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Development of the RetDQoL quality of life measure in the same interviews is reported elsewhere.

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Interviewees were 26 men, 18 women; median age 60.8 (range: 28-82), having background or proliferative retinopathy with a range of severity (one or both eyes); median visual acuity better eye 0.80 (range: 0.0025 (hand motion only) - 1.20 (6/5 vision)). Satisfaction dimensions included treatment effectiveness, emotional

and physical experiences before, during and after treatment, information provision and influence over treatment. The resulting RetTSQ has 13 items and an open question, allowing additional items to be developed if needed for future treatments. Conclusions: The RetTSQ has face and content validity for a wide range of people with diabetic retinopathy in two European countries. It is ready for further validation and for use in research and clinical contexts.

Development of the new Retinopathy Treatment Satisfaction Questionnaire (RetTSQ).

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Objective: To incorporate patients' views in the design of a measure of satisfaction with treatment for diabetic retinopathy, to be used in evaluation of currently available and anticipated new therapies. This report focuses on development of the Retinopathy Treatment Satisfaction Questionnaire (RetTSQ). Development of the RetDQoL quality of life measure in the same interviews is reported elsewhere. **Methodology:** During semi-structured interviews with 44 people with diabetic retinopathy (11 in each of 2 UK and 2 German hospitals), interviewees described their experiences of retinopathy treatments and reactions to possible new therapies. They completed and commented on a draft RetTSQ, based on the Diabetes Treatment Satisfaction Questionnaire (DTSQ). Drafts were revised and translated between centres, incorporating patients' views. Interviews were audio-taped, transcribed and content analysed. **Results:** Interviewees were 26 men, 18 women; median age 60.8 (range: 28-82), having background or proliferative retinopathy with a range of severity (one or both eyes); median visual acuity better eye 0.80 (range: 0.0025 (hand motion only) – 1.20 (6/5 vision)). Satisfaction dimensions included treatment effectiveness, emotional and physical experiences before, during and after treatment, information provision and influence over treatment. The resulting RetTSQ has 13 items and an open question, allowing additional items to be developed if needed for future treatments. **Conclusions:** The RetTSQ has face and content validity for a wide range of people with diabetic retinopathy in two European countries. It is ready for further validation and for use in research and clinical contexts.

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1. Introduction

Diabetic retinopathy (DR) is the leading cause of blindness amongst 16-64 year-olds[1]. Current management is limited to screening, laser photocoagulation and vitrectomy[2],

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with increased efforts to improve glycaemic control. Benefits of laser photocoagulation [e.g.3] are generally considered to outweigh its disadvantages[e.g.4]. DR and its management can have negative impacts, even before vision loss. To measure these, the individualized Retinopathy Dependent Quality of Life measure (RetDQoL)[5] was developed, modelled on the Audit of Diabetes Dependent Quality of Life[6]. The Retinopathy Treatment Satisfaction Questionnaire (RetTSQ), developed in parallel with the RetDQoL, is the focus of the present report. The RetTSQ needs to be relevant to current and future therapies, so is modelled on the Diabetes Treatment Satisfaction Questionnaire (DTSQ)[7]), which suits a wide range of treatment types. The DTSQ previously formed the basis of measures for end-stage renal disease (RTSQ)[8], Human Immunodeficiency Virus (HIVTSQ)[9] and genital herpes (GHerpTSQ)[10]. The RetTSQ needs to cover issues important and relevant to the range of people with DR, be easily understood and completed and include issues appropriate internationally, so it can be used in multinational trials. Medtap, Maryland, USA conducted four focus groups (unpublished) asking people with DR about laser treatments. Content analysis of the transcripts by the present authors suggested some issues to be covered by RetTSQ items. By designing the RetTSQ in four phases, alternating between UK and Germany, any translation problems could be resolved, to minimise difficulties with further translations.

2. Materials and Methods

In each of four hospital centres in turn, patients described experiences of DR treatments in a semi-structured interview and completed a draft RetTSQ. Qualitative and quantitative data were collected during questionnaire completion, but because item wording changed throughout the study, scores were not combined for statistical analysis. Local Research Ethics Committees gave approval. Demographic and clinical details were collected. Four psychologists interviewed in pairs: 3 were English, one with fluent German; the fourth was German, fluent in English. Centres 1 and 3 were diabetes centres in Scotland and Southern England; Centres 2 and 4 were eye clinics in Southwest and Northwest Germany. To sample as wide a range of views as possible, each centre selected 2 patients with non-proliferative and 9 with proliferative DR, all >18 years old, varying in age, gender, education, working background and experience of DR treatments. The hour-long interviews were audio-taped and transcribed. Each followed a question route, comprising open questions to encourage people to talk freely about views and experiences of treatments, and closed questions to obtain specific details. Interviewer and assistant completed a checklist and took notes. RetTSQ Draft 1 was in English. During design of the Macular Disease Dependent Quality of Life measure (MacDQoL)[11], people with macular disease preferred a vertical layout, so RetTSQ response options (6-0) were listed vertically, in Arial 16 point bold typeface.

