

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

Running title: The impact of diabetic retinopathy on quality of life

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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 58 years (range 27-83 years). 27 (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, socio-emotional 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

Word count: 4998

1 **Abbreviations:**

2 DME – diabetic macular oedema

3 DR – diabetic retinopathy

4 PRO – patient reported outcome measure

5 QoL – quality of life

6

1 **Introduction**

2 Diabetic retinopathy (DR) is a common microvascular complication of diabetes and it is the
3 leading cause of blindness in the working aged population.[1, 2] In its later proliferative stage
4 significant irreversible vision loss commonly occurs. Diabetic macular oedema (DME), which can
5 occur at any stage of DR, also commonly causes irreversible loss of central vision.[3, 4] After 20
6 years of living with diabetes the majority of patients will have some degree of DR.[3, 5] The
7 mainstay of treatment for DR is laser photocoagulation, and vitrectomy in late disease, but
8 evidence for the benefit of new therapies, especially anti-vascular endothelial growth factor (VEGF)
9 intravitreal injections, is emerging.[6-8]

10 The impact of DR on patients' visual functioning is substantial, particularly at the vision-
11 threatening stages such as proliferative DR and clinically significant macular oedema.[9-12] Few
12 studies, however, have systematically assessed the comprehensive impact of DR on quality of life
13 (QoL) parameters beyond vision-related activity limitation, otherwise known as visual
14 functioning.[13, 14] Qualitative studies have referred to a plethora of emotional reactions to DR,
15 related vision loss and treatment including worry, loss of confidence, loss of independence, anger,
16 depression, and low self-esteem[15-19] as well as a negative impact on family functioning, work
17 and social life.[15-18] However, these studies have been relatively small, especially regarding
18 patients at the severe spectrum of DR.

19 Quantitative research exploring the impact of DR on QoL has been restricted by the lack of
20 an appropriate DR-specific patient reported outcome measure (PRO).[13, 14] To date, only one
21 instrument, the Retinopathy Dependent Quality of Life Questionnaire (RetDQoL)[17, 20] is
22 available. However, this instrument underwent only basic validation procedures and its content and
23 structure were based largely on an existing PRO assessing the QoL impact of diabetes.[21] The
24 RetDQoL also uses a scoring method that involves multiplying two sets of patient-reports together,
25 an approach that has been demonstrated to be fundamentally flawed.[22]

26 Without an appropriate DR-specific PRO our ability to understand the full impact of DR on
27 all relevant QoL parameters is impeded. This is vital as QoL outcomes from the patient's
28 perspective are becoming increasingly important in clinical trials assessing the efficacy of new

1 treatment interventions.[23-25] This is particularly relevant for DR, where emerging therapies such
2 as anti-VEGF injections, may prove to have fewer side effects and greater visual acuity gains than
3 traditional treatments.[7]

4 Therefore, we are developing a comprehensive DR-specific QoL outcome measure which
5 will assess the impact of DR on all relevant QoL parameters. A key aspect of item generation
6 involves comprehensive qualitative consultation with patients.[30, 31] In this paper we describe
7 findings from focus groups and individual interviews covering all QoL parameters important to
8 people with DR. In particular, we explored issues relating to symptoms and treatment, vision-
9 related activity limitation, mobility, emotional well-being, social life, work life and finances, roles,
10 and convenience in a large sample of patients across the spectrum of DR severity.

11

12 **Methods**

13 Participants

14 We recruited participants primarily from the baseline phase of a large longitudinal study, the
15 Diabetes Management Project. Diabetes Management Project participants comprised patients
16 from eye clinics at the Royal Victorian Eye and Ear Hospital. The methodology of the Diabetes
17 Management Project has been described previously.[32, 33] Briefly, Diabetes Management Project
18 participants were aged 18 years or older, had type 1 or 2 diabetes, and had no significant hearing
19 or cognitive impairment.

20 We assessed DR using dilated fundus photography. We categorised DR severity as no DR
21 (Early Treatment of Diabetic Retinopathy Study[34] level 10 to 15), mild non proliferative DR
22 (NPDR) (level 20), moderate non proliferative DR (level 31 to 43), severe non proliferative DR
23 (level 53 to 60), and proliferative DR (level 61 to 80). We categorised DME severity using the
24 American Academy of Ophthalmology classification[35] as no DME=10/20, mild DME=30,
25 moderate DME=40, and severe DME=50. We also collected socio-demographic and clinical
26 information, such as visual acuity and DR severity for all participants.

