

The Impact of Diabetic Eye Diseases: A Patient-Centred Perspective

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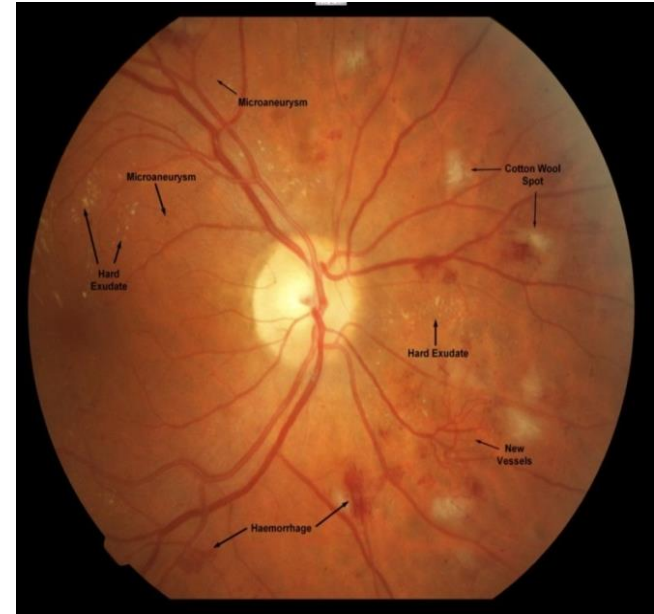
Bright Vision
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Singapore has one of the highest rates of diabetes globally

- Approximately 13% of Singaporeans between 20-79 years have diabetes (*DM; IDF Diabetes Atlas 2015*)
 - Second highest proportion among developed nations
 - Prevalence among three major ethnicities is estimated at 11.5% in Chinese, 17.1% in Malays, 21.6% in Indians ≥ 40 years (*Chiang et al, 2011*)
- DM prevalence and burden estimated to increase in coming decades due to increasing affluence and longer lifespan
- Projected economic burden of US\$2 billion by 2050

Diabetic Eye Diseases

- Diabetic retinopathy (DR) and diabetic macular edema (DME) are among the most common visual complications of diabetes.
- Leading causes of visual impairment (VI) in working-aged adults (*Cheung et al. 2010*).
- Age-standardized DR prevalence of 35.0%, 30.4% and 26.2% in Malays, Indians, and Chinese, respectively.
- Corresponding DME estimates are 5.7%, 7.2% and 6.1% (*SEED Data*)



Diabetic Eye Diseases

- Common risk factors: ↑ diabetes duration, ↑ HbA1c levels, ↑ systolic blood pressure, presence of hypertension, stroke and cardiovascular disease
- **Almost 80% of those with DR were unaware they had the condition**
(Huang et al, 2015)
- Important gaps in patients' knowledge about DR
- Potentially damaging beliefs about the cause of DR and the effect of treatments on vision

Patients' Causal Beliefs About Diabetic Retinopathy

Eva K. Fenwick*, Ecosse L. Lamoureux*, Robert P. Finger†, Lyndell Lim‡, and Gwyn Rees*

ABSTRACT

Purpose. This study explored patients' understanding of the risk factors for diabetic retinopathy (DR) and their personal beliefs about the cause and controllability of their own DR, as well as health professionals' perceptions of patients' understanding of DR and its cause.

Methods. Eight focus groups and 18 semistructured interviews were conducted with 57 patients with DR, and seven semistructured interviews were conducted with diabetes and ophthalmic specialists. Sessions were transcribed verbatim and iteratively analyzed using the constant comparative method and NVIVO software.

Results. Nearly 50% of participants had proliferative DR, and most patients had undergone laser treatment. Patients had a reasonable understanding of the basic risk factors for DR such as diabetes control, although they were less clear about specific risk factors such as blood pressure and lipid control. Regarding their own disease, most patients attributed their DR either to poor diabetes control or to failings of the health care system. Some patients believed that their DR was a result of health aspects beyond their control or environmental factors, whereas others were unsure about the cause. Diabetes and ophthalmic specialists believed that many patients lacked understanding about the cause of their DR and the goal and outcome of laser treatment. Difficulty communicating the abstract concept of laser treatment outcomes in the face of concrete (yet erroneous) anecdotal evidence of the detrimental impact of laser on visual acuity was highlighted as a major barrier to mitigating patients' harmful beliefs about treatment.