Each interviewee could suggest new items or amendments to existing items. If an interviewee could not complete the RetTSQ unaided, the interviewer read it aloud and recorded responses. For 11 patients in each of Centres 1 and 2 and for 8 in Centres 3 and 4, semi-structured questioning was first, then RetTSQ completion and discussion. This allowed spontaneous mention of sources of satisfaction /dissatisfaction, uninfluenced by the questionnaire. In Centres 3 and 4, three patients completed the RetTSQ first, 'thinking aloud' to convey their interpretation of items. No spontaneous mentions were

possible. Their comments were used to confirm that items were understood as intended, without prior discussion. Data from notes and checklists were content analysed, summarised and checked against tape transcripts. The number of spontaneous mentions relating to each item, reasons for missing any item, and distribution of scores were recorded. The researchers discussed a document summarising each centre's results, before and during preparation and translation of the draft for the next centre. The RetTSQ was finalized in English and German after Centre 4.

3. Results

Mean age was 57.1 years (sd 14.5); 26 men, 18 women. Diabetes was treated by diet (n=1), tablets (n=14), insulin (n=29); mean diabetes duration 19.4 years (sd 12.2); mean recent HbA1c 8.0% (sd 1.5). Clinical data were available for 43 interviewees: mean time since DR diagnosis 5.6 years (sd 4.8); mean corrected distance visual acuity (DVI) better

Table 1

Final RetTSQ items (following interviews), showing number of spontaneous mentions by 38 respondents

The following questions are about your experience of treatment for your diabetic eye problems – the eye problems often caused by diabetes. Your eye treatment includes: medications (e.g. tablets, eye drops); visits to the doctor and hospital for check-ups and laser treatment or surgery. In this questionnaire, please: think about the treatment for your diabetic eye problems, not for your diabetes itself; think about your eye treatment over the past 12 months. Answer each question by putting an "X" in the box next to one of the numbers from 6 to 0.

no	Short title	n/38	Source	Wording	Response range
1	<i>satisfaction</i>	1	DTSQ	How satisfied are you with the treatment for your diabetic eye problems?	very satisfied/ dissatisfied
2	<i>how well working</i>	20	interviews DTSQ	How well do you feel the treatment for your diabetic eye problems is working?	very well/ badly
3	<i>side/ after effects</i>	19	HIVTSQ	How bothered are you by any side effects or after effects of the treatment for your diabetic eye problems?	not at all/ very bothered
4	<i>discomfort/ pain</i>	22	RTSQ	How bothered are you by any discomfort or pain from the treatment for your diabetic eye problems?	not at all/ very bothered
5	<i>not unpleasant difficulty</i>	11	USA focus groups	How unpleasant do you find the treatment for your diabetic eye problems?	not at all/ very unpleasant
6	<i>difficulty</i>	9	interviews	How difficult for you is the treatment for your diabetic eye problems?	very easy/ difficult
7	<i>apprehension</i>	12	interviews	How apprehensive do you feel about the treatment for your diabetic eye problems?	not at all/ very apprehensive
8	<i>influence</i>	7	interviews	How satisfied are you with the influence you have over the treatment for your diabetic eye problems?	very satisfied/ dissatisfied
9	<i>Safety</i>	7	interviews	How satisfied are you with the safety of the treatment for your diabetic eye problems?	very satisfied/ dissatisfied
10	<i>time-consuming information</i>	5	USA focus groups	How time-consuming do you find the treatment for your diabetic eye problems?	not at all/ very time-consuming
11	<i>information</i>	8	interviews	How satisfied are you with the information provided about the treatment for your diabetic eye problems?	very satisfied/ dissatisfied
12	<i>encourage</i>	1	interviews DTSQ recommended	Would you encourage someone else with diabetic eye problems like yours to have your kind of treatment?	yes, I would/ no, I would definitely not encourage them
13	<i>continue/ repeat</i>	1	DTSQ continue	How satisfied would you be to continue or repeat the treatment for your diabetic eye problems?	very satisfied/ dissatisfied

eye 0.76 (sd 0.29). The most visually impaired could detect only hand motion at 1 metre with the better eye, coded 0.0025[12]; the least impaired had DVI 6/5 (1.20) in both eyes; 36 had received photocoagulation (laser or xenon), of whom ten had received one or more vitrectomy; 7 had experienced neither. As well as DR, 4 had an unoperated cataract in one eye and 4 in both eyes; 4 had glaucoma in one eye and 4 in both eyes; one had macular disease in both eyes; 7 had 'another' eye condition (2 in one eye; 5 in both).