27

28 Recruitment

1 The appropriate sample size for a qualitative study is one that adequately answers the
2 research question and is determined by data saturation, i.e. when no new themes emerge.[36] We
3 used a purposive sampling technique to recruit participants for this qualitative study[37, 38] in
4 order to ensure a satisfactory range of DR severity was obtained and that both older and younger
5 participants were represented. Therefore, participants from the Diabetes Management Project with
6 at least mild non-proliferative DR in the better eye and/or DME, without clinical evidence of other
7 ocular conditions were eligible (n=124).

8 We posted eligible participants a large-print invitation letter and followed up those who
9 failed to respond by telephone. To capture issues pertinent to younger participants, we carried out
10 recruitment of additional participants aged less than 55 years through a Diabetes Australia-Victoria
11 online newsletter and seminars. At the point of recruitment, we questioned Diabetes Australia-
12 Victoria participants at length about their ocular history and prior treatments to determine whether
13 they had DR. We subsequently obtained their latest visual acuity and severity of DR and DME from
14 their ophthalmologist.

15 The study had ethical approval from the Royal Victorian Eye and Ear Hospital Human
16 Research Ethics Committee (# 09/888H) and was conducted in accordance with the Declaration of
17 Helsinki. We collected written informed consent from each participant before commencing the
18 session.

19 Procedure

20 We conducted the focus groups between January and May 2010 and the interviews
21 between October and November 2010 at the Royal Victorian Eye and Ear Hospital. We chose both
22 methods of data collection as they each have certain advantages. Focus groups, for instance,
23 encourage dynamic interactions between participants by exposing them to new viewpoints and
24 provoking discussions, while semi-structured interviews allow informants to gain rapport with the
25 interviewer.[39, 40]. Individual interviews were used for participants who could not attend any of
26 the group sessions. The focus groups lasted between 77 and 114 minutes and the interviews
27 lasted between 20 and 99 minutes.

28 We developed an interview schedule for the focus group and individual interview
29 discussions using information from a comprehensive literature review[13] and input from

1 ophthalmic specialists (**Appendix 1**). The interview schedule consisted of a standard introduction,
2 open-ended questions, probes and a summary. The questions in the interview schedule began
3 generally (e.g. “How do your diabetic eye problems impact on your QoL?” and “What areas of your
4 life are affected by your diabetic eye problems?”) and progressed to more specific questions about
5 emotional well-being, social life and so on, depending on participants’ prior responses. Where
6 necessary the interviewer used prompts to encourage further discussion or more detailed
7 responses.

8 During the focus groups, a moderator’s assistant took detailed notes of the discussion.
9 After each group, the moderator [author EF] and assistant discussed the outcomes of the session
10 and the moderator produced a written summary of the session. The moderator reviewed and
11 compared the written summaries after each subsequent group to ascertain whether new themes
12 had emerged.

13 Data analysis

14 We recorded the groups and interviews using a portable digital recording device and
15 transcribed each session verbatim. We analysed the transcripts using an inductive analytical
16 approach which is based on the constant comparative method.[37, 38] This iterative process
17 involves coding utterances from the transcripts into themes and constantly comparing and
18 contrasting the coded themes within and across transcripts. A second researcher (GR) reviewed
19 the final coding and we resolved any disagreements by discussion. We used the qualitative
20 software NVIVO 2008 (QSR International Pty Ltd, 2007) to sort and store the data.

21 We performed descriptive statistical analyses on the participants’ sociodemographic and
22 clinical data using the SPSS statistical package (Version 16.0, SPSS Science, Chicago, IL). We
23 conducted univariate analyses using the χ^2 statistic for categorical data and Student’s *t*-test for
24 continuous data to assess any differences between participants from the Diabetes Management
25 Project recruitment pool who agreed and declined to take part in the study.

26

27 **Results**

28 Participants

1 Of the 124 patients from the Diabetes Management Project sample invited to participate, 50
 2 (40.3%) agreed. There were no significant differences between participants and non-participants
 3 from the Diabetes Management Project recruitment sample with regard to a range of
 4 sociodemographic and clinical variables (all $p>0.05$). Overall, we conducted eight focus groups
 5 and 18 semi-structured interviews with 57 patients with DR (50 from Diabetes Management Project
 6 and 7 from Diabetes Australia-Victoria). The size of the focus groups depended on participant
 7 availability and ranged from three to seven participants.

8 Participants had a median age and duration of diabetes of 58 years (range 27-83) and 17
 9 years (range 1-53), respectively (**Table 1**). Just under half of participants had proliferative DR in
 10 the better eye and a quarter had severe DME. Most participants ($n=39$, 68%) had no distance
 11 visual impairment (≤ 0.3 LogMAR) in the better eye, although around half had at least mild
 12 monocular distance visual acuity impairment (>0.3 LogMAR).