Conclusions. This study revealed some important gaps in patients' knowledge and potentially damaging beliefs about the cause and treatment of DR despite most patients having considerable exposure to eye health professionals and DR treatment. Improving patients' understanding of the major risk factors for DR and the realistic outcomes of laser treatment may improve patients' coping mechanisms, adaptation to disease, and ocular outcomes.
(Optom Vis Sci 2013;90:874-882)

DR & DME: Patients' perspectives

Qualitative work by our group in Australia has highlighted the diverse burden of DR/DME on QoL (Fenwick et al. 2012)

Patient focus group, transcript analysis:

*“The effects on me were **devastating**. I had to leave my **job**, which was teaching, and my **hobby** was stamp collecting and I used to write... **All my interests**, just overnight **I was unable to do them**. But probably the worst problem for me has been **psychological**...I had a fair bit to offer my wife, but when I lost my vision I suddenly felt that I had **nothing to offer** her. **So I told her to go** so that she didn't have to put up with **a...fat old man who was blind**.”*

Emotional; Economic; Activity limitation; Convenience; Social

Diabetic Eye Diseases

- DR/DME has a substantial impact on patients' vision-specific functioning (VSF) and vision-related QoL (VRQoL), particularly at the vision-threatening stages

The impact of diabetic retinopathy: understanding the patient's perspective

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ABSTRACT

Understanding the impact of a condition from the patient's perspective is important, and different types of patient-reported outcomes or instruments are available to help with this. This review article summarises the current evidence on the impact of diabetic retinopathy (DR) and its associated vision impairment on patient-reported outcomes. We have included research that has used a range of outcome measures to assess the impact of DR on generic health-related quality of life, utility, vision-functioning and vision-specific quality of life. This review also offers clarification on frequently misused psychometric terminologies to help clinicians and researchers better understand the literature associated with patient-reported outcome research. Overall, the evidence suggests that DR, particularly in its vision-threatening stages, has a substantial, negative impact on the patient. However, our understanding of the impact of

The aim of this paper is to provide a critical review of the current research investigating the impact of DR on PROs. We focus on vision-related QoL, a complex concept that encompasses functional ability, symptoms, emotional well-being, social relationships, concerns and convenience as they are affected by vision.¹⁵ However, as other parameters are often used, sometimes mistakenly, to characterise vision-related QoL, we also include studies that have assessed the impact of DR using generic health-related QoL questionnaires, utilities and visual functioning questionnaires. Table 1 summarises the different characteristics of these PROs.⁵⁴ This review also offers a critical appraisal of the outcome measures used by researchers to assess QoL, and informs the readers about future directions to overcome these limitations, such as the third generational outcome measures 'item



Impact of DR on utility

- Utilities are expressions of limitations endured as a result of a health problem
- They provide a preference-based single index of utility associated with a health impairment or QoL state (0-1 range; 1='perfect' and 0=death)
- Numerous studies have shown that utilities for DR systematically decrease with worsening visual acuity and DR severity, ranging from 0.98 to 0.53
- Considerable variance in utility values due to type of utility measure, sample size, disease severity and population

Impact Of DR On Utility

- The variation in VisQoL utilities was attributed to profound visual impairment (VI), but not mild, moderate or severe VI, or DR severity
- The EQ-5D was not sensitive to any level of DR or VI

CLINICAL AND EXPERIMENTAL

OPTOMETRY

RESEARCH PAPER

Assessing disutility associated with diabetic retinopathy, diabetic macular oedema and associated visual impairment using the Vision and Quality of Life Index

Clin Exp Optom 2012; 95: 362-370

DOI:10.1111/j.1444-0938.2012.00742.x

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Background: Use of generic multi-attribute utility instruments (MAUI) to assess the impact of diabetic retinopathy (DR) on health-related quality of life (HRQoL) has produced inconsistent findings. Therefore, we assessed the impact of DR, diabetic macular oedema (DME) and associated visual impairment on vision-related QoL (VRQoL) using a vision-specific MAUI.
Methods: In this cross-sectional study, 203 diabetic patients were recruited from specialised eye clinics in a Melbourne tertiary eye hospital. Severity of combined DR/DME was categorised as: no DR/no DME, mild non-proliferative DR (NPDR) and/or mild DME; moderate NPDR and/or moderate DME and vision-threatening DR (severe NPDR or proliferative DR (PDR) and/or severe DME) in the worse eye. Visual impairment was categorised as: none (up to 0.18 logMAR); mild (from 0.18 to 0.3 logMAR); moderate (from 0.3 to 0.48 logMAR); severe (from 0.48 to 0.78 logMAR); and profound (worse than 0.78 logMAR). The Vision and Quality of Life Index (VisQoL) vision-specific MAUI was the main outcome measure. As the distribution of the utilities was skewed, independent associations with associate were explored using multivariate

