अनुभव करते है ?				आपके आँखों की स्थिति या इलाज के वजह से इनमे से किन चीज़ो को ज्यादा मात्रा (गंभीर) में अनुभव करते है ?				आपके आँखों की स्थिति या इलाज के वजह से आपको कितनी परेशानी होती है ?			
		कभी नहीं	कभी कभी	अक्सर	बहुत ज्यादा	कभी नहीं	थोड़ा	मध्यम	बहुत ज्यादा	कुछ भी नहीं	थोड़ा	थोड़ा सा ज्यादा	बहुत ज्यादा
उदाहरण:		4	(3)	2	1	4	3	(2)	1	4	3	2	(1)
VS1	दूर का धुंधला दिखना	4	3	2	1	4	3	2	1	4	3	2	1
VS2	नज़दीक का धुंधला दिखना	4	3	2	1	4	3	2	1	4	3	2	1
VS3	दोनों आँखों से कम दिखना	4	3	2	1	4	3	2	1	4	3	2	1
VS4	एक आँख से कम दिखना	4	3	2	1	4	3	2	1	4	3	2	1
VS5	प्रभावित आँख के तरफ की चीज़े कमजोर दिखना	4	3	2	1	4	3	2	1	4	3	2	1
VS6	दोनों आँखों को एक जगह केंद्रित करने में मुश्किल	4	3	2	1	4	3	2	1	4	3	2	1
VS7	दो चीज़ों की दूरियां (गहराई) का अंदाज़ा करने में मुश्किल	4	3	2	1	4	3	2	1	4	3	2	1
VS9	चीज़ों का दुगना दिखना	4	3	2	1	4	3	2	1	4	3	2	1
VS10	थकान के समय चीज़ों का दुगना दिखना	4	3	2	1	4	3	2	1	4	3	2	1
VS11	चीज़ों के आस पास उनका प्रतिरूप दिखना	4	3	2	1	4	3	2	1	4	3	2	1

आंख की स्थिति से संबंधित लक्षण													
		आपके आँखों की स्थिति या इलाज के वजह से इनमे से किन चीज़ो को अक्सर अनुभव करते है ?				आपके आँखों की स्थिति या इलाज के वजह से इनमे से किन चीज़ो को ज्यादा मात्रा (गंभीर) में अनुभव करते है ?				आपके आँखों की स्थिति या इलाज के वजह से आपको कितनी परेशानी होती है ?			
		कभी नहीं	कभी कभी	अक्सर	बहुत ज्यादा	कभी नहीं	थोड़ा	मध्यम	बहुत ज्यादा	कुछ भी नहीं	थोड़ा	थोड़ा सा ज्यादा	बहुत ज्यादा
VS13	तीव्र प्रकाश में दिखने में मुश्किल जैसे की सूरज की रौशनी, गाड़ी की हेडलाइट	4	3	2	1	4	3	2	1	4	3	2	1
OS1	आँखों पर जोर	4	3	2	1	4	3	2	1	4	3	2	1
OS2	आँखों में थकान	4	3	2	1	4	3	2	1	4	3	2	1
OS3	आँखों में भारीपन	4	3	2	1	4	3	2	1	4	3	2	1
OS4	आँखों में सूखापन	4	3	2	1	4	3	2	1	4	3	2	1
OS5	आँखों का लाल होना	4	3	2	1	4	3	2	1	4	3	2	1
OS6	आँखों में पानी आना	4	3	2	1	4	3	2	1	4	3	2	1
OS7	आँखों में दर्द	4	3	2	1	4	3	2	1	4	3	2	1
OS9	आँखों में जलन	4	3	2	1	4	3	2	1	4	3	2	1
OS10	आंखों में चुभन	4	3	2	1	4	3	2	1	4	3	2	1
OS11	आँखों का भेंगापन (टेढ़ापन)	4	3	2	1	4	3	2	1	4	3	2	1
OS12	थकान के समय आँखों का भेंगापन (टेढ़ापन)	4	3	2	1	4	3	2	1	4	3	2	1

आंख की स्थिति से संबंधित लक्षण													
		आपके आँखों की स्थिति या इलाज के वजह से इनमे से किन चीज़ो को अक्सर अनुभव करते है ?				आपके आँखों की स्थिति या इलाज के वजह से इनमे से किन चीज़ो को ज्यादा मात्रा (गंभीर) में अनुभव करते है ?				आपके आँखों की स्थिति या इलाज के वजह से आपको कितनी परेशानी होती है ?			
		कभी नहीं	कभी कभी	अक्सर	बहुत ज्यादा	कभी नहीं	थोड़ा	मध्यम	बहुत ज्यादा	कुछ भी नहीं	थोड़ा	थोड़ा सा ज्यादा	बहुत ज्यादा
OS13i	दाएं और बाएं आंखों के आकार में अंतर, जैसे की एक आंख दूसरे की तुलना में छोटा है	4	3	2	1	4	3	2	1	4	3	2	1
GS1	सिरदर्द	4	3	2	1	4	3	2	1	4	3	2	1
GS2	पीठ दर्द	4	3	2	1	4	3	2	1	4	3	2	1
GS3	गर्दन दर्द	4	3	2	1	4	3	2	1	4	3	2	1
GS4	थकान	4	3	2	1	4	3	2	1	4	3	2	1
GS5	चक्कर आना	4	3	2	1	4	3	2	1	4	3	2	1
GS6	काम करते वक़्त निद्रा आना (जैसे की पढ़ते वक़्त)	4	3	2	1	4	3	2	1	4	3	2	1
GS8	संतुलन का खोना	4	3	2	1	4	3	2	1	4	3	2	1
GS9	असाधारण तरीके से सिर का मोड़ना, जैसे की देखते वक़्त सिर को घुमाना	4	3	2	1	4	3	2	1	4	3	2	1
GS10	ध्यान देने में मुश्किल	4	3	2	1	4	3	2	1	4	3	2	1

क्रियाकलापों पर प्रभाव								
आपके आँखों की स्थिति या इलाज के वजह से, इन चीज़ो के करने पर आपको कितनी मुश्किल होती है ?		कुछ भी नहीं	थोड़ा	थोड़ा सा ज्यादा	बहुत ज्यादा	मेरे आँखों की स्थिति की वजह से कार्य करने में असमर्थ	मेरे पर यह लागू नहीं होता / मैं यह नहीं करता	उत्तर देने से इनकार
AL1	खाना बनाना	5	4	3	2	1	9	8
AL2	सब्जियों या खाद्य पदार्थों काटना	5	4	3	2	1	9	8
AL4	बिना गिराए कॉफ़ी या पानी गिलास में डालना	5	4	3	2	1	9	8
AL6	अपने आप का ध्यान रखना जैसे अपना चेहरा, अपने बाल या दाढ़ी बनाना	5	4	3	2	1	9	8
AL7	आँखों में मेकअप करना	5	4	3	2	1	9	8
AL8	सुरक्षित रूप से नाख़ून काटना	5	4	3	2	1	9	8
AL9	चीज़ों में दूरिया का अंदाजा लगाना	5	4	3	2	1	9	8
AL10	3D फिल्म देखना	5	4	3	2	1	9	8
AL11	तीव्र प्रकाश में देखना	5	4	3	2	1	9	8
AL12	रात में साफ़ देखना	5	4	3	2	1	9	8
AL13	थकावट में साफ़ दिखना	5	4	3	2	1	9	8
AL14	दूर की चीज़े देखना जैसे अगर कोई आपको कुछ दिखाने की कोशिश करे	5	4	3	2	1	9	8
AL65i	चीज़े को बारीकी से देखना	5	4	3	2	1	9	8
AL66i	दूर से लोगो के हाव् भाव देखना	5	4	3	2	1	9	8
AL16	सुईं में धागा डालना	5	4	3	2	1	9	8
AL18	गेंद/बॉल की दिशा का अंदाज़ा लगाना	5	4	3	2	1	9	8

क्रियाकलापों पर प्रभाव								
आपके आँखों की स्थिति या इलाज के वजह से, इन चीज़ो के करने पर आपको कितनी मुश्किल होती है ?		कुछ भी नहीं	थोड़ा	थोड़ा सा ज्यादा	बहुत ज्यादा	मेरे आँखों की स्थिति की वजह से कार्य करने में असमर्थ	मेरे पर यह लागू नहीं होता / मैं यह नहीं करता	उत्तर देने से इनकार
AL19	गेंद/बॉल को पकड़ना	5	4	3	2	1	9	8
AL20	गेंद/बॉल मारना	5	4	3	2	1	9	8
AL67i	क्रिकेट खेलना	5	4	3	2	1	9	8
AL22	बास्केटबॉल या फुटबॉल खेलना	5	4	3	2	1	9	8
AL68i	सूरज की तेज़ रोशनी में खेलना	5	4	3	2	1	9	8
AL69i	बैटमिंटन खेलना	5	4	3	2	1	9	8
AL24	दफ्तर का काम करना	5	4	3	2	1	9	8
AL25	बारीकी वाला काम करना	5	4	3	2	1	9	8
AL26	हथोड़ा या पेंचकस जैसी उपकरण का इस्तेमाल करना	5	4	3	2	1	9	8
AL27	दूरबीन जैसी उपकरण (बिनोकुलर) का इस्तेमाल करना जिनमे दोनों आँखों का इस्तेमाल होता है	5	4	3	2	1	9	8
AL28	कंप्यूटर का इस्तेमाल करना	5	4	3	2	1	9	8
AL29	मोबाइल फ़ोन का इस्तेमाल करना	5	4	3	2	1	9	8
AL30	आई-पैड या टैब का इस्तेमाल करना	5	4	3	2	1	9	8
AL70i	वीडियो गेम्स का खेलना	5	4	3	2	1	9	8

क्रियाकलापों पर प्रभाव								
आपके आँखों की स्थिति या इलाज के वजह से, इन चीज़ो के करने पर आपको कितनी मुश्किल होती है ?		कुछ भी नहीं	थोड़ा	थोड़ा सा ज्यादा	बहुत ज्यादा	मेरे आँखों की स्थिति की वजह से कार्य करने में असमर्थ	मेरे पर यह लागू नहीं होता / मैं यह नहीं करता	उत्तर देने से इनकार
AL31	सीधा लिखना	5	4	3	2	1	9	8
AL32	टीवी देखना	5	4	3	2	1	9	8
AL33	शौकीन या रुचिकर चीज़ों को करना, जैसे की शिल्प कला	5	4	3	2	1	9	8
AL35	अखबार पढ़ना	5	4	3	2	1	9	8
AL71i	किताब पढ़ना	5	4	3	2	1	9	8
AL37	बारीक लिखी हुई चीज़े को पढ़ना	5	4	3	2	1	9	8
AL39	टीवी पर लिखी हुई चीज़े पढ़ना जैसे की फ़्लैश न्यूज़	5	4	3	2	1	9	8
AL40	ब्लैक-बोर्ड में से पढ़ना	5	4	3	2	1	9	8
AL41	बस के नंबर पढ़ना	5	4	3	2	1	9	8
AL43	सड़क में लगे हुए चिह्नो को पढ़ना	5	4	3	2	1	9	8
AL44	कम रोशनी में पढ़ना	5	4	3	2	1	9	8
AL45	बहुत समय तक पढ़ना	5	4	3	2	1	9	8
AL46	जल्दी पढ़ना	5	4	3	2	1	9	8

गाड़ी चलाना								
आपके आँखों की स्थिति या इलाज के वजह से, इनमे से किन चीज़ो के करने पर कितनी मुश्किल होती है ?		कुछ भी नहीं	थोड़ा	थोड़ा सा ज्यादा	बहुत ज्यादा	मेरे आँखों की स्थिति की वजह से गाड़ी चलाने में असमर्थ	किसी और वजह से गाड़ी नहीं चलाता	उत्तर देने से इनकार
AL47	दिन में गाड़ी (कार) चलाना	5	4	3	2	1	9	8
AL48	रात में गाड़ी (कार) चलाना	5	4	3	2	1	9	8
AL49	ख़राब मौसम में गाड़ी (कार) चलाना जैसे की बारिश में	5	4	3	2	1	9	8
AL50	भारी ट्रैफिक में गाड़ी (कार) चलाना	5	4	3	2	1	9	8
AL55	गाड़ी (कार) पीछे लेना	5	4	3	2	1	9	8
AL56	गाड़ी (कार) पार्क करना	5	4	3	2	1	9	8
AL64	दिन में मोटर बाइक चलाना	5	4	3	2	1	9	8
AL72i	रात में मोटर बाइक चलाना	5	4	3	2	1	9	8
AL73i	ख़राब मौसम में मोटर बाइक चलाना जैसे की बारिश में	5	4	3	2	1	9	8
AL74i	भारी ट्रैफिक में मोटर बाइक चलाना	5	4	3	2	1	9	8
AL75i	सूरज के तीव्र रौशनी में मोटर बाइक चलाना	5	4	3	2	1	9	8
AL51	अनजान जगह (सड़को)पर गाड़ी (कार) या मोटर बाइक चलाना	5	4	3	2	1	9	8
AL53	लम्बे समय तक गाड़ी (कार) या मोटर बाइक चलाना	5	4	3	2	1	9	8

गाड़ी चलाना								
आपके आँखों की स्थिति या इलाज के वजह से, इनमे से किन चीज़ो के करने पर कितनी मुश्किल होती है ?		कुछ भी नहीं	थोड़ा	थोड़ा सा ज्यादा	बहुत ज्यादा	मेरे आँखों की स्थिति की वजह से गाड़ी चलाने में असमर्थ	किसी और वजह से गाड़ी नहीं चलाता	उत्तर देने से इनकार
AL54	सामने से आती हुई गाड़ी के हेडलाइट्स में अपनी गाढ़ी चलाना	5	4	3	2	1	9	8
AL57	गाड़ी चलाते या पार्क करते वक़्त चीज़ों की दूरियां का अंदाज़ा करना	5	4	3	2	1	9	8
AL60	जब आपके सामने वाली गाड़ी की गति का अंदाज़ा करना	5	4	3	2	1	9	8
AL61	गाड़ी चलाते समय प्रभावित आँखों के किनारे वस्तुओं को देखना , जैसे की, अन्य गाड़ी, बाइक या पैदल चलने वालों को	5	4	3	2	1	9	8
AL76i	गाड़ी चलाते समय सड़क पर स्पीड ब्रेक्स का देखना	5	4	3	2	1	9	8

चलना फिरना								
आपके आँखों की स्थिति या इलाज के वजह से इन चीज़ो के करने पर आपको कितनी मुश्किल होती है ?		कुछ भी नहीं	थोड़ा	थोड़ा सा ज्यादा	बहुत ज्यादा	मेरे आँखों की स्थिति की वजह से कार्य करने में असमर्थ	मेरे पर यह लागू नहीं होता / मैं यह नहीं करता	उत्तर देने से इनकार
MB1	सड़क या गली को पार करना	5	4	3	2	1	9	8
MB2	सीढ़िया चढ़ना	5	4	3	2	1	9	8
MB3	सीढ़िया उतरना	5	4	3	2	1	9	8
MB5	एस्केलेटर (चलती सीढ़ी) का उपयोग करना	5	4	3	2	1	9	8
MB6	सामान्य मुद्रा (संतुलन) में लगातार चलना	5	4	3	2	1	9	8
MB7	अपरिचित क्षेत्रों में चलना	5	4	3	2	1	9	8
MB8	ऊबड़खाबड़/ असमान सड़क पर चलना	5	4	3	2	1	9	8
MB9	भीड़ भरे परिस्थितियों में चलना	5	4	3	2	1	9	8
MB10	चलते समय बाधाएं ध्यान से पार करना, जैसे की टेबल, लोग	5	4	3	2	1	9	8
MB12	चलते वक़्त प्रभावित आँखों के किनारे वाली वस्तुओं को देखना	5	4	3	2	1	9	8
MB13	मंद प्रकाश में चलना	5	4	3	2	1	9	8
MB14	उस वक़्त चलना जब आप दुगनी दृष्टि का अनुभव करते हैं	5	4	3	2	1	9	8

चिंता								
आपकी आंख की स्थिति या उपचार के कारण आपको निम्नलिखित के बारे में कितने चिंतित हैं?		कभी नहीं	थोड़ा	थोड़ा सा ज्यादा	बहुत ज्यादा	अत्यंत	यह मेरे लिए प्रासंगिक नहीं है	उत्तर देने से इनकार
HC1	सिर्फ एक ठीक आँख का होना	5	4	3	2	1	9	8
HC2	सिर्फ ठीक आँख पर निर्भर करना	5	4	3	2	1	9	8
HC3	ठीक आँख में और कोई बीमारी आना	5	4	3	2	1	9	8
HC4	ठीक आँख का इलाज कराना जैसे की कैटरैक्ट (मोतियबिंद)	5	4	3	2	1	9	8
HC5	ठीक आँख पर दबाव डालना	5	4	3	2	1	9	8
HC6	ठीक आँख का घायल होना	5	4	3	2	1	9	8
HC7	आपकी प्रभावित आँख	5	4	3	2	1	9	8
HC8	आपकी आँखों की सुरक्षा	5	4	3	2	1		8
HC10	बढ़ती उम्र के साथ आँख से जुडी समस्याओं का ओर बिगड़ना	5	4	3	2	1		8
HC11	आपकी नज़र या आँख से जुडी समस्याओं का ओर बिगड़ना	5	4	3	2	1		8
HC12	नेत्रहीन होना	5	4	3	2	1		8
HC13	आपकी आँखों की बीमारी आपके बच्चों को मिलना	5	4	3	2	1	9	8
HC14	टेढ़ी आंखें (भेंगापन) होना	5	4	3	2	1	9	8
HC15	मोटा चश्मा का पहनना	5	4	3	2	1	9	8

चिंता								
आपकी आंख की स्थिति या उपचार के कारण आपको निम्नलिखित के बारे में कितने चिंतित हैं?		कभी नहीं	थोड़ा	थोड़ा सा ज्यादा	बहुत ज्यादा	अत्यंत	यह मेरे लिए प्रासंगिक नहीं है	उत्तर देने से इनकार
HC63i	चश्मा या कोन्टक्ट लेंस पर निर्भर होना	5	4	3	2	1	9	8
HC64i	चश्मे के साथ नज़र का ना सुधरना	5	4	3	2	1	9	8
HC16	अपनी आँखों की दिखावट (खूबसूरती)	5	4	3	2	1	9	8
HC17	आपकी दिखावट (लुक्स)	5	4	3	2	1	9	8
HC18	तस्वीरें (फ़ोटो) में आना	5	4	3	2	1		8
HC19	बात करते वक्त लोगो से नज़रे मिलाना	5	4	3	2	1		8
HC20	दूसरों का आपके बारे में सोचना	5	4	3	2	1		8
HC21	दूसरों का आपके प्रति व्यव्हार	5	4	3	2	1	9	8
HC22	दूसरों को आपके आँखों की मुश्किल का ना समझपाना	5	4	3	2	1	9	8
HC23	दूसरों का आपको गलत पहचानना (राय बनाना)	5	4	3	2	1	9	8
HC24	दूसरों का आपकी आँखों की स्थिति के बारे में टिप्पणी करना	5	4	3	2	1	9	8
HC25	अपका मज़ाक उड़ाना	5	4	3	2	1	9	8
HC27	दूसरों का आपके प्रति अलग तरह से व्यवहार करना	5	4	3	2	1	9	8
HC28	आपकी अवहेलना / उपेक्षा करना	5	4	3	2	1	9	8
HC29	दूसरों से सम्मान अर्जित करने मैं सक्षम ना होना	5	4	3	2	1	9	8
HC31	लोग या वस्तुयों से टकराना	5	4	3	2	1	9	8

चिंता								
आपकी आंख की स्थिति या उपचार के कारण आपको निम्नलिखित के बारे में कितने चिंतित हैं?		कभी नहीं	थोड़ा	थोड़ा सा ज्यादा	बहुत ज्यादा	अत्यंत	यह मेरे लिए प्रासंगिक नहीं है	उत्तर देने से इनकार
HC32	चीज़ें गिराना या पानी फैलाना	5	4	3	2	1	9	8
HC33	लड़खड़ाना	5	4	3	2	1		8
HC34	गिरना	5	4	3	2	1		8
HC36	खेलते समय घायल होना	5	4	3	2	1	9	8
HC37	चीज़ों का दुगना दिखना	5	4	3	2	1	9	8
HC38	मोटर वाहन संबंधित दुर्घटनाएं होना, जैसे की पार्किंग के दौरान कोई पोस्ट में टक्कर लगना	5	4	3	2	1	9	8
HC39	गैर-मोटर वाहन संबंधित दुर्घटनाएं होना, जैसे की हथोड़े जैसे उपकरणों का उपयोग करते समय	5	4	3	2	1	9	8
HC65i	दूसरों को दूर से पहचानने में असुविधा होना	5	4	3	2	1		8
HC41	3 डी मूवीज ना देख पाना	5	4	3	2	1	9	8
HC42	दोनों आँखों का एकसाथ इस्तेमाल ना कर पाना	5	4	3	2	1	9	8
HC43	भविष्य में आपकी पसंदीदा चीज़ें करने में असमर्थ	5	4	3	2	1	9	8
HC44	पढ़ाई में अच्छा ना कर पाना	5	4	3	2	1	9	8
HC45	खेल, शौक या अवकाश (छुट्टी) की गतिविधियों में आगे न बढ़ पाना	5	4	3	2	1		8
HC46	लंबी अवधि के लिए ध्यान केंद्रित ना कर पाना	5	4	3	2	1	9	8

चिंता								
आपकी आंख की स्थिति या उपचार के कारण आपको निम्नलिखित के बारे में कितने चिंतित हैं?		कभी नहीं	थोड़ा	थोड़ा सा ज्यादा	बहुत ज्यादा	अत्यंत	यह मेरे लिए प्रासंगिक नहीं है	उत्तर देने से इनकार
HC47	जीवन में सफल नहीं हो पाना	5	4	3	2	1	9	8
HC49	ड्राइविंग करके अन्य लोगों को खतरे में डालना	5	4	3	2	1	9	8
HC50	अपने करियर के विकल्प को बदलना	5	4	3	2	1	9	8
HC51	नौकरी पाने या रखने की आपकी क्षमता	5	4	3	2	1	9	8
HC52	आपकी दिखावट (लुक्स) का आपके काम को प्रभावित करना	5	4	3	2	1	9	8
HC53	आपके परिवार वालों पर आपकी आँखों की स्थिति का असर होना	5	4	3	2	1	9	8
HC54	जल्दी इलाज या निदान का ना होना	5	4	3	2	1	9	8
HC55	यह जानना की आपकी आँखों की स्थिति के लिए उपचार के विकल्प सीमित या अनुपलब्ध हैं	5	4	3	2	1	9	8
HC56	आपके डॉक्टर को आपके उपचार के साधन और परिणाम के बारे में अनिश्चित होना	5	4	3	2	1	9	8
HC58	अतीत में अप्रभावी उपचार होना	5	4	3	2	1	9	8
HC59	एम्बलोपिया (आलसी आँख) उपचार की लंबी अवधि का होना	5	4	3	2	1	9	8
HC60	आँखों के भेंगापन (टेढ़ेपन) के लिए किए गए सर्जरी का परिणाम	5	4	3	2	1	9	8

चिंता								
आपकी आंख की स्थिति या उपचार के कारण आपको निम्नलिखित के बारे में कितने चिंतित हैं?		कभी नहीं	थोड़ा	थोड़ा सा ज्यादा	बहुत ज्यादा	अत्यंत	यह मेरे लिए प्रासंगिक नहीं है	उत्तर देने से इनकार
HC61	उपचार के बाद भी भेंगापन (टेढ़ेपन) का फिर से आना	5	4	3	2	1	9	8
HC62	चिकित्सा कर्मचारियों से पर्याप्त जानकारी या स्पष्टीकरण का नहीं मिल पाना	5	4	3	2	1	9	8

भावनात्मक हाल चाल							
पिछले चार हफ्तों के दौरान, आपकी आँखों की स्थिति या उसके इलाज के कारण, आपने कितनी बार ...?		कभी नहीं	थोड़े समय	कुछ समय	अधिकतर समय	हमेशा	उत्तर देने से इनकार
EM1	नाखुश महसूस करना	5	4	3	2	1	8
EM3	उदास महसूस करना	5	4	3	2	1	8
EM4	बेचैनी महसूस करना	5	4	3	2	1	8
EM5	निराश महसूस करना	5	4	3	2	1	8
EM8	तनाव महसूस करना	5	4	3	2	1	8
EM9	परेशान महसूस करना	5	4	3	2	1	8
EM12	मुसीबत महसूस करना	5	4	3	2	1	8
EM14	चिड़चिड़ा महसूस करना	5	4	3	2	1	8
EM16	रोने का मन करना	5	4	3	2	1	8
EM17	लगता है कि आप जीवन में संघर्ष करना	5	4	3	2	1	8
EM19	अतीत में आपकी आंखों की देखभाल के बारे में सोचकर अफसोस या दोषी महसूस करना	5	4	3	2	1	8
EM20	अपने इलाज के परिणाम के बारे में बुरा लगना	5	4	3	2	1	8
EM21	आपके नेत्र विशेषज्ञों ने आपको आपकी आँखों के बारे में जो बताया है, उस बारे में हैरान महसूस करना	5	4	3	2	1	8
EM22	निराश अनुभव करना	5	4	3	2	1	8
EM23	आशाहीन अनुभव करना	5	4	3	2	1	8
EM24	अपने खिलाफ भेदभाव अनुभव करना	5	4	3	2	1	8

भावनात्मक हाल चाल							
पिछले चार हफ्तों के दौरान, आपकी आँखों की स्थिति या उसके इलाज के कारण, आपने कितनी बार ...?		कभी नहीं	थोड़े समय	कुछ समय	अधिकतर समय	हमेशा	उत्तर देने से इनकार
EM25	अपने दिखावट के कारण शर्मिंदा महसूस करना	5	4	3	2	1	8
EM27	शर्म महसूस करना	5	4	3	2	1	8
EM28	अपमानित महसूस करना	5	4	3	2	1	8
EM29	दूसरे से कम महसूस करना	5	4	3	2	1	8
EM30	अस्वीकृत महसूस करना	5	4	3	2	1	8
EM31	अकेला या पृथक महसूस करना	5	4	3	2	1	8
EM33	समाजीकरण करने से अनिच्छुक मेहसूस करना	5	4	3	2	1	8
EM34	कम आत्मविश्वास का महसूस होना	5	4	3	2	1	8
EM35	कम आत्मसम्मान का महसूस होना	5	4	3	2	1	8
EM36	स्वयं को सचेत महसूस करना	5	4	3	2	1	8
EM38	अपने आप को हर किसी से अलग महसूस करना	5	4	3	2	1	8
EM39	लोगों के बीच असहज महसूस करना	5	4	3	2	1	8
EM40	जब लोग आप को घूरते हैं तो असहज महसूस करना	5	4	3	2	1	8
EM41	अपनी आँखों की समस्या के बारे में बात करने के लिए अनिच्छुक महसूस करना	5	4	3	2	1	8
EM42	आपकी अच्छी आंख में रौशनी खोने का डर रहना	5	4	3	2	1	8

भावनात्मक हाल चाल							
पिछले चार हफ्तों के दौरान, आपकी आँखों की स्थिति या उसके इलाज के कारण, आपने कितनी बार ...?		कभी नहीं	थोड़े समय	कुछ समय	अधिकतर समय	हमेशा	उत्तर देने से इनकार
EM43	अपनी आंखों के बारे में अधिक सुरक्षात्मक (over protective) महसूस करना	5	4	3	2	1	8
EM45	दुर्भाग्यपूर्ण महसूस करना	5	4	3	2	1	8
EM46	अपने लिए खेद महसूस करना	5	4	3	2	1	8
EM47	अच्छी दृष्टि वाले लोगों से ईर्ष्या करना	5	4	3	2	1	8
EM48	अपनी आंख की स्थिति के बारे में चिंता करना	5	4	3	2	1	8
EM49	काश की सब ठीक होता	5	4	3	2	1	8

सामाजिक हाल चाल								
आपकी आँखों की स्थिति या उसके इलाज के कारण, आपको कितनी समस्या होती है?		कुछ भी नहीं	थोड़ा	थोड़ा सा ज्यादा	बहुत ज्यादा	मेरी आँखों की स्थिति के कारण ऐसा करने में असमर्थ	यह कार्य मेरे लिए प्रासंगिक नहीं है /में यह कार्य नहीं करता हूँ	उत्तर देने से इनकार
SC1	लोगों के साथ बातें करना	5	4	3	2	1		8
SC2	लोगों के साथ सामाजिक रूप से बातचीत करना	5	4	3	2	1		8
SC3	पहली बार लोगों से मिलना	5	4	3	2	1		8
SC4	नए मित्र बनाना	5	4	3	2	1		8
SC5	अपनी दोस्ती बनाए रखना	5	4	3	2	1		8
SC6	काम पर अपनी भूमिकाओं और जिम्मेदारियों को बनाए रखना	5	4	3	2	1		8
SC7	अपने करीबी व्यक्तिगत संबंधों को बनाए रखना, जैसे की विवाह, जीवनसाथी, परिवार के सदस्य	5	4	3	2	1		8
SC9	विपरीत लिंग के लोगों से बात करना	5	4	3	2	1		8
SC10	सामाजिक गतिविधियों में उलझना	5	4	3	2	1		8
SC11	रात को सामाजिक गतिविधियों में भाग लेना	5	4	3	2	1		8
SC12	सहकर्मी समूहों में सामाजिक रहना	5	4	3	2	1		8
SC13	उन लोगों या समूहों के साथ सामाजिककरण करना जिन्हें आप अच्छी तरह से नहीं जानते	5	4	3	2	1		8

सामाजिक हाल चाल								
आपकी आँखों की स्थिति या उसके इलाज के कारण, आपको कितनी समस्या होती है?		कुछ भी नहीं	थोड़ा	थोड़ा सा ज्यादा	बहुत ज्यादा	मेरी आँखों की स्थिति के कारण ऐसा करने में असमर्थ	यह कार्य मेरे लिए प्रासंगिक नहीं है /में यह कार्य नहीं करता हूँ	उत्तर देने से इनकार
SC14	सामाजिककरण क्योंकि लोग आपकी आंखों पर टिप्पणी करते हैं	5	4	3	2	1	9	8
SC15	लोग आपको जिस तरह से देखते हैं उस कारण सामाजिककरण करना	5	4	3	2	1	9	8
SC16	सामाजिककरण करना क्योंकि लोगों को पता नहीं चलता कि किस आंख की तरफ देखे	5	4	3	2	1	9	8
SC17	आँख से संपर्क बनाए रखने में सक्षम नहीं होने के कारण सामाजिककरण करना	5	4	3	2	1	9	8
SC18	दुगना दिखाई देने के कारण सामाजिककरण करना	5	4	3	2	1	9	8
SC19	जब आप कुछ नहीं कर पाते, तो परिवार के सदस्यों या दोस्तों का आप पर नाराज होना	5	4	3	2	1	9	8
SC20	जब आप कोई गलती करते हैं तो परिवार के सदस्यों या दोस्तों का आप पर नाराज होना	5	4	3	2	1	9	8
SC22	अपने परिवार और दोस्तों से सहायता और समर्थन प्राप्त करना	5	4	3	2	1		8

असुविधा								
आपकी आँखों की स्थिति या उसके इलाज के कारण, आपको कितनी परेशानी (असुविधा) है ...?		कुछ भी नहीं	थोड़ा	थोड़ा सा ज्यादा	काफी	अत्यंत	यह मेरे लिए प्रासंगिक नहीं है	उत्तर देने से इनकार
CV1	धीमा या अधिक सावधान रहना	5	4	3	2	1	9	8
CV2	धीरे और अधिक ध्यान से गाड़ी चलाना	5	4	3	2	1	9	8
CV4	चीजों को करने के लिए ज़्यादा वक़्त लगाना	5	4	3	2	1	9	8
CV5	चीज़ों को लंबे समय तक कर पाने की असमथा, जैसे की लंबे समय के लिए पढ़ना या लंबी ड्राइव पर जाना	5	4	3	2	1	9	8
CV6	कुछ चीजें करने के लिए अधिक प्रयास करना, जैसे की पढ़ना, गाड़ी चलाना	5	4	3	2	1	9	8
CV7	चीजों पर ज्यादा ध्यान केंद्रित करना	5	4	3	2	1	9	8
CV8	कुछ कार्य करते समय क्षणिक आराम या अक्सर विराम लेना	5	4	3	2	1	9	8
CV9	उज्ज्वल सूरज की रोशनी में अपनी एक आँख को बंद करने	5	4	3	2	1	9	8
CV10	स्पष्ट रूप से देखने के लिए एक आंख को ढकना	5	4	3	2	1	9	8
CV11	असामान्य तरीके से सिर या शरीर को मोड़ना, जैसे की देखते वक़्त सिर को घुमाना	5	4	3	2	1	9	8
CV12	अपनी आँखों की नियुक्तियों/ अपॉइंटमेंट में जाने के लिए एक लंबी यात्रा करना	5	4	3	2	1	9	8
CV13	सही चश्मा पाने के लिए इंतजार करना	5	4	3	2	1	9	8

असुविधा								
आपकी आँखों की स्थिति या उसके इलाज के कारण, आपको कितनी परेशानी (असुविधा) है ...?		कुछ भी नहीं	थोड़ा	थोड़ा सा ज्यादा	काफी	अत्यंत	यह मेरे लिए प्रासंगिक नहीं है	उत्तर देने से इनकार
CV14	ज्यादातर समय चश्मा या कॉन्टेक्ट लेंस पहनना	5	4	3	2	1	9	8
CV15	कुछ कार्य करते समय चश्मे हटाना , जैसे की खेल	5	4	3	2	1	9	8
CV16	प्रिज्म चश्मा का उपयोग करना	5	4	3	2	1	9	8
CV17	ज्यादातर समय धूप का चश्मा पहनना	5	4	3	2	1	9	8
CV18	आँखों के भेंगापन (टेढ़ेपन) को ठीक कराने के लिए कई सर्जरीयों से गुज़रना	5	4	3	2	1	9	8
CV19	कॉन्टेक्ट लेंस का उपयोग करने में असमर्थ	5	4	3	2	1	9	8
CV20	आप जो करना चाहते हैं वह करने में सक्षम न होना	5	4	3	2	1	9	8
CV21	प्रभावित आँख की तरफ देखने के लिए अपना सिर मोड़ना	5	4	3	2	1	9	8
CV22	किसी गंदगी का आपकी अच्छी आंख में चले जाना	5	4	3	2	1	9	8
CV23	जब आप चीजों को गलती से तोड़ देते हैं	5	4	3	2	1	9	8
CV25	जब आप अचानक गाडी चलाते समय दुगनी (डबल) दृष्टि का अनुभव करते हैं	5	4	3	2	1	9	8
CV26	दुगना दिखाई देने पर ध्यान देने की कोशिश करना	5	4	3	2	1	9	8

आर्थिक प्रभाव								
आपकी आँखों की स्थिति या उसके इलाज के कारण, आप कितने चिंतित हैं ...?		कुछ भी नहीं	थोड़ा	मध्यम	थोड़ा सा ज्यादा	अत्यंत	यह मेरे लिए प्रासंगिक नहीं है	उत्तर देने से इनकार
EC1	आपकी आँखों की देखभाल या नेत्र विशेषज्ञ को दिखाने से जुड़े हुए खर्चे	5	4	3	2	1	9	8
EC2	आपकी एम्बलोपीक आँख (आलसी आँख) के उपचार का खर्चे, जैसे की दृष्टि चिकित्सा	5	4	3	2	1	9	8
EC3	अस्पताल में अपनी आँखों की स्थिति का उपचार कराने के लिए अपने काम में से समय निकालना (जैसे दृष्टि चिकित्सा)	5	4	3	2	1	9	8
EC4	अपने चश्मे या कॉन्टैक्ट लेन्स खरीदने की प्रारंभिक और चल रहे खर्चे	5	4	3	2	1	9	8
EC5	अपनी आँखों के भेंगापन (टेढ़ेपन) को ठीक करने का खर्चा	5	4	3	2	1	9	8
EC7	विशिष्ट नौकरियों के लिए दृष्टि संबंधी आवश्यकताओं की पूर्ति नहीं करना जैसे की पायलट, पुलिस	5	4	3	2	1	9	8
EC8	नौकरी खोजने या नई नौकरी पाने की आपकी क्षमता	5	4	3	2	1	9	8
EC9	कुछ विशेष प्रकार की नौकरियां करने में असक्षम, जैसे की भारी वाहन चलाना	5	4	3	2	1	9	8
EC10	अपना काम खोना	5	4	3	2	1	9	8
EC11	आपके काम का प्रभावित होना	5	4	3	2	1	9	8
EC13	आपके सहकर्मीयों के साथ संबंधों पर तनाव, जैसे की कार्यों को पूरा करने में अधिक समय लेना	5	4	3	2	1	9	8
EC14	अपनी पसंद के कैरियर (या काम) को न कर पाना	5	4	3	2	1	9	8
EC15i	अपनी आँखों की देखभाल करने के स्वरुप कहीं पहुंचने के लिए यात्रा का खर्चा	5	4	3	2	1	9	8

परछती विधियों							
अपनी आँखों की स्थिति के साथ सामना करने के लिए आप कितनी बार निम्न विधियों का उपयोग करते हैं		कुछ भी नहीं	थोड़ा	थोड़ा सा ज्यादा	बोहोत ज्यादा	अत्यंत	उत्तर देने से इनकार
CP1	सावधान रहना	1	2	3	4	5	8
CP2	मुश्किल काम करते समय अधिक ध्यान देना	1	2	3	4	5	8
CP3	कठिन कार्य करने से बचना, जैसे की, रात के समय गाड़ी चलाना	1	2	3	4	5	8
CP5	एक आँख बंद करना, जैसे की, स्पष्ट रूप से देखने के लिए, दुगना देखने से बचने के लिए	1	2	3	4	5	8
CP8	चश्मा या कॉन्टैक्ट लेन्स का उपयोग करना	1	2	3	4	5	8
CP9	अपनी आँखों के दोष को छिपाना जैसे नेत्र संपर्क से बचना या धूप का चश्मा पहनना	1	2	3	4	5	8
CP10	हास्य का उपयोग करना	1	2	3	4	5	8
CP12	अपने आप को दूसरों से दूर रखना	1	2	3	4	5	8
CP13	उन लोगों के साथ रहना जिनके साथ आप आराम से रह पाते है	1	2	3	4	5	8
CP14	मजबूत रहना, जैसे की, दूसरों की टिप्पणियों को अनदेखा करना	1	2	3	4	5	8
CP15	अपनी आँखों की स्थिति के बारे में लोगों को बताना	1	2	3	4	5	8
CP16	दूसरों से समर्थन प्राप्त करना	1	2	3	4	5	8
CP17	अपनी समस्याओं को अपनी आँखों की स्थिति के साथ सम्बंधित ना करना	1	2	3	4	5	8
CP18	अपनी आँखों की समस्याओं का श्रेय बढ़ती उम्र को देना	1	2	3	4	5	8

परछती विधियों							
अपनी आँखों की स्थिति के साथ सामना करने के लिए आप कितनी बार निम्न विधियों का उपयोग करते हैं		कुछ भी नहीं	थोड़ा	थोड़ा सा ज्यादा	बोहोत ज्यादा	अत्यंत	उत्तर देने से इनकार
CP19	आपकी आँखों की स्थिति के बारे में ना सोचना	1	2	3	4	5	8
CP20	सकारात्मक होने की कोशिश करना	1	2	3	4	5	8
CP21	यह सोचना कि लोगों की समस्याएं आपके मुकाबले बहुत खराब हैं	1	2	3	4	5	8
CP22	यह सोचना कि आपकी आँखों की स्थिति प्रगतिशील नहीं है	1	2	3	4	5	8
CP23	अपनी आँखों की स्थिति के साथ रहना सीख लेना	1	2	3	4	5	8
CP24	अपनी आँखों की स्थिति को स्वीकार करना	1	2	3	4	5	8

For office use

Eye hospital/ Practice name	
MRD Number	
Participant ID	
Participant's name	
Ocular diagnosis	
Type of amblyopia	
Type of strabismus	
Refractive error	OD: OS:
Best corrected visual acuity	OD: OS:
Cover test	Distance: Near:
Magnitude of deviation	Distance: Near:
Co-existing ocular diagnosis	
General health	

பின்வரும் கேள்விகள் அனைத்தும் அம்பலயோப்பியா (சோம்பல் கண்), ஸ்ட்ராபிஸ்மஸ் (மாறு கண்/ ஒர கண்) மற்றும் அதன் சிகிச்சை முறைகள் உங்கள் வாழ்க்கை தரத்தை எப்படி பாதிக்கின்றது என்பதைப்பற்றியதாகும்.

நீங்கள் இந்த கேள்விகளுக்கு பதில் அளிக்கும் போது, உங்கள் அம்பலயோப்பியா (சோம்பல் கண்), ஸ்ட்ராபிஸ்மஸ் (மாறு கண்/ ஒர கண்) மற்றும் தற்போதைய கண் சிகிச்சையை (உ. தா. பேட்ச்சிங் தெரபி, விஷன் தெரபி) மட்டும் கருத்தில் கொள்ளவும்.