13
 14

Table 1. The sociodemographic characteristics of the 57 participants*

Variable	n (%)
<i>Age</i>	
≤ 55 years	23 (40.4)
<i>Diabetes type</i>	
Type 2	42 (73.7)
<i>Diabetes Treatment</i>	
Tablets	40 (70.2)
Insulin	39 (68.4)
Both	24 (42.1)
<i>Gender</i>	
Male	39 (68.4)
<i>Geographical location</i>	
Inner city	4 (7.0)
Suburban	44 (77.2)
Rural / remote	9 (15.8)
<i>Country of birth</i>	

Australia	27 (47.4)
Europe	20 (35.1)
Other	10 (17.5)
<i>Main language spoken</i>	
English	48 (84.2)
English plus another	9 (15.8)
<i>Marital status</i>	
Never married	10 (17.5)
Married/de facto	40 (70.2)
Divorced/separated/widowed	7 (12.3)
<i>Education level</i>	
Secondary or less	32 (56.1)
TAFE/university degree	25 (43.9)
<i>Employment status</i>	
Currently employed	18 (31.6)
Unemployed	5 (8.8)
Medical disability pension	14 (24.6)
Retired	20 (35.1)
<i>Comorbidity (yes, self-reported)</i>	
Hypertension	31 (54.4)
Angina / heart attack	17 (29.8)
Stroke	3 (5.3)
High cholesterol	32 (56.1)
<i>Vision impairment (right eye)</i>	
None (≤ 0.3 LogMAR)	28 (49.1)
Mild (> 0.3 LogMAR ≤ 0.48)	8 (14.0)
Moderate/severe (> 0.48 LogMAR)	19 (33.3)
<i>Vision impairment (left eye)</i>	
None (≤ 0.3 LogMAR)	30 (52.6)
Mild (> 0.3 LogMAR ≤ 0.48)	11 (19.3)
Moderate/severe (> 0.48 LogMAR)	14 (24.6)
<i>Vision impairment (etter eye)</i>	
None (≤ 0.3 LogMAR)	39 (68.4)

Mild (>0.3 LogMAR ≤0.48)	8 (14.0)
Moderate/severe (>0.48 LogMAR)	8 (14.0)
<i>Severity of DR (better eye)</i>	
Mild non-proliferative DR	18 (31.6)
Moderate non-proliferative DR	7 (12.3)
Severe non-proliferative DR	4 (7.0)
Proliferative DR	27 (47.4)
<i>Severity of DME (better eye)</i>	
None	31 (54.4)
Mild diabetic macular oedema	7 (12.3)
Moderate diabetic macular oedema	3 (5.3)
Severe diabetic macular oedema	14 (24.6)
<i>DR treatment</i>	
Laser therapy	54 (94.7)
Vitrectomy surgery	12 (21.1)
Intraocular injections	5 (8.8)
<i>Other eye pathology (self-report)</i>	
Cataract	5 (8.7)
Age-related macular degeneration	3 (5.3)
Glaucoma	7 (12.3)
	Mean, median (range)
<i>Age (years)</i>	58.7, 58.4 (27.0-83.4)
<i>Duration of diabetes (years)</i>	18.8, 16.9 (1.2-53.0)

* Percentages for some variables may not equal 100% due to missing data

de facto=couples living in a marriage-like state for at least 2 years; DR=diabetic retinopathy; LogMAR=logarithm of the minimum angle of resolution; TAFE=Technical and Further Education.

1

2 **Impact of DR on relevant components of QoL**

3 Our choice of QoL domains was guided by both a “top-down” and “bottom-up” approach.

4 By top-down we refer to our comprehensive review of the literature and consideration of QoL

5 domains proposed in existing vision-related PROs, which provided us with a working conceptual

6 framework. However, we also utilised a bottom-up approach where we were guided by the data

7 and the psychometric experience of the expert panel, giving us flexibility to divide, remove or add

1 domains based on item content. As such, we started with a solid organisational structure but had
 2 the freedom to ensure that our unique data was faithfully represented.

3 We isolated nine key domains of QoL, namely **visual symptoms, ocular surface**
 4 **symptoms, vision-related activity limitation, mobility, emotional well-being, health**
 5 **concerns, convenience, social, and economic (Table 2)**. We provide results for each domain,
 6 including supporting quotes and number of supporting utterances (n) for each theme. Note that the
 7 value of *n* does not refer to the number of participants.) We counted repeated references to one
 8 theme in a dialogue by a single participant as a single utterance so as to avoid inflating the
 9 theme's importance. We also provide additional supporting quotes for the larger domains (i.e
 10 vision-related activity limitation, mobility, emotional well-being, health concerns, convenience,
 11 social, and economic) in **Suppl Tables 1-7**.