Clinical and Epidemiologic Research

The Impact of Diabetic Retinopathy and Diabetic Macular Edema on Health-Related Quality of Life in Type 1 and Type 2 Diabetes

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PURPOSE. To assess the impact of diabetic retinopathy (DR) and diabetic macular edema (DME) on health-related quality of life (HRQoL) in type 1 and type 2 diabetes using the EuroQoL EQ-5D generic multi-attribute utility instrument (MAUI).

METHODS. In this cross-sectional study, 577 patients with diabetes were recruited from specialized eye clinics in Melbourne, Australia. Each patient underwent clinical, biochemical, and anthropometric assessments. The severity of combined DR and DME (no DR/DME; mild NPDR [nonproliferative DR (NPDR)] and/or mild DME; moderate NPDR and/or moderate DME; and vision-threatening DR (VTDR) (severe NPDR or PDR and/or severe DME) in the worse eye was calculated. EQ-5D utility measures were the main outcome. Because the distribution of the utility measures was skewed, independent associations were explored using multivariate quantile regression models (five quintiles, namely 15th, 30th, 45th, 60th, 75th) ranging from poorest to highest HRQoL.

RESULTS. Median age of the participants was 66 years (range, 26-90 years). Of the 577 participants, 222 (38.3%) had no

CONCLUSIONS. Using a generic MAUI, the EQ-5D, the authors found that the presence or severity of DR/DME and concomitant vision loss were not associated with any quantile of HRQoL. These findings suggest that the EQ-5D lacks sensitivity in assessing the impact of the severity of DR/DME on HRQoL parameters and that condition-specific instruments may better capture the full impact of the association. (*Invest Ophthalmol Vis Sci.* 2012;53:000-000) DOI:10.1167/iovs.11-8992

Diabetic retinopathy (DR) is a common microvascular complication of diabetes.¹ In its early nonproliferative stages there are few visual symptoms; however, as the disease progresses to vision-threatening stages (severe nonproliferative DR [NPDR] and proliferative DR [PDR]), significant vision loss can occur. Diabetic macular edema (DME), which can occur at any stage, affects central visual acuity.² After 20 years of living with diabetes, most patients will have some degree of DR.^{2,3}

As shown by our group, the impact of DR and associated vision impairment on health-related quality of life (HRQoL) is

Impact Of DR On Utility

- Current work in Australia to develop a utility measure for DR/DME using discrete choice experiments (DCE)

	Scenario A	Scenario B
Visual symptoms <i>e.g. blur</i>	Severe difficulty	Some difficulty
Lighting and glare <i>e.g. bright lights</i>	Some difficulty	Severe difficulty
Activity limitation and mobility <i>e.g. housework, steps</i>	No difficulty	Some difficulty
Inconvenience <i>e.g. needing help</i>	Some difficulty	Severe difficulty
Emotional well-being <i>e.g. feel upset, loss of social life</i>	Some difficulty	No difficulty
	<i>You live for 1 year in this stage</i>	<i>You live for 5 years in this state</i>

Which scenario would you prefer?

Impact Of DR On VSF (Vision-dependent IADL)

- Activities with most functional decreases are reading small print, mobility, work, and leisure (Lamoureux et. al 2004)
- Those with more severe DR and VA loss consistently report worse VSF compared to those with less severe DR and VA loss (Klein et. al 2001; Cusick et. al 2005)
 - Compared to those with NPDR, those with PDR had scores 20-30 points lower (out of 100) on the NEI-VFQ (Gabrielian et. al 2010)
 - Those with DME have worse VSF than those with DR without DME (Hariprasad et. al 2007)
- However, even relatively mild levels of VA loss place substantial burden on VSF (Lloyd et. al 2008)

Impact Of DR On VSF In Singapore

- 357 participants with diabetes from SiMES answered the VF-11.
- Persons with visual threatening DR (VTDR) and proliferative DR (PDR) were **6 and 12 times** more likely to report worse VSF, respectively, independent of visual acuity.
- Interventions to prevent progression to vision-threatening stages are required.