Forty completed the RetTSQ: five of these needed interviewer assistance (3 due to poor vision and 2 because their pupils had been dilated). Four contributed views for qualitative analysis but did not complete the RetTSQ due to time constraints. The final RetTSQ has 13 items. Item 14 requests any further sources of satisfaction/dissatisfaction. Table 1 shows how many of the 38 interviewees mentioned each item content spontaneously. Requests for clarification or missing an item indicated its inappropriateness to patient experiences of DR treatment, so it was modified or dropped. Some modified items originating from questionnaires for other conditions[7-10] were retained; 7 final items arose solely from interviews. Twenty people did not recognise the term *retinopathy/diabetic retinopathy* as describing their condition so the term *diabetic eye problems* is used in the final RetTSQ. Illustrative quotes for each item (Table 2) are evidence of face and content validity. Each item provided scores across the scale.

Table 2
Patient quotes to illustrate each of the 13 final RetTSQ items

no	<i>short title of item</i>	Quotes (G=German; B=British; M=man; W=woman ; age in years)
1	<i>satisfaction</i>	After the operation, I'm incredibly satisfied. (GM67)
2	<i>how well working</i>	If it worked! If someone came along and said 'Would you like to try a new treatment?' and it might or might not work, my immediate reaction would be to try it. Provided it's got a reasonable chance of success. (BM68)
3	<i>side/after effects</i>	Great light sensitivity.... principally after the laser treatment. (GM47). Another tablet! Well we think that's what's given me this terrible indigestion. (BW68)
4	<i>discomfort/pain</i>	My eyes are a bit sore after. (BM68) God, the thing was totally painful! (GM43)
5	<i>(not)unpleasant</i>	Because you're tense and you're sitting there and it's not very pleasant, I think it probably seems longer than it is. (BW52)
6	<i>difficulty</i>	At first, I found it very disorientating because you had bright light flooding the eye which is very, very difficult to keep the eye still. (BM46)
7	<i>apprehension</i>	The first time, I was 'Oh, what's going to <u>happen</u> to me?... I was a wee bit apprehensive about what was going to happen. (BM68)
8	<i>influence</i>	I think it is good, provided you can trust the person who is doing it. You really are very dependent on their skills and you're dependent on yourself not moving. (BW74)
9	<i>safety</i>	But then there's a big risk when they're working with the eye... I say it's maybe that I've done something wrong that he stops. If he hits the wrong place, it would really destroy it. (BW74)
10	<i>time-consuming</i>	But yesterday I had over an hour's wait. The first part of the process was no problem, but ... I had to sit around waiting for the laser treatment. (BM68)
11	<i>information</i>	I said 'I don't mind what they do so long as you let me know'.(BW68). After the first couple of treatments, I had expected it to get better but it hasn't. If anything, it's got slightly worse. (BW48)
12	<i>encourage</i>	I mean the recommendation is going to come from medical staff... I can <u>encourage</u> you to do it, but I'm in no position to recommend you to have it. (BM65)
13	<i>continue/repeat</i>	After the first treatment, I said I'd rather go blind than have any more. (BM56)

4. Discussion

The RetTSQ, based directly on patient experiences and views, is the first measure of satisfaction with treatment for DR. Suitable for a wide range of treatment types, it

focuses on treatment satisfaction, rather than quality of life, which may be measured with the RetDQoL[5]. People recalling photocoagulation received many years previously reported some particularly unpleasant experiences. Recent experiences of laser photocoagulation were profoundly negative for some, whilst others found it relatively straightforward, painless and unthreatening. Interviewees highlighted the role of doctors in reducing or preventing anxiety and providing realistic expectations of treatments. Some patients expected their vision to benefit from 'laser treatment', so were disappointed to find no change or even deterioration. Whilst focal treatment for macular edema can increase the chances of visual improvement, pan-retinal photocoagulation can adversely affect vision[4]. Adequate explanation of DR and its treatment can help patients to understand why 'laser treatment' is painful on some occasions but not others. It may make existing treatments more acceptable, improve adherence to treatment recommendations and aid acceptance of new therapies.

The RetTSQ is ready for use and psychometric validation, which will indicate optimal item selection and scoring procedure (scales and/or subscales). To use the RetTSQ, please contact copyright holder, Prof Clare Bradley: email c.bradley@rhul.ac.uk.

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