Table 2 –The nine QoL domains and sub-domains identified

QoL Domains	Sub-domains
Visual symptoms	None
Ocular surface symptoms	None
Vision-related activity limitation	Day to day tasks, Self-care & diabetes management, Luminance.
Mobility	Walking, Public transport
Emotional	Sadness, Anger, Fear, Self-perception
Health concerns	Treatment, Safety, Socio-emotional
Social	Social isolation, Personal relationships, Roles
Convenience	General limitations, Treatment, Travel limitations
Economic	Work, Finance

13

14

15 **Visual symptoms (n=237)**

16 Participants described experiencing blurred, hazy and distorted vision and seeing black lines and
 17 dots. Many participants also described experiencing fluctuating vision and periods of temporary
 18 'blackness' due to retinal haemorrhage. Many participants referred to a 'worse eye' and described

1 being bothered by a visual difference between their two eyes. Other difficulties included
2 distinguishing colours, peripheral vision, and depth perception.

3 *It was like looking through...burnt trees. It's just like dead branches, burnt out dead branches*
4 *everywhere. (FG1)*

5 **Ocular surface symptoms (n=21)**

6 Ocular surface symptoms included pain, discomfort, tired or strained eyes, dry eyes and watery
7 eyes as a result of DR or related treatment.

8 *Sometimes I get this feeling of like a bruise, like bruised eyeballs. Often that's followed with a burst*
9 *blood vessel (Int5)*

10 **Vision-related activity limitation (n=803)**

11 Many participants complained of reading difficulties, especially with newspapers, books, labels,
12 ingredients or prices. Particular difficulties included missing lines or parts of words. Other
13 difficulties included reading street signs, watching TV, household tasks, sewing, gardening,
14 cooking, pouring liquids, using appliances, shopping, handling cash, recognising faces, hobbies
15 and driving (particularly at night).

16 *I am not able to watch the football properly and really enjoy it, that's really hard. You're thinking,*
17 *Who's playing? You can't see the ball (FG8)*

18 *The effects on me were devastating. I had to leave my job, which was teaching, and my hobby was*
19 *stamp collecting and I used to collect cigarette cards...I used to write...I was a church organist, but I*
20 *play it by sight. So in every way, all my interests-just overnight I was unable to do it. (FG3)*

21 Participants reported difficulty with self-care activities, such as eating, organising medication,
22 dressing oneself, putting on make-up and shaving. Patients' ability to manage their diabetes was
23 also affected, including difficulty reading nutritional information on food products, taking insulin and
24 diabetes medication, checking glucose levels, cutting toenails, caring for feet and exercising.

25 *A few weeks ago the chemist gave me the wrong insulin, and I didn't see. I ended up using it and*
26 *having hypos... (FG8)*

27 Participants reported difficulty seeing in dim lighting, at night and in glare conditions, and difficulty
28 adjusting from dim to bright lights or vice versa.

29 *I find that wet days, or really sunny days, or rooms like this with fluorescent lights and very light*
30 *walls, it's very glary (FG5)*

1 **Mobility (n=91)**

2 Participants reported difficulty negotiating steps and curbs, especially if they were not well
3 distinguished. Many also found it challenging to move in crowded places, avoid tripping, cross a
4 street, and negotiate uneven pavements or suspended objects. Participants generally had little
5 trouble moving about in their own homes, but reported some difficulty moving around at work or
6 other people's houses. Issues with catching public transport included getting on and off buses,
7 trams and trains.

8 *I tend to not see steps. I sort of walk out of a building and I'll fall over sort of thing. (Int1)*

9 **Emotional well-being**

10 We categorised patients' emotional responses about their DR below into **sadness, anger,**
11 **fear, and self-perception** based on the tree-structure of emotions proposed by Parrot (2001).[41]

12 Sadness (n=78)

13 Several participants reported feeling depressed due to their DR and some even admitted to
14 having suicidal thoughts. Others described feeling sad or low, upset, emotionally raw, miserable
15 and devastated. Other negative emotions included 'loss of motivation', 'hopelessness', 'loss of
16 pleasure in things', 'missing work or hobbies' and 'loss of spontaneity'.

17 *But you can fall back into depression and start worrying about it, like...I've thought of suicide. You*
18 *feel like you don't want to live anymore. (FG8)*

19 Anger (n=97)

20 Almost all participants reported feeling frustrated because of the limitations imposed by
21 their vision loss from DR (n=42). Many participants described feeling angry, annoyed, moody and
22 agitated, especially in cases where their eye condition continued to worsen despite vigilant diabetic
23 control. In these cases, participants often felt 'cheated' and were left despondently pondering 'why
24 me?' A few participants also reported feeling oppressed because of a sudden loss of sight or
25 gradually deteriorating vision.