நீங்கள் பொதுவாக கண்ணாடி, காண்டாக்ட் லென்ஸ் அல்லது பிற பார்வை சாதனங்கள் பயன்படுத்தினால், அதை பயன்படுத்தும் பொது உங்களது பார்வை எவ்வாறு உள்ளது என்பதை கருத்தில் கொண்டு பதிலளிக்கவும்.

For office use

Participant's name:	Participant ID:
MRD Number:	Date:
Time started:	Time finished:

Background Questionnaire

உங்களை பற்றியும் உங்கள் கண் பிரச்சனை பற்றியும் கீழ்கண்ட விவரங்களை நிரப்புங்கள்.

பெயர்	
உங்கள் மருத்துவ பதிவு எண் (MRD number)	
முகவரி	
தொலைப்பேசி / கைப்பேசி எண்	
இ-மெயில்	
பிறந்த தேதி	
வயது	
பிறந்த இடம்	
பாலினம்	*ஆண் / பெண்*
தாய் மொழி	
கல்வி	
தொழில்	
கீழ்கண்ட கேள்விகளுக்கு உங்களது பதிலை வட்டம் இடுக	
உங்களுக்கு உள்ள கண் பிரச்சனைகளை குறிப்பிடுக	*அம்பலயோப்பியா (சோம்பல் கண்) / ஸ்ட்ராபிஸ்மஸ் (மாறு கண்) / இரண்டும்*
பாதிக்கப்பட்ட கண்	*வலது / இடது / இரண்டும்*
உங்களது மாறு கண் பிறருக்கு வெளிப்படையாக தெரிகிறதா?	*ஆம் / இல்லை / எனக்கு தெரியாது / எனக்கு மாறு கண் இல்லை*
நீங்கள் கண்ணாடி அல்லது காண்டாக்ட் லென்ஸ் அணிபவரா?	*ஆம் / இல்லை*
உங்கள் கண் பிரச்சனைக்காக உங்களுக்கு அளிக்கப்பட்ட சிகிச்சை முறைகளை குறிப்பிடுக	*கண்ணாடி / காண்டாக்ட் லென்ஸ் / பேட்ச்சிங் தெரபி / கண் சொட்டு மருந்து / விஷன் தெரபி / வீடியோ கேம் தெரபி / அறுவை சிகிச்சை மற்றவை, குறிப்பிடுக _____*
இதை தவிர உங்களுக்கு பிற கண் நோய் ஏதேனும் உள்ளதா?	*ஆம் / இல்லை ; ஆம் என்றால், குறிப்பிடுக _____*
உங்களுக்கு உடலில் வேறு ஏதேனும் நோய் உள்ளதா?	*ஆம் / இல்லை ; ஆம் என்றால், குறிப்பிடுக _____*

கண் பிரச்சனை தொடர்பான அறிகுறிகள்													
		உங்கள் கண் பிரச்சனையினால் அல்லது கண் சிகிச்சையினால் கீழ்கண்ட அறிகுறிகளை எவ்வளவு அதிகமாக அனுபவிக்கிறீர்கள்?				உங்கள் கண் பிரச்சனையினால் அல்லது கண் சிகிச்சையினால் கீழ்கண்ட அறிகுறிகள் எவ்வளவு கடுமையாக உள்ளது?				உங்கள் கண் பிரச்சனையினால் அல்லது கண் சிகிச்சையினால் ஏற்படும் கீழ்கண்ட அறிகுறிகள் எவ்வளவு பிரச்சனையாக உள்ளது?			
		ஒருபோதும் இல்லை	எப்போதாவது	அடிக்கடி	மிகவும் அடிக்கடி	இல்லவே இல்லை	லேசாக உள்ளது	மிதமாக உள்ளது	கடுமையாக உள்ளது	இல்லவே இல்லை	சிறிதளவு	ஓரளவு	அதிகம்
உ தா.	கண்களில் சோர்வு	4	(3)	2	1	4	3	(2)	1	4	3	2	(1)
VS1	மங்கலான தூரப்பார்வை	4	3	2	1	4	3	2	1	4	3	2	1
VS2	மங்கலான கிட்டப்பார்வை	4	3	2	1	4	3	2	1	4	3	2	1
VS3	இரண்டு கண்களிலும் மிக குறைவான பார்வை	4	3	2	1	4	3	2	1	4	3	2	1
VS4	ஒரு கண்ணில் மட்டும் மிக குறைவான பார்வை	4	3	2	1	4	3	2	1	4	3	2	1
VS5	பாதிக்கப்பட்ட கண்ணில் குறைவான புறப்பார்வை (சைடு விஷன்)	4	3	2	1	4	3	2	1	4	3	2	1
VS6	கண்களை ஒருங்கிணைத்து ஃபோகஸ் செய்வதில் சிரமம்	4	3	2	1	4	3	2	1	4	3	2	1
VS7	இரண்டு பொருட்களினிடையே உள்ள தூரம் அல்லது ஆழம் எவ்வளவு என்பதை சரியாக அறிவதில் சிரமம்	4	3	2	1	4	3	2	1	4	3	2	1
VS9	இரட்டைப்பார்வை (நீங்கள் பார்க்கும் பொருள் இரண்டு இரண்டாக தெரிதல்)	4	3	2	1	4	3	2	1	4	3	2	1

கண் பிரச்சனை தொடர்பான அறிகுறிகள்													
		உங்கள் கண் பிரச்சனையினால் அல்லது கண் சிகிச்சையினால் கீழ்கண்ட அறிகுறிகளை எவ்வளவு அதிகமாக அனுபவிக்கிறீர்கள்?				உங்கள் கண் பிரச்சனையினால் அல்லது கண் சிகிச்சையினால் கீழ்கண்ட அறிகுறிகள் எவ்வளவு கடுமையாக உள்ளது?				உங்கள் கண் பிரச்சனையினால் அல்லது கண் சிகிச்சையினால் ஏற்படும் கீழ்கண்ட அறிகுறிகள் எவ்வளவு பிரச்சனையாக உள்ளது?			
		ஒருபோதும் இல்லை	**எப்போதாவது**	**அடிக்கடி**	**மிகவும் அடிக்கடி**	**இல்லவே இல்லை**	**லேசாக உள்ளது**	**மிதமாக உள்ளது**	**கடுமையாக உள்ளது**	**இல்லவே இல்லை**	**சிறிதளவு**	**ஓரளவு**	**அதிகம்**
VS10	நீங்கள் சோர்வாக இருக்கும் போது நீங்கள் பார்க்கும் பொருள் இரண்டு இரண்டாக தெரிதல்	4	3	2	1	4	3	2	1	4	3	2	1
VS11	நீங்கள் பார்க்கும் பொருட்களைச்சுற்றி நிழல்கள் போல தெரிதல்	4	3	2	1	4	3	2	1	4	3	2	1
VS13	சூரிய ஒளி, கார் முன் விளக்கு போன்றவற்றால் கண்கூச்சம் (கிளேர்) ஏற்படுதல்	4	3	2	1	4	3	2	1	4	3	2	1
OS1	கண்களில் சிரமம் (ஸ்ட்ரெய்ன்)	4	3	2	1	4	3	2	1	4	3	2	1
OS2	கண்களில் சோர்வு	4	3	2	1	4	3	2	1	4	3	2	1
OS3	கண்களில் கனமான உணர்வு	4	3	2	1	4	3	2	1	4	3	2	1
OS4	கண்களில் உலர்வு (வறட்சி)	4	3	2	1	4	3	2	1	4	3	2	1
OS5	கண்கள் சிகப்பாகுதல்	4	3	2	1	4	3	2	1	4	3	2	1
OS6	கண்களில் நீர் வடிதல்	4	3	2	1	4	3	2	1	4	3	2	1
OS7	கண்களில் வலி	4	3	2	1	4	3	2	1	4	3	2	1
OS9	கண்களில் எரிச்சல்	4	3	2	1	4	3	2	1	4	3	2	1
OS10	கண்களில் உறுத்தல்	4	3	2	1	4	3	2	1	4	3	2	1
OS11	மாறுகண் (இரண்டு கண்களும் வெவேறு பக்கம் பார்த்தல்)	4	3	2	1	4	3	2	1	4	3	2	1

கண் பிரச்சனை தொடர்பான அறிகுறிகள்													
		உங்கள் கண் பிரச்சனையினால் அல்லது கண் சிகிச்சையினால் கீழ்கண்ட அறிகுறிகளை எவ்வளவு அதிகமாக அனுபவிக்கிறீர்கள்?				உங்கள் கண் பிரச்சனையினால் அல்லது கண் சிகிச்சையினால் கீழ்கண்ட அறிகுறிகள் எவ்வளவு கடுமையாக உள்ளது?				உங்கள் கண் பிரச்சனையினால் அல்லது கண் சிகிச்சையினால் ஏற்படும் கீழ்கண்ட அறிகுறிகள் எவ்வளவு பிரச்சனையாக உள்ளது?			
		ஒருபோதும் இல்லை	**எப்போதாவது**	**அடிக்கடி**	**மிகவும் அடிக்கடி**	**இல்லவே இல்லை**	**லேசாக உள்ளது**	**மிதமாக உள்ளது**	**கடுமையாக உள்ளது**	**இல்லவே இல்லை**	**சிறிதளவு**	**ஓரளவு**	**அதிகம்**
OS12	சோர்வாகும் போது மாறுகண் ஏற்படுதல்	4	3	2	1	4	3	2	1	4	3	2	1
OS13i	வலது மற்றும் இடது கண்களின் அளவு (size) வெவ்வேறாக தோன்றுதல்	4	3	2	1	4	3	2	1	4	3	2	1
GS1	தலைவலி	4	3	2	1	4	3	2	1	4	3	2	1
GS2	முதுகு வலி	4	3	2	1	4	3	2	1	4	3	2	1
GS3	கழுத்து வலி	4	3	2	1	4	3	2	1	4	3	2	1
GS4	சோர்வு	4	3	2	1	4	3	2	1	4	3	2	1
GS5	தலைச்சுற்றல்	4	3	2	1	4	3	2	1	4	3	2	1
GS6	ஏதேனும் வேலை செய்யும் போது (உ தா. படிக்கும் போது) தூக்கக்கலக்கம் ஏற்படுதல்	4	3	2	1	4	3	2	1	4	3	2	1
GS8	சமநிலை இழத்தல் (தடுமாற்றம்)	4	3	2	1	4	3	2	1	4	3	2	1
GS9	இயல்பற்ற விதத்தில் தலையை திருப்புதல் அல்லது சாய்த்தல்	4	3	2	1	4	3	2	1	4	3	2	1
GS10	கவனம் செலுத்துவதில் சிரமம்	4	3	2	1	4	3	2	1	4	3	2	1

தினசரி வேலைகளிலுள்ள தாக்கம்								
உங்கள் கண் பிரச்சனையினால் அல்லது கண் சிகிச்சையினால் கீழ்கண்டவைகளை செய்ய எவ்வளவு கஷ்டமாக உள்ளது?		கஷ்டமே இல்லை	சிறிதளவு கஷ்டம்	ஓரளவு கஷ்டம்	மிகவும் கஷ்டம்	என் கண் பிரச்சனையினால் இதை செய்ய இயலவில்லை	இந்த வேலையை வேறு காரணத்தினால் நான் செய்வதில்லை / இது எனக்கு பொருந்தாது	பதிலளிக்க மறுக்கிறேன்
AL1	சமைத்தல்	5	4	3	2	1	9	8
AL2	காய்கறிகளை / உணவு பொருட்களை வெட்டுதல்	5	4	3	2	1	9	8
AL4	கீழே சிந்தாமல் ஒரு குவளையில் பானம் / தண்ணீர் ஊற்றுதல்	5	4	3	2	1	9	8
AL6	உங்கள் தோற்றத்தை கவனித்துக்கொள்ளுத்தல் (உ தா. உங்கள் முகத்தோற்றம், சவரம் செய்தல்)	5	4	3	2	1	9	8
AL7	கண்ணில் அலங்காரம் (மேக்-அப்) செய்தல்	5	4	3	2	1	9	8
AL8	உங்கள் கால் அல்லது கை விறல் நகத்தை பாதுக்காப்புடன் வெட்டுதல்	5	4	3	2	1	9	8
AL9	உங்களிடமிருந்து பொருட்கள் எவ்வளவு அருகில் அல்லது தொலைவில் உள்ளது என்பதை மதிப்பிடுதல்	5	4	3	2	1	9	8
AL10	3 டி படங்களை பார்த்தல்	5	4	3	2	1	9	8
AL11	கண் கூச்சம் ஏற்படும் சூழ்நிலையில் பார்த்தல்	5	4	3	2	1	9	8
AL12	இரவு நேரத்தில் நன்றாகப்பார்த்தல்	5	4	3	2	1	9	8
AL13	சோர்வாக இருக்கும் வேளையில் நன்றாகப்பார்த்தல்	5	4	3	2	1	9	8
AL14	பிறர் தூரத்தில் சுட்டிக்காட்டுவதைப்பார்த்தல்	5	4	3	2	1	9	8
AL65i	மிகச்சிறிய விவரங்களை பார்த்தல்	5	4	3	2	1	9	8
AL66i	முக பாவனைகளை அல்லது சைகைகளை தூரத்திலிருந்து கண்டறிதல்	5	4	3	2	1	9	8

தினசரி வேலைகளிலுள்ள தாக்கம்								
உங்கள் கண் பிரச்சனையினால் அல்லது கண் சிகிச்சையினால் கீழ்கண்டவைகளை செய்ய எவ்வளவு கஷ்டமாக உள்ளது?		கஷ்டமே இல்லை	சிறிதளவு கஷ்டம்	ஓரளவு கஷ்டம்	மிகவும் கஷ்டம்	என் கண் பிரச்சனையினால் இதை செய்ய இயலவில்லை	இந்த வேலையை வேறு காரணத்தினால் நான் செய்வதில்லை / இது எனக்கு பொருந்தாது	பதிலளிக்க மறுக்கிறேன்
AL16	ஊசியில் நூல் கோர்த்தல்	5	4	3	2	1	9	8
AL18	விளையாடும் போது, பந்து வரும் திசையை கண்டறிதல்	5	4	3	2	1	9	8
AL19	பந்தைப்பிடித்தல்	5	4	3	2	1	9	8
AL20	பந்தை அடித்தல்	5	4	3	2	1	9	8
AL67i	கிரிக்கெட் விளையாடுதல்	5	4	3	2	1	9	8
AL22	கூடைப்பந்து அல்லது கால்ப்பந்து விளையாடுதல்	5	4	3	2	1	9	8
AL68i	பிரகாசமான சூரிய வெளிச்சத்தில் விளையாடுதல்	5	4	3	2	1	9	8
AL69i	பூப்பந்து அல்லது பேட்மின்டன் விளையாடுதல்	5	4	3	2	1	9	8
AL24	பணி சம்மந்தப்பட்ட வேலைகளை செய்தல்	5	4	3	2	1	9	8
AL25	சிறிய மற்றும் நுணுக்கமான வேலைகளை செய்தல்	5	4	3	2	1	9	8
AL26	ஸ்க்ரூடிரைவர் (திருப்பளி), சுத்தி போன்ற கைக்கருவிகளை உபயோகப்படுத்துதல்	5	4	3	2	1	9	8
AL27	இரண்டு கண்களையும் ஒன்றாக சேர்த்து பயன்படுத்த தேவைப்படும் கருவிகளை உபயோகப்படுத்துதல், உ.தா பைனாகுலர்ஸ்	5	4	3	2	1	9	8
AL28	கணினி உபயோகப்படுத்துதல்	5	4	3	2	1	9	8
AL29	கைப்பேசி உபயோகப்படுத்துதல்	5	4	3	2	1	9	8
AL30	ஐபேட் (Ipad) அல்லது டாப் (Tab) உபயோகப்படுத்துதல்	5	4	3	2	1	9	8

தினசரி வேலைகளிலுள்ள தாக்கம்								
உங்கள் கண் பிரச்சனையினால் அல்லது கண் சிகிச்சையினால் கீழ்கண்டவைகளை செய்ய எவ்வளவு கஷ்டமாக உள்ளது?		கஷ்டமே இல்லை	சிறிதளவு கஷ்டம்	ஓரளவு கஷ்டம்	மிகவும் கஷ்டம்	என் கண் பிரச்சனையினால் இதை செய்ய இயலவில்லை	இந்த வேலையை வேறு காரணத்தினால் நான் செய்வதில்லை / இது எனக்கு பொருந்தாது	பதிலளிக்க மறுக்கிறேன்
AL70i	வீடியோகேம் விளையாடுதல்	5	4	3	2	1	9	8
AL31	நேர் வரியில் எழுதுதல்	5	4	3	2	1	9	8
AL32	தொலைக்காட்சி பார்த்தல்	5	4	3	2	1	9	8
AL33	பொழுதுபோக்கில் ஈடுப்படுதல் உ.தா. கைவினை கலை (க்ராஃட்)	5	4	3	2	1	9	8
AL35	செய்தித்தாள் வாசித்தல்	5	4	3	2	1	9	8
AL71i	புத்தகம் படித்தல்	5	4	3	2	1	9	8
AL37	சிறிய அச்சுடைய புத்தகங்களைப்படித்தல், உ தா எல்லோ பேஜஸ் படித்தல்	5	4	3	2	1	9	8
AL39	தொலைக்காட்சியில் ஒளிபரப்பாகும் வார்த்தைகளைப்படித்தல், உ தா பிளாஷ் நியூஸ்/ முக்கியச்செய்தி	5	4	3	2	1	9	8
AL40	பலகையில் எழுதியிருப்பதை படித்தல்	5	4	3	2	1	9	8
AL41	பஸ் நம்பரை படித்தல்	5	4	3	2	1	9	8
AL43	சாலை அறிகுறிகளை படித்தல்	5	4	3	2	1	9	8
AL44	வெளிச்சம் குறைவான சூழ்நிலையில் படித்தல்	5	4	3	2	1	9	8
AL45	வெகு நேரம் படித்தல்	5	4	3	2	1	9	8
AL46	விரைவாக படித்தல்	5	4	3	2	1	9	8

வாகனம் ஓட்டுதல்								
உங்கள் கண் பிரச்சனையினால் அல்லது கண் சிகிச்சையினால் கீழ்கண்டவைகளை செய்ய எவ்வளவு கஷ்டமாக உள்ளது?		கஷ்டமே இல்லை	சிறிதளவு கஷ்டம்	ஓரளவு கஷ்டம்	மிகவும் கஷ்டம்	என் கண் பிரச்சனையினால் இதை செய்ய இயலவில்லை	வேறு காரணத்தினால் நான் வாகனம் ஓட்டுவதில்லை	பதிலளிக்க மறுக்கிறேன்
AL47	பகல் நேரத்தில் கார் ஓட்டுதல்	5	4	3	2	1	9	8
AL48	இரவு நேரத்தில் கார் ஓட்டுதல்	5	4	3	2	1	9	8
AL49	மோசமான வானிலையில் கார் ஓட்டுதல், உ தா மழை பெய்யும் போது	5	4	3	2	1	9	8
AL50	கடுமையான போக்குவரத்து நெரிசலில் கார் ஓட்டுதல்	5	4	3	2	1	9	8
AL55	காரை பின் நோக்கி எடுத்தல் (ரிவர்ஸ் செய்தல்)	5	4	3	2	1	9	8
AL56	காரை ஓரிடத்தில் நிறுத்துதல் (பார்க் செய்தல்)	5	4	3	2	1	9	8
AL64	பகல் நேரத்தில் இரு சக்கர வாகனம் ஓட்டுதல்	5	4	3	2	1	9	8
AL72i	இரவு நேரத்தில் இரு சக்கர வாகனம் ஓட்டுதல்	5	4	3	2	1	9	8
AL73i	மோசமான வானிலையில் இரு சக்கர வாகனம் ஓட்டுதல், உ தா மழை பெய்யும் போது	5	4	3	2	1	9	8
AL74i	கடுமையான போக்குவரத்து நெரிசலில் இரு சக்கர வாகனம் ஓட்டுதல்	5	4	3	2	1	9	8
AL75i	பிரகாசமான சூரியவெளிச்சத்தில் இரு சக்கர வாகனம் ஓட்டுதல்	5	4	3	2	1	9	8
AL51	அறிமுகமில்லாத இடங்களில் கார் அல்லது இரு சக்கர வாகனம் ஓட்டுதல்	5	4	3	2	1	9	8
AL53	வெகு நேரம் கார் அல்லது இரு சக்கர வாகனம் ஓட்டுதல்	5	4	3	2	1	9	8
AL54	எதிரே வரும் வாகனத்தின் முன் விளக்குகளை (ஹெட் லைட்ஸ்) நோக்கி வாகனம் ஓட்டுதல்	5	4	3	2	1	9	8
AL57	வாகனம் ஓட்டும் போதோ அல்லது நிறுத்தும் போதோ, உங்கள் வாகனத்துக்கும் பிற வாகனத்துக்கும் உள்ள இடைவெளி (தூரம்) மதிப்பிடுதல்	5	4	3	2	1	9	8

வாகனம் ஓட்டுதல்								
உங்கள் கண் பிரச்சனையினால் அல்லது கண் சிகிச்சையினால் கீழ்கண்டவைகளை செய்ய எவ்வளவு கஷ்டமாக உள்ளது?		*கஷ்டமே இல்லை*	*சிறிதளவு கஷ்டம்*	*ஓரளவு கஷ்டம்*	*மிகவும் கஷ்டம்*	*என் கண் பிரச்சனையினால் இதை செய்ய இயலவில்லை*	*வேறு காரணத்தினால் நான் வாகனம் ஓட்டுவதில்லை*	*பதிலளிக்க மறுக்கிறேன்*
AL60	*முன்னே செல்லும் வாகனத்தின் வேகம் அதிகரிக்கும் போது அல்லது குறையும் போது, அதை சரியாக கவனித்தல்*	5	4	3	2	1	9	8
AL61	*வாகனம் ஓட்டும் போது, பாதிக்கப்பட்ட கண் பக்கமுள்ள பிற வாகனம், மக்கள் அல்லது பொருட்களை பார்ப்பதில்*	5	4	3	2	1	9	8
AL76i	*வாகனம் ஓட்டும் போது சாலையில் உள்ள வேகத்தடைகளை (ஸ்பீட் பிரேக்) கவனித்தல்*	5	4	3	2	1	9	8

நடமாடுதல்								
உங்கள் கண் பிரச்சனையினால் அல்லது கண் சிகிச்சையினால் கீழ்கண்டவைகளை செய்ய எவ்வளவு கஷ்டமாக உள்ளது?		கஷ்டமே இல்லை	சிறிதளவு கஷ்டம்	ஓரளவு கஷ்டம்	மிகவும் கஷ்டம்	என் கண் பிரச்சனையினால் இதை செய்ய முடியவில்லை	இதை வேறு காரணத்தினால் நான் செய்வதில்லை / இது எனக்கு பொருந்தாது	பதிலளிக்க மறுக்கிறேன்
MB1	சாலையை கடந்து செல்லுதல்	5	4	3	2	1	9	8
MB2	படிகட்டுகளில் ஏறுதல்	5	4	3	2	1	9	8
MB3	படிகட்டுகளில் இறங்குதல்	5	4	3	2	1	9	8
MB5	நகரும் படிக்கட்டுகளை (எஸ்கலேட்டர்) பயன்படுத்துதல்	5	4	3	2	1	9	8
MB6	தடுமாறாமல் சீராக நடத்தல்	5	4	3	2	1	9	8
MB7	அறிமுகமில்லாத இடங்களில் நடத்தல்	5	4	3	2	1	9	8
MB8	குன்றும் குழியுமான (மேடு பள்ளமான) சாலையில் நடத்தல்	5	4	3	2	1	9	8
MB9	கூட்ட நெரிசலான இடங்களில் நடத்தல்	5	4	3	2	1	9	8
MB10	நடக்கும் போது வழியிலுள்ள தடைகளை /பொருட்களை இடிக்காமல் கடந்து செல்லுதல்	5	4	3	2	1	9	8
MB12	நடக்கும் போது, பாதிக்கப்பட்ட கண் பக்கமுள்ள பொருட்களை கவனித்தல்	5	4	3	2	1	9	8
MB13	வெளிச்சம் குறைவான வேளையில் நடத்தல்	5	4	3	2	1	9	8
MB14	இரட்டை பார்வை தெரியும் போது நடத்தல்	5	4	3	2	1	9	8

கண் பிரச்சனை சார்ந்த கவலைகள்								
உங்கள் கண் பிரச்சனையினால் அல்லது கண் சிகிச்சையினால் கீழ்கண்டவைகளைக்குறித்து எவ்வளவு கவலைப்படுகிறீர்கள்?		கவலை இல்லை	சிறிதளவு கவலை	ஓரளவு கவலை	அதிகமான கவலை	மிக அதிகமான கவலை	இது எனக்கு பொருந்தாது	பதிலளிக்க மறுக்கிறேன்
HC1	ஒரே ஒரு கண் மட்டும் நன்றாக இருப்பதை குறித்து	5	4	3	2	1	9	8
HC2	நன்றாக தெரியும் கண்ணை சார்ந்து இருப்பதை குறித்து	5	4	3	2	1	9	8
HC3	நன்றாக தெரியும் கண்ணில் ஏதேனும் நோய் (பிரச்சனை) வந்துவிடுமோ என்று	5	4	3	2	1	9	8
HC4	நன்றாக தெரியும் கண்ணில் வேறு கண் பிரச்சனை காரணமாக ஏதேனும் சிகிச்சை (உ. தா பொரை அறுவை சிகிச்சை) பெறுவதைக்குறித்து	5	4	3	2	1	9	8
HC5	நன்றாக தெரியும் கண் அதிக வேலை செய்யவேண்டியிருப்பதைக்குறித்து	5	4	3	2	1	9	8
HC6	நன்றாக தெரியும் கண்ணில் ஏதேனும் காயம் பட்டுவிடுமோ என்று	5	4	3	2	1	9	8
HC7	பாதிக்கப்பட்ட (பலவீனமான) கண்ணைக்குறித்து	5	4	3	2	1	9	8
HC8	உங்கள் கண்களின் பாதுகாப்பைக்குறித்து	5	4	3	2	1		8
HC10	உங்கள் கண் சார்ந்த பிரச்சனைகள் வயதோடு சேர்ந்து அதிகரிப்பதைக்குறித்து	5	4	3	2	1		8
HC11	உங்கள் பார்வை அல்லது கண் பிரச்சனைகள் மோசமாவதைக்குறித்து	5	4	3	2	1		8
HC12	குருடாகிவிடுவோமோ என்று	5	4	3	2	1		8
HC13	உங்கள் கண் பிரச்சனை உங்கள் குழந்தைக்கும் வந்துவிடுமோ என்று	5	4	3	2	1	9	8
HC14	மாறுகண் உள்ளதைக்குறித்து	5	4	3	2	1	9	8
HC15	தடிமனான கண்ணாடி அணியவேண்டியிருப்பதைக்குறித்து	5	4	3	2	1	9	8
HC63i	கண்ணாடி அல்லது காண்டாக்ட் லென்ஸை தினசரி வாழ்க்கைக்கு சார்ந்திருப்பதைக்குறித்து	5	4	3	2	1	9	8
HC64i	கண்ணாடி அணிந்த பிறகும் பார்வையில் முன்னேற்றம் இல்லை என்று	5	4	3	2	1	9	8

கண் பிரச்சனை சார்ந்த கவலைகள்								
உங்கள் கண் பிரச்சனையினால் அல்லது கண் சிகிச்சையினால் கீழ்கண்டவைகளைக்குறித்து எவ்வளவு கவலைப்படுகிறீர்கள்?		கவலை இல்லை	சிறிதளவு கவலை	ஓரளவு கவலை	அதிகமான கவலை	மிக அதிகமான கவலை	இது எனக்கு பொருந்தாது	பதிலளிக்க மறுக்கிறேன்
HC16	உங்கள் கண்களின் (அழகு) தோற்றத்தைக்குறித்து	5	4	3	2	1	9	8
HC17	உங்கள் தோற்றத்தைக்குறித்து	5	4	3	2	1	9	8
HC18	உங்களை புகைப்படம் எடுப்பதைக்குறித்து	5	4	3	2	1		8
HC19	பிறரின் கண்களைப்பார்த்து பேசுவதைக்குறித்து	5	4	3	2	1		8
HC20	பிறர் உங்களைப்பற்றி என்ன நினைப்பார்கள் என்பதைக்குறித்து	5	4	3	2	1		8
HC21	பிறர் உங்களிடம் நடந்துகொள்கிற விதத்தைக்குறித்து	5	4	3	2	1	9	8
HC22	பிறர் உங்கள் கண் பிரச்சனையை பற்றி புரிந்துக்கொள்ளாததைக்குறித்து	5	4	3	2	1	9	8
HC23	பிறர் உங்களை தவறாக மதிப்பிடுவதைக்குறித்து	5	4	3	2	1	9	8
HC24	உங்கள் கண் பிரச்சனையைக்குறித்து பிறர் விமர்சனம் செய்வதைக்குறித்து	5	4	3	2	1	9	8
HC25	கேலி அல்லது கிண்டல் செய்யப்படுவதைக்குறித்து	5	4	3	2	1	9	8
HC27	பிறர் உங்களை வித்தியாசமாக நடத்துவதைக்குறித்து	5	4	3	2	1	9	8
HC28	பிறர் உங்களை நிராகரிப்பதைக்குறித்து	5	4	3	2	1	9	8
HC29	பிறரின் மரியாதையை பெற முடியாததைக்குறித்து	5	4	3	2	1	9	8
HC31	நடக்கும் போது, வழியிலுள்ள பொருட்கள் அல்லது மற்றவர்கள் மீது மோதுவதைக்குறித்து	5	4	3	2	1	9	8
HC32	கை தவறி பொருட்களை தவறவிடுவது அல்லது பானத்தை சிந்துவதைக்குறித்து	5	4	3	2	1	9	8
HC33	நடக்கும் பொது கால் தடுக்குவதைக்குறித்து	5	4	3	2	1		8
HC34	கீழே விழுவதைக்குறித்து	5	4	3	2	1		8

கண் பிரச்சனை சார்ந்த கவலைகள்								
உங்கள் கண் பிரச்சனையினால் அல்லது கண் சிகிச்சையினால் கீழ்கண்டவைகளைக்குறித்து எவ்வளவு கவலைப்படுகிறீர்கள்?		கவலை இல்லை	சிறிதளவு கவலை	ஓரளவு கவலை	அதிகமான கவலை	மிக அதிகமான கவலை	இது எனக்கு பொருந்தாது	பதிலளிக்க மறுக்கிறேன்
HC36	விளையாடும் போது அடிப்படுவதைக்குறித்து	5	4	3	2	1	9	8
HC37	நீங்கள் பார்ப்பது இரண்டாக (இரட்டைப்பார்வை) தெரிவதைக்குறித்து	5	4	3	2	1	9	8
HC38	வாகனம் சார்ந்த விபத்துக்கள் ஏற்படுவதைக்குறித்து, உ தா வாகனத்தை நிறுத்தும் போது தூணில்/சுவரில் இடித்தல்	5	4	3	2	1	9	8
HC39	வாகனம் சாராத மற்ற விபத்துக்கள் ஏற்படுவதைக்குறித்து (உ தா சுத்தியல் போன்ற கருவிகளை உபயோகப்படுத்தும் போது)	5	4	3	2	1	9	8
HC65i	தூரத்தில் வரும் நபர் யாரென்று அறிந்துகொள்ள முடியாததைக்குறித்து	5	4	3	2	1		8
HC41	3 டி படங்களைப்பார்த்து ரசிக்க முடியாததைக்குறித்து	5	4	3	2	1	9	8
HC42	இரண்டு கண்களையும் ஒன்றாக சேர்த்து பயன்படுத்த முடியாததைக்குறித்து	5	4	3	2	1	9	8
HC43	எதிர்காலத்தில், நீங்கள் விரும்பும் காரியத்தை செய்ய முடியாமல் போய்விடுமோ என்று	5	4	3	2	1	9	8
HC44	கல்வியில் சிறந்து விளங்க முடியாததைக்குறித்து	5	4	3	2	1	9	8
HC45	உங்களுக்கு விருப்பமுள்ள விளையாட்டுகள் அல்லது பொழுதுபோக்குகளில் ஈடுபட முடியாததைக்குறித்து	5	4	3	2	1		8
HC46	நீண்ட நேரம் எதிலும் கவனம் செலுத்த முடியாததைக்குறித்து	5	4	3	2	1	9	8
HC47	வாழ்க்கையில் வெற்றிகரமாக இல்லை என்று	5	4	3	2	1	9	8
HC49	நீங்கள் வாகனம் ஓட்டுவதினால் பிறருக்கு ஆபத்து ஏற்படுமோ என்று	5	4	3	2	1	9	8
HC50	உங்களுக்கு விருப்பமான பணி துறையை தேர்ந்தெடுக்கமுடியாததைக்குறித்து	5	4	3	2	1	9	8

கண் பிரச்சனை சார்ந்த கவலைகள்								
உங்கள் கண் பிரச்சனையினால் அல்லது கண் சிகிச்சையினால் கீழ்கண்டவைகளைக்குறித்து எவ்வளவு கவலைப்படுகிறீர்கள்?		கவலை இல்லை	சிறிதளவு கவலை	ஓரளவு கவலை	அதிகமான கவலை	மிக அதிகமான கவலை	இது எனக்கு பொருந்தாது	பதிலளிக்க மறுக்கிறேன்
HC51	ஒரு வேலையை அடையும் அல்லது தக்கவைத்துக்கொள்ளும் உங்கள் திறனைக்குறித்து	5	4	3	2	1	9	8
HC52	உங்கள் தோற்றத்தினால் வேலையில் ஏற்படும் தாக்கத்தைக்குறித்து	5	4	3	2	1	9	8
HC53	உங்கள் கண் பிரச்சனையினால் உங்கள் குடும்பத்தினருக்கு ஏற்படும் தாக்கத்தைக்குறித்து	5	4	3	2	1	9	8
HC54	உங்கள் கண் பிரச்சனை விரைவாக கண்டறியப்படவில்லை அல்லது கண் பிரச்சனைக்கு விரைவாக சிகிச்சை அளிக்கப்படவில்லை என்று	5	4	3	2	1	9	8
HC55	உங்கள் கண் பிரச்னையைக்கு சரியான சிகிச்சை முறை இல்லை என்று	5	4	3	2	1	9	8
HC56	உங்கள் கண் மருத்துவர் உங்கள் கண் சிகிச்சை முறை மற்றும் அதன் பலனைப்பற்றி நிச்சயமாக இல்லாததைக்குறித்து	5	4	3	2	1	9	8
HC58	கடந்த காலத்தில் உங்களுக்கு அளிக்கப்பட சிகிச்சை பலனளிக்காமல் போனதைக்குறித்து	5	4	3	2	1	9	8
HC59	சோம்பல் கண் சிகிச்சைக்கு நீண்ட காலம் தேவைப்படுவதைக்குறித்து	5	4	3	2	1	9	8
HC60	மாறுகண் அறுவை சிகிச்சையின் பலனைப்பற்றி	5	4	3	2	1	9	8
HC61	மாறுகண் அறுவை சிகிச்சைக்குப்பின் மீண்டும் மாறுகண் ஏற்படுமோவென்று	5	4	3	2	1	9	8
HC62	உங்கள் கண் பிரச்சனையைக்குறித்து மருத்துவ ஊழியர்கள் போதுமான தகவல் அளிக்காததைக்குறித்து	5	4	3	2	1	9	8

மன நலம்							
கடந்த நான்கு வாரங்களில் , உங்கள் கண் பிரச்சனையினால் அல்லது கண் சிகிச்சையினால் எவ்வளவு அதிகமாக..... ?		ஒருபோதும் இல்லை	எப்பொழுதாவது	சில நேரம்	பெரும்பாலான நேரம்	எப்போதும்	பதிலளிக்க மறுக்கிறேன்
EM1	சோகமாக இருந்தீர்கள்	5	4	3	2	1	8
EM3	மனசோர்வுடன் இருந்தீர்கள்	5	4	3	2	1	8
EM4	பதட்டமாக உணர்ந்தீர்கள்	5	4	3	2	1	8
EM5	விரக்தியாக உணர்ந்தீர்கள்	5	4	3	2	1	8
EM8	மன அழுத்தமாக உணர்ந்தீர்கள்	5	4	3	2	1	8
EM9	வருத்தத்தோடு இருந்தீர்கள்	5	4	3	2	1	8
EM12	கலக்கமாக இருந்தீர்கள்	5	4	3	2	1	8
EM14	எரிச்சலடைந்தீர்கள்	5	4	3	2	1	8
EM16	அழ வேண்டும் போல உணர்ந்தீர்கள்	5	4	3	2	1	8
EM17	வாழ்க்கையில் நீங்கள் போராடுவது போல் உணர்ந்தீர்கள்	5	4	3	2	1	8
EM19	கடந்த காலத்தில் உங்கள் கண்களை சரியாக கவனிக்காமல் போனதைக்குறித்து எண்ணி குற்ற உணர்வுடன் இருந்தீர்கள்	5	4	3	2	1	8
EM20	உங்களுக்கு அளிக்கப்பட்ட சிகைச்சையின் பலனை எண்ணி வருத்தப்பட்டீர்கள்	5	4	3	2	1	8
EM21	உங்கள் கண் மருத்துவர் உங்கள் கண்களைக்குறித்து சொன்னதைக்கேட்டு அதிர்ச்சி அடைந்தீர்கள்	5	4	3	2	1	8
EM22	ஏமாற்றமாய் உணர்ந்தீர்கள்	5	4	3	2	1	8
EM23	நம்பிக்கையற்று இருந்தீர்கள்	5	4	3	2	1	8
EM24	பிறர் உங்களை பாரபட்சம் பார்ப்பது போல உணர்ந்தீர்கள்	5	4	3	2	1	8
EM25	உங்கள் தோற்றத்தைக்குறித்து தர்மசங்கடமாய் உணர்ந்தீர்கள்	5	4	3	2	1	8

மன நலம்							
கடந்த நான்கு வாரங்களில் , உங்கள் கண் பிரச்சனையினால் அல்லது கண் சிகிச்சையினால் எவ்வளவு அதிகமாக..... ?		ஒருபோதும் இல்லை	எப்பொழுதாவது	சில நேரம்	பெரும்பாலான நேரம்	எப்போதும்	பதிலளிக்க மறுக்கிறேன்
EM27	வெட்கமாக உணந்தீர்கள்	5	4	3	2	1	8
EM28	அவமானப்படுத்தப்பட்டதாக உணந்தீர்கள்	5	4	3	2	1	8
EM29	பிறரை விட தாழ்வாக உணர்ந்தீர்கள்	5	4	3	2	1	8
EM30	பிறரால் நிராகரிக்கப்பட்டதாக உணர்ந்தீர்கள்	5	4	3	2	1	8
EM31	தனிமையாக உணர்ந்தீர்கள்	5	4	3	2	1	8
EM33	பிறருடன் பழக தயக்கமாய் உணர்ந்தீர்கள்	5	4	3	2	1	8
EM34	உங்களுக்கு தன்னம்பிக்கை குறைவாக உள்ளதாக உணர்ந்தீர்கள்	5	4	3	2	1	8
EM35	உங்களுக்கு சுயமரியாதை குறைவாக உள்ளதாக உணர்ந்தீர்கள்	5	4	3	2	1	8
EM36	தன் தோற்றத்தைப்பற்றி சுய உணர்வுடன் இருந்தீர்கள்	5	4	3	2	1	8
EM38	பிறரோடு ஒப்பிடும் பொது நீங்கள் வித்தியாசமாக இருப்பதாக உணர்ந்தீர்கள்	5	4	3	2	1	8
EM39	பொது இடத்தில் சங்கடமாக உணர்ந்தீர்கள்	5	4	3	2	1	8
EM40	பிறர் உங்களை உற்றுப்பார்க்கும் போது சங்கடப்பட்டீர்கள்	5	4	3	2	1	8
EM41	பிறரிடம் உங்கள் கண் பிரச்சனையைப்பற்றி பேச தயங்கினீர்கள்	5	4	3	2	1	8
EM42	நன்றாக தெரியும் கண்ணில் பார்வை இழந்துவிடுவோமோ என்று பயந்தீர்கள்	5	4	3	2	1	8
EM43	உங்கள் கண்களை பாதுகாக்க வேண்டும் என்ற உணர்வு அளவுக்கதிகமாக உள்ளதாக உணர்ந்தீர்கள்	5	4	3	2	1	8
EM45	துரதிருஷ்டவசமாக உணர்ந்தீர்கள்	5	4	3	2	1	8
EM46	உங்களைக்குறித்து பரிதாபப்பட்டீர்கள்	5	4	3	2	1	8