Impact of Diabetic Retinopathy on Vision-Specific Function

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Objective: To assess the influence of the spectrum of diabetic retinopathy (DR) on vision-specific function in an Asian population.

Design: Population-based cross-sectional study.

Participants: Persons aged 40 to 80 years of Malay ethnicity in Singapore.

Methods: The Singapore Malay Eye Study was a population-based, cross-sectional study of 3280 Asian Malays (78.7% response rate). Five end points were considered: (1) any DR, (2) macular edema (ME), (3) clinically significant macular edema (CSME), (4) vision-threatening DR (VTDR), and (5) DR severity levels ranging from none to proliferative diabetic retinopathy (PDR). Vision function was assessed using the Vision-Specific Functioning Scale validated using Rasch analysis.

Main Outcome Measures: Vision-specific functioning score.

Impact of DR on social and emotional well-being

- Patients with DR believe they experience more symptoms relating to their diabetes and that diabetes has a greater impact on their life
 - Negative beliefs about diabetes were associated with higher levels of depression and anxiety
- Severe DR independently associated with greater depressive symptoms ($\beta=0.69$; 95% CI 0.03-1.34)
 - Explaining 19% of the variance in depression

CLINICAL AND EXPERIMENTAL
OPTOMETRY

RESEARCH PAPER

Impact of diabetic retinopathy on patients' beliefs about diabetes

Clin Exp Optom 2012; 95: 371–376

DOI:10.1111/j.1444-0938.2012.00745.x

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Background: The aim was to compare beliefs about diabetes and determine their

Original Investigation

Association Between Diabetes-Related Eye Complications and Symptoms of Anxiety and Depression

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← Invited Commentary
+ Supplemental content at
jamaophththalmology.com

IMPORTANCE This study is needed to clarify inconsistent findings regarding the association between diabetes-related eye complications and psychological well-being.

OBJECTIVE To examine the association between severity of diabetic retinopathy (DR) and diabetic macular edema (DME) with symptoms of depression and anxiety in adults with diabetes.

DESIGN, SETTING, AND PARTICIPANTS A cross-sectional study was conducted in a tertiary eye hospital in Melbourne, Australia. The study comprised 519 participants with diabetes. The median duration of diabetes was 13.0 (interquartile range, 14.0) years. The study was conducted from March 1, 2009, to December 24, 2010.

EXPOSURES Patients underwent a comprehensive eye examination in which dilated fundus photographs (disc and macula centered) were obtained and graded for the presence and severity of DR and DME. Presenting distance unocular and binocular visual acuity were assessed using a 3-m logMAR chart.

MAIN OUTCOMES AND MEASURES Symptoms of depression and anxiety were measured using the Hospital Anxiety and Depression Scale (HADS), which comprises 7 questions specific to

Impact Of DR On Social And Emotional Well-being

- Disruption of family functioning, relationships and roles; increased social isolation and dependence; deterioration of work prospects; increased financial strain.
- Fear, anxiety, vulnerability, guilt, loss of confidence, anger, stress and poor self-perception

Social and emotional impact of diabetic retinopathy: a review

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ABSTRACT

People
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Qual Life Res
DOI 10.1007/s11336-012-0110-1

roles; increased social isolation and dependence; and

The impact of diabetic retinopathy on quality of life: qualitative findings from an item bank development project

Eva K. Fenwick · Konrad Pesudovs ·
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Tien Y. Wong · Ecosse L. Lamoureux

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Abstract

Purpose Assessing the efficacy of treatment modalities for diabetic retinopathy (DR) from the patient's perspective is restricted due to a lack of a comprehensive patient-reported outcome measure. We are developing a DR-specific quality of life (QoL) item bank, and we report here on the qualitative results from the first phase of this project. **Methods** Eight focus groups and 18 semi-structured interviews were conducted with 57 patients with DR. The sessions were transcribed verbatim and iteratively analysed using the constant comparative method and NVIVO software.

Results Participants had a median age of 58 years (range 27–83 years). Twenty-seven (47%) participants had proliferative DR in the better eye, and 14 (25%) had clinically significant macular oedema. Nine QoL domains were identified, namely visual symptoms, ocular surface symptoms, vision-related activity limitation, mobility, emotional

well-being, health concerns, convenience, social, and economic. Participants described many vision-related activity limitations, particularly under challenging lighting conditions; however, socioemotional issues were equally important. Participants felt frustrated due to their visual restrictions, concerned about further vision loss and had difficulty coping with this uncertainty. Restrictions on driving were pervasive, affecting transport, social life, relationships, responsibilities, work and independence. **Conclusions** Patients with DR experience many socio-emotional issues in addition to vision-related activity limitations. Data from this study will be used to generate data for a DR-specific QoL item bank.