26 *Definitely angry because I can't do the things I used to do, or I can't do them the way I want to do*
27 *them...And then I'll get depressed...It can be a bit of a rollercoaster sometimes. (Int9)*

28 Fear (n=38)

1 The time of diagnosis of DR was very frightening for participants. Many felt stressed about
2 their vision and reported that it was 'always on their mind'. Others described feeling scared when
3 unexpected events occurred such as sudden loss of vision from a haemorrhage. Several
4 participants described situations in which they felt vulnerable, disconcerted or nervous. Others
5 described feeling extra pressure to maintain their vision so they could continue to care for their
6 family.

7 *When the blood vessels burst or something you can't see anything and it's very scary. (FG1)*

8 Self-perception (n=47)

9 Participants often described feeling a loss of self-worth, self-image or self-confidence.
10 Many felt older, less competent, inadequate or less important because of their restricted role in the
11 family or community. In contrast, reliance on family members made other participants feel
12 burdensome and like non-productive adults. Several participants also felt embarrassed when they
13 had to ask a stranger for help or made a social faux pas.

14 *I'm not ready to be a useless couch potato. And that's how I feel most of the time. A useless couch*
15 *potato. (Int2)*

16 *Going out to dinner with the girls...My husband will drop me off and collect me...sort of feel like a 2*
17 *year old sometimes. (Int1)*

18 **Health concerns**

19 Treatment (n=59)

20 Participants were concerned about the pain associated with laser treatment, side effects
21 from laser treatment, and undergoing injections or an operation. Several participants felt they did
22 not fully understand their eye treatment and pondered whether it was working.

23 *I have had laser, which was awful. I found it really hard to cope with...not only was it painful, the light*
24 *– I actually ended up having to take Valium before each session...It was really distressing, and I*
25 *would start hyperventilating, and I nearly fainted a few times. (Int15)*

26 Socioemotional (n=169)

27 One of the most commonly reported concerns was fear of further deterioration in vision and
28 going blind (n=33). Participants also worried about future impacts, such as loss of driver's license
29 resulting in increased isolation, increased dependence, loss of employment and coping. Daily

1 concerns included worrying about the impact of vision loss on family members, being taken
2 advantage of, missing out on things, and offending people by not recognising them.

3 *Yeah, really freaking out. Not outwardly, but inwardly. What am I going to do? I'm going to lose my*
4 *job, I'm not going to be able to drive my car, I'm not going to be able to get around, I'm going to be*
5 *stuck inside. What sort of a job could I do if I did lose my sight? All that sort of stuff. (Int7)*

6 Participants reported that their level of vision impairment varied according to tiredness,
7 lighting conditions, and day to day acuity fluctuations. Because of this variation, and also because
8 their vision impairment was not visibly obvious to others, patients' frequently felt misunderstood.
9 Consequently, they were often upset when people became frustrated with their restricted vision.

10 *People don't understand...because they can't see what's happening to you. I can't explain to them*
11 *my situation. And then what do I do? I go somewhere and cry. (FG8)*

12 Many participants struggled to cope with the unpredictability of not knowing what and when
13 things might happen. One participant described how being diagnosed with DR had made her
14 ponder her own mortality and worry about getting other diabetic complications.

15 *For me it's the unknown, where it's going to go and how long it's going to take. (FG1)*

16 Family concerns included worrying about children growing up with a blind parent, worrying
17 about a spouse leaving, being apprehensive about becoming pregnant and feeling sad about not
18 being able to see family members' faces.

19 *One thing that probably makes me a bit apprehensive is we're trying to conceive for another child...I*
20 *know there's quite a good chance that my retinopathy will get worse while I'm pregnant. So that*
21 *makes me quite anxious about being pregnant again. (Int15)*

22 Safety (n=46)

23 Safety concerns included fear of tripping, falling, and bumping into things. Participants also
24 worried about their personal safety around the house, such as cutting or scalding themselves or
25 using appliances safely.

26 **Convenience**

27 General limitations

28 Participants made a number of emphatic statements about the profound impact of their DR
29 and vision problems on their lifestyle. Particular complaints (n=100) included not being able to do

1 things they used to do or not doing them as well, taking longer to do things and having to be slower
2 or concentrate longer on tasks. Many participants also felt restricted in when and where they could
3 do things.

