

Appendix D. Characteristics of the health-related quality of life assessment tools used in studies of the treatment of diabetic retinopathy

Instrument	Administration	Domains Measured	Items/ Response Options	Scoring
Generic HRQL assessment tools				
Short Form-36 (SF-36) ⁵⁶ Primary author: Ware, JE Date of 1st publication: 1992 Alternate versions: SF-36v2 (2000) Related instruments: SF-12; SF-18; SF-20;	Target population: general pt population, aged >14 yr Mode of administration: self-complete questionnaire (paper or electronic), interview, etc. Time needed to complete: 5–10 minutes	Physical functioning (10 items); Role limitations because of physical health problems (4 items); Bodily pain (2 items); Social functioning (2 items); General mental health (5 items); Role limitations because of emotional problems (3 items); Vitality (4 items); General health perceptions (5 items); Health transition (1 item)	Items: 8 items (excluding health transition); 8 scales that include 2–10 questions each; 2 summary measures, the Physical Composite Score, and the Mental Composite Score, aggregate the scales Response options: Items 1–3, 6–11: answered on rating scales; Item 1/2: excellent/much better to poor/much worse (5 options); Item 3: limited a lot, to not limited at all (3 options); Items 4/5: answered with a yes/no Item 6/8: not at all to extremely (5 options); Item 7: none to very severe (6 options); Item 9: all of the time to none of the time (6 options); Item 10: all of the time to none of the time (5 options); Item 11: definitely true to definitely false (5 options)	Scoring: each item is assigned a score on the rating scale by the pt Final score algorithm: items and scales were constructed for scoring using the Likert method of summated ratings Possible range: all scales are linearly transformed to a score between 0 (least favorable) to 100 (most favorable)

DM = diabetes mellitus; DR = diabetic retinopathy; d/t = due to; max = maximum; pt = patient; QoL: Quality of Life; r/t = related to; tx = treatment; yr = year

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Instrument	Administration	Domains Measured	Items/ Response Options	Scoring
Low vision-related HRQL assessment tools				
<p>National Eye Institute Visual Function Questionnaire-25 (VFQ-25)⁶³</p> <p>Primary author: RAND Corporation</p> <p>Date of 1st publication: 2001</p> <p>Alternate versions: NEI-VFQ-51</p>	<p>Target population: pt with low vision</p> <p>Mode of administration: pt interview; self administered</p> <p>Time needed to complete: 5 minutes</p>	<p>Overall health (1 item); Overall vision (1 item); Difficulty with near vision (3 items); Difficulty with distance vision (3 items); Limitations in social functioning d/t vision (2 items); Role limitations d/t vision (2 items); Dependency on others d/t vision (3 items); Mental health symptoms d/t vision (4 items); Driving difficulties (2–3 items depending on version); Pain and discomfort around the eyes (2 items); Peripheral vision (1 item); Color vision (1 item)</p>	<p>Items: 25 or 26 items (versions vary between 2 and 3 questions in the driving domain) answer questions r/t 12 areas of visual function</p> <p>Response options: <i>Items 1–4:</i> 5 or 6-point rating scale 1 (excellent) to 5/6 (severe); <i>Items 5–14, 16:</i> 6-point rating scale 1 (no difficulty) to 5 (stopped d/t eyesight) or 6 (stopped for reason other than eyesight); <i>Item 15:</i> Yes/No; <i>Item 15a and 15b:</i> multiple choice responses; <i>Items 17–25:</i> 5-point rating scale 1 (most difficulty) to 5 (no difficulty)</p>	<p>Scoring: each item assigned a score by the pt out of 4/5/6, according to the scale used on the specific item</p> <p>Final score algorithm: <i>Subscales Scores:</i> an average of the items on each subscale transformed to a score on a 0 to 100 scale; <i>Composite Score:</i> an unweighted average of the responses to all items except for the general health rating question, which is treated as a stand-alone item</p> <p>Possible range: 0 (most severe impairment) to 100 (no impairment)</p>
<p>Visual Function-14 (VF-14)⁶⁶</p> <p>Primary author: Steinberg, EP</p> <p>Date of 1st publication: 1994</p> <p>Alternate versions: None</p>	<p>Target population: pt treated with cataract surgery</p> <p>Mode of administration: NR</p> <p>Time needed to complete: NR</p>	<p>Vision dependent functional activities: e.g. reading; recognizing people; seeing steps, stairs or curbs; doing fine handwork; writing checks or filling out forms; playing games, taking part in sports, cooking, watching television; and driving</p>	<p>Items: 18 questions cover 14 items</p> <p>Response options: items 1–12, 2-part questions; <i>Items 1-12:</i> Yes/No/Not Applicable; If yes, 4-point rating scale: 1 (a little difficulty)–4 (unable to do activity); <i>Items 13/16:</i> Yes/No; <i>Items 14/15:</i> 4 point rating scale: 1(no difficulty)–4 (unable to do activity); <i>Items 17/18:</i> Multiple choice responses</p>	<p>Scoring: each item is assigned a score out of 4; Score of 0 assigned when pt unable to do activity d/t visual impairment; If pt did not do activity for a reason other than vision, item not included in scoring; No min number of applicable activities required</p> <p>Final score algorithm: scores from all items pt performed or did not perform d/t their vision were averaged, resulting in a score between 0 and 4; Average score multiplied by 25</p> <p>Possible range: 0 (most severe impairment) to 100 (no impairment)</p>