மன நலம்							
கடந்த நான்கு வாரங்களில் , உங்கள் கண் பிரச்சனையினால் அல்லது கண் சிகிச்சையினால் எவ்வளவு அதிகமாக..... ?		ஒருபோதும் இல்லை	எப்பொழுதாவது	சில நேரம்	பெரும்பாலான நேரம்	எப்போதும்	பதிலளிக்க மறுக்கிறேன்
EM48	உங்கள் கண் பிரச்சனையைப்பற்றி எண்ணி துக்கப்பட்டீர்கள்	5	4	3	2	1	8
EM49	எந்த கண் பிரச்சனையும் இல்லை என்றால் நன்றாயிருக்கும் என்று எண்ணினீர்கள்	5	4	3	2	1	8
EM47	பார்வை நல்லாயிருக்கும் பிறரைப்பார்த்து பொறாமைப்பட்டீர்கள்	5	4	3	2	1	8

சமூக நலவாழ்வு								
உங்கள் கண்களில் உள்ள பிரச்சனையினால் அல்லது கண் சிகிச்சையினால் கீழ்கண்டவைள் எவ்வளவு கஷ்டமாக உள்ளது?		கஷ்டமே இல்லை	சிறிதளவு கஷ்டம்	ஓரளவு கஷ்டம்	மிகவும் கஷ்டம்	என் கண் பிரச்சனையினால் இதை செய்ய முடியவில்லை	இதை வேறு காரணத்தினால் நான் செய்வதில்லை / இது எனக்கு பொருந்தாது	பதிலளிக்க மறுக்கிறேன்
SC1	பிறருடன் அரட்டை அடித்தல்	5	4	3	2	1		8
SC2	பிறருடன் சகஜமாக பழகுதல்	5	4	3	2	1		8
SC3	முதல் முறையாக ஒருவரை சந்தித்தல்	5	4	3	2	1		8
SC4	புதிய நபருடன் நட்புக்கொள்ளுதல்	5	4	3	2	1		8
SC5	நட்பை தக்கவைத்துக்கொள்ளுதல்	5	4	3	2	1		8
SC6	பணியில், உங்கள் வேலைகள் மற்றும் பொறுப்புகளை சரிவரச்செய்தல்	5	4	3	2	1		8
SC7	நெருக்கமான உறவுகளை தக்கவைத்துக்கொள்ளுதல், உ தா கணவன்-மனைவி, குடுப்பத்தினர்	5	4	3	2	1		8
SC9	எதிர் பாலினரோடு பேசுதல்	5	4	3	2	1		8
SC10	சமூக நிகழ்ச்சிகளில் பங்கு பெறுதல்	5	4	3	2	1		8
SC11	இரவில் நடைப்பெறும் சமூக நிகழ்ச்சிகளில் பங்கு பெறுதல்	5	4	3	2	1		8
SC12	சக நண்பர்கள் அல்லது சக ஊழியர்களுடன் பழகுதல்	5	4	3	2	1		8
SC13	உங்களுக்கு அதிகம் அறிமுகமில்லாத நபர்களுடன் பழகுதல்	5	4	3	2	1		8
SC14	பிறர் உங்கள் கண்களைப்பற்றி கேலிச்செய்வதால், பிறருடன் பழகுதலில் கஷ்டம்	5	4	3	2	1	9	8
SC15	பிறர் உங்களை வித்தியாசமாக பார்ப்பதால், பிறருடன் பழகுதலில் கஷ்டம்	5	4	3	2	1	9	8

சமூக நலவாழ்வு								
உங்கள் கண்களில் உள்ள பிரச்சனையினால் அல்லது கண் சிகிச்சையினால் கீழ்கண்டவைள் எவ்வளவு கஷ்டமாக உள்ளது?		கஷ்டமே இல்லை	சிறிதளவு கஷ்டம்	ஓரளவு கஷ்டம்	மிகவும் கஷ்டம்	என் கண் பிரச்சனையினால் இதை செய்ய முடியவில்லை	இதை வேறு காரணத்தினால் நான் செய்வதில்லை / இது எனக்கு பொருந்தாது	பதிலளிக்க மறுக்கிறேன்
SC16	பிறர் உங்களிடம் பேசும் போது எந்த கண்ணைப்பார்த்து பேசுவது என்று குழம்புவதால், பழகுதலில் கஷ்டம்	5	4	3	2	1	9	8
SC17	பிறரின் கண்ணைப்பார்த்து பேச முடியாததால், பிறருடன் பழகுதலில் கஷ்டம்	5	4	3	2	1	9	8
SC18	உங்களுக்கு இரட்டைப்பார்வை தெரிவதால், பிறருடன் பழகுதலில் கஷ்டம்	5	4	3	2	1	9	8
SC19	ஏதேனும் ஒரு வேலையை செய்ய முடியாத காரணத்தினால், உங்கள் குடும்பத்தினர்கள் அல்லது நண்பர்கள் எரிச்சலடைதல்	5	4	3	2	1	9	8
SC20	ஏதேனும் ஒரு தவறு செய்யும் போது, உங்கள் குடும்பத்தினர்கள் அல்லது நண்பர்கள் எரிச்சலடைதல்	5	4	3	2	1	9	8
SC22	நண்பர்கள் மற்றும் குடும்பத்தினரின் உதவி மற்றும் ஆதரவு பெறுதல்	5	4	3	2	1		8

கண் பிரச்சனையினால் ஏற்படும் அசௌகரியங்கள் (சிரமங்கள்)								
உங்கள் கண் பிரச்சனையினால் அல்லது கண் சிகிச்சையினால் கீழ்கண்டவைள் எவ்வளவு சிரமமாக (அசௌகரியமாக) உள்ளது?		சிரமம் இல்லை	சிறிதளவு சிரமம்	ஓரளவு சிரமம்	அதிக சிரமம்	மிக அதிக சிரமம்	இது எனக்கு பொருந்தாது	பதிலளிக்க மறுக்கிறேன்
CV1	மெதுவாக அல்லது அதிக கவனத்துடன் இருக்க வேண்டிருப்பது	5	4	3	2	1	9	8
CV2	மெதுவாக அல்லது அதிக கவனத்துடன் வாகனம் ஓட்ட வேண்டிருப்பது	5	4	3	2	1	9	8
CV4	ஏதேனும் ஒரு வேலை செய்வதற்கு அதிக நேரம் தேவைப்படுவது	5	4	3	2	1	9	8
CV5	நீண்ட நேரம் ஏதேனும் ஒரு வேலையை தொடர்ந்து செய்ய முடியாதது, உ தா நீண்ட நேரம் படித்தல், வாகனம் ஓட்டுதல்	5	4	3	2	1	9	8
CV6	ஏதேனும் ஒரு வேலையை செய்வதற்கு அதிக முயற்சி செலுத்த வேண்டிருப்பது, உ தா படித்தல், வாகனம் ஓட்டுதல்	5	4	3	2	1	9	8
CV7	எதிலும் அதிக கவனம் செலுத்த வேண்டிருப்பது	5	4	3	2	1	9	8
CV8	வேலையினிடையே அதிக இடைவேளை அல்லது ஓய்வு எடுக்க வேண்டிருப்பது	5	4	3	2	1	9	8
CV9	பிரகாசமான சூரிய ஒளியில் ஒரு கண்ணை சுருக்க அல்லது மூட வேண்டிருப்பது	5	4	3	2	1	9	8
CV10	ஏதேனும் ஒன்றை தெளிவாக பார்க்க ஒரு கண்ணை மூட வேண்டிருப்பது	5	4	3	2	1	9	8
CV11	ஏதேனும் ஒரு பொருளை பார்க்க, தலையை அல்லது உடலை அசாதாரணமான விதத்தில் திருப்ப வேண்டிருப்பது	5	4	3	2	1	9	8
CV12	கண் பரிசோதனை அல்லது சிகிச்சைக்காக நீண்ட தூரம் பிரயாணம் செய்ய வேண்டிருப்பது	5	4	3	2	1	9	8
CV13	சரியான கண்ணாடி செய்து கிடைப்பதற்கு காத்திருப்பது	5	4	3	2	1	9	8
CV14	பெரும்பாலான நேரம் கண்ணாடி அல்லது காண்டாக்ட் லென்ஸ் அணிய வேண்டிருப்பது	5	4	3	2	1	9	8
CV15	ஒரு சில வேலைகளைச்செய்ய கண்ணாடியை கழற்ற வேண்டிருப்பது, உ தா. விளையாடும் போது	5	4	3	2	1	9	8
CV16	ப்ரிஸம் பொருத்திய கண்ணாடி அணிய வேண்டிருப்பது	5	4	3	2	1	9	8

கண் பிரச்சனையினால் ஏற்படும் அசௌகரியங்கள் (சிரமங்கள்)								
உங்கள் கண் பிரச்சனையினால் அல்லது கண் சிகிச்சையினால் கீழ்கண்டவைள் எவ்வளவு சிரமமாக (அசௌகரியமாக) உள்ளது?		சிரமம் இல்லை	சிறிதளவு சிரமம்	ஓரளவு சிரமம்	அதிக சிரமம்	மிக அதிக சிரமம்	இது எனக்கு பொருந்தாது	பதிலளிக்க மறுக்கிறேன்
CV17	பெரும்பாலான நேரம் கூலிங் கிளாஸ் அணிய வேண்டிருப்பது	5	4	3	2	1	9	8
CV18	மாறுகண்ணை சரிப்படுத்த பலமுறை கண் அறுவை சிகிச்சை மேற்கொள்ள வேண்டிருப்பது	5	4	3	2	1	9	8
CV19	காண்டாக்ட் லென்ஸ் உபயோகப்படுத்த முடியாதது	5	4	3	2	1	9	8
CV20	நீங்கள் விரும்பிய காரியத்தை செய்ய முடியாதது	5	4	3	2	1	9	8
CV21	பாதிக்கப்பட்ட கண்ணின் பக்கம் உள்ளவற்றை பார்க்க உங்கள் தலையை திருப்ப வேண்டிருப்பது	5	4	3	2	1	9	8
CV22	நன்றாக தெரியும் கண்ணில் ஏதேனும் தூசி விழுந்தால்	5	4	3	2	1	9	8
CV23	பொருட்களை தெரியாமல் இடித்து, தட்டி உடைப்பது	5	4	3	2	1	9	8
CV25	வாகனம் ஓட்டும் போது திடீரென்று நீங்கள் பார்க்கும் பொருள் இரண்டாக தெரிவது	5	4	3	2	1	9	8
CV26	நீங்கள் பார்ப்பது இரண்டாக தெரியும் போது அதை ஒன்றாக பார்க்க முயற்சி செய்ய வேண்டிருப்பது	5	4	3	2	1	9	8

பொருளாதார தாக்கம்								
உங்கள் கண் பிரச்சனையினால் அல்லது கண் சிகிச்சையினால் கீழ்கண்டவைகளைக்குறித்து எவ்வளவு கவலைப்படுகிறீர்கள்?		கவலை இல்லை	சிறிதளவு கவலை	ஓரளவு கவலை	அதிகமான கவலை	மிக அதிகமான கவலை	இது எனக்கு பொருந்தாது	பதிலளிக்க மறுக்கிறேன்
EC1	கண் நிபுணர் அல்லது கண் மருத்துவரை சந்திக்க ஆகும் செலவைக்குறித்து	5	4	3	2	1	9	8
EC2	உங்கள் சோம்பல் கண் சிகிச்சைக்கு செலவாகும் கட்டணத்தைக்குறித்து (உ தா விஷன் தெரபி, கண் பயிற்சி)	5	4	3	2	1	9	8
EC3	மருத்துவமனை சென்று சிகிச்சை (உ தா கண் பயிச்சி) பெற பணியிலிருந்து விடுமுறை பெறுவதைக்குறித்து	5	4	3	2	1	9	8
EC4	கண்ணாடி அல்லது காண்டாக்ட் லென்ஸ் வாங்க தேவைப்படும் செலவைக்குறித்து	5	4	3	2	1	9	8
EC5	மாறுகண் அறுவைச்சிகிச்சைக்கான கட்டணத்தைக்குறித்து	5	4	3	2	1	9	8
EC7	ஒருசில வேலைகள் செய்வதற்கான பார்வை தகுதி இல்லத்தைக்குறித்து (உ தா காவல்துறை அதிகாரி, விமானி)	5	4	3	2	1	9	8
EC8	ஒரு வேலையை அடையும் உங்கள் திறனைக்குறித்து	5	4	3	2	1	9	8
EC9	உங்களால் சில தொழில்களை செய்ய முடியாததைக்குறித்து உ தா கனரக வாகனங்கள் ஓட்டுவது	5	4	3	2	1	9	8
EC10	உங்கள் வேலையை இழப்பத்தைக்குறித்து	5	4	3	2	1	9	8
EC11	உங்கள் வேலை பணிகள் பாதிக்கப்படுவதைக்குறித்து	5	4	3	2	1	9	8
EC13	பணிப்புரியும் இடத்தில் சக தொழிலாளர்களுடன் உள்ள உறவு சுமுகமாய் இல்லாததைக்குறித்து (உ தா நீங்கள் ஒரு வேலையை முடிக்க அதிக நேரம் எடுத்துக்கொள்வதால்)	5	4	3	2	1	9	8
EC14	நீங்கள் விரும்பிய தொழிலை செய்ய முடியாமல் போனதைக்குறித்து	5	4	3	2	1	9	8
EC15i	கண் பரிசோதனை அல்லது சிகிச்சைக்காக ஆகும் பிரயாணக்கட்டணத்தைக்குறித்து	5	4	3	2	1	9	8

சமாளிக்கும் முறை							
உங்கள் கண் பிரச்சனையினால் ஏற்படும் பாதிப்பை, எவ்வளவு அதிகமாக கீழ்கண்ட முறைகளைப்பயன்படுத்தி சமாளிக்கின்றீர்கள்?		இல்லவே இல்லை	சிறிதளவு	ஓரளவு	அதிகமாக	மிக அதிகமாக	பதிலளிக்க மறுக்கிறேன் / இது எனக்கு பொருந்தாது
CP1	கவனமாக இருத்தல்	1	2	3	4	5	8
CP2	கடினமான வேலை செய்யும் போது அதிக கவனம் செலுத்துதல்	1	2	3	4	5	8
CP3	கடினமான வேலையை தவிர்த்தல், உ தா இரவு நேரத்தில் வாகனம் ஓட்டுவதை தவிர்த்தல்	1	2	3	4	5	8
CP5	தெளிவாக பார்க்க அல்லது இரட்டைப்பார்வையை தவிர்க்க ஒரு கண்ணை மூடுதல்	1	2	3	4	5	8
CP8	கண்ணாடி அல்லது காண்டாக்ட் லென்ஸ் பயன்படுத்துதல்	1	2	3	4	5	8
CP9	உங்கள் கண்ணிலுள்ள குறைப்பாட்டை பிறரிடமிருந்து மறைத்தல், உ தா பிறரின் கண்ணைப்பார்த்து பேசுவதை தவிர்த்தல், கூலிங் கிளாஸ் அணிதல்	1	2	3	4	5	8
CP10	நகைச்சுவை உணர்வை பயன்படுத்துதல்	1	2	3	4	5	8
CP12	உங்களை தனிமைப்படுத்திக்கொள்ளுதல்	1	2	3	4	5	8
CP13	உங்களை சங்கடப்படுத்தாத நபர்களுடன் மட்டும் பழுகுதல்	1	2	3	4	5	8
CP14	மன தைரியத்துடன் இருத்தல், உ தா பிறர் உங்களை கேலி செய்வதை கண்டுகொள்ளாமல் இருத்தல்	1	2	3	4	5	8
CP15	பிறரிடம் உங்கள் கண் பிரச்சனை குறித்து பகிர்ந்து கொள்ளுதல்	1	2	3	4	5	8
CP16	பிறரின் உதவி நாடுதல்	1	2	3	4	5	8
CP17	உங்களுக்கு ஏற்படும் சிரமத்தை உங்கள் கண் பிரச்சனையோடு சம்பந்தப்படுத்தாமல் இருத்தல்	1	2	3	4	5	8
CP18	உங்கள் கண் பிரச்சனையை வயதோடு தொடர்பு படுத்துதல்	1	2	3	4	5	8
CP19	உங்கள் கண் பிரச்சனையைப்பற்றி யோசிக்காமல் இருத்தல்	1	2	3	4	5	8
CP20	நேர்மறை சிந்தனையோடு (பாசிட்டிவாக) இருத்தல்	1	2	3	4	5	8

சமாளிக்கும் முறை							
உங்கள் கண் பிரச்சனையினால் ஏற்படும் பாதிப்பை, எவ்வளவு அதிகமாக கீழ்கண்ட முறைகளைப்பயன்படுத்தி சமாளிக்கின்றீர்கள்?		இல்லவே இல்லை	*சிறிதளவு*	*ஓரளவு*	*அதிகமாக*	*மிக அதிகமாக*	*பதிலளிக்க மறுக்கிறேன் / இது எனக்கு பொருந்தாது*
CP21	*தன்னை விட மோசமான நிலையில் பலர் இருக்கிறார்கள் என்று எண்ணுதல்*	1	2	3	4	5	8
CP22	*தன் கண் பிரச்சனை மேலும் மோசமடையாது என்று எண்ணுதல்*	1	2	3	4	5	8
CP23	*தன் கண் பிரச்சனையோடு வாழ பழகுதல்*	1	2	3	4	5	8
CP24	*தனக்கு ஏற்பட்ட கண் பிரச்சனையை ஏற்றுக்கொள்ளுதல்*	1	2	3	4	5	8

For office use

Eye hospital/ practice name	
MRD Number	
Participant ID	
Participant's name	
Ocular diagnosis	
Type of amblyopia	
Type of strabismus	
Refractive error	OD: OS:
Best corrected visual acuity	OD: OS:
Cover test	Distance: Near:
Magnitude of deviation	Distance: Near:
Co-existing ocular diagnosis	
General health	

Appendix 9

Phase 2 Participant information sheets and consent forms

English, Hindi & Tamil

Government of South Australia
SA Health

Flinders UNIVERSITY

PARTICIPANT INFORMATION SHEET

Title of the project: Questionnaire Study – Phase II
A system for measurement of Amblyopia (lazy eye) and Strabismic (turned eye) - specific quality of life using item banking and computer adaptive testing (Eye-tem Bank): Phase II- Developing the item bank

Name of organizations:
This is a collaborative study carried out between Flinders University as a lead orgnization and the four centres: The Queen Elizabeth Hospital, SA; The Royal Adelaide Hospital, SA, the Royal Victorian Eye and Ear Hospital, VIC, Optometry Sunbury and Vision for Children, Victoria and OPSM, Broken Hill, NSW and Elite School of Optometry, Sankara Nethralaya, India.

This is a research project, and you do not have to be involved. If you do not wish to participate, your medical care will not be affected in any way.

You are invited to take part in Phase II of a research study conducted by the Discipline of Optometry and Vision Science at Flinders University. This study aims to develop and refine banks of items (questions) that will be used for the assessment of quality of life in patients with Amblyopia (lazy eye) and Strabismic (turned eye) and its treatment. The item bank will assist eye doctors and researchers to gain a better understanding of the impact of refractive error and its correction on each patient and determine the appropriate course for treatment.

If you choose to participate, you may be invited to attend an interview (face-to-face or telephone) in which you will be asked a set of questions about how your eye problem and its treatments are affecting you and your life. Face-to-face interviews will be carried out at one of our facilities at Flinders Medical Centre (Adelaide), The Royal Adelaide Hospital (Adelaide) The Queen Elizabeth Hospital (Adelaide), The Royal Victorian Eye and Ear Hospital (Melbourne) and the Elite school of optometry, Sankara Nethralaya eye Hospital, Chennai.

A trained interviewer will ask the questions and record your answers. The session will last for about an hour. Your answers will be recorded on a password protected iPad but your identity and your answers will remain forever confidential. Apart from attending the interview, you will not be asked to attend any further visits. If you come for a face to face interview, you will receive a flat rate of AUD 20 to assist with transportation costs. If you choose a telephone interview, one of our staff will contact you at a convenient time. You will need to fill out the demographic form and sign the consent (attached) before participating in the study - this should only take few minutes to complete. If you agree to participate, we will acquire measurements of your vision and diagnosis from your clinical file. If you do not consent, we will not access your clinical files.

There are no direct benefits to you from being associated with this study. However, the information obtained from your interview will help us refine our item banks. Therefore, your input may help eye doctors and researchers in being better able to assess how lazy eye and turned eye and its correction affect quality of life in future patients.

Your involvement in this study will not affect your treatment in any way. Your participation in the study is entirely voluntary and you have the right to withdraw at any time. If you decide not to participate in this study or if you withdraw, you may do this freely without prejudice to any treatment.

If you suffer injury as a result of participation in this research or study, compensation might be paid without litigation. However, such compensation is not automatic and you may have to take legal action to determine whether you should be paid.

All records containing personal information will remain confidential and no information that could lead to your identification will be released. Records will be kept in a securely locked filing cabinet and in a password protected computer. Data will be deleted and destroyed 5 years after the study is completed.. We expect that once the study is completed, the results will be published in a scientific journal. However, all your answers will be de-identified and then collated so that your identity and any personal information will remain completely confidential.

Should you require further details about the project, either before, during or after the study, you may contact the research personnel (PhD Candidate), Ms Sheela Kumaran, Mobile No +61 448 326 022 (Australia), +91 98401 84001 (India) (Discipline of Optometry and Vision Science, Flinders University).

This study has been reviewed by the Southern Adelaide Clinical Human Research Ethics Committee. If you wish to discuss the study with someone not directly involved, in particular in relation to policies, your rights as a participant, or should you wish to make a confidential complaint, you may contact Prof Villis Marshall on 8204 6453 or email SALHNOfficeforResearch@sa.gov.au

Government of South Australia
SA Health

Flinders UNIVERSITY

SOUTHERN ADELAIDE CLINICAL HUMAN RESEARCH ETHICS COMMITTEE / FLINDERS UNIVERSITY

CONSENT TO PARTICIPATION IN RESEARCH

I, ... request and give consent
(first or given names) *(last name)*

to my involvement in the research project: Questionnaire Study – Phase II
A system for measurement of Amblyopia & Strabismus -specific quality of life using item banking and computer adaptive testing (Eye-tem Bank) Phase II: Developing the Item bank

I acknowledge the nature, purpose and contemplated effects of the research project, especially as far as they affect me, have been fully explained to my satisfaction by.....
(first or given names) *(last name)*

and my consent is given voluntarily.

I acknowledge that the detail(s) of the following has/have been explained to me, including indications of risks, any discomfort involved, anticipation of length of time, and the frequency with which they will be performed.

I will be involved in an interview which requires me to answer a set of questions about how my Amblyopia & Strabismus and its treatment are affecting me and my life (approx. 1hour duration).

I have understood and am satisfied with the explanations that I have been given.

I have been provided with a written information sheet.

I understand that my involvement in this research project may not be of any direct benefit to me and that I may withdraw my consent at any stage without affecting my rights or the responsibilities of the researchers in any respect.

I understand that my medical records may be accessed to confirm my diagnosis.

I declare that I am over the age of 18 years.

I also consent to extracting my clinical details (measurements of vision and diagnosis) from my clinical file for this research *(please tick)* ☐ Yes ☐ No

I acknowledge that I have been informed that should I receive an injury as a result of taking part in this study, I may need to start legal action to determine whether I should be paid.

Signature of Research Participant : ..... Date: .....

I, ... have described to .....
the research project and nature and effects of procedure(s) involved. In my opinion he/she understands the explanation and has freely given his/her consent.

Signature: ..... Date: .....

Status in Project: .....

सहभागी जानकारी पत्र

परियोजना का शीर्षक: प्रश्नावली अध्ययन : चरण II

एम्बीओलोपिया मंधदृष्टी) और स्ट्रैबिस्मस भेंगी आंखें) की माप के लिए एक प्रणाली-आइटम बैंकिंग और कंप्यूटर अनुकूली परीक्षण आई -टेम्पल बैंक) का उपयोग करके जीवन की बेहतर गुणवत्ता: चरण II: आइटम बैंक का विकास करना

संगठनों का नाम:

फ्लिंडर्स यूनिवर्सिटी द्वारा एक सहयोगी अध्ययन अन्य चार केंद्रों के साथ किया गया है: द क्वीन एलिज़बेथ हॉस्पिटल , (सौथ ऑस्ट्रेलिया) , द रॉयल एडिलेड हॉस्पिटल , (सौथ ऑस्ट्रेलिया), द रॉयल विक्टोरियन ऑय एंड एयर हॉस्पिटल, (विक्टोरिय), ओप्टोमेट्री संबरी एंड विज़न फॉर चिल्ड्रन ,(विक्टोरिय), ओ प यस एम ,(ब्रोकन हिल) एवं इलीट स्कूल ऑफ़ ओप्टोमेट्री, सनकरा नेत्रालय ,(इंडिया)।

यह एक शोध परियोजना है और आपको इसमें शामिल नहीं होना है। यदि आप भाग नहीं लेना चाहते हैं, तो आपकी चिकित्सा देखभाल किसी भी तरह से प्रभावित नहीं होगी।

आपको फ़्लिंडर्स यूनिवर्सिटी में ऑप्टोमेट्री का अनुशासन और विज़न साइंस द्वारा आयोजित एक शोध अध्ययन के द्वितीय चरण में भाग लेने के लिए आमंत्रित किया जाता है। इस अध्ययन का उद्देश्य उन वस्तुओं प्रश्नों) के बैंकों को विकसित करना और परिष्कृत करना है, जिनका उपयोग एंब्लोपिया आलसी आँख) और स्ट्रैबिस्मिक भेंगी आँख) और इसके उपचार के रोगियों के जीवन की गुणवत्ता के मूल्यांकन के लिए किया जाएगा। आइटम बैंक नेत्र चिकित्सक और शोधकर्ताओं को अपवर्तक त्रुटि के प्रभाव की बेहतर समझ और प्रत्येक रोगी पर इसके सुधार के लिए सहायता करेगा और उपचार के लिए उचित पाठ्यक्रम निर्धारित करेगा।

यदि आप भाग लेना चाहते हैं, तो आपको एक साक्षात्कार फेस -टू-फेस या टेलीफोन) में भाग लेने के लिए आमंत्रित किया जा सकता है जिसमें आपसे यह सवाल पूछा जाएगा कि आपकी आंख की समस्या और इसके उपचार आपके और आपके जीवन को कैसे प्रभावित कर रहे हैं। फ़्लैंडर्स मेडिकल सेंटर एडिलेड) , द रॉयल एडिलेड हॉस्पिटल एडिलेड) द क्वीन एलिज़ाबे थ हॉस्पिटल एडिलेड) , द रॉयल विक्टोरियन आई एंड इयर हॉस्पिटल मेलबर्न) और एलीट स्कूल ऑफ़ ऑप्टोमेट्री , शंकर नेत्रालय आई हॉस्पिटल, (चेन्नई) में आमने-सामने साक्षात्कार किए जाएंगे।

एक प्रशिक्षित साक्षात्कारकर्ता प्रश्न पूछेगा और आपके उत्तर रिकॉर्ड करेगा। सत्र लगभग एक घंटे तक चलेगा। आपके उत्तर एक पासवर्ड संरक्षित iPad पर दर्ज किए जाएंगे लेकिन आपकी पहचान और आपके उत्तर हमेशा के लिए गोपनीय रहेंगे। साक्षात्कार में भाग लेने के अलावा, आपको किसी भी आगे की भेंट में भाग लेने के लिए नहीं कहा जाएगा। यदि आप एक आमने-सामने साक्षात्कार के लिए आते हैं, तो आपको यात्रा भत्ता के रूप में AUD 20 दिया जायेगा । यदि आप एक टेलीफोन साक्षात्कार चुनते हैं, तो हमारा एक कर्मचारी आपसे सुविधाजनक समय पर संपर्क करेगा। आपको अध्ययन में भाग लेने से पहले जनसांख्यिकीय रूप को भरना होगा और सहमति संलग्न) पर हस्ताक्षर करना होगा - इसे पूरा करने में केवल कुछ मिनट लगने चाहिए। यदि आप भाग लेने के लिए सहमत हैं, तो हम आपके क्लीनिकल फ़ाइल से आपकी दृष्टि और निदान के माप का अधिग्रहण करेंगे।यदि आप सहमति नहीं देते हैं, तो हम आपकी नैदानिक फ़ाइलों को नहीं देखेंगे।

इस अध्ययन से जुड़े होने से आपको कोई प्रत्यक्ष लाभ नहीं है। हालाँकि, आपके साक्षात्कार से प्राप्त जानकारी से हमें अपने आइटम बैंकों को परिष्कृत करने में मदद मिलेगी। इसलिए, आपका इनपुट नेत्र डॉक्टरों और शोधकर्ताओं को यह आकलन करने में बेहतर बनाने में मदद कर सकता है कि आलसी आंख और भेंगी आंख और इसका सुधार भविष्य के रोगियों में जीवन की गुणवत्ता को प्रभावित करता है।

इस अध्ययन में आपकी भागीदारी किसी भी तरह से आपके उपचार को प्रभावित नहीं करेगी।अध्ययन में आपकी भागीदारी पूरी तरह से स्वैच्छिक है और आपको किसी भी समय वापस लेने का अधिकार है।यदि आप इस अध्ययन में भाग नहीं लेने का निर्णय लेते हैं या यदि आप वापस लेते हैं, तो आप किसी भी उपचार के लिए बिना किसी पूर्वाग्रह के स्वतंत्र रूप से ऐसा कर सकते हैं।

यदि आपको इस शोध या अध्ययन में भाग लेने के परिणामस्वरूप चोट लगी है, तो मुकदमेबाजी के बिना मुआवजे का भुगतान किया जा सकता है। हालांकि, ऐसा मुआवजा स्वचालित नहीं है और आपको यह निर्धारित करने के लिए कानूनी कार्रवाई करनी पड़ सकती है कि क्या आपको भुगतान किया जाना चाहिए।

व्यक्तिगत जानकारी वाले सभी रिकॉर्ड गोपनीय रहेंगे और कोई भी जानकारी जो आपकी पहचान को जन्म नहीं दे सकती है।रिकॉर्ड सुरक्षित रूप से लॉक फाइलिंग कैबिनेट और एक पासवर्ड संरक्षित कंप्यूटर में रखा जाएगा।अध्ययन पूरा होने के 5 साल बाद डेटा को हटा दिया जाएगा और नष्ट कर दिया जाएगा।हम उम्मीद करते हैं कि एक बार अध्ययन पूरा होने के बाद, परिणाम एक वैज्ञानिक पत्रिका में प्रकाशित किए जाएंगे। सभी रोगी प्रतिक्रियाओं को अज्ञात किया जाएगा और फिर मिलाया जाएगा, ताकि आपकी पहचान और कोई भी व्यक्तिगत जानकारी पूरी तरह से गुप्त बनी रहे।

यदि आपको अध्ययन के दौरान या उससे पहले परियोजना के बारे में और अधिक विवरणों की आवश्यकता है, आप अनुसंधान कर्मियों पीएचडी उम्मीदवार) , सुश्री शीला कुमारन, मोबाइल नंबर +61 448 326 022 (ऑस्ट्रेलिया) / +91 984-284 84 (भारत) से संपर्क कर सकते हैं।) ऑप्टोमेट्री एंड विजन साइंस , फ्लिंडर्स यूनिवर्सिटी)।

इस अध्ययन की समीक्षा दक्षिणी एडिलेड क्लिनिकल ह्यूमन रिसर्च एथिक्स कमेटी ने की है।यदि आप किसी ऐसे व्यक्ति के साथ अध्ययन पर चर्चा नहीं करना चाहते हैं जो सीधे तौर पर शामिल नहीं है, विशेष रूप से नीतियों के संबंध में, एक प्रतिभागी के रूप में आपके अधिकार, या क्या आपको गोपनीय शिकायत करने की इच्छा है, तो आप 8204 6453 पर प्रोफेसर विली मार्शल से संपर्क कर सकते हैं या ईमेल SALHNOfficeforResearch@sa.gov.au

दक्षिण एडिलेड क्लिनिकल मानव अनुसंधान आचार समिति/ फ्लिंडर्स यूनिवर्सिटी

अनुसंधान में भागीदारी के लिए सहमति

मैं_____अनुसंधान परियोजना में अपनी भागीदारी के लिए अनुरोध करता/ करती हूं और सहमति देता हूं। प्रश्नावली अध्ययन: फेज II

एम्बीओलोपिया और स्ट्रैबिस्मस की माप के लिए एक प्रणाली-आइटम बैंकिंग और कंप्यूटर अनुकूली परीक्षण आई -टेम्पल बैंक) का उपयोग करके जीवन की विशिष्ट गुणवत्ता: चरण II- आइटम बैंक का विकास करना

मैं अनुसंधान परियोजना की प्रकृति, उद्देश्य और चिंतनशील प्रभावों को स्वीकार करता/ करती हूं, विशेष रूप से जहां तक वे मुझे प्रभावित करते हैं, _____द्वारा मेरी संतुष्टि के लिए पूरी तरह से समझाया गया है और मेरी स्वेच्छा से सहमति दि गयी है । मैं स्वीकार करता/ करती हूं कि निम्नलिखित विवरणओं) को मुझे समझाया गया है, जिनमें जोखिम के संकेत, किसी भी असुविधा का होना, समय की लंबाई की संभावना, और आवृत्ति का प्रदर्शन किया जाएगा।

मैं एक फोकस समूह / रू -बरु साक्षात्कार के माध्यम से इस बारे में बात करने वाला हूं कि कैसे एंबीलिया और स्ट्रैबिस्मस मुझे और मेरे जीवन को प्रभावित करते हैं। इसमें लगभग 1-2 घंटे लगेंगे।

मैं समझ गया/ गयी हूं और मुझे दिये गये स्पष्टीकरण से संतुष्ट हूं।

मुझे एक लिखित सूचना पत्र प्रदान किया गया है।

मैं समझता/ समझती हूं कि इस अनुसंधान परियोजना में मेरी भागीदारी मेरे लिए किसी भी प्रत्यक्ष लाभ का नहीं हो सकती है और मैं किसी भी स्तर पर अपने अधिकारों या

शोधकर्ताओं की जिम्मेदारियों को प्रभावित किए बिना किसी भी स्तर पर अपनी सहमति वापस ले सकता हूं।

मैं समझता/ समझती हूं कि मेरे निदान की पुष्टि करने के लिए मेरे मेडिकल रिकॉर्ड तक पहुंचा जा सकता है।

मैं घोषणा करता/ करती हूं कि मैं 18 वर्ष से अधिक आयु का हूं।

मैं इस शोध के लिए अपने नैदानिक विवरण से अपने नैदानिक विवरण दृष्टि और निदान के माप) निकालने के लिए भी सहमत हूं (कृपया सही का निशान लगाएं) हाँ नहीं

मैं स्वीकार करता/ करती हूं कि मुझे सूचित किया गया है कि इस अध्ययन में भाग लेने के परिणामस्वरूप, यदि मैं घायल हो जाता/ जाती हूं, तो मुझे यह निर्धारित करने के लिए कानूनी कार्रवाई शुरू करने की आवश्यकता हो सकती है कि क्या मुझे भुगतान किया जाना चाहिए।

अनुसंधान प्रतिभागी का हस्ताक्षर:..... दिनांक:.....

मैं.....ने ..... को अनुसंधान परियोजना और प्रकृति और प्रक्रिया के प्रभावों के बारे में बताया है। मेरी राय में वह स्पष्टीकरण को समझते है और स्वतंत्र रूप से अपनी सहमति दे दी है।

हस्ताक्षर:..... दिनांक:.....

परियोजना में

पद:.....

Government of South Australia
SA Health

Flinders UNIVERSITY

பங்கேற்பாளர் தகவல் தாள்

ஆய்வுத் தலைப்பு: வினாப்பட்டியல் ஆராய்ச்சி - **கட்டம் II**

வினா (உருப்படி) **வங்கி** (Item Bank) **மற்றும்** கணினிவழி சோதனை **மூலமாக சோம்பல் கண் மற்றும் மாறு கண் (ஓரக்கண்) நோயால் பாதிக்கப்பட்டவரின்** வாழ்க்கை தரத்தை **அறிய ஒரு** அளவீடு முறை. **கட்டம் II: வினா** (உருப்படி) **வங்கி** (Eye-tem Bank) **உருவாக்கம்**.

நிறுவனங்களின் பெயர்:

இந்த ஆய்வு ஃபிலின்டர்ஸ் பல்கலைக்கழகம் (முன்னணி மையம்) மற்றும் நான்கு பிற மையங்களின் (தி குஈன் எலிசபெத் மருத்துவமனை, தெ.ஆ , தி ராயல் அடிலெயிட் மருத்துவமனை, தெ.ஆ, தி ராயல் விக்டோரியன் கண் மற்றும் காது மருத்துவமனை, விக்டோரியா, ஆப்டோமெட்ரி சன்பரி அண்ட் விஷன் பார் சில்ட்ரன், விக்டோரியா, ஓ பி எஸ் ம், ப்ரோகென் ஹில் மற்றும் தி எலைட் ஸ்கூல் ஒப் ஆப்டோமெட்ரி, சங்கர நேத்ராலயா, இந்தியா) கூட்டு முயற்சி.

இது ஒரு ஆராய்ச்சி ஆய்வு. இதில் நீங்கள் கலந்து கொள்வது கட்டாயம் இல்லை. நீங்கள் இதில் கலந்துக்கொள்ள விரும்பவில்லையென்றாலும் உங்களது மருத்துவ கவனிப்பு பாதிக்கப்படாது.

உங்களை ஃபிலின்டர்ஸ் பல்கலைகழகத்தின் ஆப்டோமெட்ரி மற்றும் பார்வை அறிவியல் துறை நடத்தும் ஆய்வின் கட்டம் II யில் பங்கேற்க அழைக்கிறோம். இந்த ஆய்வு, பல்வேறு கண் கோளாறால் [சோம்பல் கண் மற்றும் மாறு கண் (ஓரக்கண்)] பாதிக்கப்பட்டவரின் வாழ்க்கைத்தரத்தை அளக்க ஒரு விரிவான வினா (உருப்படி) வங்கி (Item Bank) தயாரிக்க உதவும். இந்த வினா வங்கி கண் மருத்துவர்களுக்கும் ஆராய்ச்சியாளர்களுக்கும் ஒரு நோயாளி மீது உள்ள கண் நோய் தாக்கத்தை மதிபீடவும், சிறந்த சிகிச்சை முறையை தேர்ந்தெடுக்கவும் துணை புரியும்.

இந்த ஆராய்ச்சியில் பங்கேற்க நீங்கள் விரும்பினால், ஒரு நேர்முக தேர்வில் பங்கேற்க அழைக்கப்படுவீர்கள். உங்களது கண் கோளாறும் அதின் சிகிச்சை முறையும் உங்களையும் உங்கள் வாழ்க்கையும் எவ்வாறு பாதிக்கின்றது என்பதைப்பற்றி ஒரு கேள்வித்தொகுப்பு கேட்கப்படும். இந்த நேர்முக தேர்வு சங்கர நேத்ராலயா கண் மருத்துவமனையில் நடத்தப்படும்.

ஒரு பயிற்சி பெற்ற பேட்டியாளர் உங்களிடம் கேள்விகளை கேட்டு பதில்களை பதிவு செய்வார். இந்த நேர்முக தேர்வின் கால அவகாசம் கிட்டத்தட்ட ஒரு மணி நேரம் ஆகும். உங்களது பதில்கள் கடவுச்சொல்லால் பாதுக்காக்கப்பட்ட ஐ பேடில் (IPadயில்) பதிவு

செய்யப்படும். தங்களது அடையாளமும் பதில்களும் ரகசியமாக வைக்கப்படும். இந்த நேர்முக தேர்வைத்தவிர வேறொன்றிற்கும் உங்களை மீண்டும் அழைக்க மாட்டோம். உங்களது போக்குவரத்து செலவுக்காக உங்களுக்கு ரூபாய் முன்னூறு வழங்கப்படும். நீங்கள் ஒரு வேளை தொலைப்பேசி தேர்வை விரும்பினால், எங்கள் ஊழியர்களில் ஒருவர், நீங்கள் விரும்பும் நேரத்தில் உங்களை அழைத்து தொலைப்பேசி தேர்வை நடத்துவார். உங்களை குறித்த தகவல்கள் நேர்முக தேர்வுக்கு முன்பு பெறப்படும். நீங்கள் பின் வரும் ஒப்புதல் படிவத்தில் கை ஒப்பம் இட வேண்டும். இதற்கு அதிக நேரம் தேவைப்படாது. நீங்கள் பங்கேற்க சம்மதித்தால், உங்களது மருத்துவ பதிவேட்டிலிருந்து உங்கள் மருத்துவ விவரங்கள் (பார்வை அளவீடுகள் மற்றும் வியாதி நிர்ணயம்) சேகரிக்கப்படும். நீங்கள் இதற்க்கு ஒப்புதல் அளிக்கவில்லையென்றால் உங்களது மருத்துவ பதிவேடு அனுகப்படாது.

இந்த ஆய்வில் ஈடுபடுவதால் உங்களுக்கு நேரடியாக எந்த பயனும் இருக்காது. எனினும். நீங்கள் அளிக்கும் தகவல் எங்கள் வினா (உருப்படி) வங்கியை வடிவமைக்கவும், எதிர்காலத்தில் கண் மருத்துவர்களுக்கும், ஆராய்ச்சியாளர்களுக்கும், கண் நோயால் வாழ்க்கைத்தரத்தில் ஏற்படும் தாக்கத்தை மதிப்பிட உதவும்.