4 *Just slows me down from doing things. I can only stand out in the outside bright light for so long*
5 *before it starts hurting, I don't get out as much, I don't read as much, don't watch TV or movies or*
6 *anything like that as much as I used to. (Int9)*

7 Treatment

8 Having multiple treatments, attending frequent appointments, and having dilating drops at
9 every clinic appointment was burdensome for many participants (n=28) due to various associated
10 logistical issues.

11 *I had to arrange for someone to drive me and pick me up...And I've got a toddler as well so had to*
12 *arrange babysitting. Just the logistics of it all. (Int15)*

13 Travel limitations

14 Similarly, driving limitations not only inconvenienced participants in getting around but also
15 affected their social life, personal relationships, roles, work and independence.

16 *Well, first thing in my case, my license was taken off me, that was my source of income. And*
17 *also...that is my quality of life because I cannot go out, hop in the car go wherever. But now I've got*
18 *to rely heavily on my wife. (FG1)*

19 **Social life**

20 Social isolation

21 Participants reported a substantial reduction in their social life (n=79). Many found
22 themselves more reluctant to attend social occasions because they no longer enjoyed them.
23 Attending social events in the evening was particularly difficult for participants due to poor night
24 vision. Consequently, many participants reported feeling socially isolated and staying home most
25 of the time.

26 *I was the social animal, I was the social king, that was my nickname, The King. I've pushed*
27 *everyone away. I'm pretty much a hermit at the moment. That includes my family, I've pushed them*
28 *away too because I don't want my kids...to see my struggle (Int2)*

29 Personal relationships

1 Considerable strain on personal relationships (n=49), particularly with partners, was
2 reported by many participants due to the frustrations of day to day living and needing more
3 support. Some participants also felt that family members tended to fuss over things unnecessarily.

4 Participants also reported difficulty maintaining family relationships or friendships due to
5 difficulty visiting and attending social functions. For younger participants, having DR also affected
6 important decisions such as starting a family.

7 *My wife said to me one day, "You're becoming a very grumpy old man". And I've noticed that I've*
8 *become very agitated. If things don't go my way it upsets me. And sometimes I regret the way I*
9 *speak to her (FG4)*

10 *I've lost friends because of it, too, because you can't help them do things...they think you're milking*
11 *it. (FG8)*

12 Roles

13 Many participants felt like they had lost their role in their family, as they could no longer do
14 things like manage the household or provide financially (n=17) and consequently felt a loss of
15 respect from family members. Others felt that they had lost their role in friendship groups, or in
16 community endeavours such as in the church or local clubs.

17 *Yes, definitely. I'm not the breadwinner anymore....Lower in the pecking order. I'm like an old lion*
18 *that's had his day, gets kicked out of the pride. No, I'm down the bottom. Definitely. (FG8)*

19

20 **Economic**

21 Work (n=67)

22 Many participants stated that they had stopped working prematurely as a result of their DR.
23 Others reported needing longer to complete tasks and finding things more difficult to accomplish.
24 Some participants also described inconvenience associated with having to take time off work after
25 a retinal haemorrhage or to have treatment which affected their work relationships. Some
26 participants felt that their capacity to find employment was also affected, due to their reduced skill
27 set or difficulty reading newspaper advertisements. Others described how their choice of career or
28 ability to access new job opportunities such as training or promotions were now more limited.

1 *Because I was a courier...I found it hard to park the van properly, because with one eye I can't see*
2 *at all on the left. I've just stopped work. (FG4)*

3 *When the situation arose that I had to mostly keep one eye closed, I didn't go to work. It happened*
4 *three or four times a year...It was problematic to my boss...It was problematic to me too because*
5 *you don't look so good. (Int4)*

6 Finance

7 Participants reported several direct financial implications (n=24) as a result of their DR,
8 including reduced income from loss of employment or restricted work hours, the cost of purchasing
9 glasses or visual aids and the cost of treatment and specialist care. Incidental costs (n=11)
10 included those associated with attending DR-related appointments such as parking or loss of
11 income, having to hire help such as cleaners or taking taxis, and making mistakes such as
12 breaking things, being taken advantage of or accidentally incurring fees from businesses.