Keywords Diabetic retinopathy · Quality of life · Patient-reported outcomes · Vision impairment · Item bank · Focus group

Impact of Severity of DR on QoL in Singapore

- We explored the impact of DR on QoL in 292 patients with diabetes in the SCES
- Impact of Vision Impairment Questionnaire (IVI) assesses Reading and Accessing Information; Mobility and Independence; Emotional well-being.
- Of the 292 participants, 31.2% had any DR; 9.3% had VTDR; and 7.5% had PDR.

	Reading	%	Emotional	%
Any DR	$\beta = -0.46$ (CI -0.87, -0.04)	7.4	$\beta = -0.50$ (CI -0.96, -0.23)	7.0
VTDR	$\beta = -0.65$ (CI -1.31, -0.06)	10.7	$\beta = -1.14$ (CI -1.86, -0.42)	16.1
PDR	$\beta = -0.69$ (CI -1.47, -0.01)	11.2	$\beta = -1.36$ (CI -2.19, -0.53)	19.0

Bolded values represent independent variables significantly associated with QoL outcome ($p < 0.05$)

Adjusted for age, gender, stroke, socioeconomic factors (education and income) and presenting VA, and diabetic risk factors (including BMI, HbA1c, duration of DM, chronic kidney disease, hyperlipidemia, and hypertension)

Impact of Severity of DR on VRQoL in Singapore

- Similar findings to the SiMES study which used the VF-11
- Only VTDR and PDR were associated with worse visual functioning when presenting VA was included in the model
- In contrast, we found that *Mobility* was not associated with DR
 - May suggest that *Mobility is a less important construct for Chinese patients* than *Reading* and *Emotional*
 - Few 'mobility' items in the VF-14

Impact of unilateral and bilateral DR on VRQoL

Singapore Diabetes Management Project (S-DMP) was a cross-sectional, clinical study of 390 individuals of Malay, Indian and Chinese ethnicity with diabetes

[Invest Ophthalmol Vis Sci](#). 2016 Sep 1;57(11):4655-60. doi: 10.1167/iovs.16-20165.

Differential Impact of Unilateral and Bilateral Classifications of Diabetic Retinopathy and Diabetic Macular Edema on Vision-Related Quality of Life.

[Man RE](#)¹, [Fenwick EK](#)², [Sabanayagam C](#)³, [Li LJ](#)³, [Tey CS](#)¹, [Soon HJ](#)¹, [Cheung GC](#)⁴, [Tan GS](#)⁴, [Wong TY](#)², [Lamoureux EL](#)³.

⊕ Author information

Abstract

PURPOSE: To evaluate and compare the impact of unilateral better-eye and bilateral categorizations of diabetic retinopathy (DR) and diabetic macular edema (DME) on vision-related quality of life (VRQoL) in individuals with type 2 diabetes (T2DM).

METHODS: We recruited 390 subjects (116 females; age range, 22-78 years) of Malay, Indian, and Chinese ethnicities from the Singapore Diabetes Management Project (S-DMP), a cross-sectional clinic-based study conducted from 2010 to 2013. Diabetic retinopathy and DME were graded using the Modified Airlie House and American Academy of Ophthalmology classification systems, respectively. Subjects were categorized, using unilateral better-eye classifications, into no DR (n = 189), any DR only (n = 164), and any DME (n = 37); and with bilateral classifications into no DR (n = 144), DR/DME in one eye only (n = 45), DR in one eye and DR/DME in the other (n = 164), and DME in both eyes (n = 37). Vision-related quality of life was assessed using the composite Rasch-transformed score of the Impact of Visual Impairment (IVI) questionnaire.

RESULTS: For unilateral better-eye classifications, multivariable linear models revealed a 9% reduction in VRQoL for any DR (β [95% confidence interval (CI)], -0.44 [-0.86, -0.03]) and a 17% reduction for any DME (-0.81 [-1.53, -0.08]) compared to individuals with no DR/DME. Bilateral categorizations revealed significant decrements in VRQoL that occurred only when both eyes had either DR or DME (11%), which worsened when both eyes were affected by DME (22%).