உங்களது பங்கேற்ப்பு உங்களது சிகிச்சையை எந்த விதத்திலும் பாதிக்காது. உங்களது பங்கேற்பு முழுமையாக உங்களது விருப்பம். இந்த ஆய்விலிருந்து எந்த நேரத்திலும் நீங்கள் விலகிக்கொள்ளலாம். நீங்கள் இந்த ஆய்வில் பங்கேற்காமல் போனாலும் அல்லது விலகினாலும், அது உங்கள் சிகிச்சையை பாதிக்காது.

இந்த ஆய்வில் பங்கேர்ப்பதினால் ஏதேனும் கெடுதி ஏற்பட்டால் வழக்கு இல்லாமல் இழப்பீடு கிடைக்ககூடும். ஆகினும் அந்த இழப்பீடு கிடைக்குமா என்பதை உறுதி செய்ய சட்டரீதியான நடவடிக்கை எடுக்க வேண்டும்.

தனிப்பட்ட தகவல்கள் கொண்ட ஆவணங்கள் அனைத்தும் ரகசியமாக காக்கப்படும். உங்கள் அடையாளத்தை வெளிப்படுத்தும் எந்த தகவலும் வெளியிடப்படாது. ஆவணங்கள் அனைத்தும் பூட்டுடை நிலைப் பெட்டியில் வைக்கப்பட்டு மற்றும் கடவுச்சொல்லால் பாதுக்காக்கப்பட்ட கணினியிலும் சேமிக்கப்படும். இந்த ஆராய்ச்சி முழுமையடைந்தவுடன், ஆய்வுவின் முடிவுகள் அறிவியல் பத்திரிக்கையில் வெளியாகும் என்று எதிர்பார்க்கிறோம். அணைத்து பங்கேற்ப்பாளரின் அடையாளம் மறைக்கப்பட்டு, தொகுக்கப்பட்ட தகவல்கள் மட்டுமே வெளியாகும். தனிப்பட்ட தகவல்கள் அனைத்தும் ரகசியமாக காக்கப்படும்.

இந்த ஆராய்ச்சிக்கு முன்பாகவோ, இறுதியிலோ அல்லது ஆராய்ச்சியின் பொழுதோ நீங்கள் இந்த ஆராய்ச்சிக்கு தொடர்பாக மேலும் விவரங்கள் தெரிந்துக்கொள்ள விரும்பினால், நீங்கள் PhD வேட்பாளர், ஷீலா குமரன் அவர்களை +61 448 326 022 (ஆஸ்திரேலியா) / +91 98401 84001 (இந்தியா) என்ற தொலைப்பேசி எண்ணில் அழைக்கலாம்.

இந்த ஆராய்ச்சி தெற்கு அடிலெயிட் மருத்துவ ஆராய்ச்சி நெறிமுறைகள் குழுவால் மதிப்பாய்வுரை செய்யப்பட்டது. இந்த ஆய்வைப்பற்றி, குறிப்பாக ஆராய்ச்சி பங்கேற்பாளராகிய உங்களுடைய உரிமைகளை பற்றி அல்லது ஆராய்ச்சி கொள்கை பற்றி, இதில் நேரடியாக தொடர்பில்லாதவர்களிடம் பேச விரும்பினால், அல்லது இந்த ஆய்வின் நடத்தைக்குறித்து புகார் தர விரும்பினால், பேராசிரியர் வில்லிஸ் மார்ஷல் அவர்களை +61 8204 6453 என்ற தொலைப்பேசி எண்ணில் அல்லது SALHNOfficeforResearch@sa.gov.au என்ற மின்னஞ்சலில் தொடர்புக்கொள்ளலாம்.

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(தெற்கு அடிலெய்ட் சுகாதார சேவை / ஃபிலின்டர்ஸ் பல்கலைக்கழகம்)
ஆராய்ச்சியில் பங்கேற்பதற்கு இணக்கம்

ஆய்வுத் தலைப்பு: **வினா** (உருப்படி) **வங்கி** (Item Bank) **மற்றும்** கணினிவழி சோதனை **மூலமாக சோம்பல் கண்** (lazy eye) **மற்றும் மாறு கண்** (**ஓரக்கண்**) **நோயால் பாதிக்கப்பட்டவரின்** வாழ்க்கை தரத்தை **அறிய ஒரு** அளவீடு முறை. **கட்டம் II : வினா** (உருப்படி) **வங்கி** (Eye-tem Bank) **உருவாக்கம்.**

நான், ..., மேலே சொல்லப்பட்டு இருக்கும் வினாப்பட்டியல் ஆராய்ச்சி ஆய்வில் பங்கேற்பதற்கு என் ஒப்புதலையும் தெரிவித்துக்கொள்கிறேன்.

இந்த ஆய்வுடைய இயல்பு, நோக்கம், சாத்தியமான விளைவுகள், குறிப்பாக, இந்த ஆய்வு என்னை எவ்வாறு பாதிக்ககூடும் என்பதை பற்றி முழுமையாக, திருப்திகரமாக, ... விளக்கினார். என் சுய விருப்பத்தின் அடிப்படையில் என் ஒப்புதல் அளிக்கிறேன்

பின் வரும் விவரங்கள், குறிப்பாக, இந்த ஆய்வால் ஏற்படக்கூடிய ஆபத்துக்கான அறிகுறிகள், அசௌகரியம், தோராயமான நேர அவகாசம் பற்றி எனக்கு விவரிக்கப்பட்டது என்று ஒப்புக்கொள்கிறேன்.

இந்த நேர்முக தேர்வில், சோம்பல் கண் / ஓரக்கண் மற்றும் அதின் சிகிச்சை முறை என்னையும் என் வாழ்க்கையும் எவ்வாறு பாதிக்கின்றது என்பதை அறிந்துக்கொள்ள என்னிடம் ஒரு கேள்வித்தொகுப்பு கேட்கப்படும். இந்த நேர்முக தேர்வின் கால அவகாசம் கிட்டத்தட்ட ஒரு மணி நேரம் ஆகும்.

எனக்கு கொடுக்கப்பட்ட விளக்கங்களை நான் புரிந்து கொண்டேன். அவைகள் எனக்கு திருப்திகரமாக உள்ளது.

எழுதப்பட்ட ஒப்புதல் வடிவம் எனக்கு வழங்கப்பட்டுள்ளது.

இந்த ஆய்வில் என்னுடைய ஈடுபாட்டால் எனக்கு நேரடியாக எந்த பயனும் இருக்காது என்றும், நான் என் ஒப்புதலை எந்த நேரத்தில்லும் என் உரிமையும், ஆராய்ச்சியாளரின் பொறுப்புகளும் எந்த விதத்திலும் பாதிக்கபாடாமல் வாபஸ் பெற இயலும் என்று அறிந்திருக்கிறேன்.

என்னுடைய மருத்துவ பதிவேடுகள் என் மருத்துவ நிர்ணயத்தை உறுதிபடுத்திக்கொள்ள அணுகப்பட கூடும்.

நான் பதினெட்டு வயதுக்கு மேற்பட்டவர் என்று தெரிவித்துக்கொள்கிறேன்.

இந்த ஆய்வுக்காக, என் மருத்துவ பதிவேட்டிலிருந்து என் மருத்துவ விவரங்கள் (பார்வை அளவீடுகள் மற்றும் மருத்துவ நிர்ணயம்) சேகரிக்கப்பட என் ஒப்புதல் அளிக்கிறேன்.
(தயவு செய்து குறிப்பிடவும்) ஆம் ☐ இல்லை ☐

இந்த ஆய்வில் பங்கேர்ப்பதினால் எனக்கு ஏதேனும் கெடுதி ஏற்பட்டால், எனக்கு இழப்பீடு கிடைக்குமா என்பதை உறுதி செய்ய நான் சட்டரீதியான நடவடிக்கை எடுக்க வேண்டும் என்று எனக்கு தெரிவிக்கப்பட்டுள்ளது என்று ஒப்புக்கொள்கிறேன்.

....

ஆராய்ச்சி பங்கேற்பாளரின் கையொப்பம் தேதி

நான் ......, ஆராய்ச்சி பங்கேற்பாளர், ...க்கு இந்த ஆய்வை பற்றியும், அதன் இயல்பு, வழிமுறை, மற்றும் பாதிப்பு பற்றியும் விளக்கியுள்ளேன். என்னுடைய பார்வையில், இவர் கொடுக்கப்பட்ட விளக்கங்களை புரிந்து கொண்டதின் அடிப்படையில் தன்னுடைய ஒப்புதலை அளித்துள்ளார்.

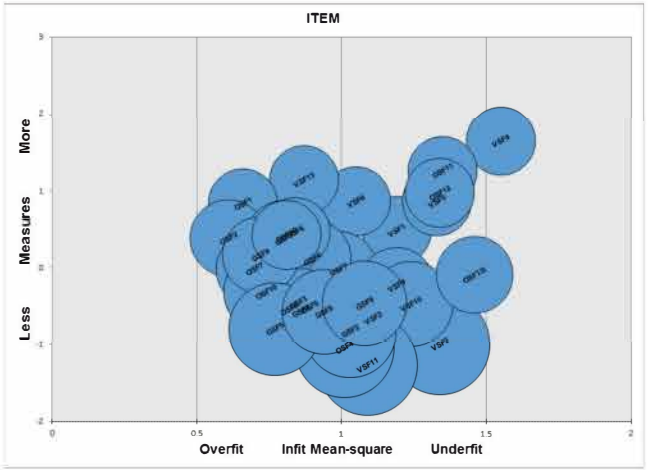
....

கையொப்பம் தேதி

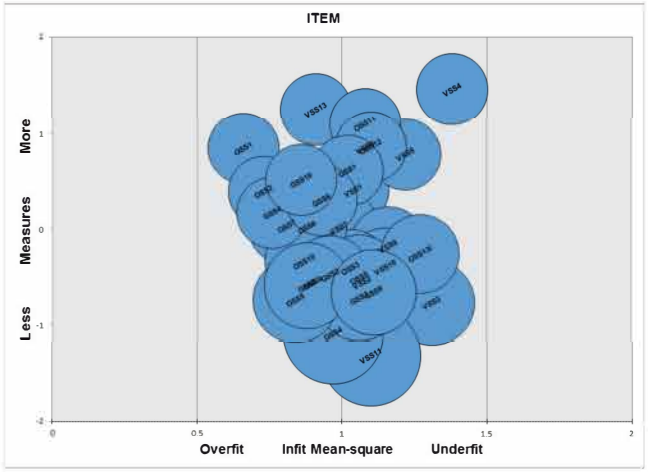
ஆராய்ச்சி நிலை .....

Appendix 10

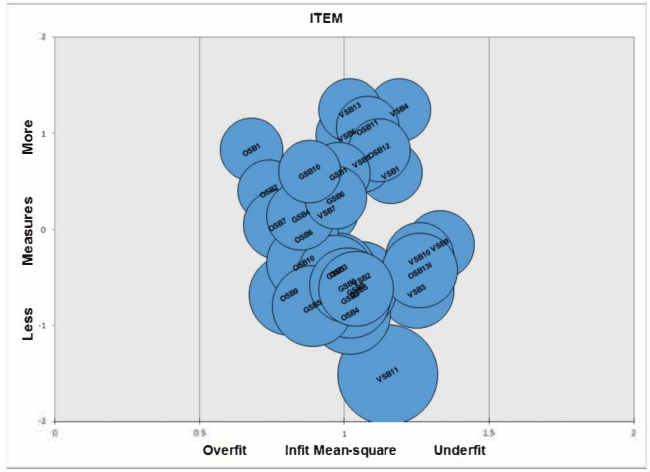
Bubble charts showing item infit MNSQs and size of standard errors



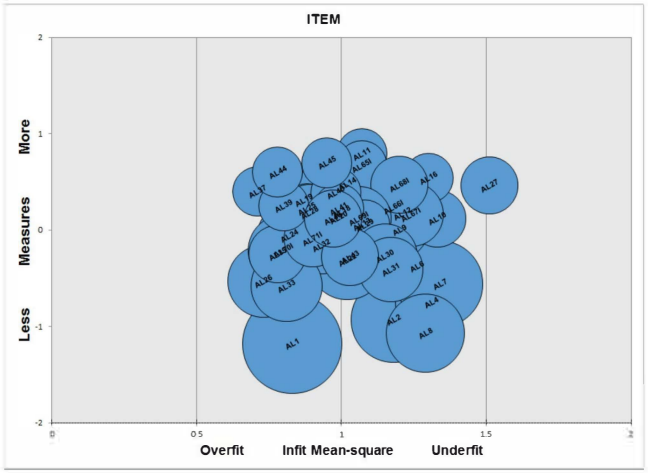
Symptoms - frequency



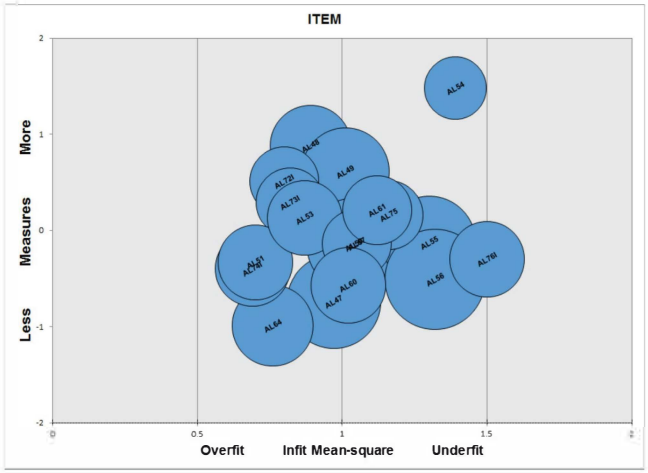
Symptoms - severity



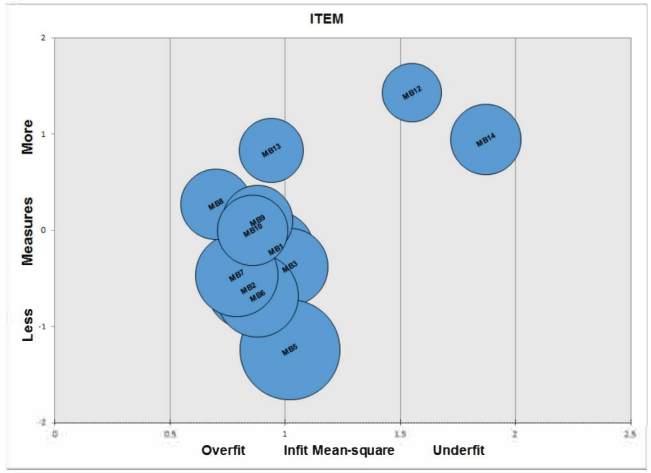
Symptoms - bothersome



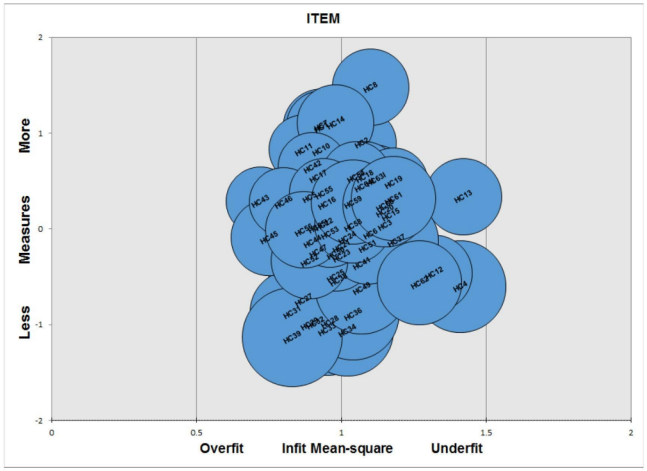
Activity limitations



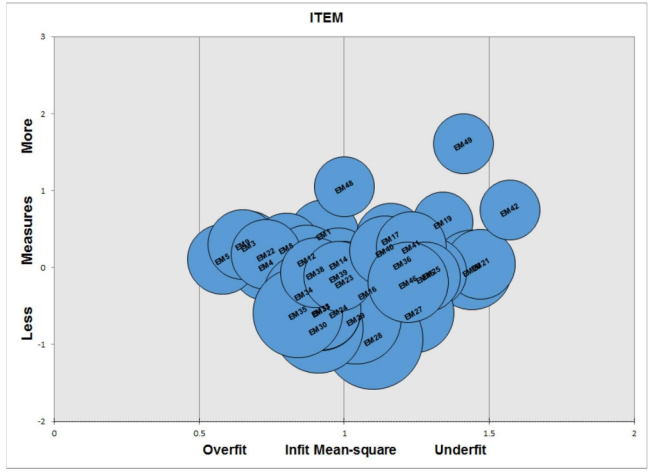
Driving



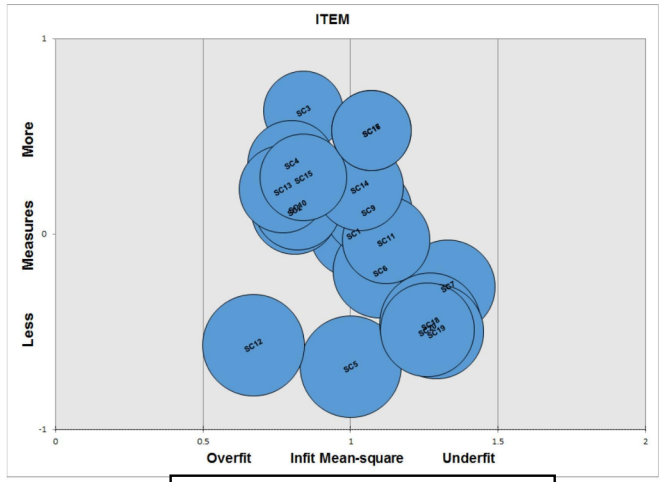
Mobility



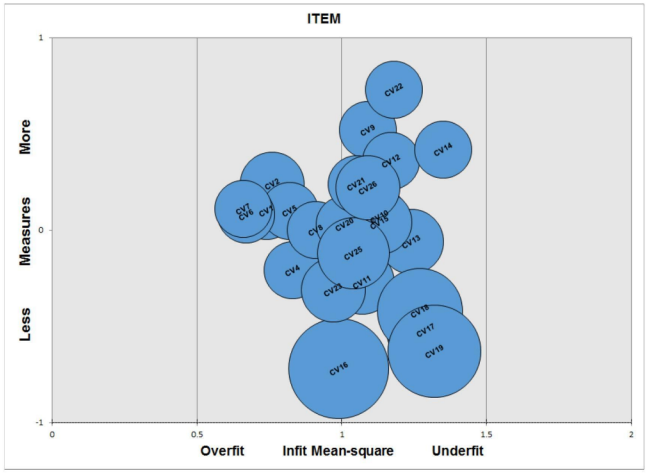
Concerns



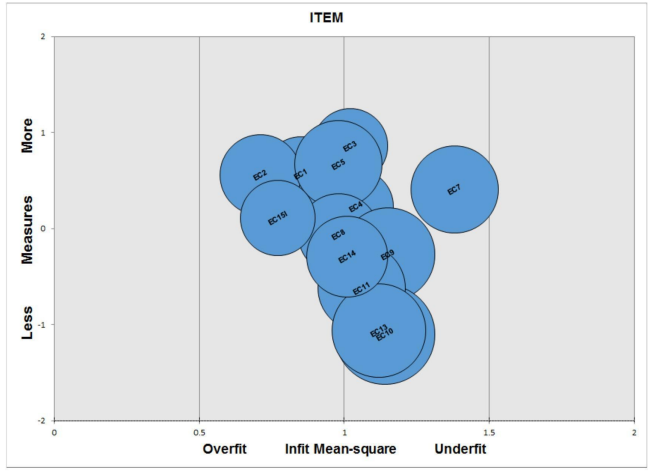
Emotional wellbeing



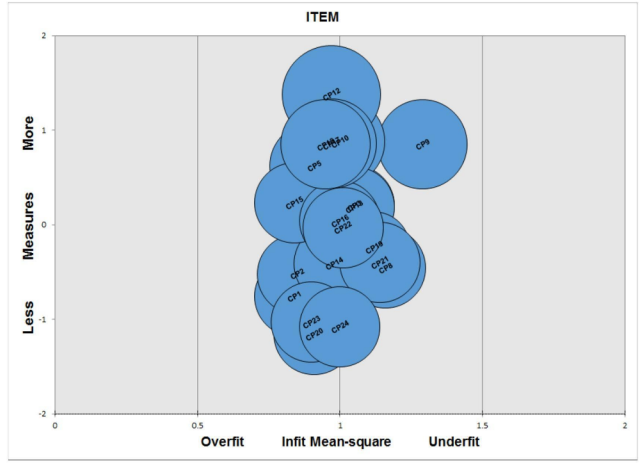
Social impact



Convenience



Economic impact



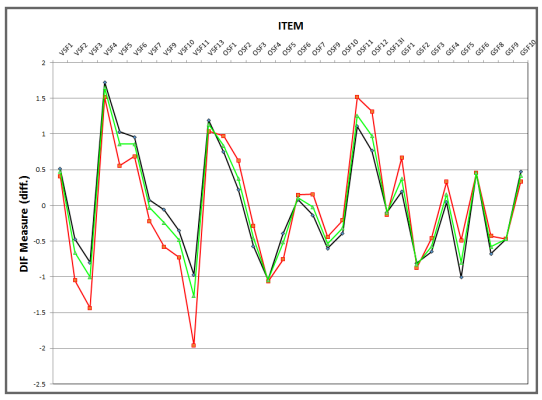
Coping

Appendix 11

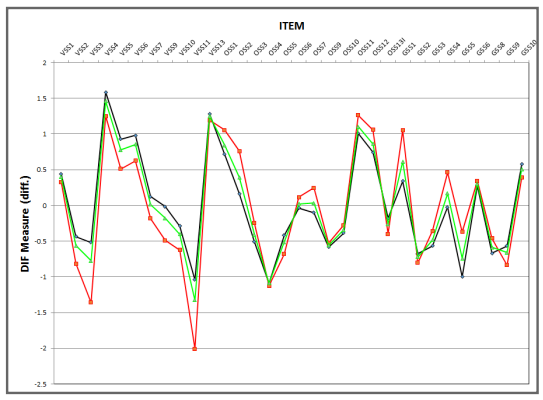
Differential item functioning (DIF) Plots

Person DIF plots (variable: Gender)

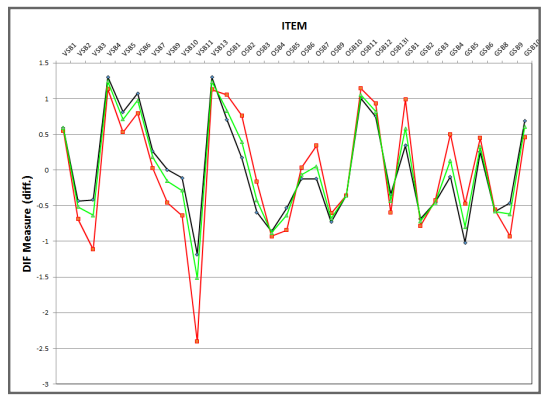
Symptoms - Frequency



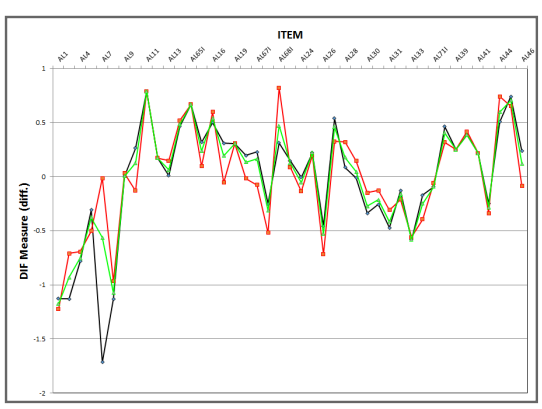
Symptoms - Severity



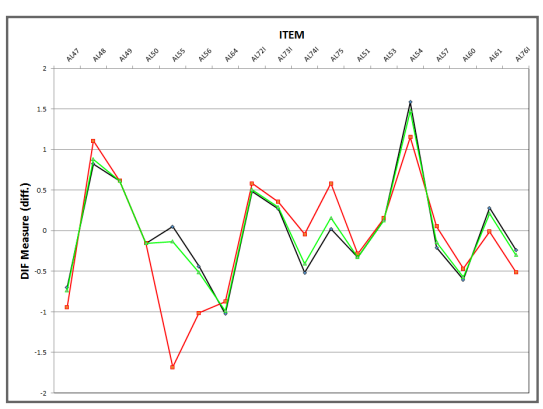
Symptoms - Bothersome



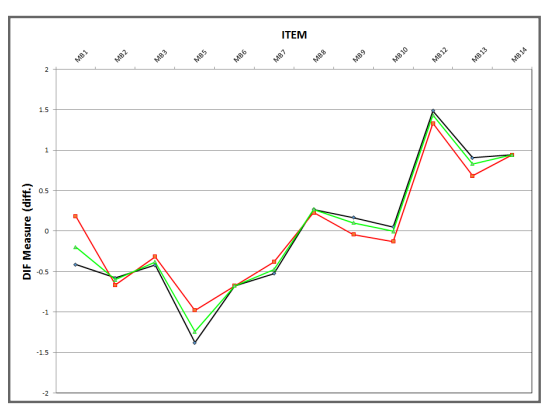
Activity Limitation



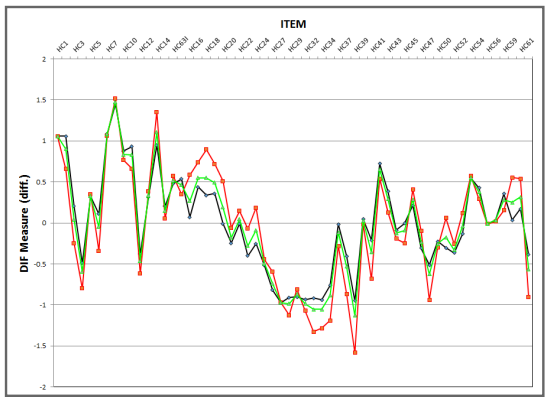
Driving



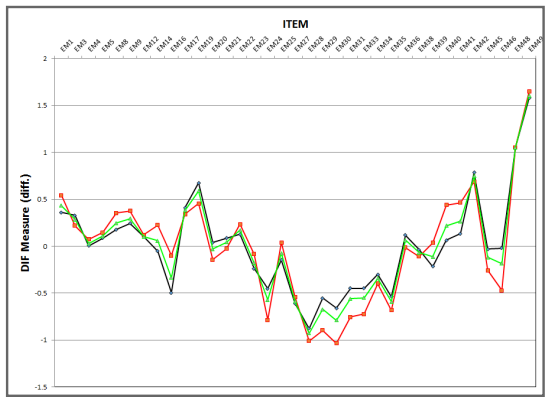
Mobility



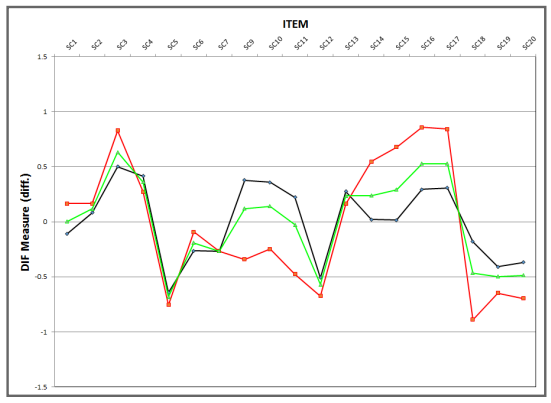
Concerns



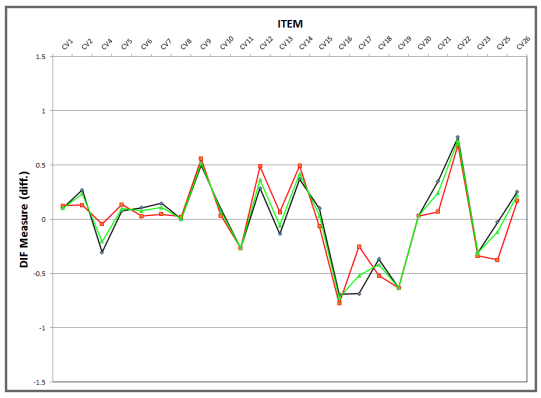
Emotional wellbeing



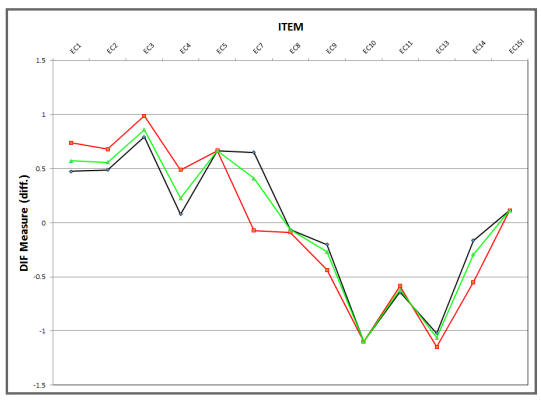
Social impact



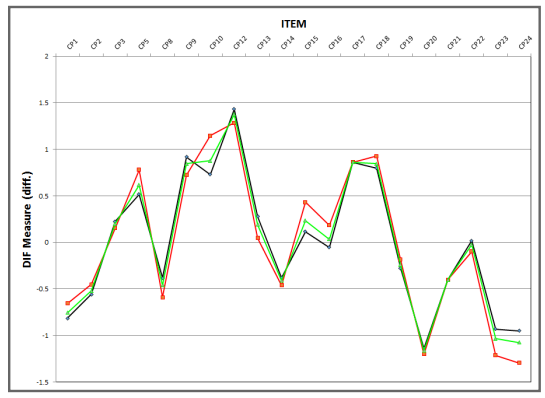
Convenience



Economic impact



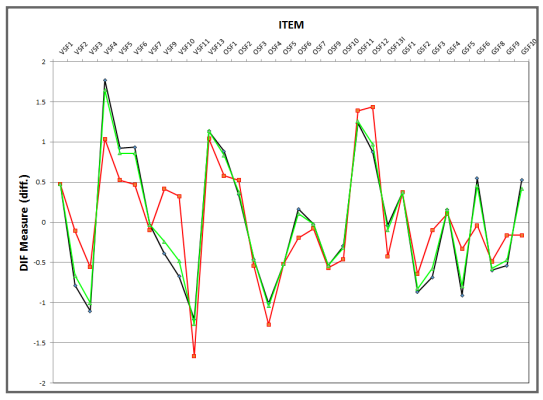
Coping



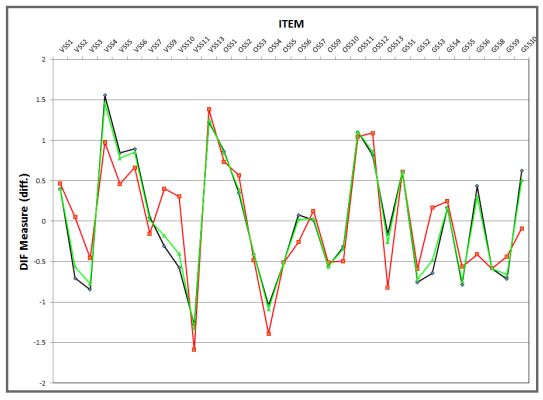
Male Female Baseline

Person DIF plots (variable: Age)

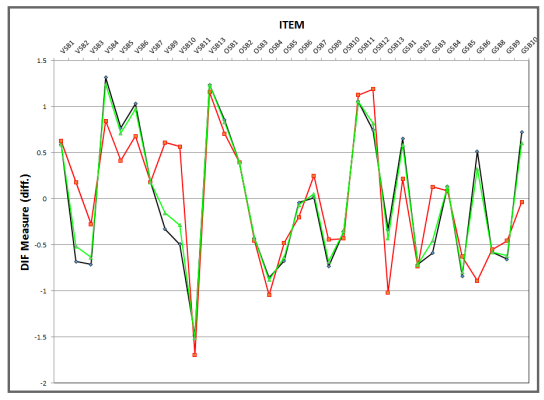
Symptoms - Frequency



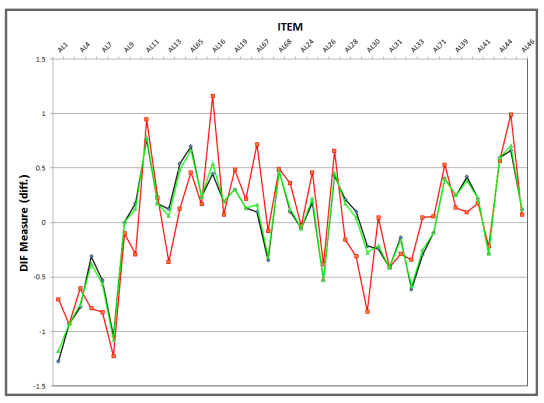
Symptoms - Severity



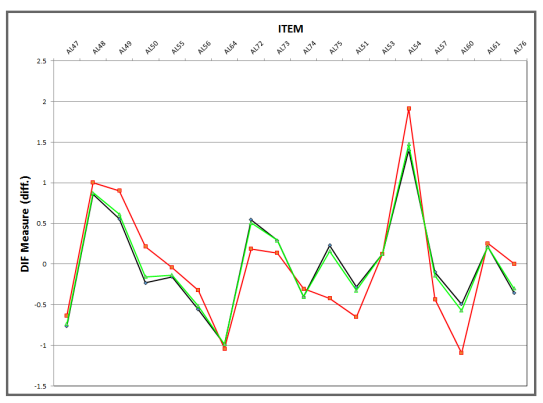
Symptoms - Bothersome



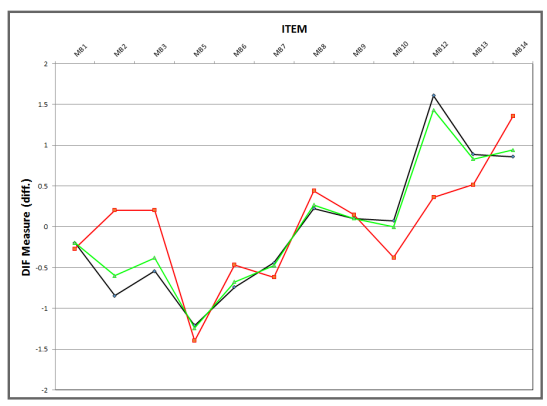
Activity Limitation



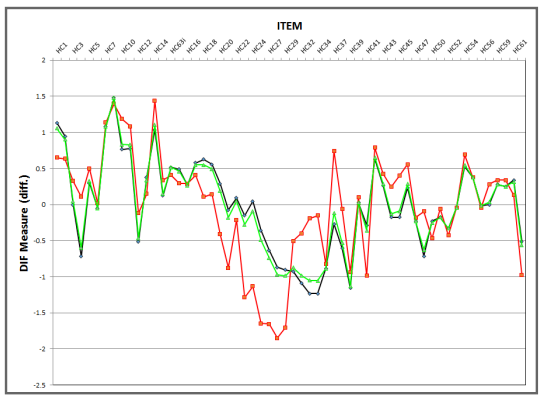
Driving



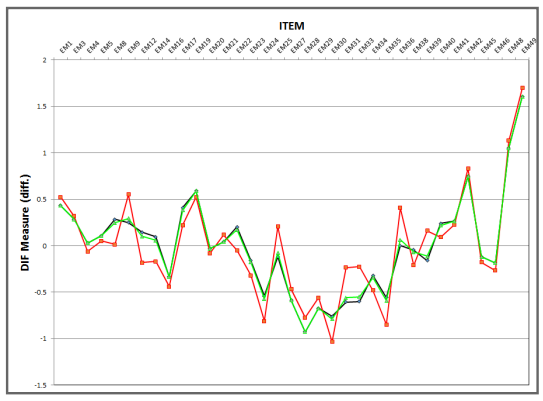
Mobility



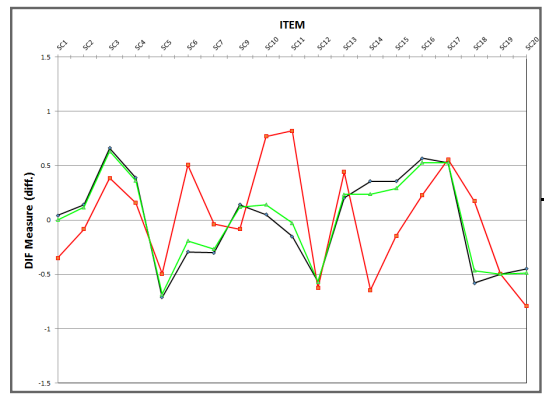
Concerns



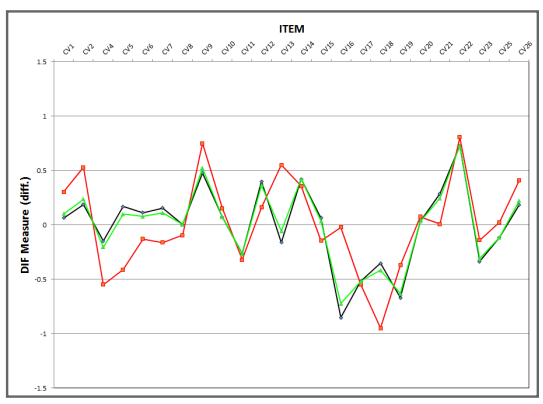
Emotional wellbeing



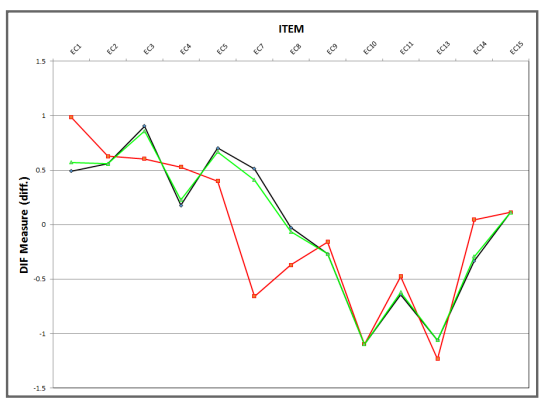
Social impact



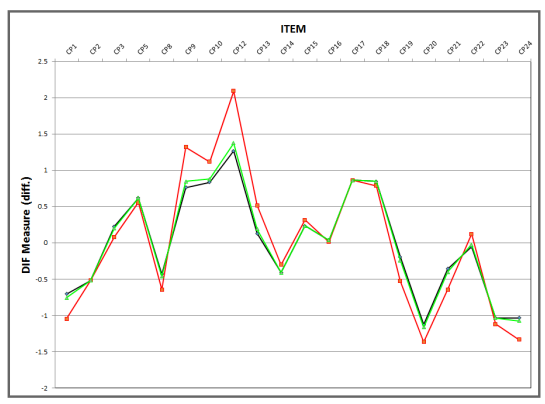
Convenience



Economic impact



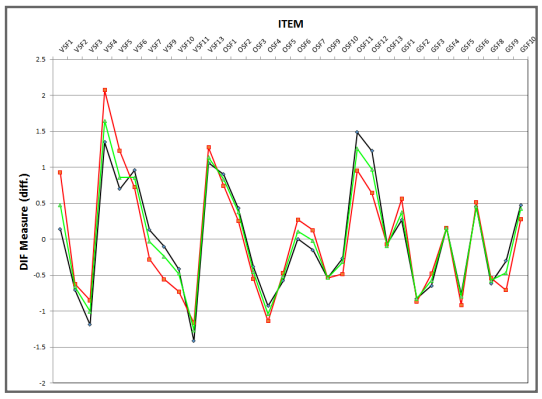
Coping



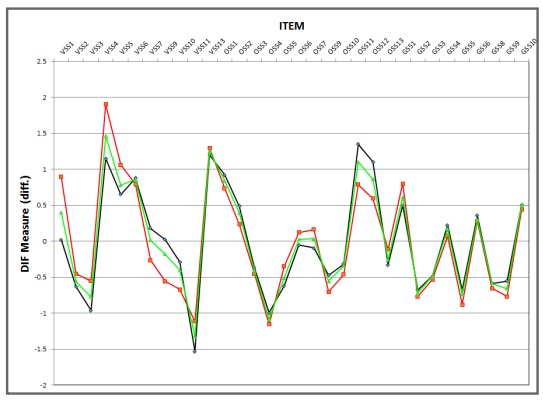
Less than 40 years 40 years and above Baseline

Person DIF plots (variable: Education)