13 *Well financially I guess the bottom line is the laser. It's the time out to seek the treatment and to*
14 *continually stay on top of those things...For me, that's visits down to Melbourne. That's a day out of*
15 *work for me and my hubby who comes as carer because I'm not able to drive back (Int5)*

16 *Because the eyesight's crap, this is where it's cost me money...Every time I turned the laptop on it*
17 *updated software and it's downloading. And it cost me a fortune...It wouldn't have happened if I had*
18 *eyesight. (Int2)*

19 **Discussion**

20 This paper describes in detail the impact of DR and related vision loss on all relevant QoL
21 parameters. As expected, participants reported many aspects of vision-related activity limitation
22 particularly under difficult lighting conditions; however, emotional well-being, health concerns and
23 social issues were equally important. Participants repeatedly described feeling frustrated due to
24 their visual restrictions, concerned about further vision loss and future prospects and had difficulty
25 coping with this uncertainty. Feeling misunderstood by others and issues around self-perception
26 also frequently concerned participants. Driving restrictions affected many facets of life beyond
27 transport, including social opportunities, relationships, responsibilities, work and independence.

28 The diverse emotional reactions revealed in our study, such as frustration, uncertainty, fear
29 of becoming blind, concern about driving, working and independence in the future, and self-
30 perception issues are supported by previous qualitative work.[15, 17, 18] Strain on personal
31 relationships, social isolation, inability to maintain responsibilities, loss of employment, and

1 financial implications were also key themes in Devenney and colleagues' recent exploratory
2 study.[15] In contrast, the frequent grievance by participants in our study that other people did not
3 understand their vision impairment has only briefly been mentioned previously.[17]

4 Given that ability to regulate emotions and access social support networks are central
5 disease coping strategies for patients,[42-44] it is possible that DR patients with heightened
6 emotional responses and impaired personal relationships may exhibit poor coping ability and
7 subsequently experience worse disease outcomes. Therefore, interventions such as counselling,
8 support groups, education for family members and strategies to enhance work-related
9 opportunities may considerably improve patients' overall QoL.

10 Our data substantiate previous qualitative and quantitative findings suggesting that DR
11 considerably contributes to vision-related activity limitation and mobility issues.[9, 10, 12, 16, 17,
12 45, 46] Of particular note is our finding that many participants were impaired under difficult lighting
13 conditions which supports previous quantitative findings.[47-49] In the current study, poor night
14 vision was a particularly pervasive restriction as it affected participants' ability to drive, work, attend
15 social or sports events or perform family responsibilities, resulting in feelings of dependence and
16 poor self-esteem.

17 These findings are critical as patients may not be asked to describe impairment under
18 difficult lighting conditions during routine eye examinations or at busy clinics. Similarly, many
19 questionnaires assessing vision-related activity limitation, with the exception of some glaucoma-
20 specific instruments, often contain little content targeting varying lighting conditions.[50]
21 Consequently, it is important that clinicians assess low luminance functioning and consider early
22 referrals to low vision services even if visual acuity loss is minimal. Researchers should ensure
23 they choose an outcome measure which captures vision-related activity limitation in a range of
24 lighting conditions.

25 Consistent with two previous qualitative studies,[15, 16] we found that the presence of DR
26 can negatively affects patients' ability to manage their diabetes. This is vital as it suggests the
27 existence of a detrimental cyclic relationship, namely that poor diabetes control may lead to
28 development and progression of DR, while presence of severe DR may result in poor diabetes

1 control. Diabetes and retinal specialists should be aware of the additional difficulty experienced by
2 visually impaired diabetics in managing their diabetes and support them in finding practical ways to
3 overcome this harmful cycle.

4 The variety of themes reported in this study regarding the impact of DR on QoL surpass
5 those usually found in existing vision-specific and generic QoL outcome measures,[51-53] which
6 tend to focus primarily on activity limitation and mobility. In addition, the themes emerging from the
7 Emotional, Health Concerns, Social, Convenience and Economic domains, are more
8 comprehensive than those captured by the RetDQoL, the only other DR-specific QoL outcome
9 measure currently available.

10 As this is a qualitative study, it is not possible to draw statistical inferences from the data.
11 Potential bias from the purposive sampling technique may also be present. However, the aim was
12 to provide depth and breadth of information about DR-related QoL impact rather than results that
13 are generalizable to the population. The large number of examples provided support the
14 conclusions drawn in this study. Strengths of this study include our large sample size of 57
15 participants compared with smaller samples of previous qualitative studies,[15, 16] as well as
16 having participants across the spectrum of DR including many with vision-threatening disease and
17 those of both working and non-working age.