CONCLUSIONS: Our results suggest that interventions to prevent the onset of DR and/or DME in the second eye are strongly recommended to significantly reduce the bilateral impact of these conditions on VRQoL.

Differential Impact Of Unilateral And Bilateral DR On QoL

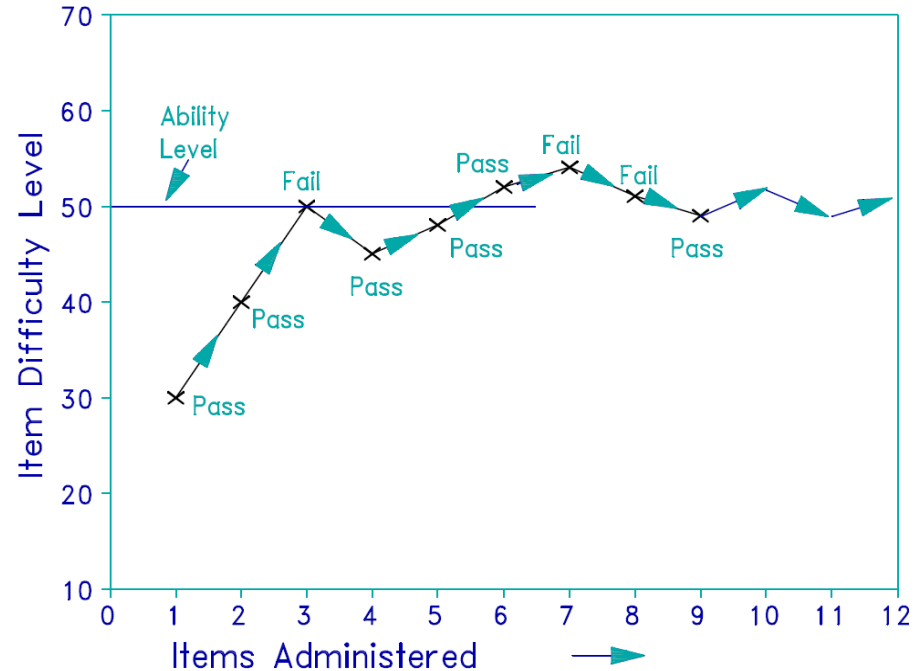
- Unilateral classification of DR:
 - 9% reduction in VRQoL for any DR ($\beta = -0.44$ CI -0.86, -0.03)
 - 17% reduction in VRQoL for any DME ($\beta = -0.81$ CI -1.53, -0.08)
- Bilateral classification of DR:
 - 11% reduction in VRQoL for Any DR / any DR or DME ($\beta = -0.57$ CI -1.01, -0.13)
 - 22% reduction in VRQoL for any DME in both eyes ($\beta = -1.08$ CI -1.81, -0.35)
- Research into the patient-centered impact of DR and DME should account for the contralateral eye.
- Interventions to prevent the onset of DR and/or DME in the second eye are strongly recommended.

More Research Needed?

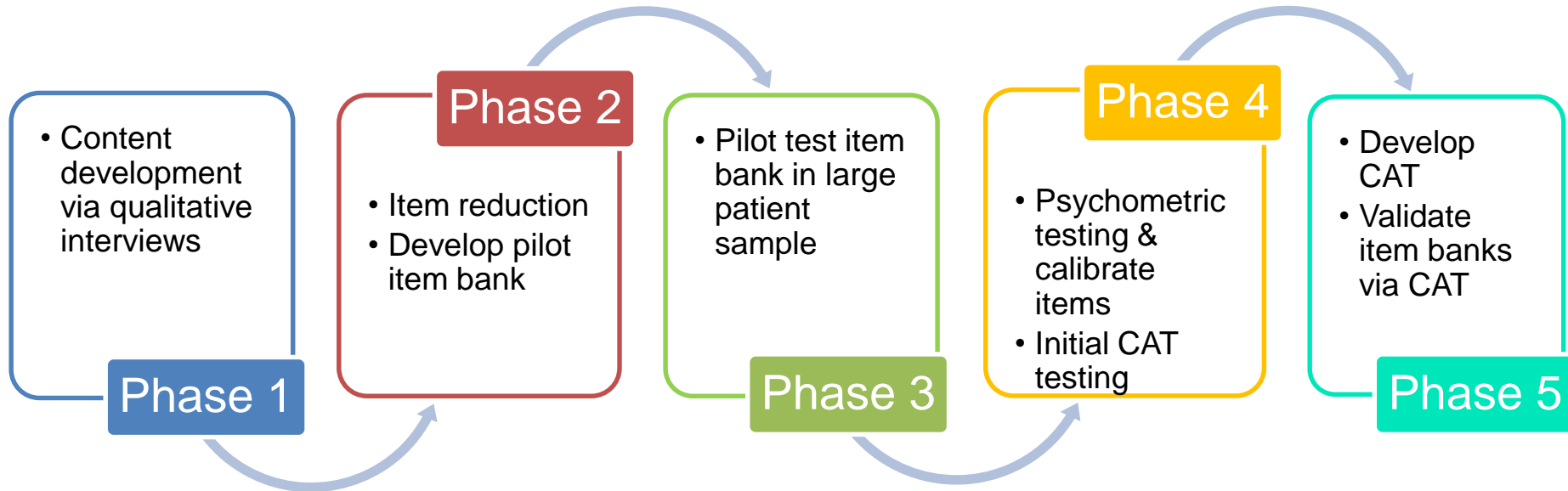
- Limitations with the existing PROs
 - Most measure 1-3 QoL domains
- Limited number of items
 - Not suitable for population (too easy or too difficult)
- Traditional summative scoring method
 - Well-known psychometric limitations
- Paper and pencil based
 - No real-time data collection & feedback