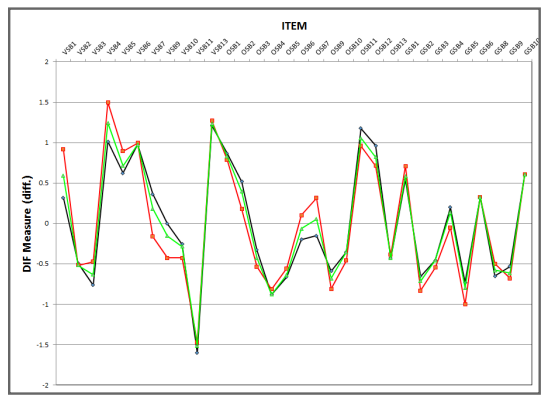
Symptoms - Frequency



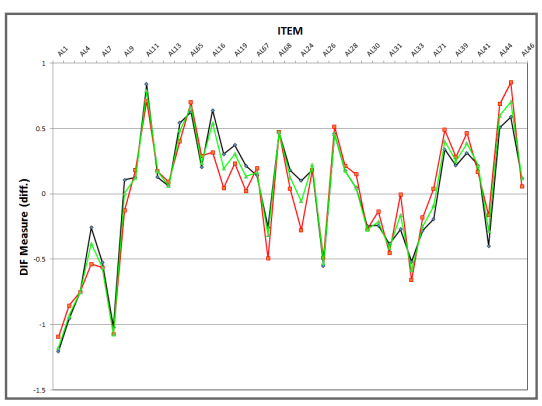
Symptoms - Severity



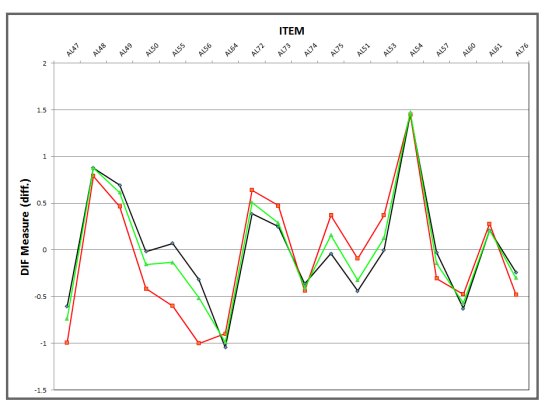
Symptoms - Bothersome



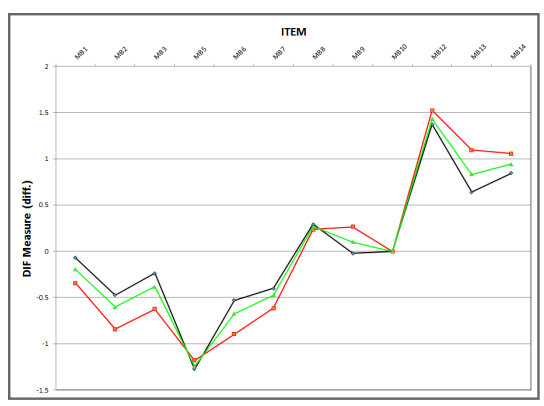
Activity Limitation



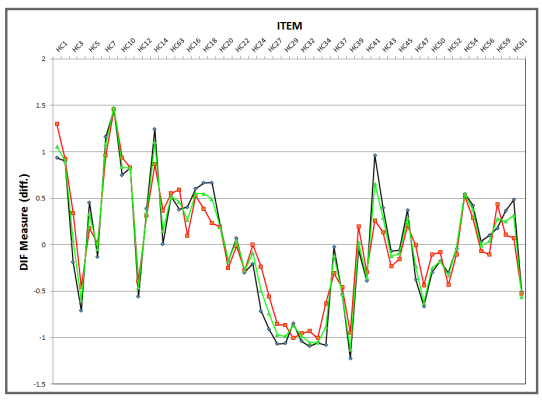
Driving



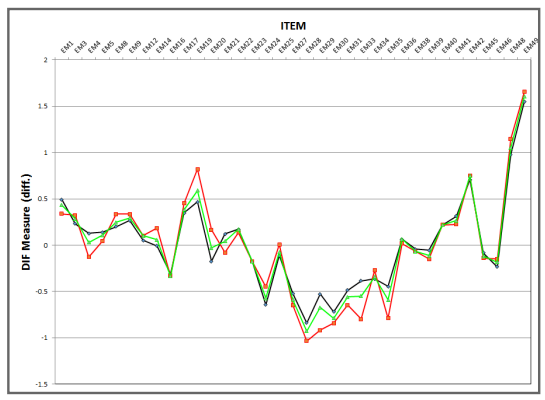
Mobility



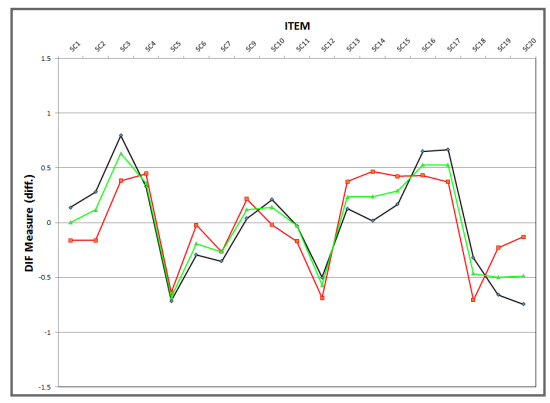
Concerns



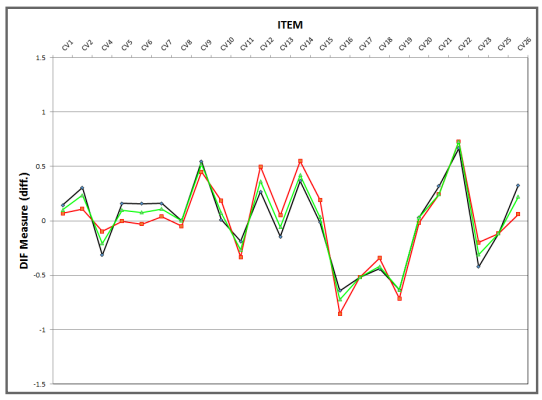
Emotional wellbeing



Social impact

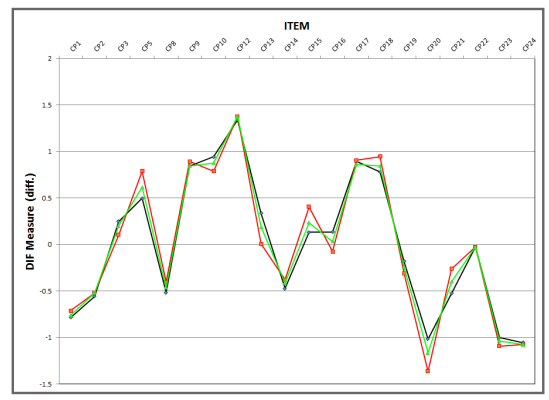


Convenience



Economic impact

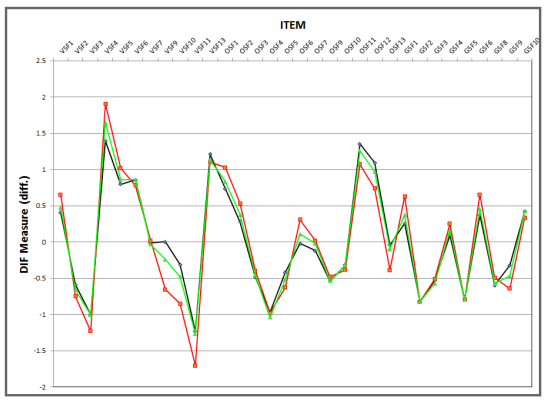
Coping



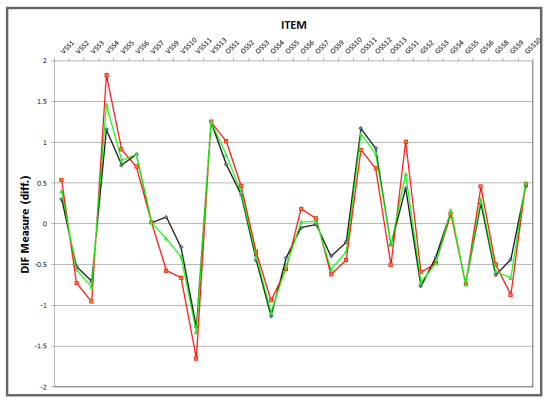
Degree or higher
Diploma, certificate or lower
Baseline

Person DIF plots (variable: Occupation)

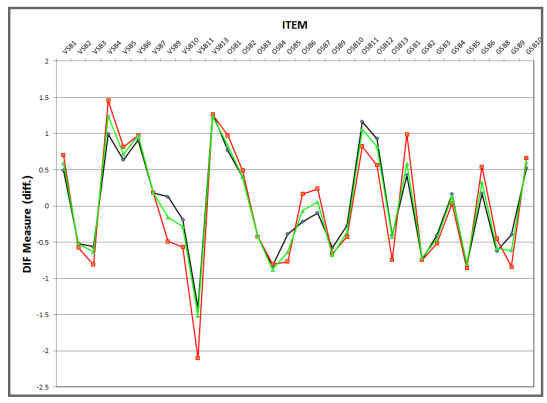
Symptoms - Frequency



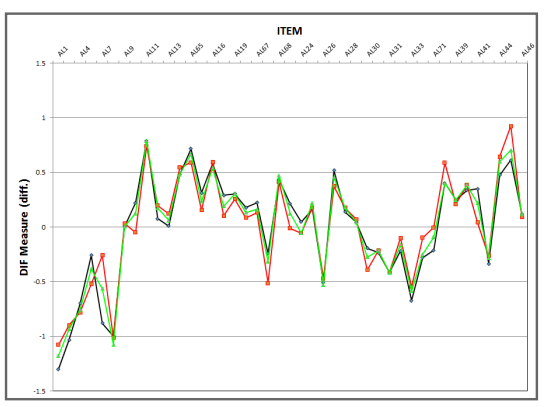
Symptoms - Severity



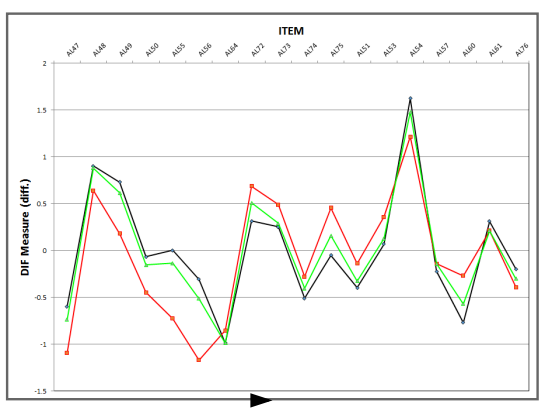
Symptoms - Bothersome



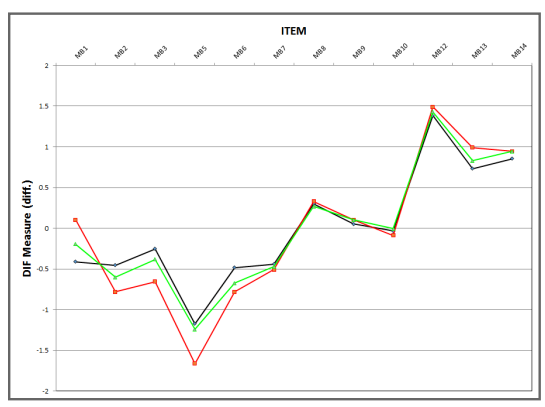
Activity Limitation



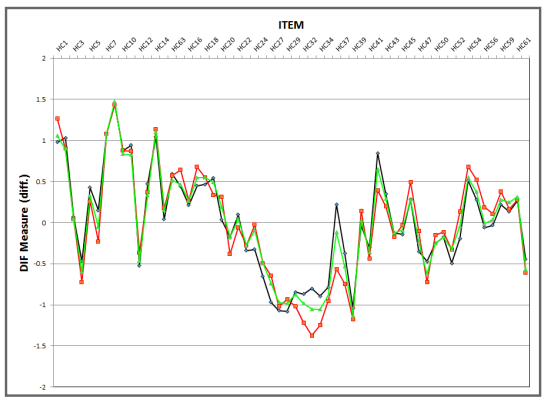
Driving



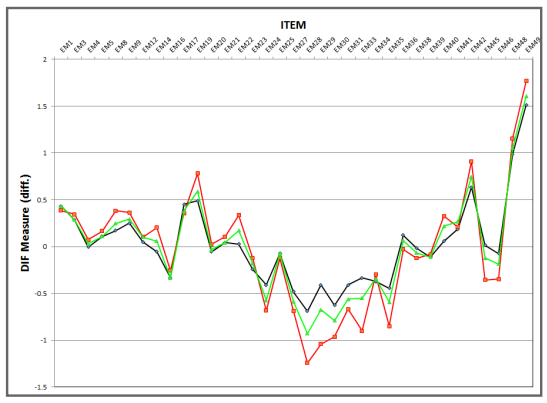
Mobility



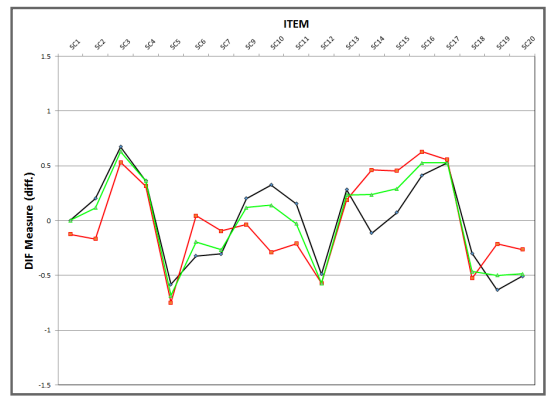
Concerns



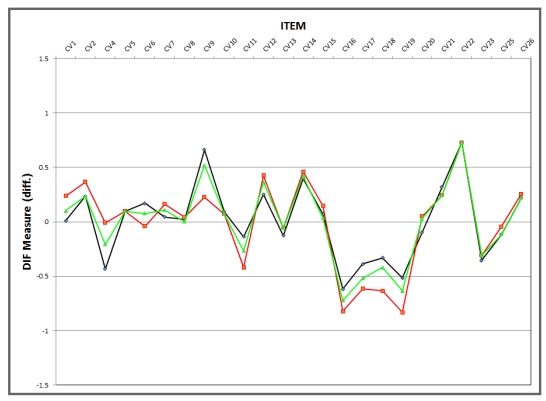
Emotional wellbeing



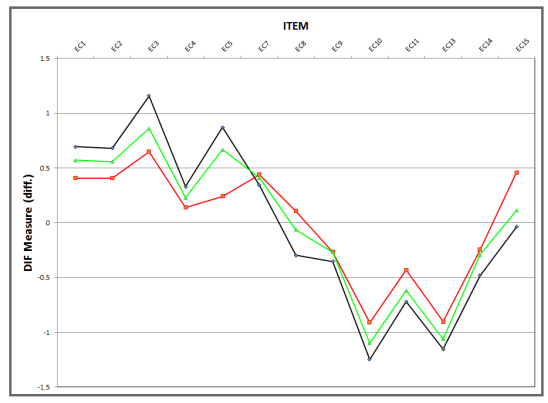
Social impact



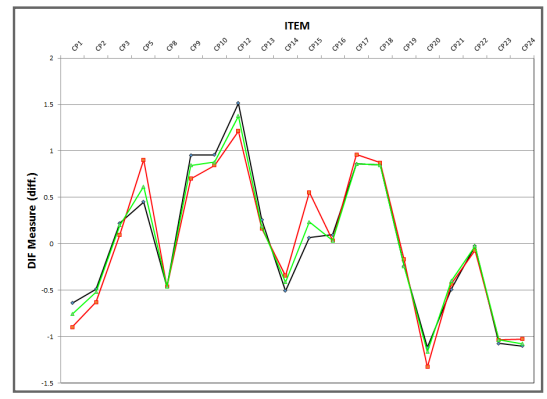
Convenience



Economic impact



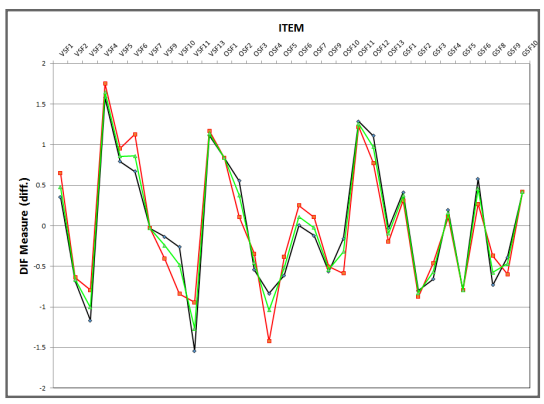
Coping



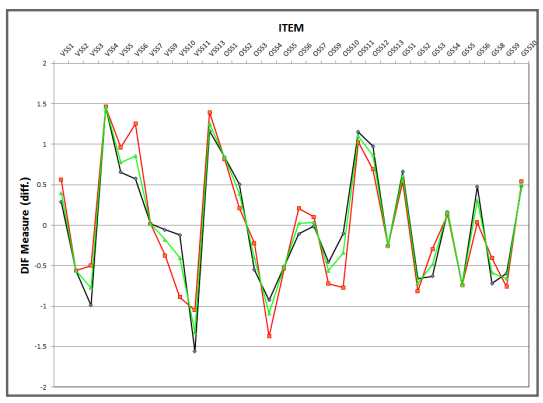
Employed Unemployed Baseline

Person DIF plots (variable: Questionnaire language)

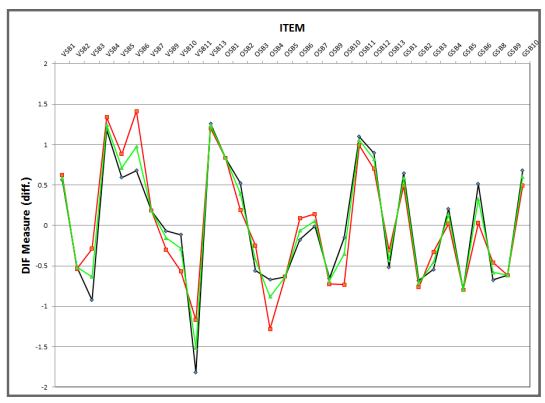
Symptoms - Frequency



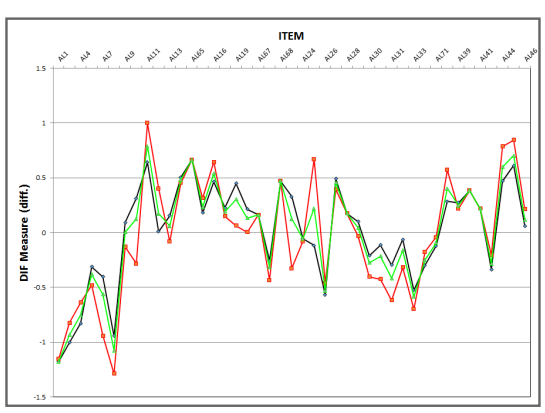
Symptoms - Severity



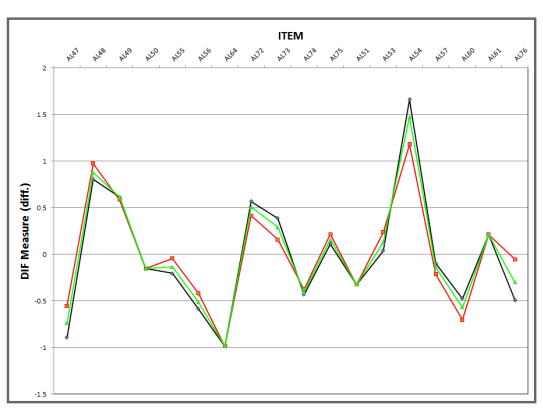
Symptoms - Bothersome



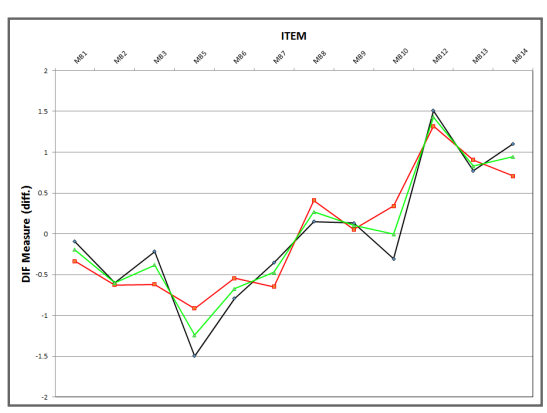
Activity Limitation



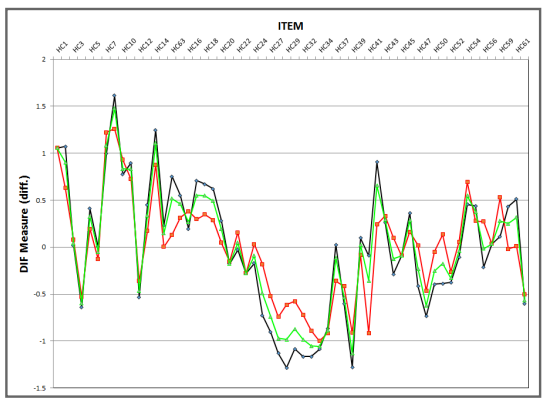
Driving



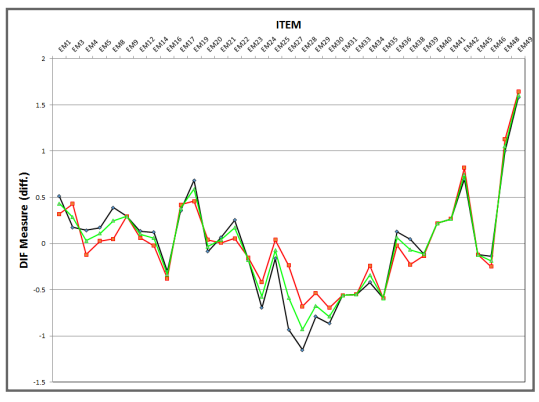
Mobility



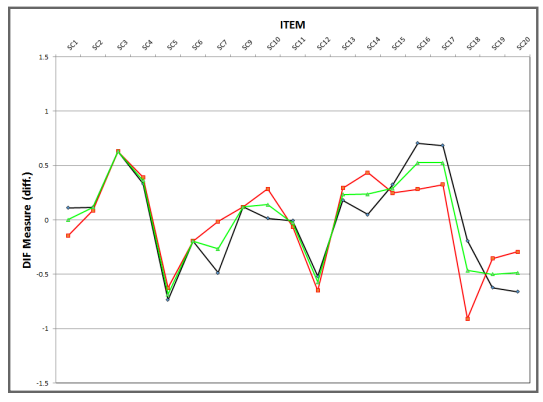
Concerns



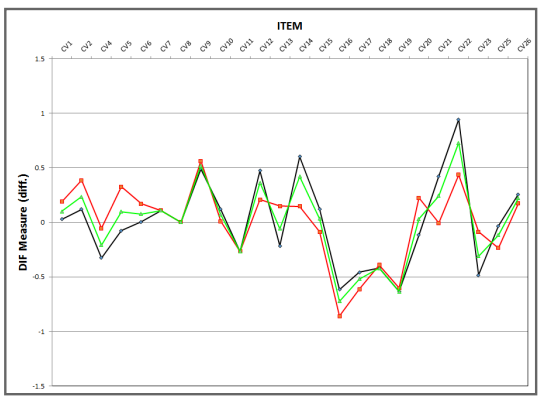
Emotional wellbeing



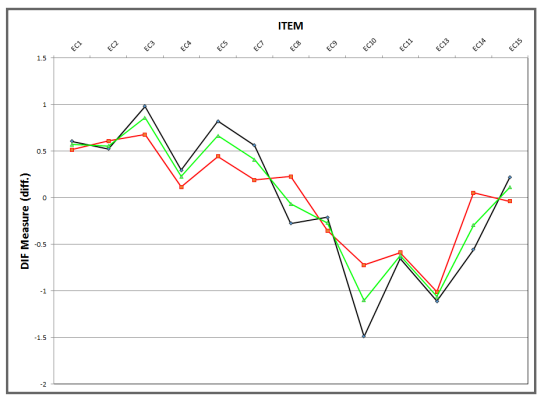
Social impact



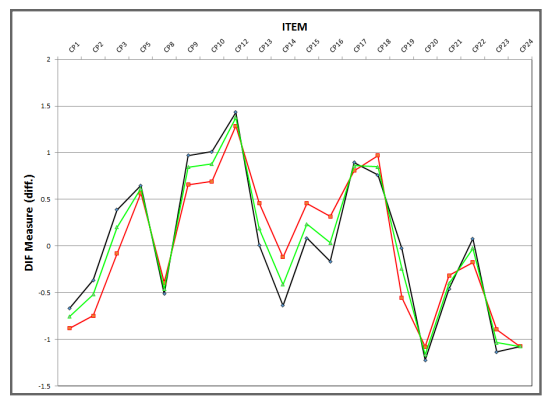
Convenience



Economic impact



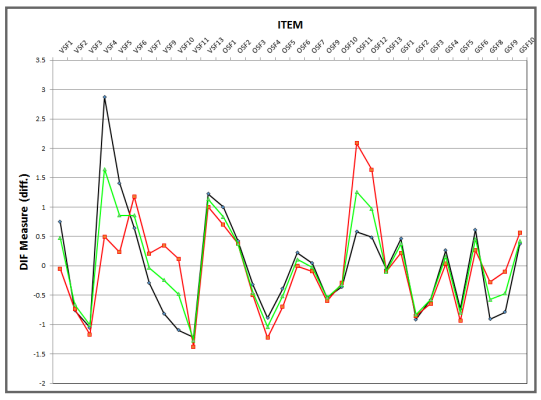
Coping



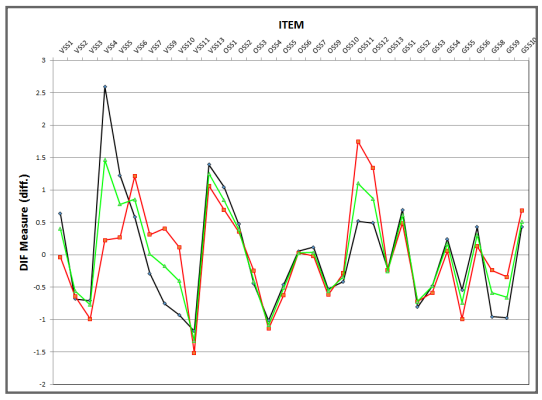
English Indian languages Baseline

Person DIF plots (variable: Presence of amblyopia)

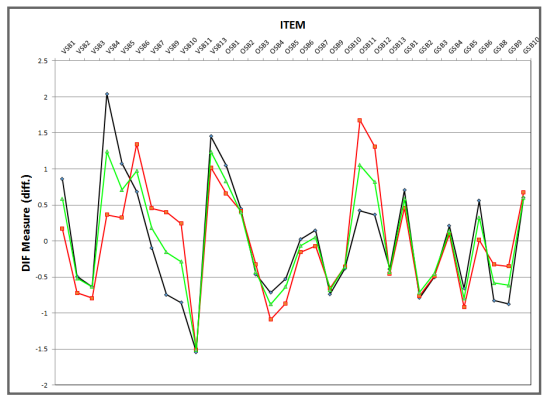
Symptoms - Frequency



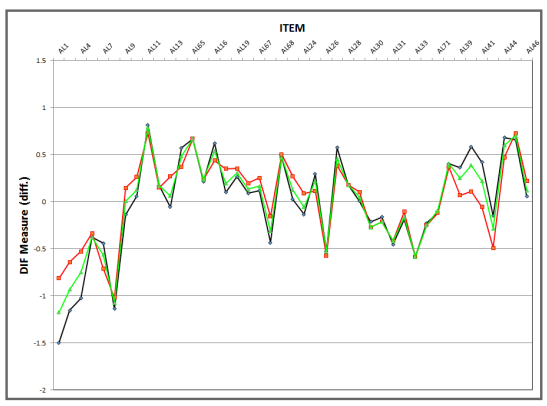
Symptoms - Severity



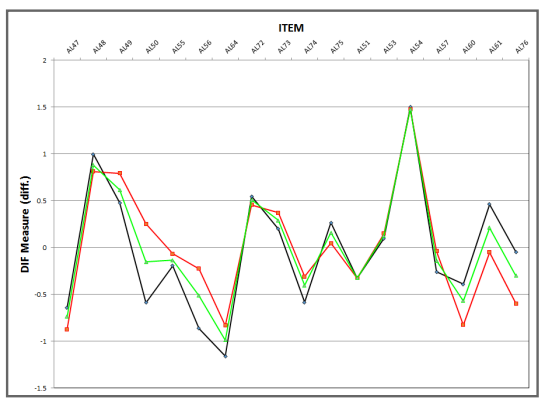
Symptoms - Bothersome



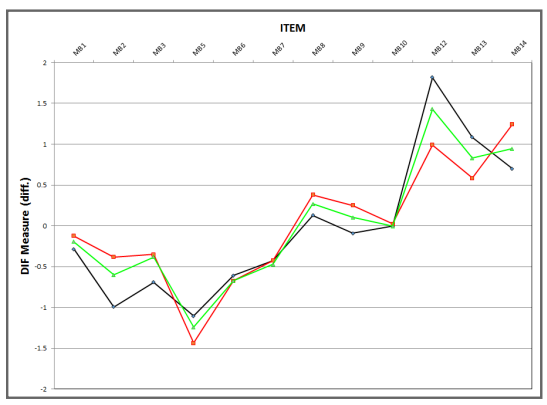
Activity Limitation



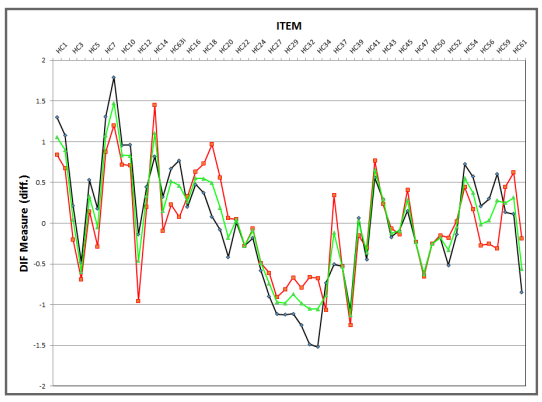
Driving



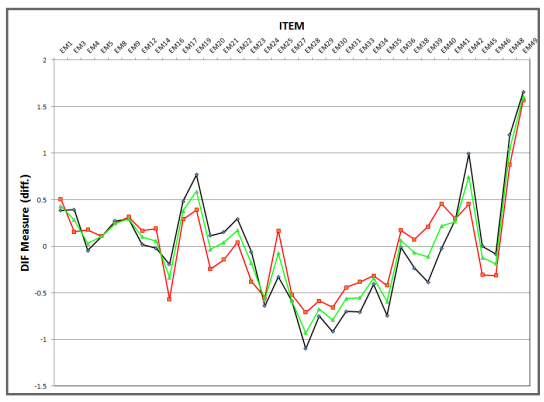
Mobility



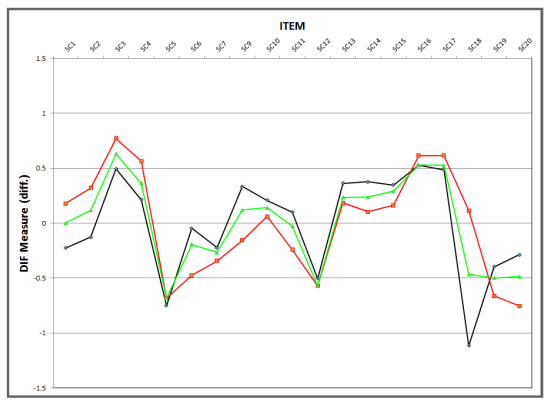
Concerns



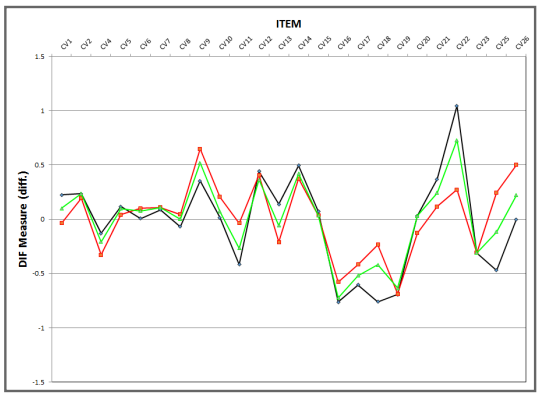
Emotional wellbeing



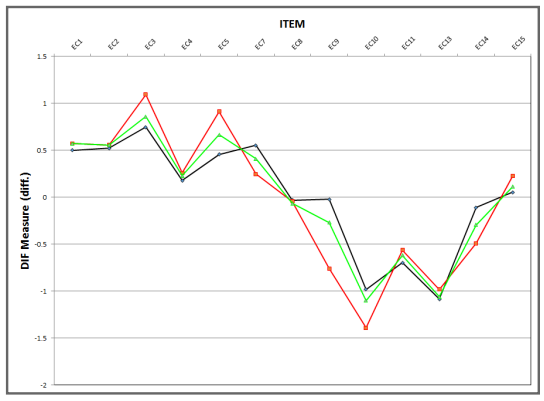
Social impact



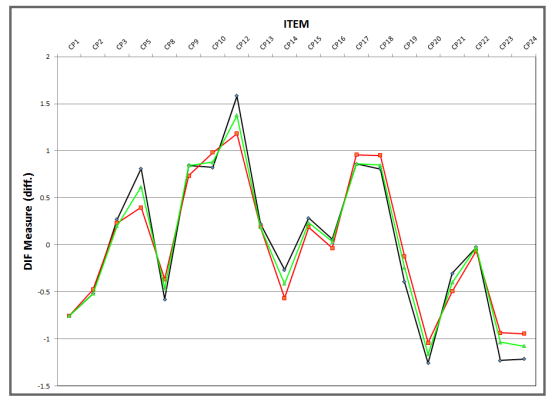
Convenience



Economic impact



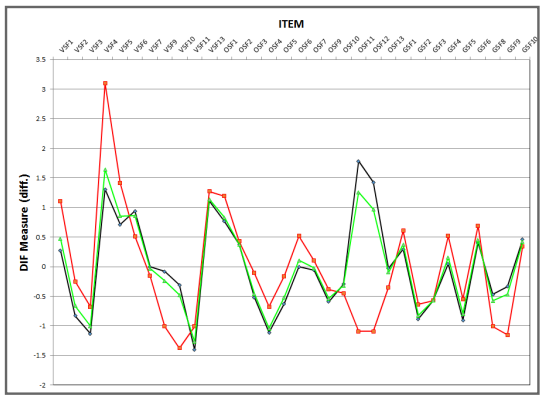
Coping



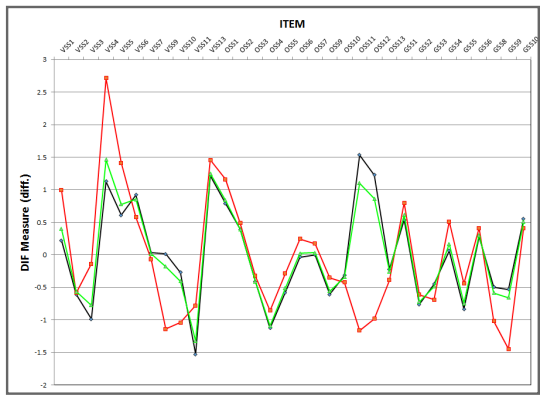
Amblyopia Isolated strabismus Baseline

Person DIF plots (variable: Presence of Strabismus)

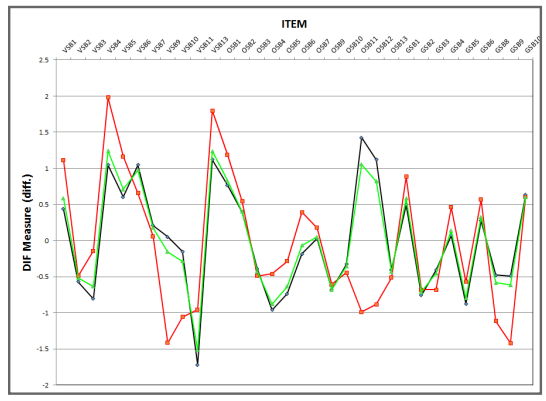
Symptoms - Frequency



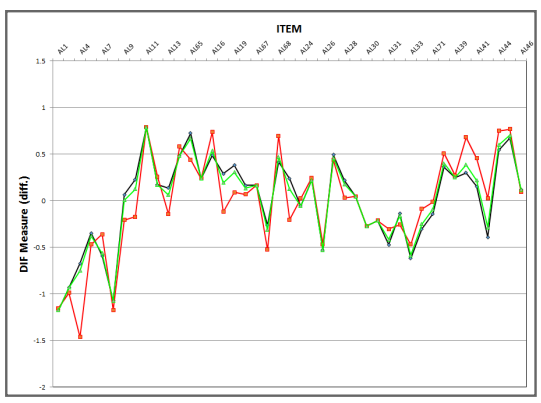
Symptoms - Severity



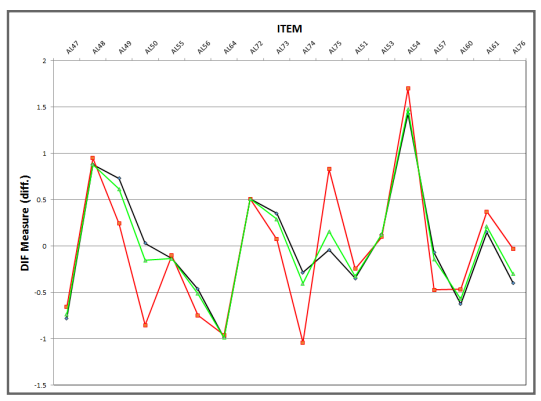
Symptoms - Bothersome



Activity Limitation

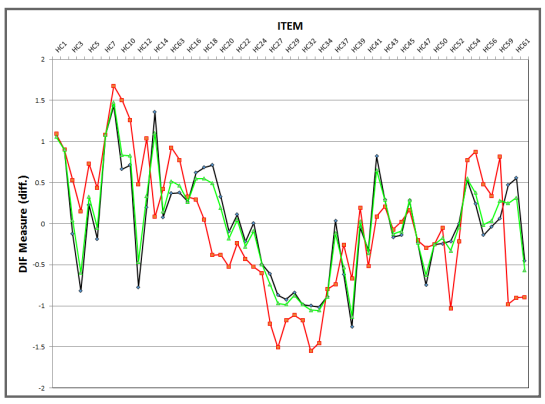


Driving

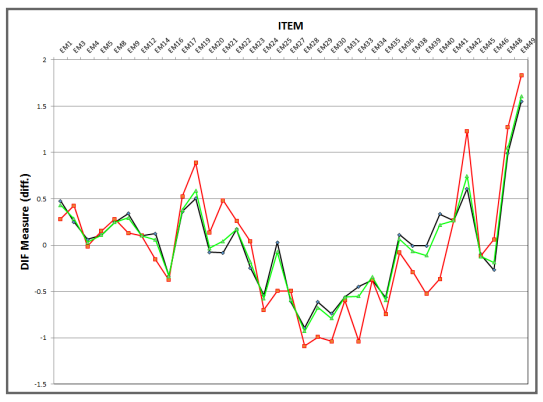


Mobility

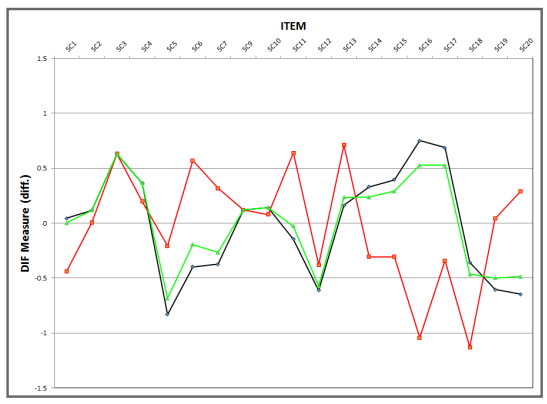
Concerns



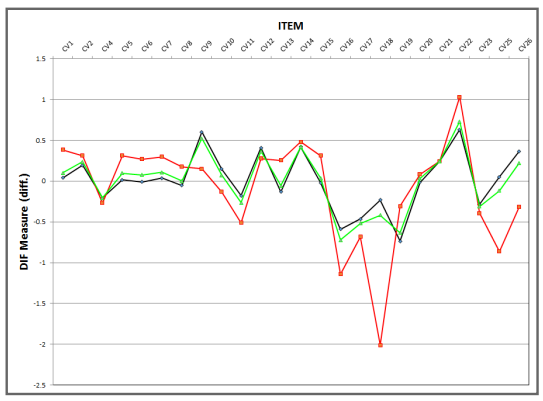
Emotional wellbeing



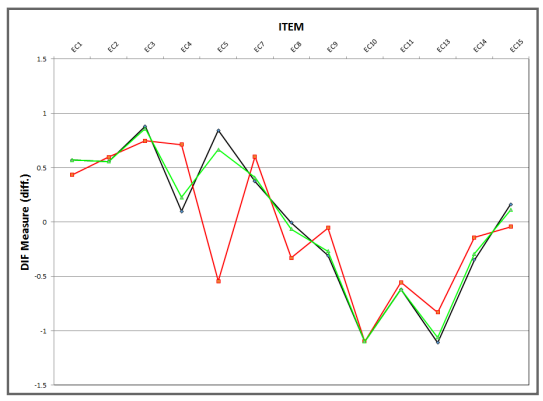
Social impact



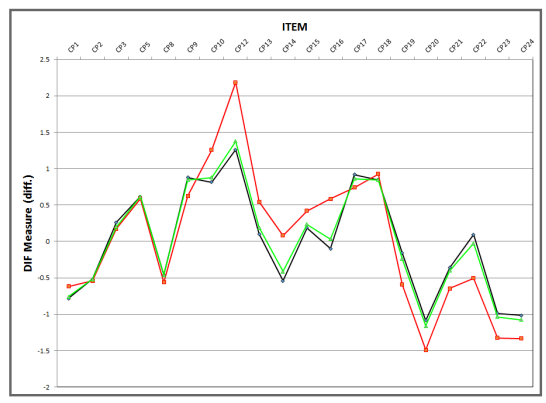
Convenience



Economic impact



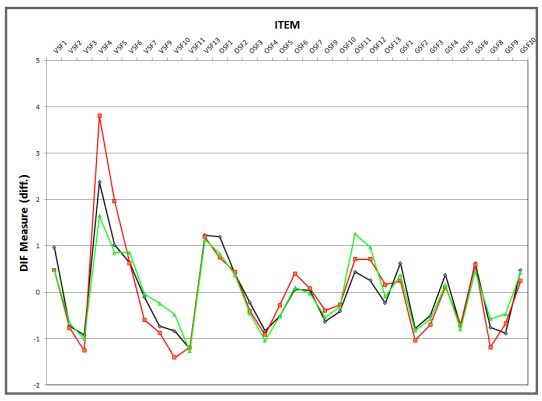
Coping



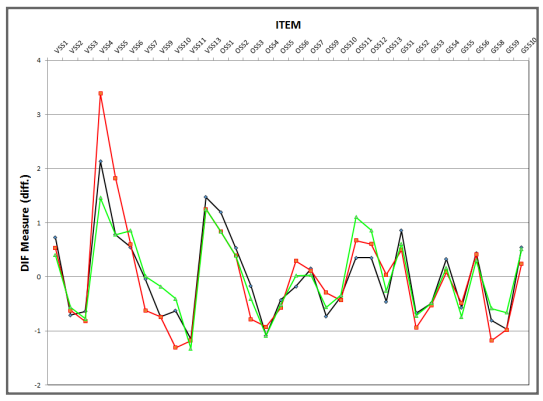
Strabismus Isolated amblyopia Baseline

Person DIF plots (variable: Visual acuity)