18 We have used these data, along with data from qualitative interviews with diabetic and
19 retinal specialists and a comprehensive literature review [13, 14], to develop a comprehensive DR-
20 specific QoL item bank. An item bank is simply a set of items (questions) measuring a specific
21 latent trait that have been calibrated for difficulty on the same scale. Items are selected from the
22 item bank by a computer algorithm according to the ability level of each participant and their
23 responses to previous questions. This is known as computer adaptive testing.[26, 27] Item banking
24 and adaptive testing provide a more sophisticated approach to the assessment of patient reported
25 outcomes than traditional paper-pencil questionnaires as they are flexible and adaptable, allowing
26 more accurate, precise, valid and reliable measurements of the desired trait whilst requiring
27 implementation of fewer items.[28, 29]

1 The findings reported in this paper thus represent the foundation of a rigorously developed,
2 high-quality PRO to assess comprehensively the impact of DR and associated vision loss on all
3 domains of patients' QoL across the spectrum of the condition. In addition, the item bank will be
4 valuable for researchers to assess accurately the outcomes of both traditional and novel treatment
5 therapies for DR from the patient's perspective. Future research will involve pilot testing and
6 validation of the DR-specific QoL item bank with a large participant sample using modern
7 psychometric methods such as Rasch analysis.

8 In summary, this study found that DR and associated visual loss had a substantial impact
9 on a range of QoL parameters. Crucially, socio-emotional factors, such as frustration, feeling
10 misunderstood, poor self-perception, social isolation and role limitations were of great importance.
11 Clinicians, researchers and rehabilitation workers should be aware of the detrimental socio-
12 emotional issues experienced by participants with DR, in addition to understanding their vision-
13 related activity limitations. We have used the data from this study to generate items for a DR-
14 specific QoL item bank to assess comprehensively DR-related QoL impact and treatment
15 outcomes.

16
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19

20

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9

10 **Appendix 1 – Moderator’s guide for the focus group and interview discussions**

11

12 **Warm up questions**

13 Let’s start by getting to know each other. Let’s go around the group. Briefly, please let us know
14 your name and how long you have had diabetes.

15

16 **Questions and prompts**

17 We are interested today in your diabetic eye problems and how they impact on your life.

18

19 Symptoms

20 First, what are some of the symptoms you experience as a result of your diabetic eye problems?

21 *Can you describe your eyesight/vision?*

22 *How well can you see?*

23 *What factors influence your vision?*

24

25 Impact on QoL

26 How do your eye problems impact on your QoL?

27 *What areas of your life are affected by your diabetic eye problems?*

28 *How much would you say your diabetic eye problems impact on your QoL?*

29 *What things are harder to do because of vision loss from your diabetic eye problems?*

1 *Can you think of specific examples where your diabetic eye problem has caused you or*
2 *someone else difficulty?*

3 *Do you need help from others for some things because of your eye problems?*

4

5 **Depending on responses so far:**

6

7 In other groups I have talked to many people about how their diabetic eye problems affect them
8 emotionally. I'm interested in your experience of this.

9

10 Can you describe how your diabetic eye problems make you feel emotionally?

11 *How do you feel about your eye problems?*

12 *Can you describe some of your emotional reactions to vision loss?*

13

14 In what ways do your diabetic eye problems affect your social or family life?

15 *What things are you missing out on because of your vision?*

16 *What social occasions or leisure activities are affected by your vision loss?*

17 *How has your eye problem affected your family and personal relationships?*

18

19 Thinking about travelling and getting out and about, can you describe how your diabetes eye
20 problems have affected this?

21 *What things are most difficult when travelling outside or in crowded places?*

22 *What do you find difficult when moving about in your own home?*

23

24 In what ways have your diabetic eye problems impacted on your work life?

25 *What aspects of your work are harder to do?*

26 *How have your diabetic eye problems impacted on you financially?*

27 *What things have cost you money because of your diabetic eye problems?*

28

29 How about managing your diabetes? In what ways do your diabetic eye problems affect this?

1 *What things [e.g. insulin shots, glucose monitoring, exercise] are hard to do because of*
2 *your vision loss?*

3
4 Finally, what is the worst thing about having diabetic eye disease?

5 *What do you find the most annoying about your vision loss from diabetes?*

6
7 Thank you all very much for sharing your experiences. I know this can be a difficult area to discuss
8 but your input has been really valuable. Before we move on, I will briefly summarise what we have
9 discussed so far.....

10
11 *Is there anything else you'd like to add to this before we move on?*

12
13 Treatment and impact

14 I'd now like to move on to talk about eye treatments.

15 Has anyone had any treatment for their diabetic eye problems? What was it?

16 *What were your experiences with this treatment?*

17 *What side effects, if any, have you experienced?*

18 *In what ways has your treatment experience affected your QoL?*

19
20 Useful prompts to use throughout the focus group:

21 *Are there any other views on this?*

22 *Is there anything else?*

23 *Would you explain further?*

24 *Can you give me an example of what you mean?*

25
26 **Summary**

27 We are reaching the end of our time now. I would like to summarise the key ideas that I have
28 heard...

1 *Is there anything I have missed or that you would like to add to my summary?*

2