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Instrument	Administration	Domains Measured	Items/ Response Options	Scoring
<i>Diabetes-related HRQL assessment tools</i>				
Diabetes Treatment Satisfaction Questionnaire Status Version (DTSQs)⁷⁵ Primary author: Lewis, K Date of 1st publication: 1988 Alternate versions: DTSQc (change version)	Target population: pt with DM Mode of administration: self-completed questionnaire Time needed to complete: NR	Treatment Satisfaction (items 1, 4–8); Perceived frequency of hyperglycemia (item 2); Perceived frequency of hypoglycemia (item 3)	Items: 8 items Response options: <i>All items:</i> 7 point rating scale: 0 (very dissatisfied/none of the time) to 6 (very satisfied/most of the time);	Scoring: each item assigned a score by the pt out of 6 Final score algorithm: items, 1, 4–8 are summed to produce an overall score; Items 2 and 3 are treated individually Possible range: <i>Treatment Satisfaction:</i> 0 (most dissatisfied) to 36 (most satisfied); <i>Perceived frequency of hyperglycemia/hypoglycemia:</i> 0 (least frequent) to 6 (most frequent)

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Instrument	Administration	Domains Measured	Items/ Response Options	Scoring
Diabetic retinopathy-related HRQL assessment tools				
<p>Retinopathy Dependent Quality of Life (RetDQoL)^{18,70}</p> <p>Primary author: Woodcock, A</p> <p>Copyright holder: Bradley, C</p> <p>Date of 1st publication: 2004</p> <p>Alternate versions: None</p>	<p>Target population: pt with DR</p> <p>Mode of administration: paper based questionnaire, written in a large font with a layout designed to facilitate reading by those with visual impairments</p> <p>Time needed to complete: NR</p>	<p>Retinopathy-dependent quality of life: e.g. household tasks; personal affairs; shopping; feelings about the future/past; working life; close personal relationship; family life; social life; do things for others; get out and about; journeys; holidays; finances; peoples reaction to me; physical appearance, physical ability; leisure; hobbies/interests; self-confidence; motivation; dependence; mishaps/losses; time; care of diabetes; enjoy nature</p>	<p>Items: overview questions: 1) present QoL; and 2) overall retinopathy-dependent QoL initiates questionnaire; Remaining 24 items r/t specific activities, which may be hindered by poor vision and affect QoL; Items 1-24 contained a part b, which assesses the importance of each item to the pt</p> <p>Response options: <i>Overall QoL:</i> 7-point rating scale: -3 (extremely bad) to 3 (excellent) <i>Overall DR QoL:</i> 5-point rating scale: -3 (very much better) to 1 (worse) <i>Specific domain Items 1–24:</i> 5-point rating scale: -3 (best/easiest) to 1 (worse/more difficult) ; <i>Importance ratings:</i> very important (3), important (2), somewhat important (1), not at all important (0) <i>Open-ended question:</i> asks whether diabetic eye problems affect QoL in any way not covered by the questionnaire</p>	<p>Scoring: <i>Weighted Impact score:</i> each specific domain is assigned an impact rating by the pt of -3 to 1 and is multiplied by the importance rating of 0 to 3, for a possible range of -9 (max negative impact) to 3 (max positive impact); Non-applicable domains are not scored</p> <p>Final score algorithm: <i>Average Weighted Impact score:</i> calculated from a max of 23 specific domain items; Sum of weighted ratings of applicable domains divided by the number of applicable domains <i>Note:</i> the ‘work’ items has not undergone psychometric analysis and should therefore be excluded from the average weighted impact score</p> <p>Possible range: -9 (max negative impact of DR on QoL) to 3 (max positive impact of DR on QoL)</p>

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Instrument	Administration	Domains Measured	Items/ Response Options	Scoring
<p>Retinopathy Treatment Satisfaction Questionnaire (RetTSQ)^{71,81}</p> <p>Primary author: Woodcock, A</p> <p>Copyright holder: Bradley, C</p> <p>Date of 1st publication: 2005</p> <p>Alternate versions: None</p>	<p>Target population pt with DR</p> <p>Mode of administration: paper based questionnaire, written in a large font with a layout designed to facilitate reading by those with visual impairments</p> <p>Time needed to complete: NR</p>	<p>Satisfaction of treatment for diabetic retinopathy: e.g. tx satisfaction, perceived effectiveness of tx; tx side effects; discomfort or pain; unpleasantness of tx; difficulty of tx; feelings of apprehension r/t tx; feelings of satisfaction regarding influence over tx; safety of tx; time-consumed by tx; information about tx; recommend tx to someone else; willingness to continue/repeat tx</p>	<p>Items: 13 items asking pt to rate different aspects of treatment; Items 1, 2, 8, 9, 11–13 compile the positive aspects subscale; Items 3–7 & 10 compile the negative aspects subscale</p> <p>Response options: 7-point rating scale: 0 (very dissatisfied/bothered/unpleasant/difficult/apprehensive/time-consuming) to 6 (very satisfied, not at all bothered/apprehensive/unpleasant/time consuming); <i>Open-ended question:</i> asks respondents for any further aspects of treatment which cause satisfaction or dissatisfaction</p>	<p>Scoring: each item is assigned a score by the pt out of 6</p> <p>Final score algorithm: <i>Positive aspects subscale:</i> calculated by summing the scores from the 7 items that make up the subscale; <i>Negative aspects subscale:</i> calculated by summing the scores from 6 items that make up the subscale <i>Total score:</i> sum of all of the 13 items that make up the RetTSQ</p> <p>Possible range: <i>Positive aspects subscale:</i> 0 (worst) to 42 (best); <i>Negative aspects subscale:</i> 0 (worst) to 36 (best); <i>Total score:</i> 0 (worst) to 78 (best)</p>