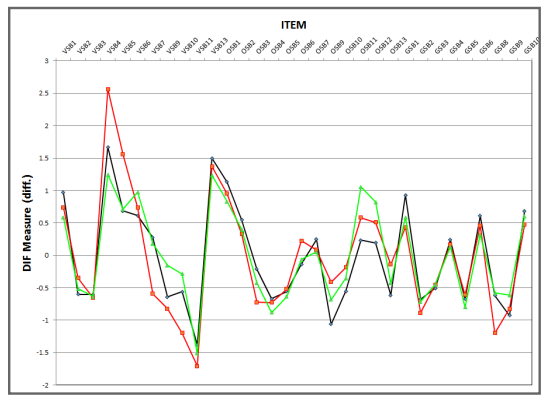
Symptoms - Frequency



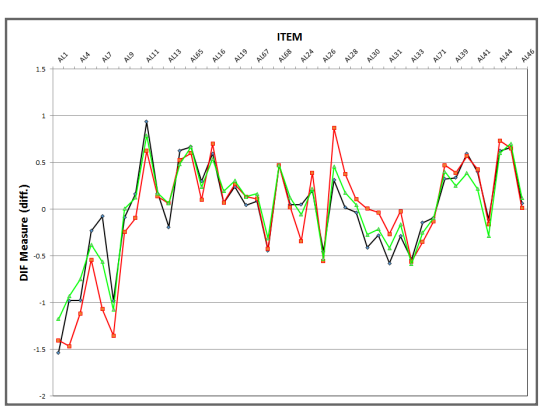
Symptoms - Severity



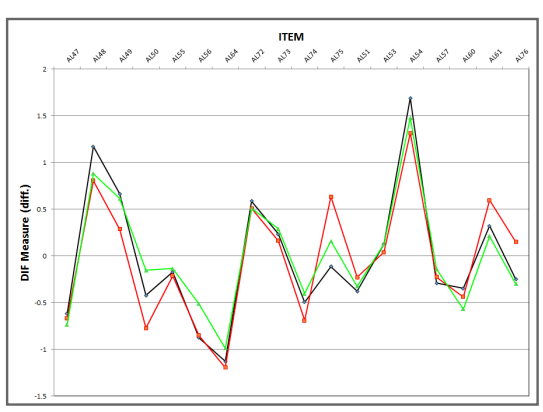
Symptoms - Bothersome



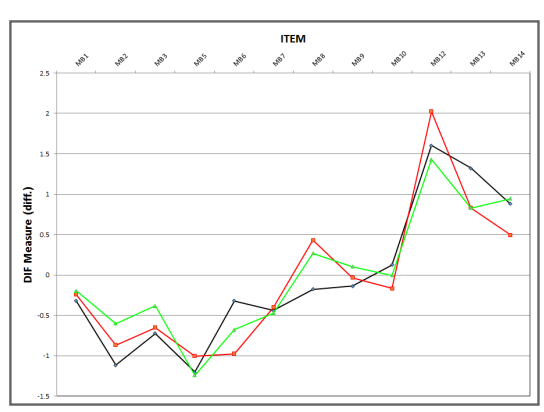
Activity Limitation



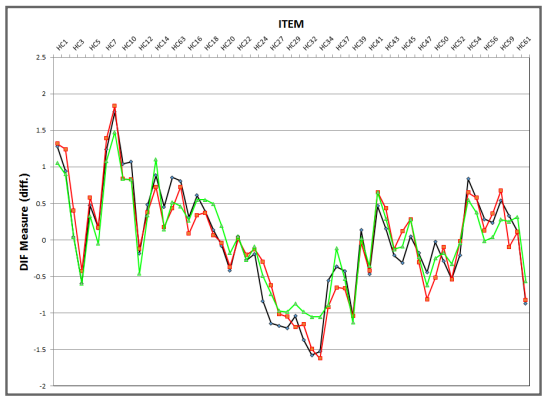
Driving



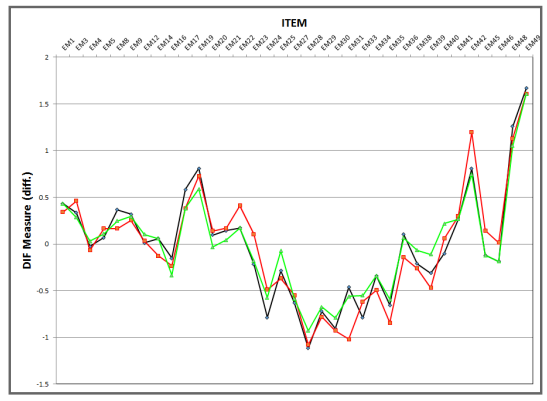
Mobility



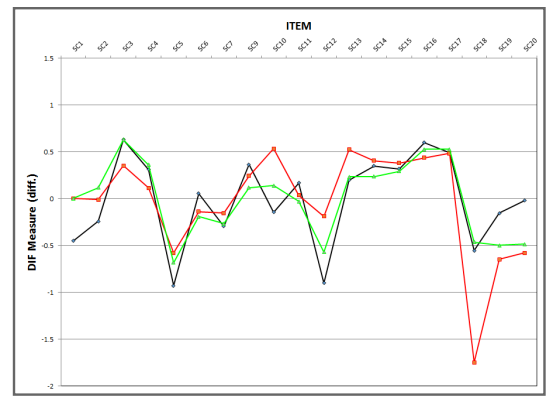
Concerns



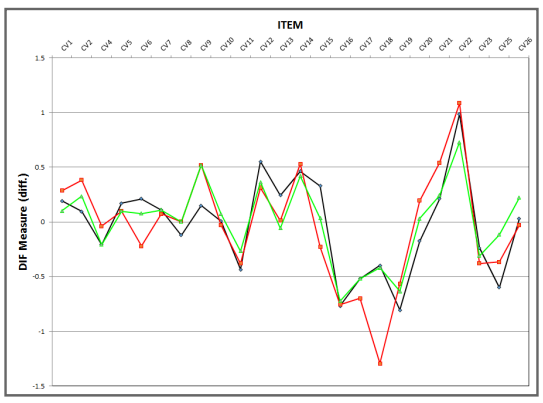
Emotional wellbeing



Social impact

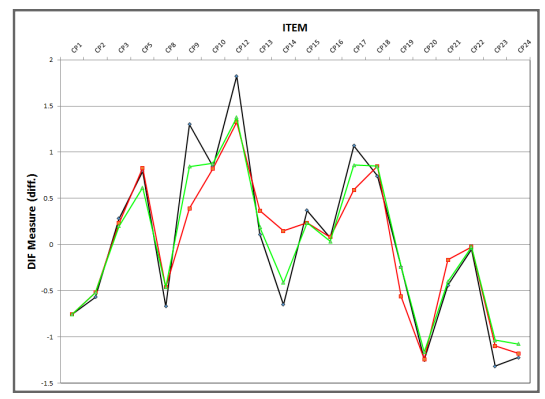


Convenience



Economic impact

Coping



6/19 or better worse than 6/19 Baseline

Appendix 12
Clinical and demographic details – Phase 2 Australia participants

Clinical and demographic variables	
Age (years)	
Median	47
Range	21-75
Gender n (%)	
Male	15 (27.3)
Female	40 (72.7)
Diagnosis n (%)	
Amblyopia	24 (43.6)
Strabismic amblyopia	9 (16.4)
Anisometropic amblyopia	6 (10.9)
Combined-mechanism amblyopia	6 (10.9)
Deprivational amblyopia	3 (5.45)
Isolated strabismus	17 (30.9)
Visual acuity in the worse amblyopic eye n (%)	
0.2 to 0.5 logMAR (6/9.5 to 6/19)	18 (75)
0.6 to 1 logMAR (6/24 to 6/60)	1 (4.2)
> 1 logMAR (> 6/60)	3 (12.5)
Type of ocular deviation (in those with strabismus) n (%)	
Horizontal	17 (53.1)
Vertical	3 (9.4)
Oblique	4 (12.5)
Magnitude of ocular deviation n (%)	
< 25 prism dioptres	13 (40.6)
>/= 25 prism dioptres	4 (12.5)
Education n (%)	
Degree or higher	23 (41.8)
Diploma	8 (14.5)
Certificate	6 (10.9)
No post school qualification	4 (7.3)
Country of birth n (%)	
Australia	30 (54.5)
Others	12 (21.8)
Sum of the percentages for some variables may not be 100% due to missing data	

Appendix 13
Phase 2 Australia: Preliminary evaluation of psychometric properties

Parameters	Symptoms - Frequency	Symptoms - Severity	Symptoms - Bothersome
No of items / persons	37/55	37/55	37/55
No of categories	4	4	4
Category functioning			
Average measures	Ordered	Ordered	Ordered
Threshold calibration	Disordered	Ordered	Ordered
Category misfit	Nil	Nil	Category 1 (Outfit MNSQ = 1.57)
Separation and reliability statistics			
PSI (person reliability)	2.73 (0.88)	2.65 (0.88)	2.63 (0.87)
ISI (item reliability)	3.17 (0.91)	3.14 (0.91)	2.72 (0.88)
Item misfit			
Infit MNSQ > 1.5	2 (VSF5, VSF4)	3 (VSS5, VSS10, VSS4)	6 (VSB5, GSB7, VSB10, VSB4, GSB8, OSB11)
Outfit MNSQ > 1.5	2 (VSF5, VSF4)	3 (VSS5, VSS10, VSS4)	5 (VSB5, GSB7, VSB10, VSB4, OSB5)
Targeting			
Difference between person and item means	0.79	1.22	1.28
Dimensionality (PCA of residuals)			
Variance explained by the Rasch dimension (observed / expected)	32.4% / 33.5%	32.1%/ 32.9%	30.2% / 31.4%
Variance explained by the items	22.2%	21.6%	19.5%
Eigen value of the first contrast	5.28	5.09	4.8
Variance explained by the first contrast	9.6%	9.4%	9.0%
Items loading on first contrast (number, item IDs)	10 (VSF 1-6, 8, 11, 13, 15)	11 (VSS 1-6, 8, 11, 13, 14, 15)	6 (VSB1-4, 13, 15)
Disattenuated correlation between the first and second item clusters	0.65	0.58	0.84
Measurement range	2.79 (-1.80 to 0.99)	3.32 (-2.02 to 1.30)	2.64 (-1.63 to 1.01)

Parameters	Activity limitations	Driving	Mobility
No of items / persons	46/55	18/53	14/55
No of categories	5	5	5
Category functioning			
Average measures	Ordered	Ordered	Ordered
Threshold calibration	Ordered	Ordered	Ordered
Category misfit	Nil	Nil	Category 2 (Outfit MNSQ = 1.93)
Separation and reliability statistics			
PSI (person reliability)	3.5 (0.92)	2.16 (0.82)	1.53 (0.70)
ISI (item reliability)	4.02 (0.94)	2.7 (0.88)	1.82 (0.77)
Item misfit			
Infit MNSQ > 1.5	4 (AL10, 5,7, 27)	2 (AL63, AL64)	2 (MB5, MB14)
Outfit MNSQ > 1.5	5 (AL6, 10, 46, 7, 27)	3 (AL61, 62, 63)	3 (MB5, 14, 12)
Targeting			
Difference between person and item means	1.94	2.6	3.03
Dimensionality (PCA of residuals)			
Variance explained by the Rasch dimension (observed / expected)	52.2% / 54.5%	55.1% / 55.8%	47.0% / 48.2%
Variance explained by the items	26%	14.5%	16.7%
Eigen value of the first contrast	8.10	3.80	3.00
Variance explained by the first contrast	8.4%	9.5%	11.4%
Items loading on first contrast (number, item IDs)	13 (AL2-5, AL9-10, AL18-22, 27, 34)	3 (AL48, 49, 54)	3 (MB2-4)
Disattenuated correlation between the first and second item clusters	0.78	0.89	1
Measurement range	5.72 (-3.23 to 2.49)	3.57 (-1.88 to 1.69)	2.35 (-1.51 to 0.84)

Parameters	Concerns	Emotional impact	Social impact
No of items / persons	62/55	49/54	22/55
No of categories	5	5	5
Category functioning			
Average measures	Ordered	Ordered	Ordered
Threshold calibration	Disordered	Ordered	Ordered
Category misfit	Nil	Category 1 (Outfit MNSQ = 3.63)	Category 3 (Outfit MNSQ =1.84)
Separation and reliability statistics			
PSI (person reliability)	4.04 (0.94)	2.2 (0.83)	1.0 (0.50)
ISI (item reliability)	2.51 (0.86)	1.66 (0.73)	0.52 (0.21)
Item misfit			
Infit MNSQ > 1.5	4 (HC13, 61, 29, 62)	7 (EM44, 48, 43, 42, 21, 40, 41)	4 (SC8, 6, 20, 19)
Outfit MNSQ > 1.5	7 (HC13, 46, 36, 34, 15, 33, 3)	7 (EM44, 48, 43, 42, 21, 47, 7)	5 (SC21, 8, 6, 14, 19)
Targeting			
Difference between person and item means	0.95	2.59	3.92
Dimensionality (PCA of residuals)			
Variance explained by the Rasch dimension (observed / expected)	49.9% / 50.3%	54.9% / 58.4%	66% / 64.8%
Variance explained by the items	13.8%	13.9%	12.6%
Eigen value of the first contrast	10.48	6.49	4.49
Variance explained by the first contrast	8.5%	6%	6.9%
Items loading on first contrast (number, item IDs)	17 (HC 14, 16-29, 52, 56)	9 (EM1, 8-14, 16)	5 (SC3, 10, 12, 13, 17)
Disattenuated correlation between the first and second item clusters	0.92	1	1
Measurement range	1.92 (-0.95 TO 0.97)	2.02 (-0.88 to 1.14)	1.74 (-1.15 to 0.59)

Parameters	Convenience	Economic impact	Coping
No of items / persons	26/54	14/55	24/54
No of categories	5	5	5
Category functioning			
Average measures	Ordered	Ordered	Ordered
Threshold calibration	Disordered	Disordered	Disordered
Category misfit	Nil	Nil	Nil
Separation and reliability statistics			
PSI (person reliability)	1.49 (0.69)	1.26 (0.61)	2.26 (0.84)
ISI (item reliability)	1.7 (0.74)	2.49 (0.86)	3.05 (0.90)
Item misfit			
Infit MNSQ > 1.5	3 (CV 18, 16, 21)	Nil	1 (CP9)
Outfit MNSQ > 1.5	4 (CV 18, 16, 3, 22)	1 (EC7)	2 (CP3, 9)
Targeting			
Difference between person and item means	1.53	1.44	-0.65
Dimensionality (PCA of residuals)			
Variance explained by the Rasch dimension (observed / expected)	35.3% / 37%	52.8% / 55.6%	40.7% / 40.3%
Variance explained by the items	16.9%	16.8%	20.2%
Eigen value of the first contrast	3.69	5.29	4.22
Variance explained by the first contrast	9.2%	17.8%	10.4%
Items loading on first contrast (number, item IDs)	6 (CV13-15, 17, 19, 22)	7 (EC8-14)	9 (CP 13, 14, 17, 19-24)
Disattenuated correlation between the first and second item clusters	0.75	1	0.77
Measurement range	2.07 (-1.21 to 0.86)	2.04 (-0.91 to 1.13)	2.06 (-0.97 to 1.09)

Appendix 14

LID-free item measures

Content removed due to privacy reasons

Supplement 1

Publications

CLINICAL AND EXPERIMENTAL
OPTOMETRY

INVITED SYSTEMATIC REVIEW

Patient-reported outcome measures in amblyopia and strabismus: a systematic review

Clin Exp Optom 2018; 101: 460–484 DOI:10.1111/cxo.12553

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Background: Many patient-reported outcome measures (PROMs) have been developed and/or used to measure the impact of amblyopia and strabismus on quality of life (QoL). Identifying the one with superior quality is important for evaluating the effectiveness of novel therapy for amblyopia and for directing improved clinical decision-making in adults considering strabismic surgery. Therefore, the aim of this review is to identify all PROMs previously developed/used to study the impact of amblyopia and/or strabismus on QoL and to appraise the quality and comprehensiveness of content of the disease-specific instruments.

Methods: A systematic search was carried out in the electronic databases of PubMed, Cochrane, Web of Science and PsycINFO. The quality of content and measurement properties of all the disease-specific instruments were assessed using established quality standards. Further, the content of the instruments were examined for comprehensiveness by categorising each item across the eight ophthalmic QoL domains (activity limitation, concerns, emotional well-being, social well-being, economic, convenience, symptoms and mobility).

Results: Seventy-one PROMs were identified, out of which 32 were amblyopia- and/or strabismus-specific. Out of all the disease-specific instruments, just four have been subjected to modern psychometric tests and only the adult strabismus questionnaire (AS-20) demonstrated good measurement properties. Most of the amblyopia-specific instruments measured the impact of the treatment of amblyopia on children, while most of the strabismus-specific instruments measured concerns related to appearance and treatment outcome in adults. All instruments have gaps in their content and failed to address QoL comprehensively.

Conclusion: All the existing amblyopia- and/or strabismus-specific instruments fall short of desired quality and/or comprehensiveness of content. The review identifies the need for developing an instrument with superior quality and discusses potential directions of future research.

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Key words: amblyopia, patient reported outcome, quality assessment, quality of life, questionnaire, strabismus

Amblyopia and strabismus are common developmental conditions of childhood and are known to cause functional deficits like impaired stereoscopic depth perception and defective sensory, motor, visual cognition and prehension skills.[1–3] These functional deficits manifest in the individual as imprecise or inefficient performance of real-life activities like reading, grasping and driving and affect quality of life (QoL).[4,5] Apart from the implications of these functional deficits, socially noticeable strabismus also affects the psychosocial and emotional well-being of individuals.[6–10]

Analysis of the cost-effectiveness of screening for amblyopia and its utility are limited by the lack of evidence about the long-term impact, the degree of disability and the impact of amblyopia on QoL.[11–13] Incorporating patient-reported outcome measures (PROMs) as one of the treatment outcomes is considered important to substantiate the recent evidence claiming benefits of adult amblyopia therapy.[14,15] It is also important to evaluate the impact of amblyopia against the well-known negative impact of treatment of amblyopia (particularly patching therapy) to facilitate a broader understanding of the realities and to potentially improve treatment compliance.[16,17] Further, a robust and comprehensive strabismus-specific instrument is vital to substantiate the functional benefits of strabismus surgery in adults[18,19] and the psychosocial benefits in those who are barely able to visualise their ocular misalignment due to severe bilateral visual impairment.[20] Also a recent study suggests incorporating QoL criteria to define the success of strabismus surgery, as individuals classified as surgical failures by motor and diplopia criteria showed improvement in QoL scores.[21]

While many instruments are currently available or in the process of development for these purposes, it is vital to identify a scientifically robust and sound instrument for reliable, precise and comprehensive measurement of QoL, as the results are crucial to guide clinical decisions and health-care policies.

Thus the objectives of this systematic review are to:

1. identify all PROMs currently used to study the impact of amblyopia and/or strabismus;
2. appraise the content, quality and measurement properties of the disease-specific instruments to identify instrument(s) with high quality and robustness; and
3. examine the content of all disease-specific instruments and identify the instrument(s) that offer comprehensive measurement of QoL.

METHODS

The systematic review and analysis was carried out by two investigators (SEK and JK) independently and any discrepancy was resolved by discussion and consensus.

Search strategy

The electronic databases of PubMed, Cochrane, Web of Science and PsycINFO were searched using the following syntax: (Amblyopia OR 'Lazy eye' OR Strabismus OR Squint OR Exotropia OR Esotropia OR Hypotropia OR Hypertropia OR 'Cross* eye*') AND ('self-report*' OR 'symptom*' OR 'self-esteem' OR Satisfaction OR 'Patient reported outcome' OR Questionnaire OR Driving OR Concern OR Disability OR 'Psycho*' OR Emotional OR Social OR 'Quality of life')

No age restriction was applied. Articles in English, published prior to July 2016 were included, if they:

1. described the development or validation of a PROM for amblyopia or strabismus or
2. used a PROM to study the impact of amblyopia and/or strabismus on QoL or any of its attributes.

Qualitative articles, conference abstracts, review papers and PROMs measuring the impact of the disease on family (other than self) were not included. The bibliographies of the articles included were handsearched for additional relevant references. Figure 1 represents the screening and selection of articles for the review. Eight full-text articles were excluded, as they did not measure QoL constructs. Reasons for exclusion are displayed in Appendix 1.

Quality assessment

The quality of content, psychometric properties and measures of validity, reliability and responsiveness of all disease-specific instruments were evaluated using established quality standards, displayed in Appendix 2. These quality standards were adapted from Khadka, McAlindin and Pesudovs[22] and comply with the FDA[23] and COSMIN[24,25] standards for evaluating the quality of health-related PROMs. These standards are being used by our research group to appraise PROMs developed for various ocular diseases.

QUALITY OF CONTENT

Instruments for which content development was guided by comprehensive consultation with patients and item selection was guided by pilot testing of the instrument using Rasch or factor analysis, received high quality grading.[26]

PSYCHOMETRIC PROPERTIES

The psychometric properties of the instruments could be tested, based on classical test theory or Rasch analysis model.

The classical test theory uses summary scoring by assuming equal difficulty of all items and equal distance between response categories and relies on Cronbach's alpha for its reliability. Unidimensionality is tested using factor analysis. The assumptions of the classical test theory have been disproved by modern psychometrics and the results can be significantly distorted by the presence of missing data or a large sample.[27]

Instruments validated based on classical test theory received high quality grading, if they had up to five per cent of missing data, end-point responses up to five per cent for the majority of items, internal consistency by Cronbach's alpha in the range 0.7 to 0.95 and inter-item correlations less than 0.3. Dimensionality of the instrument was graded superior if the first factor loading was greater than 0.4 for all items, variance explained by the measure using principal component analysis was greater than 60 per cent and the eigenvalue of the first contrast was less than 2.0.[28–31]

The Rasch analysis model is probability based and has its foundation on explicit mathematical models. The items and persons are ranked, based on their difficulty and ability levels, respectively, along a single continuum interval scale. It also provides assessment of critical psychometric properties of the instrument, such as measures of response category utility and functioning, measurement precision, items fit to the instrument, unidimensionality, local item dependency and targeting.[26,27]

Instruments validated using the Rasch analysis model received high grading if the response categories were ordered and evenly spaced, variance explained by the measure was 60 per cent or greater and eigenvalue of the first contrast was less than two (indicating unidimensionality), person separation index 2.5 or greater (indicating measurement precision), item fit mean squares between 0.70 and 1.30, differential item functioning (DIF) less than 0.5 logits and difference between item and person measures up to one logit (indicating targeting).[22,26]

VALIDITY, RELIABILITY AND RESPONSIVENESS

The studies that used these instruments were screened for measures of validity (convergent, discriminant, concurrent and known group), reliability (test-retest, inter-observer/inter-mode agreement) and responsiveness (score changes over time and effect size). Instruments demonstrating correlation of 0.3 to 0.9 tested against appropriate measures were graded high for convergent and concurrent validity and correlation of less than 0.3 against appropriate measures was graded high for discriminant validity. Significant difference between appropriate clinical groups was given high grade on known group validity. An intra-class correlation of 0.8 or greater, limits of agreement less than minimally important difference (MID), weighted kappa greater than 0.8, inter-modal correlation greater than 0.70, score changes over time greater than MID and effect size of one or greater were graded high.[22,26]

OVERALL QUALITY

The PROM that received maximum number of higher grades across all the quality criteria was considered superior.

Content extraction

The content of all disease-specific instruments, excluding proxy measures and those instruments, the items of which were not reported, were included for content extraction. Each item was examined and was classified under eight pre-identified ophthalmic QoL domains, namely activity limitation, concerns, emotional well-being, social well-being, economic, convenience,

symptoms and mobility (Appendix 3).[32–34] Each instrument was examined for the main attributes it measures. Further, items from all these instruments were pooled together under each QoL domain and unique items were identified. The number of unique items in each QoL domain was calculated to ascertain what these instruments predominantly measure and to identify the QoL domains that are least represented.

RESULTS

The search yielded 108 articles addressing 71 PROMs: three generic, two vision-specific, 32 disease-specific (amblyopia and/or strabismus-specific), 14 psychological measures, five behavioural inventories, three beliefs and cognition, one social support, five appearance-related, four functional measures and two utilities. Out of the 32 disease-specific, 12 were amblyopia-specific, 18 were strabismus-specific and two were amblyopia and strabismus-specific. The list of these instruments and the number of studies that used them are displayed in Table 1.

What do the widely used non-disease-specific instruments measure?

The medical outcomes Short Form (SF-36) and the Pediatric Quality of Life Inventory (PedsQL) are the two generic instruments that have been used widely in adults and children, respectively. The SF-36 instrument measures the health-related QoL across eight domains: physical functioning, role limitations due to physical problems, social functioning, bodily pain, general mental health, role limitations due to emotional problems, vitality and general health perceptions.[35] The PedsQL measures the physical, emotional, social and school functioning of children with age-specific versions and has both self-reporting by children and proxy.[36]

The National Eye Institute Visual Function Questionnaire (NEI VFQ-25) has been used predominantly to measure vision-related QoL and to validate new instruments. The developers claim that the NEI VFQ measures difficulties with near and distance activities, limitations in social functioning, role limitations, dependency on others, mental symptoms, driving difficulties, limitations with peripheral vision, colour vision and ocular pain.[37]

Hospital Anxiety and Depression Scale (HADS) and the Derriford Appearance Scale (DAS-59 and DAS-24) have been widely used to evaluate the psychological problems and appearance-related distress and anxiety in adults with strabismus. The HADS is a validated 14-item instrument that detects the state of depression and anxiety of those undergoing treatment for

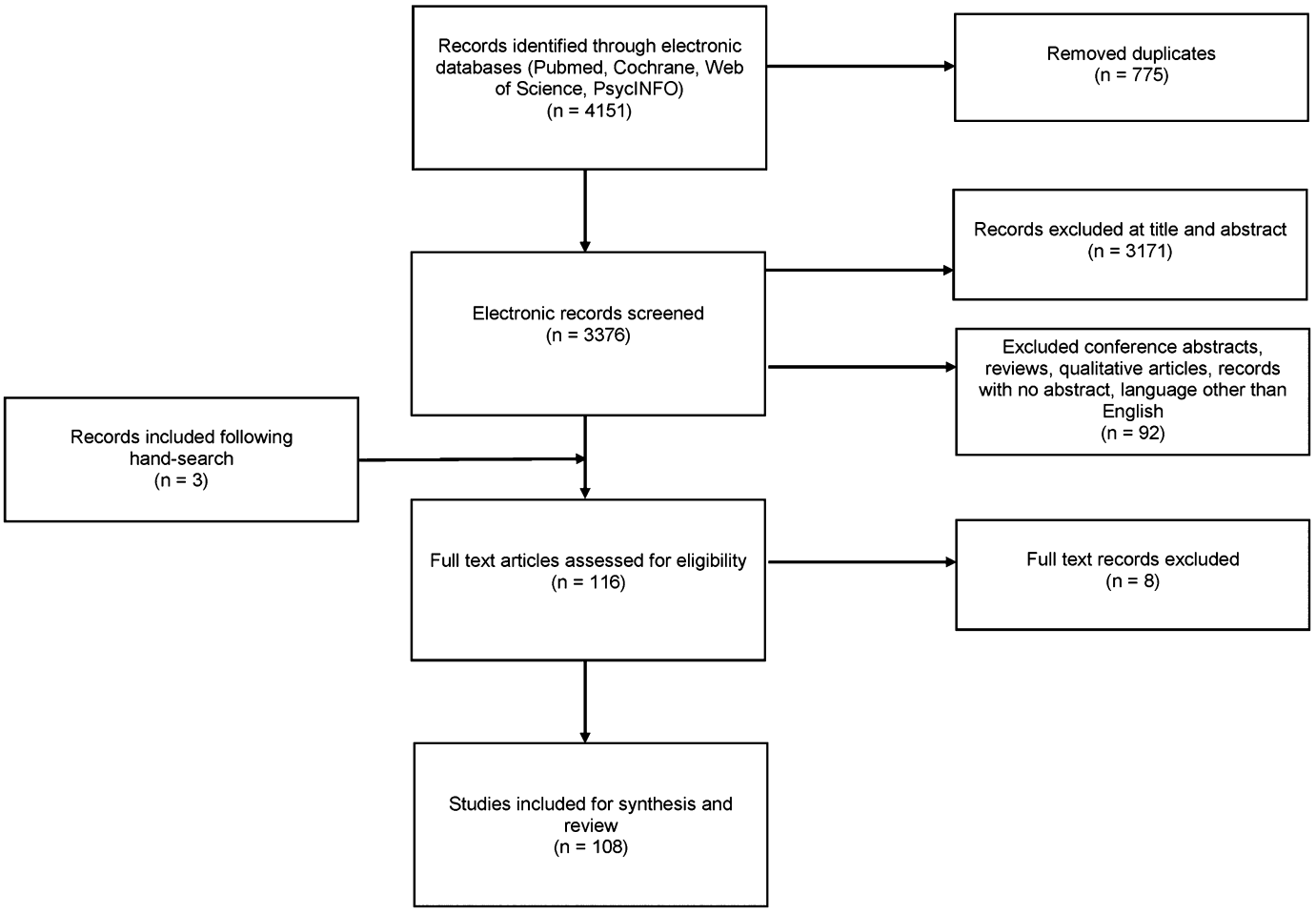

Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram displaying the process of article selection for review

Instrument (number of studies that used them, n)

Generic – *measures general well-being and contains generic items that tap into a range of quality of life (QoL) domain (e.g. functioning, social and emotional well-being, concerns and convenience)*

Medical outcomes Short Form health surveys and variants (SF-36 [n = 3],[35,99,100] SF-20 [n =1],[62] SF-12 [n =1],[83] SF-8 [n =1][101])
WHOQOL-BREF (n = 2)[71,102]
Paediatric Quality of Life Inventory (PedsQL) (n = 3)[36,103,104]

Vision-specific – *measures impact of visual impairment or disability and contains vision-specific items that taps into one or a range of QoL domains*

National Eye Institute Visual Function Questionnaire (NEI VFQ-25) (Original [n = 7],[37,42,43,83,101,105,106] Chinese [n = 4],[78,86,107,108] German [n = 1][109])
Visual function 14 (VF-14) (n = 3)[35,110,111]

Amblyopia-specific – *measures impact due to amblyopia and its treatment and contains amblyopia-specific items that tap into one or a range of QoL domains*

Amblyopia Survey (n =1)[46]
Patching Success Questionnaire (PSQ) (n = 2)[48,112]
Amblyopia Treatment Index (ATI) (English [n =7],[49,50,58,59,90,113,114] Chinese [n = 1][115])
Child Amblyopia Treatment Index (n = 1)[50]
Perceived Psychosocial Questionnaire (PPQ) (n = 1)[51]
Emotional Impact of Amblyopia Treatment Questionnaire (n = 2)[52,116]
Occlusion Patch Comfort Questionnaire (OCQ) (n = 1)[53]
Child Amblyopia Treatment Questionnaire (CATQoL) (n = 1)[54]
Children's Vision for Living Scale (CVLS) (n = 1)[55]
46-item QoL questionnaire (n = 1)[56]
QoL questionnaire for children with anisometropic amblyopia (n = 1)[57]
Socio-Professional Integration Questionnaire (n = 1)[47]

Strabismus-specific – *measures impact due to strabismus and its treatment and contains strabismus-specific items that tap into one or a range of QoL domains*

Adult Strabismus-20 (AS-20) questionnaire (Original [n = 24],[21,37,39,42,43,60,63,73,79,82,105,117–129] Adapted [n = 1],[130] Chinese [n = 4],[77,78,86,131] Danish [n = 1][80])
Intermittent Exotropia Questionnaire (IXTQ) (n = 8)[61,81,103,128,132–135]
Perspectives Questionnaire (n = 1)[74]
Disability Questionnaire (n = 2)[65,136]
Repertory Grid (n = 1)[66]
Perceived Visibility of Strabismus (n = 2)[63,73]
Expectations of Strabismus Surgery Questionnaire (n = 1)[73]
Psychosocial Experience Questionnaire (n = 1)[67]
Vision Function Scale (n = 1)[62]
8-item QoL instrument (n = 1)[64]
Exotropia Symptom Questionnaire (n = 1)[69]
Effect of Diplopia Questionnaire (n = 1)[76]
Post Strabismus Surgery Symptom Questionnaire (n = 1)[75]
Psychosocial effects of strabismus pre- and post-operative questionnaire (n = 2)[68,137]
Strabismus Survey (n = 1)[45]
Satisfaction of Surgical Outcome (n = 1)[70]

Strabismus-specific – Adapted from generic instruments (non-strabismus specific instruments were modified by altering or adding items to measure the QoL impact of strabismus)

Visual Analog Scale (n = 1)[71]
Modified RAND Health Insurance Study QoL Instrument (n = 1)[72]

Amblyopia and strabismus-specific – *measures impact due to amblyopia and strabismus and its treatment and contains disease-specific items that tap into one or a range of QoL domains*

Amblyopia and Strabismus Questionnaire (A&SQ) (Original – Dutch [n = 3],[83,138,139] English [n = 5],[85,88,100,105,123] Chinese [n = 2],[86,140] Italian [n = 1][87])
Psychological Impact Questionnaire (PIQ) (n = 2)[84,141]

Psychological measures – *measures psychological impact and contains items that tap into a range of psychological disorders*

Center for Epidemiologic Studies Depression Scale – Revised (CESD-R) depression screening questionnaire (n = 1)[126]
Children's Depression Inventory (CDI) (n = 1)[142]
DS-14 distressed personality questionnaire (n = 1)[126]

List of all patient-reported outcome measures (n = 71) used to study the impact of amblyopia and strabismus and number of studies that used them (n)

Instrument (number of studies that used them, n)

Hopkins Symptom Check List (HSCL) (n = 2)[45,46]
Hospital Anxiety and Depression Scale (HADS) (n = 8)[38,63,71,73,99,102,108,143]
Liebowitz Social Anxiety Scale (LSAS) (n = 2)[99,143]
Perceived Stress Index (PSI) (n = 1)[51]
Psychiatric Symptom Checklist-90-Revised (SCL-90-R) (n = 1)[143]
Screen for Child Anxiety Related Emotional Disorders (SCARED) (n = 1)[142]
Harter Self-Perception Profile for Children (SPPC) (n = 1)[144]
Fear of Negative Evaluation (FNE) scale (n = 1)[63]
Rosenberg Self-esteem Scale (n = 1)[145]
Screening for Anxiety (n = 1)[146]
Screening for Depression – US Preventive Services Task Force and National Institute for Health and Care Excellence (n = 1)[146]
Behavioural inventories – *measures anomalous behaviours and problems in social adjustment*

Behaviour Assessment System for Children (n = 1)[17]
Korean Child Behavior Checklist (CBCL) (n = 1)[90]
Rutter scale (n = 1)[147]
Bristol Social Adjustment guides (n = 1)[147]
Revised Rutter Parent Scale for Preschool Children (n = 1)[52]
Beliefs and cognition – *measures perception and beliefs of the patient about themselves and the condition*

Revised Illness Perception Questionnaire (n = 1)[63]
Treatment Representations Inventory (n = 1)[63]
Pictorial Scale of Perceived Competence & Social Acceptance for Young Children (n = 1)[148]
Social support – *measures support from family and others*

Multidimensional Scale of Perceived Social Support (MSPSS) (n = 1)[63]

Appearance-related – *measures appearance-related distress and perceptions*

Derriford Appearance Scale (DAS) (DAS 59 [n = 3],[39,71,102] DAS 24 [n = 2][38,73])
Salience of Appearance scale (CARSAL) (n = 2)[38,63]
Valence of Appearance scale (CARVAL) (n = 2)[38,63]
Iowa-Netherlands Comparison Orientation Scale (n = 1)[38]
Physical Appearance Discrepancy questionnaire (n = 1)[38]
Functional measures – *measures difficulties in performing activities of daily living*

Child's Balance Performance in Daily Life (n = 1)[148]
Index of ADL (n = 1)[35]
Instrumental ADL (n = 1)[35]
Sheehan Disability Scale (n = 2)[99,143]
Utilities – *measures the value of health to the patient through patient's preference*

Time trade off (n = 5)[111,149–152]
Standard gamble (n = 2)[151,152]

Table 1. Continued

physical health problems.[38] The DAS-59 was developed for those with congenital and acquired facial or bodily disfigurements and deformities and measures distress and problems in social functioning due to appearance. The domains include general self-consciousness of appearance, social self-consciousness of appearance, sexual and bodily self-consciousness of appearance, negative self-concept, facial self-consciousness of appearance, physical distress and dysfunction and focus on potential benefits of plastic and aesthetic surgery.[39]

Generic QoL instruments offer a superficial understanding of a person's well-being, as they do not contain disease/condition-specific items to capture the real-life implications of the disease and may not be sensitive to the disease and changes in QoL after intervention. Similarly, psychological and behavioural inventories measure general depression or behavioural problems that are not specific to the disease. Utilities that are used for cost-effective analysis offer global measures of QoL and lack resolution (ability to differentiate between different levels of ability). The non-disease-specific instruments generally lack discriminatory ability and demonstrate poor targeting to the respondent's ability.[40,41]

Studies have shown that the NEI-VFQ is less sensitive, responsive and reliable compared to the adult strabismus (AS-20) questionnaire, which was developed specifically for adults with strabismus.[37,42,43] Moreover, the overall score and many of the subscales of the NEI-VFQ were found to be invalid.[44] The credibility of using non-disease-specific instruments to understand the impact of a disease or to evaluate the effectiveness of an intervention is thus questionable. Hence this review focuses on the disease-specific instruments used to study the impact of amblyopia and/or strabismus.

Disease-specific instruments

The first strabismus-specific survey instrument was developed in 1993 by Satterfield, Keltner and Morrison[45] and was used to assess the psychosocial implications of strabismus. Following this, Packwood and colleagues[46] in 1999, developed a survey to measure the psychosocial effects of isolated amblyopia (non-strabismic amblyopia). From then on, many instruments have been developed to study the disease impact and to evaluate the treatment outcome. Thirty-two instruments have been developed over the past 24 years, out of which 12 have been developed in the last four years.