Item Banking and CAT

- Item bank – large pool of items (questions) calibrated for difficulty on the same scale using Rasch analysis
- Computer adaptive testing – method of administering tests where computer software adapts the item asked *depending on a person's response to previous items*



DR/DME Item Banking and CAT Development



Phase 3: Specific item banks and 314 items

Quality of life Domains		Number of items
1	Activity limitation (AL)	120
2	Mobility (MB)	19
3	Visual symptoms (VS)	18
4	Ocular comfort symptoms (OS)	10
5	Convenience (CV)	30
6	Health concerns (HC)	36
7	Emotional well-being (EM)	48
8	Social (SC)	21
9	Economic (EC)	12
Total		314



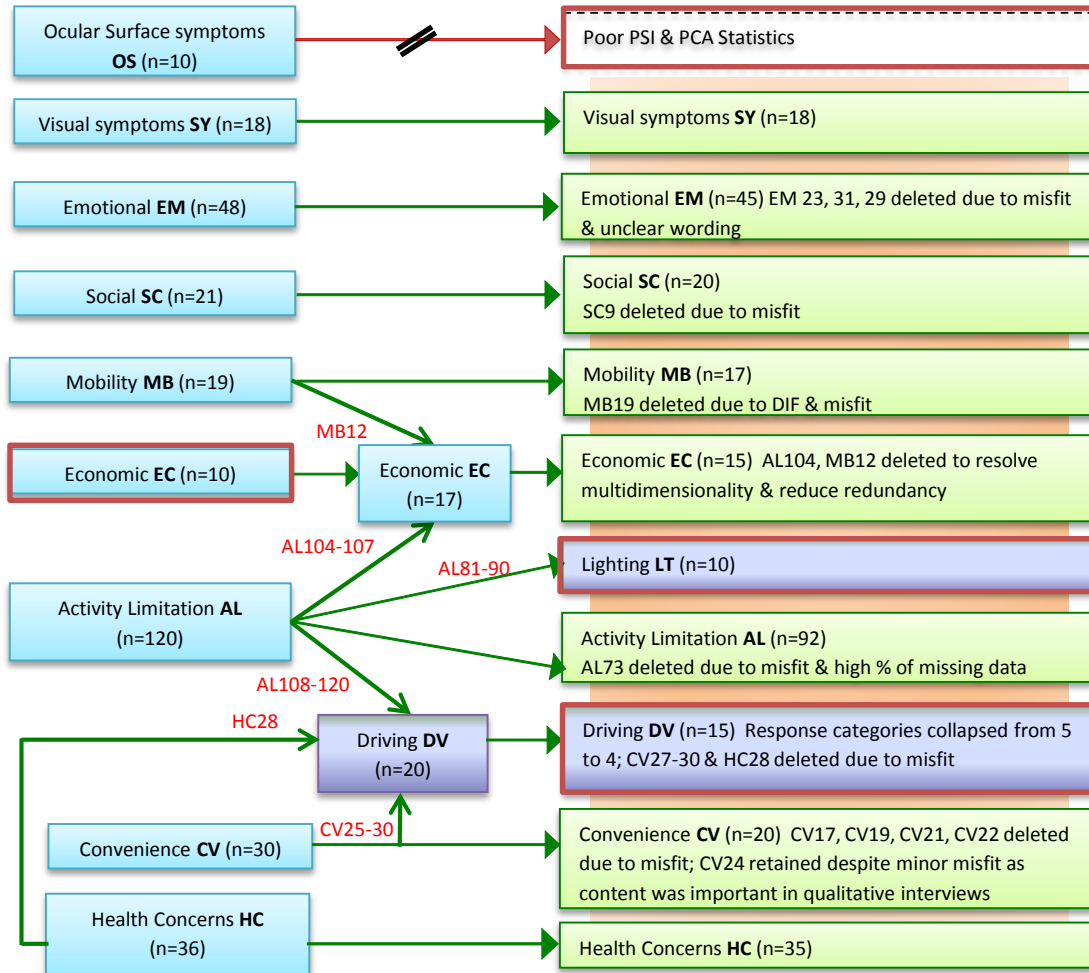
RESEARCH
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Phase 4 A: Psychometric Evaluation