Amblyopia-specific instruments

CHARACTERISTICS

The characteristics of all amblyopia-specific instruments are summarised in Table 2. Twelve amblyopia-specific instruments were identified; however, only two instruments, namely, the Amblyopia Survey[46] and the Socio-Professional Integration Questionnaire,[47] measure the impact of amblyopia itself. The other 10 instruments, namely the Patching Success Questionnaire,[48] the Amblyopia Treatment Index (ATI),[49] the child Amblyopia Treatment Index (cATI),[50] Perceived Psychosocial Questionnaire,[51] Emotional Impact of Amblyopia Treatment,[52] the Occlusion Patch Comfort Questionnaire,[53] Child Amblyopia Treatment Questionnaire,[54] Children's Vision for Living Scale (CVLS),[55] 46-item QoL questionnaire[56] and a QoL questionnaire for anisometropic amblyopia,[57] measure the impact of treatment of amblyopia by patching or atropine. The Amblyopia Survey is the only questionnaire developed for adults and measures the psychosocial impact of amblyopia.[46] All treatment-related questionnaires were developed for children and six of them are proxy measures (measures the impact on children as reported by parents).[48,49,51–53,56] These instruments predominantly explore the child's experience undergoing treatment and measure the inconveniences affecting compliance and adherence to the treatment. While most instruments were developed generally for amblyopia, two were developed specifically for isolated amblyopia (amblyopia without strabismus): the Amblyopia Survey measuring impact of non-strabismic amblyopia[46] and a QoL questionnaire measuring the impact of treating anisometropic amblyopia on children.[57]

QUALITY

The quality assessments of the amblyopia-specific instruments are summarised in Table 3. The CVLS is the only instrument that was developed, based on patient's perspectives and has been validated using Rasch analysis; however, the scale shows multidimensionality.[55] The ATI,[58,59] cATI[50] and the QoL questionnaire for anisometropia,[57] which were developed based on clinician's perspectives and literature shows good acceptability, internal consistency and dimensionality using classical test theory-based psychometric properties and factor analysis but has not been validated by modern psychometric tests. The Amblyopia Survey,[46] which is the only instrument developed for adults, has not been subjected to validation.

Strabismus-specific instruments

CHARACTERISTICS

Table 4 displays the characteristics of all strabismus-specific instruments. Sixteen strabismus-specific instruments were identified, out of which 14 were developed specifically for strabismus and two were adapted from non-strabismus-specific instruments. Out of all, six instruments, namely, the Adult Strabismus-20 (AS-20) questionnaire,[60] the Intermittent Exotropia Questionnaire (IXTQ),[61] the Vision Function Scale,[62] the Perceived Visibility of Strabismus,[63] Strabismus Survey[45] and an eight item QoL instrument[64] were developed to measure the impact of strabismus on QoL. The Disability Questionnaire,[65] the Repertory Grid,[66] the Psychosocial Experience Questionnaire,[67] Psychosocial Effects of Strabismus Questionnaire,[68] the Exotropia Symptom Questionnaire,[69] Satisfaction of Surgical Outcome,[70] the adapted Visual Analog Scale[71] and the modified RAND Health Insurance Questionnaire,[72] were developed to mainly assess the improvement in psychosocial well-being post-strabismus surgery. The Expectations of Strabismus Surgery Questionnaire,[73] the Perspectives Questionnaire[74] and the Post-surgery Symptom Questionnaire[75] measure the patient's expectations about post-operative symptoms and concerns about treatment outcome. The Effect of Diplopia Questionnaire[76] is the only diplopia-specific instrument and measures the impact of post-operative diplopia on daily life. The IXTQ is the only questionnaire with age-specific self-reporting and proxy versions to measure the impact of intermittent exotropia in children. The eight-item QoL questionnaire, the RAND Health Insurance QoL Questionnaire, the Vision Function Scale and the Effect of Diplopia Questionnaire were used to study the impact on children; however, the former two are proxy measures and latter two were not specifically developed for children. The AS-20 questionnaire has been translated from English to Chinese,[77,78] Hindi, Telugu[79] and Danish[80] and has been used widely to study the impact and evaluate the effectiveness of strabismus intervention.

QUALITY

The IXTQ questionnaire is the only validated child-specific questionnaire for strabismus and was developed using patients' perspectives. The quality assessment of the IXTQ is shown in Table 5. Despite holding good classical test theory-based psychometric properties, the instrument (child and proxy versions) does not demonstrate good measurement precision and unidimensionality, when validated using the Rasch model.[81]

The quality assessment of the strabismus-specific instruments developed for adults is shown in Table 6. The AS-20 questionnaire has been translated into many languages and has been validated by multiple studies. It has been shown to have good reliability,[43] responsiveness[37] and validity;[42] however, validation of the English AS-20 using Rasch analysis revealed that two subscales (interaction and general function) fall short of measurement precision.[82] The Hindi and Telugu versions of the AS-11 scale and the eight-item psychosocial and nine-item functional subscales shows good dimensionality, fit and targeting but have satisfactory measurement precision.[79] The Chinese[77,78] and the Danish[80] versions of AS-20 were found to have high ceiling effects and the nine-item functional subscale of Chinese AS-20 lacked precision. The Danish AS-20 has not been tested using the Rasch analysis model. The clinician-derived 'Expectations of Strabismus Surgery Questionnaire' showed good internal consistency and acceptable dimensionality; however, it has not been validated by Rasch analysis.[73]

Amblyopia and strabismus-specific instruments

CHARACTERISTICS

Table 7 displays the characteristics of two instruments, namely, the Amblyopia and

Name of the instrument Country of origin; intended population Number of items; Language; Self/Proxy	Proposed aim	QoL domains addressed	Question format	Response categories
Condition-specific				
Amblyopia Survey[46] USA; over 15 years 8 items; English; Self	To assess the psychosocial effects of growing up and living with non-strabismic amblyopia	Activity limitation, concerns, emotional well-being and economic impact	Effect of amblyopia on self-image? Did amblyopia interfere with work?	Five-point multiple (no concern, rarely concern, think about occasionally, worry about, major lifestyle concern / advantage, no effect, slight problem, moderate problem, severe problem)
Socio-Professional Integration Questionnaire[47] Romania; 12 to 17 years 12 items; unspecified; Self	To evaluate the socio-professional difficulties faced by amblyopic patients	Not reported	Not reported	Not reported
Treatment-related				
Patching Success Questionnaire (PSQ)[48] Netherlands; child 60 items; English; Proxy	To explore the impact of amblyopia and its treatment	Concerns, activity limitation, convenience, emotional and social well-being	I expect to patch my child as recommended; I am concerned about my child's visual impairment; If left untreated, what are the chances that your child's visual impairment will restrict his/her future choice of occupation	Five-point multiple (strongly disagree to strongly agree/ very low, somewhat low, neither low nor high [i.e. 50/ 50], somewhat high, very high)
Amblyopia Treatment Index (ATI)[49] USA; child 3 to 6 years 20 items; English; Proxy	To assess the impact of amblyopia treatment on the child and family	Concerns, activity limitation, emotional and social well-being, convenience and symptoms	My child does not seem to mind wearing the patch once it is on; My child does not seem to mind using the drops	Five-point agreement scale (strongly agree, agree, neither agree or disagree, disagree, strongly disagree and not applicable)
Child Amblyopia Treatment Index (cATI)[50] USA; over 7 years 19 items; English; Self	To assess the impact of amblyopia treatment from the child's perspective	Concerns, emotional well-being, convenience and symptoms	It bothers me to use the drops	Five-point frequency scale (always, a lot, sometimes, a little, never and not applicable)
Perceived Psychosocial Questionnaire (PPQ)[51] UK; child 10 items; English; Proxy	To measure the psychosocial effects of occlusion therapy as perceived by carers	Emotional and social well-being	Not reported	Not reported
Emotional Impact of Amblyopia Treatment Questionnaire[52] UK; over 3 years 15 items; English; Proxy	To explore experience of treatment for child and family, child's general well-being since diagnosis	Concerns, emotional and social well-being	How well has your child been coping with his/her treatment? Have you had any difficulties getting your child to wear his/her glasses? Do you worry about your child's vision? Over the last three months has your child been: happy/ unhappy	Multiple (very well, fairly well, not very well, not coping at all/ very easy, fairly easy, fairly difficult, very difficult/ a lot, slightly, occasionally, not at all/ happy all of the time to unhappy always)
Occlusion Patch Comfort Questionnaire (OCQ)[53] Netherlands; child 21 items; English; Proxy	Evaluate comfort of wear with different eye patch used in amblyopia treatment	Concerns, emotional and social well-being, convenience and symptoms	The patch my child wore was; The patch sticks to the skin of my child; How much pain did your child have when removing the patch from the skin? How well did	Multiple (very large, large, about right, small, very small / very strong, strong, about right, weak, very weak /none, mild, moderate, severe, very severe /excellent, good,

Characteristics of amblyopia-specific quality of life instruments

Name of the instrument Country of origin; intended population Number of items; Language; Self/Proxy	Proposed aim	QoL domains addressed	Question format	Response categories
			the patch stick on the eye of your child? My child does not seem to mind wearing the patch once it is on	fair, poor, very poor, NA/ strongly agree, agree, neither agree nor disagree, disagree, strongly disagree / visual analogue 0 to 10)
Child Amblyopia Treatment Questionnaire (CATQoL)[54] UK; 4 to 7 years 11 items; English; Self	To assess the health-related QoL implications of amblyopia treatment from child's perspective	Concerns, emotional well-being, convenience and symptoms	Sad: My patch has not made me feel sad; My patch has made me feel a little bit sad; My patch has made me feel a bit sad; My patch has made me feel quite sad; My patch has made me feel very sad	Five- or six-point severity scale; forms a part of the question itself
Children's Vision for Living Scale (CVLS)[55] Saudi Arabia; 5 to 12 years 21 items; Arabic; Self	To assess the vision-related QoL of children with amblyopia who are undergoing treatment	Activity limitation, concerns, emotional well-being, symptoms and mobility	How much do you think that you are good looking?	Five-point difficulty scale (not at all, a little, moderately, a lot, extremely)
46-item QoL questionnaire[56] Romania; 4 to 16 years 46 items; Romanian; Proxy	To measure QoL of parents and children with amblyopia and assess the psychosocial implication for their family and adherence to treatment	Not reported	Not reported	Not reported
QoL questionnaire for children with anisometropic amblyopia[57] China; 7 to 12 years 16 items; Chinese; Self	To assess the impact of amblyopia treatment on health-related QoL through the perspective of children undergoing amblyopia treatment	Activity limitation, concerns, emotional and social well-being	How difficult do you feel when reading paper books in the daytime?	Five-point difficulty scale (not difficult at all, a little difficult, moderately difficult, extremely difficult, nothing could be seen)

Table 2. Continued

Strabismus Questionnaire (A&SQ)[83] and the Psychological Impact Questionnaire,[84] which were developed to measure the impact of both amblyopia and strabismus. Both these instruments were developed for adults. The A&SQ was first developed in Dutch and later translated into English,[85] Chinese[86] and Italian[87] and has been widely used.

QUALITY

Table 8 displays the quality assessment of the A&SQ. The Dutch and the English versions of the A&SQ were shown to have good acceptability and internal consistency;[83,85] however, only the English version was validated using Rasch analysis and was found to lack unidimensionality. In addition, it was also found that the targeting of the instrument to the ability of the respondents was just fair for the isolated amblyopia group as compared to good targeting for the strabismus group.[88] The Chinese and Italian versions had high floor and ceiling effects, demonstrating fair or poor targeting.[86,87] The Psychological Impact Questionnaire has not been validated.

Content coverage

Three hundred and eighty-nine items were pooled from 22 instruments (five amblyopia-specific, 15 strabismus-specific and two amblyopia and strabismus-specific). On examining what each item measured, some items were found to be generic, measuring general/overall impact (for example, overall satisfaction with strabismus surgery) and some could not be classified, as they measured something different from QoL (for example, knowledge of the condition). These were not considered for item extraction and evaluation.

The amblyopia-specific instruments predominantly measure activity limitation and emotional impact related to treatment, in addition to concerns and inconveniences caused by the treatment. The strabismus-specific instruments mainly measure concerns related to appearance and treatment outcome. The amblyopia- and strabismus-specific instruments measure activity limitation, concerns and emotional well-being. None of these instruments address QoL constructs comprehensively. The distribution of the number of items of each instrument across the eight ophthalmic QoL domains and the gaps in measurement are displayed in Table 9.

Reference Study location (number of subjects, n); Original / Revised / Adapted (Scale / Subscale)	Subscales (number of items)/ factors (number of items)	Content development	Classical test theory-based psychometric properties	Rasch-based psychometric properties	Measures of validity / reliability and responsiveness
Amblyopia Treatment Index (ATI) – English					
Cole et al. (2001)[49] USA (n = 64); Original (Scale)	Unclassified (20) Factor analysis revealed 11 items	Item identification: C Item selection: B	Acceptability: A Targeting: B Internal consistency: A (for 11 items) Item dependency: NR Dimensionality: A (for 11 items)		
Holmes et al. (2003)[59] USA (n = 364); Revised (Scale)	Three factors (16) Adverse effects of treatment (8) Difficulties with compliance (5) Social stigma of the treatment (3)		Acceptability: A Targeting: B Internal consistency: A Item dependency: NR Dimensionality: A		
Holmes et al. (2008)[58] USA (n = 794); Revised (Scale)	Three factors (16) Adverse effects of treatment (8) Treatment compliance (5) Social stigma (3)		Acceptability: A Targeting: B Internal consistency: A Item dependency: NR Dimensionality: A		
Amblyopia Treatment Index (ATI) – Chinese					
Xu et al. (2014)[115] China (n = 109); Adapted (Scale) Translated from original	Three factors (16) Adverse effects of treatment (6) Difficulties with compliance (6) Social stigma (4)		Acceptability: A Targeting: B Internal consistency: A Item dependency: NR Dimensionality: A		Reliability (ICC): A
Child Amblyopia Treatment Index (cATI) – English					
Felius et al. (2010)[50] USA (n = 233); Original (Adapted from ATI)	Two factors (10) Adverse effects (7) Treatment compliance (3)	Item identification: C Item selection: B	Acceptability: A Targeting: B Internal consistency: A Item dependency: NR Dimensionality: A		
Children's Vision for Living Scale (CVLS) – Arabic					
Bokhary et al. (2013)[55] Saudi Arabia (n = 48); Original (Scale)	Unclassified (21)	Item identification: A Item selection: A	Internal consistency: A Dimensionality: C	Model: PCM Response category: A Dimensionality: C Measurement precision: B Item fit statistics: A DIF: B Targeting: A	
QoL questionnaire for children with anisometropic amblyopia – Chinese					
Chen et al. (2016)[57] China (n = 44); Original (Scale)	Four factors (16) Visual function (6) Psychosocial impact (6) Social interaction (2) Worries about vision (2)	Item identification: C Item selection: B	Acceptability: A Targeting: NR Internal consistency: A Item dependency: NR Dimensionality: A		Reliability (ICC): A Responsiveness: B

A: high/positive quality, B: fair/minimal acceptable quality, C: negative/poor quality, DIF: differential item functioning, ICC: intra-class correlation, NR: not reported, PCM: partial credit model.

Table 3. Quality assessment of amblyopia-specific instruments

Name of the instrument Country of origin; intended population Number of items; Language; Self/Proxy	Proposed aim	QoL domains addressed	Question format	Response categories
Condition-specific				
Adult Strabismus-20 (AS-20) questionnaire[60] USA; adults 20 items; English; Self	To assess health-related QoL of adults with strabismus	Activity limitation, concerns, emotional and social well-being, convenience and symptoms	I worry about what people will think about my eyes	Five-point (never, rarely, sometimes, often and always)
Intermittent Exotropia Questionnaire (IXTQ)[61] USA; children 12 items; English; Self: child 5–7 years (C1) & child 8–17 years (C2) Proxy (P): 2–17 years	Impact of intermittent exotropia upon health-related QoL of children and parents	Concerns, social well-being and convenience	C1: Are you worried about your eyes? C2: I worry about my eyes P: My child worries about his/her eyes	C1: three-point (not at all, sometimes, a lot, I don't know) C2 and P: five-point (never, almost never, sometimes, often, almost always [I don't know included for C2])
Vision Function Scale[62] USA; 8–46 years 9 items; English; Self	Measure visual function of intermittent exotropia patients	Activity limitation, concerns, emotional well-being and symptoms	How often have you had episodes of blurred vision and/or double vision during the past four weeks? To what extent does bright light and/or dim light affect your ability to do certain tasks?	Multiple (six-point: all of the time, most of the time, a good bit of the time, some of the time, a little of the time and none of the time / five-point: extremely, quite a bit, moderately, slightly and not at all)
Perceived Visibility of Strabismus[63] UK; over 17 years 1 item; English; Self	To assess the perceived visibility of strabismus from the patient's view	Symptoms	Rate the visibility of the strabismus on a seven-point scale	Seven-point: one (not at all visible) to seven (extremely visible)
Strabismus Survey[45] USA; over 15 years 25 items (including medical history); English; Self	To assess the impact of noticeable strabismus	Concerns, social and emotional well-being	The effect of strabismus on relations with same-sex friends	Five-point (advantageous or good, no effect, slight problem, moderate problem, severe problem)
8-item QoL instrument[64] India; under 16 years 8 items; native language (unspecified); Proxy	Evaluate the psychosocial and emotional consequences of strabismus on the child and family	Concerns, emotional and social well-being	How distressed do you get when you see (squint in the) face of your child? How distressed does the child get when other people remark about the facial feature (squint) of your child?	Multiple (four-point: not at all, a little, moderately, extremely/ ordinal: yes and no)
Treatment-related				
Disability Questionnaire[65] USA; adults 6 items; English; Self 105 items; English; Self	To measure the disability of people with strabismus before and after strabismus surgery	Activity limitation, concerns, emotional and social well-being, economic impact and symptoms	Please indicate on a scale from 1–10, the degree to which your strabismus (eye misalignment) affects your life in the ways described, now and before your surgery	Visual analogue scale (one [no effect] to 10 [severe effect])
Repertory Grid[66] UK; over 18 years 105 items; English; Self	To assess the impact of noticeable strabismus in adults and the psychosocial effects of surgical correction	Concerns, emotional and social well-being	Grid Row: 15 personality traits (e.g. confident, attractive) Column: seven scenarios (e.g. 'myself prior to squint surgery', 'myself now after squint surgery')	Five-point: scored 1–5 with options relevant to the question; for example: score 5 (confident), 4 (fairly confident), 3 (average), 2 (fairly shy), 1 (shy)

Characteristics of strabismus-specific quality of life instruments

Name of the instrument Country of origin; intended population Number of items; Language; Self/Proxy	Proposed aim	QoL domains addressed	Question format	Response categories
Psychosocial Experience Questionnaire[67] USA; over 14 years 11 items preoperative version & 6 items post-operative version; English; Self	To assess psychosocial difficulties faced by patients with strabismus	Activity limitation, concerns, emotional and social well-being, economic impact and symptoms	Did strabismus embarrass you? Did surgery improve your self-esteem/self-image?	Two-point ordinal (Yes or No)
Expectations of Strabismus Surgery Questionnaire[73] UK; over 16 years 17 items; English; Self	To assess expectations about outcomes post-strabismus surgery	Concerns	Please rate how you expect surgery to change the various aspects of your life	Five-point (made considerably worse, made worse, remain the same, improve and considerably improve)
Effect of Diplopia Questionnaire[76] China; 6–68 years 6 items; unspecified language; Self	To measure the impact of post-operative diplopia on daily life	Activity limitation and concerns	Not reported	Ordinal: influence (1), no influence (0)
Perspectives Questionnaire[74] USA; adults (patient & practitioner) 5 items; English; Self	To assess patient and provider perspectives on various factors contributing to strabismus treatment and care	Concerns and symptoms	Please indicate the relative contributions of each of the following (in percent or fraction of 100) to the outcome and value of services related to the care and management of your strabismus problem; Please rate the severity of your strabismus before and after treatment	Multiple open-ended (percentage) Visual analogue scale: 1–10
Post Strabismus Surgery Symptom Questionnaire[75] Korea; adults 9 items; unspecified language; Self	To evaluate patient's expectation of symptoms post-strabismus surgery	Concerns	Subjects were asked to rate each symptom on a scale of 0 to 10	Scale of 0 (absent) to 10 (severe)
Psychosocial effects of strabismus pre- and post-operative questionnaire[68] China; over 16 years 17 items preoperative version and 8 items post-operative version; English; Self Adapted from Menon et al. (2002)[137]	To assess the impact of strabismus on social and personal life preoperatively and post-operatively	Activity limitation, concerns, social and emotional well-being	Effect of strabismus on making new friends? Do you notice any change in your appearance?	Multiple three-point (nil, to some extent, to a large extent) and ordinal response options relevant to each other questions
Exotropia Symptom Questionnaire[69] Korea; children 15 items; English; Self and Proxy	To evaluate clinical pre-operative symptoms and post-operative changes in patients with exotropia	Activity limitation, concerns, social well-being, symptoms and mobility	Question format: not reported Items: Stereopsis, difficulty in sense of distance, etc.	Five-point (none, mild, moderate, severe, extremely severe)
Satisfaction of Surgical Outcome[70] Australia; adults 1 item; English; Self	Satisfaction on surgical outcome of adult strabismus surgery	Concerns	Comment subjectively on the surgical outcome	Five-point (very satisfied, satisfied, neutral, unsatisfied, very dissatisfied)

Continued

Name of the instrument Country of origin; intended population Number of items; Language; Self/Proxy	Proposed aim	QoL domains addressed	Question format	Response categories
Adapted from non-Strabismus specific instruments				
Visual Analogue Scale[71] UK; over 15 years 7 items; English; Self	To assess the psychosocial impact of strabismus after a year of surgery	Concerns and symptoms	To what extent has your strabismus affected your lifestyle? Do you worry about your strabismus?	Visual Analogue Scale (0–10)
Modified RAND Health Insurance Study QoL Instrument[72] USA; under 15 years 41 items; English; Proxy	Evaluate the psychosocial effects of childhood strabismus surgery	Activity limitation, emotional and social well-being, concerns and convenience	Does this child's health keep (him or her) from taking part in ordinary play? Does your child avoid eye contact with you when you talk? Does your child feel close to you?	Multiple (frequency / degree of intensity/ definitely true, mostly true, don't know, mostly false, definitely false/ excellent, good, fair, poor/ a great deal, some, a little, none at all/ very satisfied, somewhat satisfied, neither satisfied nor worried, somewhat worried, very worried)

Table 4. Continued

Out of the 389 items, 117 were unique in terms of their content. Domains: concerns (41), activity limitation (24) and emotional well-being (19) had maximum numbers of items, while economic impact (two) and mobility (three) had the least number of items. The distribution of the items (Figure 2) across the eight QoL domains suggests that there exist limitations in terms of number of items available to measure comprehensively all the important ophthalmic QoL constructs.

Summary of the results

PROMs that have been developed and used to study the impact of amblyopia and/or strabismus were identified and extensively reviewed in terms of quality and content coverage. Seventy-one different PROMs have been used to study the impact of strabismus and/or amblyopia, out of which 32 were strabismus and/or amblyopia-specific. Most of the amblyopia-specific instruments were developed for children and measured the impact of treatment of amblyopia, while most of the strabismus-specific instruments were developed for adults and measured concerns related to appearance and treatment outcome. Only four questionnaires, the CVLS, IXTQ, AS-20 and A&SQ, have been subjected to modern psychometric tests and the AS-20 was found to have better psychometric properties than others; however, none of these instruments offer comprehensive measurement of QoL and have gaps in their contents.

DISCUSSION

This paper extensively reviews all PROMs developed and used in the amblyopia and strabismus disease group. Non-validated instruments were also included for the comprehensiveness of the review. Although myriad instruments have been developed, only a few have been used more than once (Table 1). The review underlines the lack of a comprehensive and valid instrument to measure the impact of amblyopia and strabismus on children and adults by presenting the shortfalls in instrument development, psychometric properties and comprehensiveness of the content.

All the currently available amblyopia-specific instruments for children measure the impact of treatment of amblyopia and none measure the impact of the condition 'amblyopia' itself. The only amblyopia-specific instrument for adults, the Amblyopia Survey, is limited in content and has not been validated.[46] The majority of the strabismus-specific instruments were developed for adults and particularly measure concerns related to noticeable strabismus and outcome of strabismic surgery. The only strabismus-specific instrument with self-reporting for children is the IXTQ;[61] however, no instrument has been developed to measure the sole impact of strabismus on children (other than intermittent exotropia).

Just four of the amblyopia- and/or strabismus-specific instruments, namely, the IXTQ, CVLS, AS-20 and A&SQ, have been validated using the Rasch analysis and only the AS-20 questionnaire demonstrates good psychometric properties.[82] Both the instruments for children, namely, the IXTQ[81] and the CVLS,[55] lack unidimensionality, an important attribute of any valid instrument.[26] A&SQ, the only validated instrument that claims to measure the impact of amblyopia and strabismus, has items which are not specific to amblyopia and falls short of targeting when tested on the isolated amblyopia group and hence, are deemed unsuitable for assessing the impact of amblyopia.[88]

None of the existing instruments offers a comprehensive measurement of QoL either for children or adults. 'Quality of life' is multidimensional and consists of many unidimensional constructs or subscales (for example, emotional well-being, social well-being).[89] Eight ophthalmic QoL

Reference Study location (number of subjects, n); Original / Revised / Adapted (Scale / Subscale)	Subscales (number of items)/ Factors (number of items)	Content development	Classical test theory-based psychometric properties	Rasch-based psychometric properties	Measures of validity / reliability and responsiveness
Intermittent Exotropia Questionnaire (IXTQ) – English					
Hatt et al. (2010)[61] USA (n = 33); Original (Scale) Child & proxy version	One factor (12)	Item identification: A Item selection: A	Acceptability: A Targeting: A Internal consistency: A Item dependency: NR Dimensionality: C		Known group validity: A
Hatt et al. (2010)[103] USA (n = 51); Original (Scale)	Unclassified (11)			Model: ARS Response category: A Dimensionality: C Measurement precision: C Item fit statistics: B DIF: A Targeting: B	Known group validity: A Convergent validity: B (for proxy version)
Leske et al. (2015)[81] USA (n = 575); Revised (Scale) Child (5 to 7 years) version					
Leske et al. (2015)[81] USA (n = 575); Revised (Scale) Child (8 to 17 years) version	Unclassified (11)			Model: ARS Response category: A Dimensionality: C Measurement precision: C Item fit statistics: B DIF: C Targeting: B	
Leske et al. (2015)[81] USA (n = 575); Revised (Scale) Proxy version	Unclassified (11)			Model: ARS Response category: A Dimensionality: C Measurement precision: C Item fit statistics: B DIF: C Targeting: C	

A: high/positive quality, ARS: Andrich rating scale model, B: fair/minimal acceptable quality, C: negative/poor quality, DIF: differential item functioning, NR: not reported.

Table 5. Quality assessment of strabismus-specific instruments for children

domains[34] have been identified in the process of developing PROM for diabetic retinopathy[33] and glaucoma.[32] Although the domains use the same nomenclature across the range of ocular diseases and intend to measure the same construct, each domain contains a different set of items specific to that particular disease, identified by literature review and qualitative research. We examined the content of all the available self-report amblyopia and/or strabismus-specific instruments to see how the items fit into these domains. Most of these instruments measure activity limitation, concerns and emotional constructs of QoL and do not offer comprehensive measurement, even when items from all these instruments were pooled together. Furthermore, these instruments are limited in validity of the content, as most of them were not 'patient derived'. Instruments that are patient derived are regarded more valid, as they reflect the QoL of the patients through their own perspectives.[26] Out of the four validated instruments, only the IXTQ, CVLS and the AS-20 are patient derived; however, none of these instruments offer comprehensive measurement of QoL. Lack of adequate content could be a potential reason why amblyopia and strabismus-specific instruments are often used in conjunction with other measures, particularly one of the psychological and behavioural inventories.[63,73,90]

Negative psychosocial and economic impacts of strabismus are well known. Studies have shown that people with strabismus are negatively perceived,[7,91] not given preference for employment[8,92] and have

Reference Study location (number of subjects, n); Original / Revised / Adapted (Scale / Subscale)	Subscales (number of items)/ Factors (number of items)	Content development	Classical test theory-based psychometric properties	Rasch-based psychometric properties	Measures of validity / reliability and responsiveness
Adult Strabismus-20 (AS-20) questionnaire – English					
Hatt et al. (2009)[60] USA (n = 29 [pilot testing] & 32 [final testing]); Original (Scale)	Two factors (20) Psychosocial (10) Function (10)	Item identification: A Item selection: A (Factor analysis revealed 49 items but 10 items with highest loading in each factor was chosen)	Acceptability: A Targeting: NR Internal consistency: A Item dependency: NR Dimensionality: A		Known group validity: A
Hatt et al. (2009)[42] USA (n = 84); Original (Scale)					Known group validity: A (for subscales)
Hatt et al. (2010)[37] USA (n =106); Original (Scale)					Responsiveness: A
Leske et al. (2010)[43] USA (n = 55); Original (Scale)					Reliability (ICC): A
Leske et al. (2012)[82] USA (n = 348); Revised (Subscales)	Self-perception (5)	Item identification: A Item selection: A		Model: ARS Response category: A Dimensionality: A Measurement precision: A Item fit statistics: B DIF: B Targeting: B	
	Interaction (5)			Model: ARS Response category: A Dimensionality: A Measurement precision: C Item fit statistics: B DIF: A Targeting: C	
	Reading (4)			Model: ARS Response category: A Dimensionality: A Measurement precision: A Item fit statistics: B DIF: B Targeting: A	
	General function (4)			Model: ARS Response category: A Dimensionality: B Measurement precision: C Item fit statistics: B DIF: B Targeting: A	
Adult Strabismus-11 (AS-11) questionnaire & 2 subscales – Hindi & Telugu					
Gothwal et al. (2015)[79] India (n = 584); Revised (Subscales) Translated from original	Overall (11)	Item identification: A Item selection: A		Model: ARS Response category: A Dimensionality: A Measurement precision: B Item fit statistics: A DIF: B Targeting: A	

Quality assessment of strabismus-specific instruments for adults

Reference Study location (number of subjects, n); Original / Revised / Adapted (Scale / Subscale)	Subscales (number of items)/ Factors (number of items)	Content development	Classical test theory-based psychometric properties	Rasch-based psychometric properties	Measures of validity / reliability and responsiveness
	Psychosocial (8)			Model: ARS Response category: A Dimensionality: A Measurement precision: B Item fit statistics: A DIF: B Targeting: A	
	Functional (9)			Model: ARS Response category: A Dimensionality: A Measurement precision: B Item fit statistics: A DIF: B Targeting: A	
Adult Strabismus-20 (AS-20) questionnaire – Chinese					
Yu et al. (2013)[77] China (n = 102); Adapted (Scale) Translated from original	Two factors Psychosocial (10) Functional (10)		Acceptability: NR Targeting: B Internal consistency: A Item dependency: NR Dimensionality: A		Known group validity: A Reliability (ICC): A
Wang et al. (2013)[78] China (n = 255); Adapted (Scale)	Translated from original Two factors Psychosocial (12) Functional (6)		Acceptability: NR Targeting: NR Internal consistency: A Item dependency: NR Dimensionality: B		Known group validity: A Convergent validity: B (only functional subscale)
Wang et al. (2014)[86] China (n = 304); Adapted (Scale)	Translated from original		Targeting: B Internal consistency: A		Known group validity: A Convergent validity: C
Wang et al. (2015)[131] China (n = 247); Adapted (Subscale)	Psychosocial (11)		Item dependency: A	Model: ARS Response category: A Dimensionality: B Measurement precision: A Item fit statistics: A DIF: A Targeting: A	
	Functional (9)		Item dependency: A	Model: ARS Response category: A Dimensionality: B Measurement precision: C Item fit statistics: A DIF: A Targeting: A	
Adult Strabismus-20 (AS-20) questionnaire – Danish					
Ali et al. (2016)[80] Denmark (n = 64); Adapted (Scale) Translated from original			Acceptability: A Targeting: B Internal consistency: A Item dependency: B Dimensionality: NR		Known group validity: A

Continued

Reference Study location (number of subjects, n); Original / Revised / Adapted (Scale / Subscale)	Subscales (number of items)/ Factors (number of items)	Content development	Classical test theory-based psychometric properties	Rasch-based psychometric properties	Measures of validity / reliability and responsiveness
Expectations of Strabismus Surgery Questionnaire (ESSQ) – English					
McBain et al. (2016)[73] UK (n = 220); Original (Scale)	Three factors (17 items) Intimacy and appearance-related issues (5) Visual functioning (7) Social relationships (5)	Item identification: C Item selection: B	Acceptability: A Targeting: B Internal consistency: A Item dependency: NR Dimensionality: B		Convergent validity: B Concurrent validity: A (for visual functioning subscale)

A: high/positive quality, ARS: Andrich rating scale model, B: fair/minimal acceptable quality, C: negative/poor quality, DIF: differential item functioning, ICC: intra-class correlation, NR: not reported.

Table 6. Continued

problems in finding a life partner.[10] These issues are unique to those with socially noticeable strabismus and may significantly affect their QoL. In addition, studies have shown that those with strabismus are at a risk for developing coexistent mental illness and psychiatric disorders;[93,94] however, many of these issues are not reflected in the content of the existing instruments. Furthermore, the primary concerns of those with and without diplopia vary. Studies have shown that patients with diplopia have greater functional difficulties and lesser psychosocial impact compared to those without diplopia;[37,42,95] however, none of the available instruments have been developed to extensively assess the impact of strabismus on QoL of patients with diplopia and most of them enquire merely on the presence of double vision (symptom). The Effect of Diplopia Questionnaire[76] assesses the impact of post-operative diplopia on life and not the impact of diplopia associated with strabismus.

While amblyopia and strabismus are often considered together, they are two separate entities that can occur in the absence of each other and may have unique issues, concerns and effect on QoL. Little is known about the impact of isolated amblyopia on QoL and its effect on educational achievement and occupation. The Amblyopia Survey[46] and the QoL instrument for anisometropic amblyopia[57] were developed to measure the impact of isolated amblyopia/treatment in adults and children, respectively; however, these instruments did not follow a robust method of content development and did not consider patients' perspectives for development. Further research exploring the QoL issues of those with isolated strabismus, isolated amblyopia and strabismic amblyopia is necessary to guide whether amblyopia and strabismus should be integrated or split for the purpose of QoL measurement.

The ophthalmic QoL domains identified by previous studies may not perfectly and

Name of the instrument Country of origin; intended population Number of items; Language; Self/Proxy	Proposed aim	QoL domains addressed	Question format	Response categories
Amblyopia and Strabismus Questionnaire (A&SQ)[83] Netherlands; adults 26 items; Dutch; Self	To assess the QoL of people with amblyopia and strabismus	Activity limitation, concerns, emotional and social well-being, symptoms and mobility	I am afraid of losing my better eye	Five-point (none of the time, a little of the time, some of the time, most of the time and all of the time)
Psychological Impact Questionnaire (PIQ)[84] UK; over 15 years 33 items; English; Self	To assess the psychological impact of amblyopia and amblyopia without strabismus	Activity limitation, concerns, emotional well-being, symptoms and mobility	In your general daily life how often do you become frustrated? How did you find the experience of patching?	Five-point (rarely, occasionally, sometimes, mostly, almost always) Unpleasant, acceptable, cannot remember

Table 7. Characteristics of amblyopia and strabismus-specific quality of life instruments

Reference Study location (number of subjects, n); Original / Revised / Adapted (Scale / Subscale)	Subscales (number of items)/ Factors (number of items)	Content development	Classical test theory-based psychometric properties	Rasch-based psychometric properties	Measures of validity / reliability and responsiveness
Amblyopia and Strabismus Questionnaire (A&SQ) – Dutch					
van de Graaf et al. (2004)[83] Netherlands (n = 68 outpatients and 174 cohort); Original (Scale)		Item identification: B Item selection: B	Acceptability: A Internal consistency: A		Convergent validity: B Known group validity: A
van de Graaf et al. (2007)[138] Netherlands (n = 137); Original (Scale)					Concurrent validity: A
van de Graaf et al. (2009)[139] Netherlands (n = 245); Revised (Scale)	Six factors (24): fear of losing better eye (3), near distance estimation (5), far distance estimation (4), visual disorientation (3), diplopia (4), problems with social contact and cosmetic problems (5)		Dimensionality: A		
Amblyopia and Strabismus Questionnaire (A&SQ) – English					
Felius et al. (2007)[85] USA (n = 150); Adapted (Scale) Translated from original	Five subscales (26)		Acceptability: A Targeting: B Internal consistency: A Item dependency: NR Dimensionality: NR		Convergent validity: B Concurrent validity: A
Vianya-Estopa et al. (2010)[88] UK (n = 102); Adapted (Scale)	Unclassified (23 strabismic group; 21 isolated amblyopia group) Identified two subscales: visual function and psychosocial as a result of Rasch analysis			Model: ARS Response category: A Dimensionality: C Measurement precision: B Item fit statistics: B DIF: C Targeting: A (strabismus group) / B (isolated amblyopic group)	
Amblyopia and Strabismus Questionnaire (A&SQ) – Chinese					
Wang et al. (2014)[86] China (n = 304); Adapted (Scale) Translated from original	Five subscales (23)		Targeting: C Internal consistency: A		Known group validity: A Convergent validity: B
Bian et al. (2015)[140] China (n = 202); Adapted (Scale)	Six factors (22 items) Far distance estimation (7) Social contact and appearance (4) Visual disorientation (3) Near distance estimation (3) Double vision (2) Fear of losing eye (3)		Acceptability: NR Targeting: NR Internal consistency: A Item dependency: NR Dimensionality: A		Convergent validity: A Known group validity: A Reliability (ICC): A
Amblyopia and Strabismus Questionnaire (A&SQ) – Italian					
Marcon and Pittino (2014)[87] Italian (n = 99); Adapted (Scale) Translated from English version	Seven factors Fear of losing better eye (3) Object's interaction (5) Spatial interaction (6) Visual disorientation (3) Diplopia (2) Social contact (3) Appearance (3)		Acceptability: A Targeting: C Internal consistency: B Item dependency: NR Dimensionality: A		Known group validity: A Reliability (ICC): A

A: high/positive quality, ARS: Andrich rating scale model, B: fair/minimal acceptable quality, C: negative/poor quality, DIF: differential item functioning, ICC: intra-class correlation, NR: not reported.

Table 8. Quality assessment of amblyopia and strabismus-specific instruments for adults

comprehensively represent the QoL of this disease group. Thus, an extensive qualitative research is vital to confirm these domains and to aid the development of a comprehensive PROM specific to amblyopia and strabismus. Further, the questionnaires developed for a given population may not be appropriate to another culture. This could be the reason for high ceiling effects observed in the translated versions of the AS-20[77,78,80] and A&SQ,[86,87] warranting the need for developing culture-specific instruments.

In response to these considerations, our research group is developing amblyopia and strabismus-specific item banks measuring a series of QoL domains using robust research methods. Item banking and computer adaptive testing (CAT) are the latest innovations in patient-reported outcomes research.[96,97] An item bank consists of a huge collection of items, which are derived from extensive qualitative research with patients and calibrated by modern psychometric methods, like Rasch analysis.[96] Having a large pool of calibrated items would help us to customise the test, based on patient characteristics; for example, driving items would not be presented to those who do not drive due to reasons other than their ocular condition and other items with the same difficulty level would be presented instead. CAT is used for this purpose as it enables us to obtain an accurate measurement of QoL using fewer calibrated items by tailoring items to a respondent's responses to previous items and greatly reduces respondent burden by substantially reducing the test length.[98] Amblyopia and strabismus-specific item banks will aid in broadening our understanding of the disease impact and complement research and clinical trials.

CONCLUSION

This paper comprehensively reviews all the PROMs used to study the impact of amblyopia and strabismus. The characteristics, quality and content of all amblyopia and strabismus-specific instruments were

		Spread of the items across the domains							
Instruments considered for item extraction	**No of items classified**	**Activity limitation**	**Concerns**	**Emotional well-being**	**Social well-being**	**Economic impact**	**Convenience**	**Symptoms**	**Mobility**
Amblyopia-specific instruments									
Amblyopia survey	8	1	4	2	-	1	-	-	-
Child Amblyopia Treatment Index	18	-	5	1	-	-	11	1	-
Child Amblyopia Treatment Questionnaire	11	-	1	5	-	-	4	1	-
Children's Vision for Living Scale	19	11	1	1	5	-	-	-	1
QoL questionnaire for children with anisometropic amblyopia	15	5	4	5	1	-	-	-	-
Strabismus-specific instruments									
Adult Strabismus-20 questionnaire	20	3	10	3	1	-	1	2	-
Intermittent Exotropia Questionnaire – child	12	-	9	-	1	-	2	-	-
Perspectives Questionnaire†	0	-	-	-	-	-	-	-	-
Disability Questionnaire	6	1	1	1	1	1	-	1	-
Repertory Grid	98	-	21	42	35	-	-	-	-
Perceived Visibility of Strabismus	1	-	-	-	-	-	-	1	-
Expectations of Strabismus Surgery Questionnaire	17	-	17	-	-	-	-	-	-
Psychosocial Experience Questionnaire	16	1	8	2	2	2	-	1	-
Vision Function Scale	8	3	1	1	-	-	-	3	-
Exotropia Symptom Questionnaire	15	2	2	-	1	-	-	9	1
Effect of Diplopia Questionnaire	5	2	3	-	-	-	-	-	-
Post Strabismus Surgery Symptom Questionnaire	9	-	9	-	-	-	-	-	-
Psychosocial effects of strabismus pre- and post-operative questionnaire	22	2	12	4	4	-	-	-	-
Satisfaction of Surgical Outcome†	0	-	-	-	-	-	-	-	-
Visual Analogue Scale	6		5	-	-	-	-	1	-
Amblyopia and strabismus-specific instruments									
Amblyopia and Strabismus Questionnaire	26	7	6	2	2	-	-	5	4
Psychological Impact Questionnaire	9	1	3	3	1	-	-	-	1

†All items were either generic/global or could not be classified under any QoL domain.

Table 9. Content coverage of the amblyopia and/or strabismus specific instruments

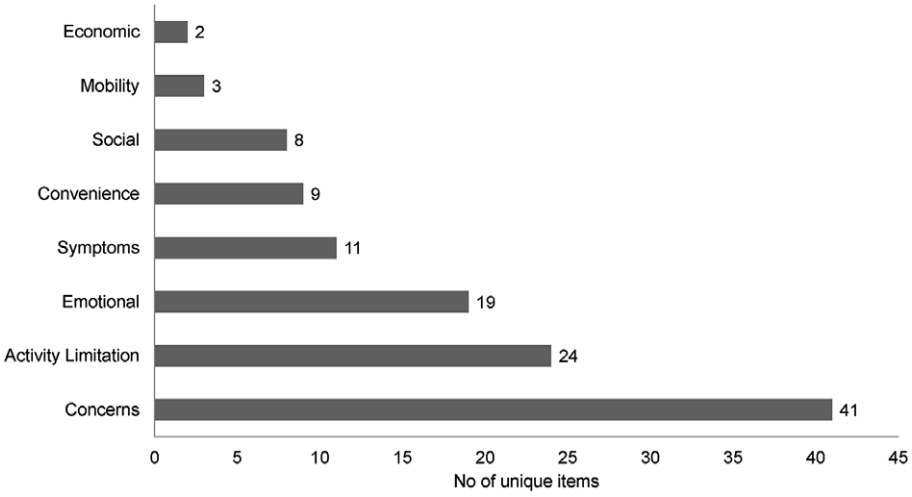

Figure 2. Content coverage: showing number of unique items across the ophthalmic domains of quality of life (QoL)

appraised and the paper underlines the lack of a high quality and comprehensive instrument to measure the QoL impact on children and adults.

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APPENDIX 1

Reasons for excluding articles at full-text

Reference	Reason for exclusion
Costello et al. (2001)[153]	Measured the perception of parents of children undergoing treatment for acquired esotropia
Eustis and Smith (1987)[154]	Assessed parental understanding of strabismus and treatment by surgery
Holmes et al. (2005)[155]	Measured the frequency of diplopia in several positions of gaze
Tonge et al. (1984)[94]	Evaluated the educational performance of children by a questionnaire filled by the teacher
Escardo-Paton and Harrad (2009)[156]	Assessed the severity and duration of conjunctival redness post-strabismus surgery
Horwood et al. (2005)[157]	Assessed bullying behaviour of children
Mruthyunjaya et al. (1996)[158]	Assessed parent's perception of pre-operative, surgical and post-operative experiences
Norman et al. (2003)[159]	Assessed parent's protection motivation for their children and adherence to eye patching recommendations

APPENDIX 2

Quality assessment criteria

Content development[22,26]	
Item identification	A Comprehensive consultation with patients, experts and literature review
	B Minimal consultation with patients, experts and literature review
	C No consultation with patients
Item selection	A Pilot instrument was developed and tested with Rasch analysis or factor analysis; items with floor and ceiling effects were removed; missing data considered; statistical justification is given for selecting and reducing items
	B Only some of these techniques were employed
	C No pilot instrument was developed or no statistical justification of selecting items were provided
Classical test theory-based psychometric properties[26,28–31]	
Acceptability	A The percentage of missing data for majority of items: ≤5%
	B The percentage of missing data for majority of items: >5% ≤ 40%

Appendix 2

	C	The percentage of missing data for majority of items: > 40%
Targeting	A	End-point responses (floor and ceiling effects) ≤ 5% for majority of items
	B	End-point responses > 5% or ≤ 40% for majority of items
	C	End-point responses > 40% for majority of items
Internal consistency	A	0.95 ≥ Cronbach's α ≥ 0.70
	B	0.70 > Cronbach's α ≥ 0.60; or Cronbach's α > 0.95
	C	Cronbach's α < 0.60
Item dependency	A	Inter-item correlations <0.3
	B	Inter-item correlations ≥ 0.3 or < 0.6
	C	Inter-item correlations ≥ 0.6
Dimensionality	A	First factor loading >0.4 for all items; principal component analysis (PCA): variance explained by the measure > 60% and eigenvalue of first contrast <2.0
	B	0.7 < Cronbach's α > 0.90; PCA: variance explained by the measure ≥ 50% or < 60% and eigenvalue <2.0
	C	Cronbach's α < 0.70 or > 0.90; PCA: variance explained by the measure < 50% and eigenvalue >2 (indicating multidimensionality)
Rasch-based psychometric properties[22,26]		
Response categories	A	Ordered response categories or ordering of categories were obtained by repairing disordered categories; evenly spaced response categories
	B	Ordered response categories or ordering of categories were obtained by repairing disordered categories; categories not evenly spaced
	C	Unrepairable disordered categories
Dimensionality	A	PCA of residuals: variance explained by the measure ≥ 60% and eigenvalue of the first contrast < 2.0
	B	PCA of residuals: variance explained by the measure ≥ 50% to < 60% and eigenvalue <2.0
	C	PCA of residuals: variance explained by the measure < 50% and eigenvalue > 2.0 (indicating multidimensionality)
Measurement precision	A	Person separation index (PSI) ≥ 2.5; reliability (α) > 0.85
	B	2.0 ≤ PSI < 2.50; 0.80 ≤ α < 0.85
	C	PSI < 2.0; α < 0.80
Item fit statistics	A	All items with infit and outfit mean squares between 0.70 to 1.30
	B	Most items within 0.70 to 1.30 and one or two items within the 0.50 to 1.50 limit
	C	More than two items within or outside 0.50 to 1.50 limit
Differential item functioning (DIF)	A	All items with DIF < 0.50 logit
	B	Some items with DIF 0.5 to 1 logits and at the most DIF for one item >1 logit
	C	More than one item > 1.0 logit
Targeting	A	Difference between item and person means ≤ 1 logit
	B	Difference between item and person means > 1 to ≤ 2 logits
	C	Difference between item and person means > 2 logits
Validity[22,26]		
Convergent	A	Tested with appropriate measure and correlation: 0.3 to 0.9
	B	Tested with debatable choice of measure and correlation: 0.3 to 0.9
	C	Correlation < 0.3 or > 0.90
Discriminant	A	Tested against an appropriate measure and correlation: < 0.3
	B	Tested against debatable choice of measure and correlation: < 0.3
	C	Correlation ≥ 0.3
Concurrent	A	Tested with an appropriate clinical measure and correlation: 0.3 to 0.90
	B	Tested with a debatable clinical measure and correlation: 0.3 to 0.90
	C	Correlation < 0.3 or > 0.90

Appendix 2 Continued

Known group	A	Tested between appropriate clinical groups and significant difference is found between groups
	B	Tested between debatable clinical groups and significant difference is found between groups
	C	Insignificant difference between groups
Reliability and responsiveness[22,26]		
Test-retest agreement	A	Intra-class correlation (ICC) ≥ 0.8
	B	0.6 ≤ ICC < 0.8
	C	ICC < 0.6
Inter-observer / intermode agreement	A	Limits of agreement (LOA) < minimally important difference (MID), weighted kappa > 0.8, intermodal correlation > 0.7
	B	LOA broader but still close to MID; kappa: 0.6 to 0.79; intermodal correlation 0.5 to 0.7
	C	LOA > MID, kappa < 0.6, intermodal correlation <0.5 or incorrect statistical test or inadequate sample (n <30)
Responsiveness	A	Score changes over time > MID or change with intervention; effect size ≥ 1 or responsiveness statistics given
	B	Changes over time but relationship to MID not reported; effect size ≥ 0.5 to <1; small sample or inadequate time frame
	C	Score changes ≤ MID; effect size < 0.5

A: high/positive quality, B: fair/minimal acceptable quality, C: negative/poor quality.

Appendix 2 Continued

APPENDIX 3

Quality of life domains,[32,33] definitions[34] and examples from existing amblyopia and/or strabismus-specific PROMs

Domain	Definition	Examples
Activity limitation	The difficulties an individual has in executing vision-specific physical, social or recreational activities due to impairment resulting from an eye disease/condition and its treatment/s	How clearly (well) can you see the picture on your TV? (CVLS) I have difficulty parking my car (A&SQ)
Concerns	The health-specific issues that affect an individual's attention, interest, care, safety, welfare or happiness associated with an eye disease/condition and its treatment/s	I worry about my eyes (IXTQ) Fear of losing vision in good eye? (ASu)
Social well-being	An individual's inability to engage in social activities and fulfill social obligations due to impairment resulting from an eye disease/condition and its treatment/s	How easy is it for you to make new friends? (CVLS) Difficulty in making eye contact (ExSymQ)
Emotional well-being	The emotional and psychological issues or disorders an individual has to face due to an eye disease/condition and its treatment	My patch has made me feel very sad (CAT) I feel stressed because of my eyes (AS-20)
Symptoms	Visual: the unwanted visual sensations arising from or accompanying an eye disease/condition and its treatment/s Ocular surface: the unwanted non-visual signs and sensations in and around the eyes arising from or accompanying an eye disease/condition and its treatment/s General: the unwanted non-ocular sensations or manifestations in the body that arise from or accompany an eye disease/condition and its treatment/s	How often have you had episodes of blurred vision and/or double vision during the past four weeks? (VFS) The drops make my eyes or eyelids red (ATI)

Appendix 3

Domain	Definition	Examples
Convenience	The quality of an individual's comfort, time, needs, desire and purposes compromised due to an eye disease/condition and its treatment/s	My patch made it very hard to do my work (CAT) It bothers me because I have to wait for my eyes to clear up (IXTQ)
Economic	The economic implications and impacts associated with an eye disease and its treatment/s. These include but are not limited to, cost of illness (that is cost of treatment and accessing health service/s) and impact on employment, productivity and income	Did amblyopia interfere with work? (ASu) Job related problems – including being hired, retained and/or promoted (DisQ)
Mobility	The difficulties an individual has in performing vision-specific tasks related to mobility situations due to impairment resulting from an eye disease/condition and its treatment/s	How easy is it for you to see steps when you walk up or down stairs? (CVLS) I have difficulties finding my way in a shopping mall, especially when I am there for the first time (A&SQ)

A&SQ: Amblyopia and Strabismus Questionnaire, AS-20: Adult Strabismus-20 questionnaire, ASu: Amblyopia Survey, ATI: Amblyopia Treatment Index, CAT: Child Amblyopia Treatment Questionnaire, CVLS: Children's Vision for Living Scale, DisQ: Disability Questionnaire, ExSymQ: Exotropia Symptom Questionnaire, IXTQ: Intermittent Exotropia Questionnaire, PEQ: Psychosocial Experience Questionnaire, PES: Psychosocial Effects of Strabismus Questionnaire, VFS: Vision Function Scale.

Appendix 3 Continued

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Functional limitations recognised by adults with amblyopia and strabismus in daily life: a qualitative exploration

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Abstract

Purpose: Patients' perceptions about the functional impact of amblyopia and strabismus in daily life have not been explored extensively. Therefore, this study aimed to explore the lived experiences of adults with these conditions and understand the functional limitations they face in their day-to-day life.

Methods: A qualitative study design was adopted. Participants over 18 years of age, with a primary diagnosis of amblyopia (with or without strabismus) were recruited from the community and various eye care practices in South Australia and Victoria, Australia. Participants took part in either focus group discussions or individual interviews and described the functional limitations they experienced in their daily life due to their eye condition. These sessions were audio recorded, transcribed verbatim, coded inductively, and analysed iteratively to form emergent themes.

Results: Thirty-seven adult participants took part in the study: 23 (62%) had strabismic amblyopia; 5 (14%) anisometropic amblyopia;, 7 (19%) combined-mechanism amblyopia; and 2 (5%) deprivational amblyopia. Their median age was 54 years (range: 21–82 years) and 19 (51%) were female. Participants reported several challenges in performing everyday tasks such as driving (e.g. judging distances, changing lanes), reading (e.g. fine print, reading for prolonged time) and sports (e.g. catching a ball). They also articulated trouble in navigating safely (e.g. using stairs, bumping into objects), performing work-tasks (e.g. taking longer than peers to complete tasks) and other routine tasks (e.g. chopping vegetables with care).

Conclusions: Several functional limitations were encountered by adults living with amblyopia and strabismus. Participants recognised these limitations in their normal day-to-day life and related the challenges they faced to symptoms associated with their eye condition. By presenting rich in-depth qualitative data, the paper demonstrates qualitative evidence of the functional impacts associated with amblyopia and strabismus.

Introduction

Amblyopia is a common developmental vision disorder, traditionally characterised in terms of reduced best corrected, high contrast visual acuity in the absence of any organic cause.[1] It is often predisposed by strabismus, anisometropia, or both. When not treated successfully, amblyopia endures as a chronic problem[2] and is a significant cause of unilateral visual impairment in adults.[3] The prevalence of amblyopia among adults range from 0.35% to 3.2%.[4–9]

A range of lower and higher order visual and motor deficits have been identified in those with amblyopia and strabismus; these include impairments in contour, shape,

motion and depth perception, contrast sensitivity, eye-hand coordination, prehension skills, visual search and positional uncertainty.[10–16] In addition, experimental studies have demonstrated functional impacts in the performance of real-life tasks such as reading, driving and reaching and grasping.[16–18] However, it is not clear whether these deficits translate into functional limitations that are recognised by individuals themselves in normal everyday situations.

Disagreement regarding the impact of amblyopia exists between evidences of population-based outcomes such as education and occupation[19–21] and questionnaire-based patient reported outcomes.[22,23] However, these studies do not adequately explore individual perceptions or experiences that can be best studied using in-depth qualitative exploration.[24] The extant qualitative investigations in relation to amblyopia focus more on the impact of treatment on children.[25,26] Therefore, this study aimed to explore the lived experiences of adults with amblyopia (with or without strabismus) and understand the functional limitations and disabilities recognised by them in their day to day life.

Methods

The study was approved by the Southern Adelaide Clinical Human Research Ethics Committee (reference number: 469.11) and adheres to the tenets of the Declaration of Helsinki.

Participants

Participants over 18 years of age, with a primary diagnosis of amblyopia (best corrected visual acuity of 6/9 or worse in at least one eye without any underlying organic cause)[20] were eligible to take part in the study. All types of amblyopia were included (strabismic: amblyopia in the presence of heterotropia or microtropia and absence of anisometropia; anisometropic: amblyopia in the presence of at least one dioptre of refractive error difference between the two eyes in any optical meridian and no strabismus; combined-mechanism: co-existence of anisometropic and strabismic amblyopia; and deprivational: amblyopia that resulted from obstruction of vision during the critical period of visual development due to causes such as congenital cataract or high ametropia). Participants were referred by the collaborating eye care practitioners in South Australia and Victoria, Australia and were also recruited from the community through flyers and newspaper advertisements. Sampling was non-probabilistic and sample size was determined by thematic saturation (i.e. redundancy of information with no further emergence of themes). Those with co-existing ocular pathology, known history of cognitive impairment or psychological disorders were excluded.

Procedure

All eligible participants were provided with a written information sheet and participation was voluntary. Participants signed an informed consent to take part in the study and provided an additional consent to access clinical details about their eye condition such as visual acuity and ocular deviation from their eye care practitioner. They also completed a demographic form with details such as age, gender and country of birth.

A phenomenological qualitative approach[27] that explores the lived experiences of individuals was adopted for the study. Participants took part in either focus group discussions or in-depth individual interviews (conducted face-to-face or via telephone) and described the functional limitations they face in their daily life because of their eye condition. An interview guide with open-ended questions such as, 'What sort of difficulties do you experience in your day-to-day life because of your eye condition? Are you aware of any tasks that you can't perform or avoid doing? Have there been any instances in which you need to change the way you complete day-to-day tasks?' was used to facilitate the interviews and discussions. English was the medium of conversation and all sessions were recorded using a digital audio recorder.

Data analysis

Data was transcribed verbatim and all transcripts were imported, stored and managed by NVivo (Version 11), a qualitative data analysis software developed by QSR International Pty Ltd (www.qrsinternational.com). The transcripts were familiarised, coded inductively, and analysed iteratively using a method of constant comparison.[28] The words and phrases used by participants to describe their experiences were used to code the data. Codes describing similar concepts were aggregated to form categories and emergent themes. All coding was performed by SK and validated by JK. The final categories and emergent themes were confirmed by a panel comprising of SK, JK and KP.

Results

Thirty-seven participants took part in the study; 16 participated in one of the four focus group discussions and 21 participated in individual interviews. Their median age was 54 years (21–82 years) with 19 (51%) female. Of the participants, 23 (62%) had strabismic amblyopia; 5 (14%) anisometropic amblyopia; 7 (19%) combined-mechanism amblyopia; and 2 (5%) deprivational amblyopia. The best corrected visual acuity in the amblyopic eye ranged from 6/9.5 (0.2 logMAR) to perception of hand movements (approximately 6/1200 Snellen equivalent or 2.3 logMAR)[29]

with a median of 6/30 (0.7 logMAR). The clinical and demographic characteristics of the sample are provided in *Table* 1. Six themes characterising the functional limitations associated with amblyopia and strabismus emerged from the qualitative analysis of participant narratives. These themes described the impacts on (1) driving, (2) reading, (3) sports, (4) mobility, (5) work-tasks and (6) other everyday tasks and are depicted in *Figure 1* along with examples of impact. The number (*n*) and percentage of participants who endorsed each theme and the number of coding references (participant statements) underlying each theme (N) are provided as supplementary information in the figure. The rest of the results section expands on each theme and enumerates the kinds of impacts perceived by individuals in their day-to-day life. These are substantiated by direct participant quotes in *Table* 2.

Impact on driving (Quotes Q1-Q8)

Participants faced numerous challenges in driving and parking a car. They were sensitive to bright light and were troubled by the glare caused by the headlights of oncoming vehicles in the evening (Q1). They faced difficulties in judging distances (Q2), especially while parking and reversing their car (Q3). Seeing road markings in dim light and turning their head to see things (other vehicles, pedestrians) on the side of their amblyopic eye while driving (Q4) were troublesome. Changing lanes in traffic, judging the lane of the oncoming traffic at intersections (Q5) and gauging the speed of other vehicles ahead of them (Q6) were difficult. Participants recalled several accidents ranging from bumping into roadside curbs to road traffic accidents, which they associated with their eye condition (Q2, Q7). Because of these limitations, some gave up driving and others were overly cautious; they avoided long drives, driving at night, and driving in unfamiliar areas (Q8).

Table 1. The clinical and demographic characteristics of the sample

Clinical and demographic variables	*N* (%)
Diagnosis	
Strabismic amblyopia	23 (62%)
Anisometropic amblyopia	5 (14%)
Combined-mechanism amblyopia	7 (19%)
Deprivational amblyopia	2 (5%)
Visual acuity in the amblyopic eye	
0.2 to 0.3 logMAR (6/9.5 to 6/12)	10 (27%)
0.4 to 0.5 logMAR (6/15 to 6/19)	3 (8%)
0.6 to 1 logMAR (6/24 to 6/60)	8 (22%)
>1 logMAR (>6/60)	9 (24%)
Ocular deviation (in those with strabismic and combined-mechanism amblyopia)	
Horizontal	23 (77%)
Vertical	1 (3%)
Oblique	4 (13%)
Orthotropic after strabismus surgery	2 (7%)
History of treatment	
Patching therapy	17 (46%)
Penalization with atropine	3 (8%)
Other orthoptic vision therapy	2 (5%)
Corrective strabismus surgery	13 (35%)
Education	
University	18 (49%)
Certificate or vocational qualifications	8 (22%)
No post-school qualifications	8 (22%)
Country of birth	
Australia	28 (76%)
Others	7 (19%)

Sum of the percentages for some variables may not be 100% due to missing data.

Impact on reading (Quotes Q9-Q15)

Despite normal visual acuity in the non-amblyopic eye, participants articulated difficulties in reading fine prints such as the phone book (Q9) and certain font types such as *Times New Roman* (Q10). Participants also reported that reading for a prolonged time was troublesome (Q11) and caused eye strain and headaches. Reading closely spaced content was challenging and participants admitted missing words/numbers while doing so. Some felt that their inability to concentrate (Q12) and difficulties in reading affected their academic performance (Q13). Some referred the difficulties in reading as 'frustrating' and 'annoying' and hence refrained from reading (Q14). While many coped by taking frequent breaks, some reported that closing the amblyopic eye eased the effort required for reading and therefore made it a habit (Q15).

Impact on sports (Quotes Q16-Q23)

Participants expressed difficulty in playing ball games, especially catching a ball (Q16) and hitting a ball (Q17), which they related to poor depth perception and eye-hand coordination (Q18). Playing fast sports such as cricket and tennis was hard due to difficulties in seeing through the amblyopic eye (Q19), seeing the ball in motion, judging depth, distances, and the direction of ball movement (Q20). Some felt frustrated because they could not pursue sports they liked (Q21), while some others refrained from sports due to failures and embarrassment (Q22). Participants coped by engaging in other visually less-demanding sports and activities such as athletics, rowing, and horse riding (Q23).

Impact on mobility (Quotes Q24-Q30)

Participants had trouble in moving around safely. They reported difficulties in using stairs, especially walking down

Table 2. Direct participant quotes substantiating the functional impact described by participants

Quotation number	Functional limitations	Direct participant quotes
Theme 1: Impacts on driving		
Q1	Difficulty driving at night time, glare	'I find driving on dusk really difficult. . . with lights driving at night I struggle with. Like any lights that come towards me or anything like that, I find that really hard; I almost lose my vision. Other than the - like I slow right down.' 41 years old female, Interview number: 23
Q2	Difficulty in distance judgement, accidents	'Driving in general I find it really difficult to work out where I am and where the car next to me is, so I've had a couple of accidents in my car because of that.' 21 years old female, Interview number: 22
Q3	Difficulty parking	'I don't do much of the parallel parking. Never liked parallel parking and that could well be because of my eyesight because you do back in onto your left and that's where my judgment isn't so good.' 67 years old female, Interview number: 15
Q4	Turning head around to see oncoming traffic at intersections	'The other thing I find when you're driving, you come to an intersection and there's cars coming this way and that way, you've really got to kind of turn right around to make sure there are no cars coming that way.' male, Focus group discussion participant number: 4.1
Q5	Difficulty in judging lanes at intersections	'For instance, another example would be if I'm at a major traffic intersection and its dual lane and I have traffic approaching me, from a distance I have no idea what lane they're in so I just have to be patient.' 31 years old male, Interview number: 3
Q6	Gauging speed of other vehicles on road	'The car in front when it's – if it's slowing down, because with only one eye effective it takes a little longer before you realise that car is slowing down.' 82 years old male, Focus group discussion participant number: 4.2
Q7	Difficulty in perceiving depth, accidents	'I can't see the depth so I'm not sure how fast – like I'm not sure how fast we were going so I always end up crashing and I can't see over there so I usually crash into something because I can't see peripherally; it was very dangerous.' 21 years old female, Interview number: 9
Q8	Coping strategies – being cautious, limit driving to familiar places	'I was very cautious of parking. . . I just went mainly in familiar places and things like that.' 57 years old female, Interview number: 18
Theme 2: Impacts on reading		
Q9	Difficulty reading fine print	'I still can't read the phone book, no matter what the glasses prescription is, it's too small. I can't read the Rolodex either.' 49 years old female, Focus group discussion participant number: 3.1
Q10	Symptoms of eye strain associated with reading	'Reading's the worst. . . Eye strain. Times New Roman is the worst possible script. Absolutely hopeless.' 65 years old male, Focus group discussion participant number: 1.3
Q11	Difficulty in reading for a long time	'After a couple of pages, I can't – it's all a blur; I can't read anymore.' 70 years old female, Focus group discussion participant number: 1.1
Q12	Difficulty concentrating	'It was hard to see what was being presented and straining to actually see what was on the board and listening to someone talk at the same time is a bit more of a challenge than it would be for other people.' 67 years old female, Interview number: 15
Q13	Impact on academics	'I was a university student and what have you and I knew I couldn't study like my contemporaries were studying. I just – my eyes wouldn't allow me to do the study that I knew I could have been doing or should have been doing.' 65 years old male, Focus group discussion participant number: 1.3
Q14	Annoyance	'I just stop reading. Like I said, I can hardly read anymore; it's really annoying.' 54 years old male, Interview number: 17
Q15	Coping strategy - Reading with one eye closed	'If I go outside and I've got to try and read 'meeting room' and I strain my eyes I have to virtually close my right eye.' 48 years old male, Focus group discussion participant number: 1.4
Theme 3: Impacts on sports		
Q16	Catching a ball	'The thing that I find is that right through my life, through sport and so forth, I can't even catch a ball type of thing and that annoys me. Grandchildren throw a ball at you and you can see it coming but you just can't catch it.' 71 years old male, Focus group discussion participant number: 1.5
Q17	Hitting a ball, playing tennis	'The tennis ball would come towards you and you'd swipe, and the ball would go straight through.' 71 years old male, Focus group discussion participant number: 2.2
Q18	Perceiving distances and depth while playing	'We played netball as kids and that was hard because judging like shooting and things like that, trying to judge the distance and that whole depth perception where you need both your eyes was difficult and it still is.' 41 years old female, Interview number: 23

(continued)

Table 2 (continued)

Quotation number	Functional limitations	Direct participant quotes
Q19	Difficulty in seeing through the amblyopic eye, playing cricket	'I couldn't see down my left side as well as what I would have liked, playing cricket especially. I was a right-handed cricketer so therefore I'm looking at the bowler with my left eye, so to actually bat I'd have to turn a bit squarer to the bowler, so I could actually see the bowler with my right eye. . .' 57 years old male, Interview number: 20
Q20	Difficulty in seeing and following the ball	'I'm just generally terrible at sport now. Anything that involves a small ball I can't see, can't follow it, can't play it.' 21 years old female, Interview number: 22
Q21	Feeling cross	'I love tennis, but I really couldn't see the ball and I'd actually get very cross with myself that I couldn't do it because I loved it. . .' 68 years old female, Interview number: 4
Q22	Refrain from playing sports	'I don't do sport; you can cancel that one out. Never have. When I was young, under ten or about ten, I tried to do tennis but, as I said, I always missed the ball.' 66 years old female, Interview number: 19
Q23	Engaging in athletics and swimming	'So, I took up athletics, so you try and start running to do it as a sport. You take up swimming because that doesn't need an eye and anything that doesn't need an eye is a sport that you try. . .' 72 years old male, Focus group discussion participant number: 4.3
Theme 4: Impacts on mobility		
Q24	Using stairs	'Walking down stairs can be a problem. . . Yeah because particularly if they are variable height steps.' 82 years old male, Focus group discussion participant number: 4.2
Q25	Coping - Cautious	'I do hold on. I've always held onto steps. Probably felt a bit shaky, I guess. . . I've always held onto stairs. When I've come upstairs, downstairs, I've always made sure that I held onto a wall or a rail.' 54 years old male, Interview number: 5
Q26	Crossing a road safely, coping by being careful	'I can't really see out of that right – like if I'm looking at a road to cross it I don't trust my right eye so I do look a couple of times properly because I can't sort of see to my far right out of.' 43 years old female, Interview number: 1
Q27	Judging doorways	'The judge thing is, as I find going through a doorway – and I've done it that many times its unreal – it's on my right side and I'll clip onto the latch of the door.' 71 years old male, Focus group discussion participant number: 1.5
Q28	Peripheral awareness	'I can't see – I'm aware when I think about it that that side of – that the left side is darker and that I'm not really looking at what's over there very much' 61 years old female, Focus group discussion participant number: 2.1
Q29	Bumping, loss of balance	'Well I move over that way and when I'm near people I'll be very, very careful I don't bump into them because I'm walking straight and all of a sudden I'll lose my balance and I have to do a dodgy trick and get out of it or otherwise I'll be bumping into them.' 70 years old male, Focus group discussion participant number: 2.5
Q30	Tripping, Falling	'Again, on the blind side, if I'm going to bump into anything. . . Mind you, I did have one big one, one day when I tripped myself up and fell flat on my face and broke both my elbows. . .' 68 years old male, Interview number: 13
Theme 5: Impact on work and work -tasks		
Q31	Not meeting vision standards	'Yeah, I used to get upset, you know, like failure - like pass [the exam] and then fail eyesight, remembering that I failed - firstly I failed with the locomotive engineer. Secondly, I failed with the navy. Thirdly I failed with the police force. Fourthly I failed as a technician.' 68 years old male, Interview number: 13
Q32	Functional limitations affecting job choice	'Oh, well, myself I would have avoided jobs. Like I said to you, I enjoy tinkering with mechanics. Well, there's no way known I would have become a mechanic because I knew that I couldn't. . . couldn't see and you just couldn't do it for eight hours a day because you'd end up with such massive headaches. . .' 48 years old male, Focus group discussion participant number: 1.4
Q33	Impact on job (Doctor)	'I'm a doctor and one of the things I couldn't do is surgery. Even assisting at surgery, I actually really struggled with it early on and then did a bit of assisting and realised that it was my vision that I couldn't actually see the depth so that was a big thing.' 68 years old female, Interview number: 4
Q34	Impact on job (using a forklift)	'At work I drive a vehicle, a forklift, and it takes me longer to focus on the exact position I have to be in than other people who don't wear glasses. I have to get it exactly right before I do it.' 54 years old male, Interview number: 17
Q35	Impact on job (Computer programmer)	'I couldn't see properly so I had to check – I learned to check a few times before I deliver to my manager, so I'm always checking myself.' 42 years old female, Interview number: 7

(continued)

Figure 1. Themes denoting the functional limitations recognised by participants in their everyday life. The number (*n*) and percentage of participants who endorsed each theme and the number of coding references (participant statements) underlying each theme (N) are provided as supplementary information.

steps and curbs (Q24). As a result, some avoided stairs or were extremely cautious and held onto the side-rails (Q25). Trouble crossing a road safely (Q26), judging doorways and negotiating obstacles on the path (Q27) were reported. These were attributed to poor depth perception and lack of peripheral awareness (Q28) in the amblyopic eye. Bumping into objects was a common issue and some individuals reported that they lost their balance while walking (Q29). Trips, falls, and accidents due to these challenges were reported by some participants (Q30).

Impact on work and work-tasks (Quotes Q31-Q38)

The career choice of the participants was affected not only due to the failure to meet vision standards set for specific jobs (Q31) but also because of the functional impairments (e.g. impaired depth perception) associated with their eye condition (Q32). For example, participants employed in a range of occupations articulated several challenges that affected their work-tasks, productivity and efficiency (Q33-Q37). They recognised that they had to work longer and harder to complete tasks in comparison to their non-amblyopic colleagues (Q34, Q35). Some admitted that they refrained from disclosing their eye condition to their employers (Q38) to avoid any potential negative impact on their job prospects.

Impact on other everyday tasks (Quotes Q39-Q45)

Participants described themselves as 'clumsy'. They faced challenges in cutting food/chopping vegetables safely (Q39), pouring a drink without spilling it and picking up or putting back cups on the table without dropping them (Q40). Limitations in seeing 3D movies, using mobile phones (Q 41), pursuing hobbies (Q42), grooming (Q43) and using hand tools (Q44) and devices such as binoculars and stereoscopes (Q45) were reported. Participants coped by avoiding tasks that were difficult, being careful and eventually learnt to accept their limitations.

Table 2 (continued)

Quotation number	Functional limitations	Direct participant quotes
Q36	Impact on job (Optometrist)	'It's just added complexity to the job. . . like through the microscopes and stuff I'll only ever be able to see down one eye and I don't get that 3D vision a lot of other people will get.' 21 years old female, Interview number: 22
Q37	Impact on job (Salesman)	'I got a job as a sales rep, as a salesman – I was going like that, you know, a job every third or fourth day you're trying to find yourself and got in this great big truck. But a truck salesman, when I get in the truck, I can't bloody see anything. I only lasted a day.' 72 years old male, Focus group discussion participant number: 4.3
Q38	Non-disclosure of eye condition to employers	'No. I don't tell employers or anything like that [about my eye condition] because I don't want it to have any effect on my job or anything like that.' 50 years old female, Interview number: 11
Theme 6: Impact on other everyday tasks		
Q39	Chopping vegetables	'When I am chopping vegetables, cutting things, you know. Yeah, I am likely to cut my thumb off. Kids used to say, 'oh God we're going to be eating tomato sauce again; mum's cut her finger'.' 70 years old female, Focus group discussion participant number: 1.1
Q40	Being clumsy, dropping things	'I worked in a coffee shop and things like that. I thought I was clumsy. . . I was called a clumsy child and used to drop a lot of things and maybe it had a lot to do with that.' 54 years old male, Interview number: 5
Q41	Using mobile phones	'Yeah but I find it annoying when I am trying to do something – as I say, that game or typing – I'm always hitting the wrong key, even when I'm texting. The key on the sides but not the key I want.' 70 years old female, Focus group discussion participant number: 1.1
Q42	Craft work - hobbies	'I do a lot of craftwork and patchwork, that's what I really enjoy doing, so I have been limited with my vision doing those types of things.' 57 years old female, Interview number: 18
Q43	Shaving	'It's frustrating when you're shaving in the morning. You've kind of got to look that way and so I have to close my left eye, so I can see the left side of my face and that sort of thing' 60 years old male, Focus group discussion participant number: 2.4
Q44	Using a screwdriver	'Another thing is too is. . . putting the screwdriver into the head of a screw. I've been in the building industry for 40 odd years and when you get down to those fine things you've really got to close your eye and concentrate on the other eye to get that screwdriver to do the screw.' 71 years old male, Focus group discussion participant number: 1.5
Q45	Using binocular devices	'I can't watch 3D and I can't see through stereoscope.' 49 years old female, Focus group discussion participant number: 3.1

Discussion

Using a qualitative phenomenological methodology, this study highlighted the functional limitations and associated disabilities perceived by stakeholders themselves in their daily life (uncontrolled real-life settings). Analysis of the participants narratives indicates that (1) several functional limitations are encountered by adults with amblyopia and strabismus, especially in driving, reading, playing sports, mobility and work; (2) participants recognise these limitations in normal day-to-day situations; and (3) participants relate the challenges they face to the symptoms associated with their eye condition (for example, difficulties in catching a ball and clumsiness in pouring liquids into a cup were associated with lack of eye-hand coordination and impaired depth perception).

The current study underlined several limitations in driving (e.g. difficulties in judging distances, speed, changing lanes and driving in dim illumination) which according to the participants made them accident-prone. Reports of accidents in our study ranged from minor (e.g. bumping into roadside curbs) to major road traffic accidents and supports the association found between moderate and severe amblyopia and road traffic accidents.[19] To combat the difficulties encountered while driving, participants in our study adopted a more cautious driving behaviour, which is similar to that observed in stereo-reduced motorists by a methodologically different study.[17] It is worthwhile to note that the impact for some in our study was significant in that that they gave up driving or limited driving to familiar places or closer distances. In countries like Australia, where self-driving is common and is the preferred mode of transport,[30] an inability to drive might have more significant consequences affecting independence, work and social participation.

Reading, especially for a prolonged time, was affected by symptoms (e.g. eye strain), font style, size and spacing. These qualitative findings supports the reading impairments identified in children with microstrabismic amblyopia,[31] adults with strabismic amblyopia[18] and children with anisometropic amblyopia.[32] While it is known that reading fine print with the amblyopic eye is impaired by

crowding,[33] participants in our study noted this difficulty even under their habitual binocular reading conditions. A possible explanation for this could be related to the suppression scotoma apparent during binocular reading as suggested by Kanonidou *et al.*,[18] which further explains why some participants in our study preferred to read by closing one eye, although this involved associated inconvenience. These findings indicate that the impacts on reading are notable and significant to participants in daily life, although not reflected in the evidence of current population-based investigations.[19,20]

The other major finding of the study was the impact on engaging in sporting activities which supports the findings of Satterfield, *et al.*,[34] and Packwood, *et al.*,[23] who investigated the psychosocial impacts of strabismus and amblyopia respectively through surveys. Our study adds to this knowledge by enumerating the difficulties that participants' face (e.g. catching a ball, judging a ball's flight in motion). These impairments in turn influenced the choice of sports; participants chose sports/activities that were less visually demanding as an alternative to those that were more difficult. This could be the reason why Rahi *et al.*[19] did not find an association between amblyopia and participation in sports. Nevertheless it should be noted that participants in our study, despite engaging in some kind of sport expressed regret about not being able to pursue the sports they liked.

Participants in our study recognised difficulties in moving around safely, especially while going down stairs and reported difficulties with their balance, tripping and falling. These findings are not surprising because of the known relationship between impaired contrast sensitivity, stereopsis and decreased visual field (common visual deficits associated with amblyopia and strabismus[16]) and falls[35] and gait instability.[36] Trouble negotiating obstacles and bumping into objects, articulated by our study participants, further supports the known effects of long-standing reduced stereoacuity associated with amblyopia on adaptive gait.[37] Considering the increased odds of falling in those with unilateral visual impairment,[38] the challenges encountered by participants in navigating the real word environment safely should not be underestimated.

In addition to the well-known impact of amblyopia on career choice (owing to failure in meeting occupational vision standards)[16] and the negative implications of socially noticeable strabismus in gaining employment and promotions,[39] the current study expands our understanding of the functional impacts on work. These include limitations in performing certain work-tasks (e.g. impaired depth perception excluding a doctor from performing surgery) and being less efficient/productive (e.g. taking more time to finish a task). In addition to these, the study identified several functional limitations in other everyday tasks which ranged from chopping vegetables safely in the preparation of food to capacity for personal grooming. Although there was no explicit mention in the participant narratives about the speed with which participants were able to perform fine motor tasks such as sewing, craft and using hand tools, it was clear that these tasks were challenging. This could be because of the impairments in performing manual dexterity tasks with speed and accuracy.[16,17,40] It is interesting to note that many of our study findings (e.g. difficulties in driving, reading, using stairs, walking) are similar to a previous study which explored the quality of life in adults with diplopic and non-diplopic strabismus[41]; nevertheless, our study focussed on amblyopia (with or without strabismus) and provides a more exhaustive qualitative narrative.

While the participant responses in our study did not suggest if the limitations they experienced were more pronounced during childhood or now, we noted that the participants' priorities and concerns changed over time. For example, a participant who was concerned about not being good at sports in childhood was no longer bothered about it; instead limitations in driving was her main concern now. The limitations faced by the participants influenced the activities that they chose to undertake; they avoided tasks that were difficult if they had a choice. This has been noted in the results section; for instance, participants avoided visually demanding sports, driving at night time and career that demanded performing tasks that were challenging for them. Adaptations to tasks that they chose to undertake was mainly being slow and cautious (e.g. driving slowly, taking more time to complete work tasks). With advancing age, participants admitted that they try to accept their limitations and learn to live with their eye condition.

The major strength of this study is the use of qualitative methods for in-depth exploration of the functional implications of amblyopia and strabismus in everyday life. The use of both focus groups and interviews for data collection and the diversity in sample characteristics enhances the rigour of the study.[42,43] As concepts rather than frequencies (number of occurrences) are important in qualitative studies,[44] the number of participants who endorsed each theme and the number of coding references are given as a supplementary information in *Figure 1* and should not be used to guide any quantitative interpretations such as the importance of a particular theme over others. However, it is worthwhile to note that about 95% of our sample had reported some kind of functional limitation and >50% of them had endorsed each theme.

While one might expect lesser functional limitations in participants with better visual acuity, six out of seven (86%) of our study participants with milder form of amblyopia (best corrected visual acuity of 6/9.5) reported some kind of functional limitation (number of coding

references = 75). This could be because of the other compromised visual functions such as stereo acuity; studies have shown that loss of stereo acuity rather than the severity of amblyopia correlates with impairments in performing visuomotor tasks.[17] It is beyond the scope of this qualitative study to investigate whether the degree of limitations reported by participants vary with the severity of amblyopia. Further quantitative investigations through a valid and comprehensive patient reported outcome measure is warranted.

As amblyopia is often associated with strabismus and refractive error, it is difficult to distinguish the effects of amblyopia from its comorbidities and is beyond the scope of this study. The current study reported all functional limitations reported by participants irrespective of amblyopia-type. Due to the high number of strabismic amblyopes in this study, one might argue that our results are more representative of strabismic amblyopia; however, we observed similar issues across participants irrespective of amblyopia-type. As a next step, we are using this qualitative evidence to develop a comprehensive item bank calibrated by Rasch analysis, to measure the functional limitations posed by amblyopia and strabismus on a valid interval scale.[45,46] This scale will then be used to measure and compare the level of impacts across the different amblyopia and strabismus diagnoses.

Amblyopia may be underestimated in terms of its real-life impact owing to the presence of one eye with clinically normal visual acuity. By identifying and describing the several functional limitations perceived by individual themselves in their normal day-to-day situations, this study widens our knowledge about the impact of amblyopia and strabismus on quality of life. With recent advancements in the treatment of adult amblyopia,[47] these findings would be of interest to researchers and clinicians providing care.

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Conflict of interest

The authors declare no conflicts of interest.

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