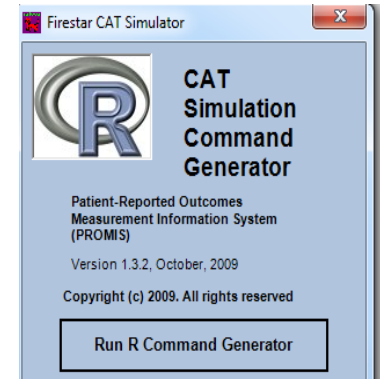
Ocular Surface Symptoms had unresolvable psychometric issues

Activity Limitation & Convenience were modified due to multidimensionality
 → Two new item pools:
Driving and Lighting

Economic was expanded to include work-related items from Activity Limitation and Mobility

Phase 4B: CAT Simulations

- CAT simulation: Firestar-D-Software (<http://cran.r-project.org/>) (n=1000)
 - Estimate number of items required to obtain high and moderate levels of precision – set stopping rules
- Simulation 1: High precision, Standard Error of Measurement (SEM)= 0.387 (reliability = 0.85)
- Simulation 2: Moderate precision, SEM = 0.521 (reliability = 0.72)



Preliminary results 4B

Table 2. CAT simulation results for the diabetic retinopathy item banks: **high precision**

Item bank	No. of items available for CAT	Average no. of items used by CAT	Correlation between CAT and item bank theta	Mean SEM (sem.CAT)
Visual Symptoms	18	7.7	0.97	0.38
Activity Limitation	92	5.3	0.94	0.37
Mobility	17	9.1	0.97	0.38
Emotional	45	6.5	0.94	0.38
Health Concerns	35	5.8	0.95	0.37
Social	20	7.1	0.96	0.37
Convenience	20	6.7	0.96	0.38
Economic	15	5.9	0.97	0.37
Driving	15	8.7	0.98	0.38
Lighting	10	8.1	0.99	0.38
Total	287	70.8 (24.7%)	0.96	0.38

Preliminary results 4B

Table 2. CAT simulation results for the diabetic retinopathy item banks: **moderate precision**

Item bank	No. of items available for CAT	Average no. of items used by CAT	Correlation between CAT and item bank theta	Mean SEM (sem.CAT)
Visual Symptoms	18	3.3	0.88	0.50
Activity Limitation	92	3.1	0.88	0.47
Mobility	17	4.5	0.91	0.50
Emotional	45	3.3	0.89	0.50
Health Concerns	35	3.1	0.89	0.48
Social	20	3.4	0.89	0.49
Convenience	20	3.3	0.90	0.49
Economic	15	2.9	0.91	0.48
Driving	15	3.9	0.91	0.50
Lighting	10	4.1	0.93	0.49
Total	287	34.8 (12.1%)	0.90	0.49

Future Work- Phase 5

- Validation of the 10 item banks using CAT via an online platform with tablet administration
- English and other Languages
 - Completion time
 - Content range coverage and test precision
 - Temporal reliability
 - Criterion, convergent and divergent validity

Summary

- DR has a substantial impact on daily activities and several aspects of VSF and QoL especially, emotional well-being
- However, work in this area could be improved with a DR/DME item bank a more sophisticated, sensitive and comprehensive PRO
- Valuable clinical and research applications
- Timely as new treatments for DR/DME continue to emerge and need evaluation from the patient's perspective and cost-effectiveness

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