Appendix H Studies providing other useful recommendations

Table H.1 Description of studies providing other useful recommendations

Reviews designed to consider the psychometric properties of PROMs in measuring select groups of diabetes specific

PROs: description of objectives and methods, and appraisal of this evidence.

KEY

Relevance of the evidence		Patient importance of the recommended PROs	
✓✓✓	Recommendations for PROs that should be included in a core outcome set collected in routine diabetes practice and used to inform care and/or service development (consensus work)	✓	Recommendations reflect PROs that are important to people with diabetes
✓✓	Recommendations for PROs that should be collected in routine diabetes practice and used to inform care and/or service development	✗	Recommendations do not reflect PROs that are important to people with diabetes
✓	Recommendations for PROs based on attributes that would make them clinically useful only	?	Not clear whether recommendations reflect PROs that are important to people with diabetes
✗	Recommendations for PROs that are not clinically useful but are helpful for deciding the PROs that should be included in an outcome set		

Study (population)	Objective/method	Relevance of the evidence	Patient importance of the recommended PROs
El Achhab (2008)[1] Type 1 and 2 diabetes mellitus	Literature review of PROMs capturing diabetes-specific quality of life; PROMs considered reflect heterogeneous PROs. Recommendations are based on psychometric properties (i.e. reliability and validity; construct, convergent/divergent, and discriminatory) and responsiveness to change.	✗ **No recommendation to collect PROs in routine diabetes practice or using PROs to inform individual patient care or service provision.** PROs reflect those that can be measured most accurately and with tools that are most responsive to change.	✗ Patient perspective on important outcomes not considered.
Garrat (2002)[2] Type 1 and 2 diabetes mellitus	Literature review of PROMs capturing diabetes-specific quality of life; PROMs considered reflect heterogeneous PROs. Recommendations are based on psychometric properties (reliability and validity; face/content) and responsiveness to change.	✗ **No recommendation to collect PROs in routine diabetes practice or using PROs to inform individual patient care or service provision.** PROs reflect those that can be measured most accurately and with tools that are most responsive to change.	✗ Patient perspective on important outcomes not considered.
Roborel de Climens (2015)[3]	Literature review of PROMs capturing 'health-related quality of life' and treatment satisfaction in Type 2	✗ **No recommendation to collect PROs in routine**	✗

Type 2 diabetes mellitus (treated with oral therapy)	diabetes mellitus (treated with oral therapy); PROMs considered reflect heterogeneous PROs. Recommendations based on PROs/PROMs that have good psychometric properties (i.e. reliability, validity; content and construct) and are responsive to change (and do not introduce participant burden/have been used extensively and hence provide conclusive results in this population.	**diabetes practice or using PROs to inform individual patient care or service provision.** PROs reflect those that can be measured most accurately and with tools that are most responsive to change.	Patient perspective on important outcomes not considered.
Palamenghi (2020)[4] Type 1 and 2 diabetes mellitus	Literature review of PROMs capturing diabetes-specific quality of life; PROMs considered reflect heterogeneous PROs (the authors included some PROMs not explicitly developed to assess quality of life but still relevant since they measure the impact of diabetes or its treatment on patents' daily life and habits). Recommendations are based on content validity/scope; PROs with PROMs that tap all five distinct domains comprising a theoretical framework of quality of life or that are similarly broad in coverage when assessing allied PROs (i.e. they synthesise the highest number of possible 'aspects' of the outcome)	✗ **No recommendation to collect PROs in routine diabetes practice or using PROs to inform individual patient care or service provision.** PROs reflect those that can be measured comprehensively (using the PROM(s) recommended).	✗ Patient perspective on important outcomes not considered.
Bredfeldt (2015)[5] Diabetes Peripheral Neuropathy	Literature review comparing and contrasting PROs in Diabetes Peripheral Neuropathy. Recommendations are based on PROs/PROMs that collectively capture the full spectrum of Diabetes Peripheral Neuropathy effects. *Limited to a focus on Diabetes Peripheral Neuropathy.*	✗ **No recommendation to collect PROs in routine diabetes practice or using PROs to inform individual patient care or service provision.** PROs reflect the best representation of Diabetes Peripheral Neuropathy effects.	✗ Patient perspective on important outcomes not considered.

References

[1] El Achhab Y, Nejjari C, Chikri M, Lyoussi B. Disease-specific health-related quality of life instruments among adults diabetic: a systematic review. Diabetes Res Clin Pract 2008;80:171-84.

[2] Garratt AM, Schmidt L, Fitzpatrick R. Patient-assessed health outcome measures for diabetes: a structured review. Diabet Med 2002;19:1-11.

[3] Roborel de Climens A, Tunceli K, Arnould B, Germain N, Iglay K, Norquist J, Brodovicz KG. Review of patient-reported outcome instruments measuring health-related quality of life and satisfaction in patients with type 2 diabetes treated with oral therapy. Curr Med Res Opin 2015;31:643-65.

[4] Palamenghi L, Carlucci MM, Graffigna G. Measuring the quality of life in diabetic patients: a scoping review. J Diabetes Res 2020;2020:5419298.

[5] Bredfeldt C, Altschuler A, Adams AS, Portz JD, Bayliss EA. Patient reported outcomes for diabetic peripheral neuropathy. J Diabetes Complicat 2015;29:1112-8.

Table H.2 Recommended patient reported outcome measures

Measures recommended by reviews designed to consider the psychometric properties of PROMs in measuring select groups of diabetes specific PROs.

Patient-reported outcome	Definition	Patient-reported outcome measure(s)	Type of diabetes patient-reported outcome recommended for	No. studies endorsing patient-reported outcome	Evidence endorsing patient-reported outcome
Diabetes-specific					
PSYCHOLOGICAL: Diabetes specific psychological well-being					
Diabetes distress	Emotional response to aspects of living with and managing diabetes	Diabetes Distress Scale (DDS)	Both	2	El-Achhab (2008); Palamenghi (2020);
Diabetes Peripheral Neuropathy related emotional distress	Emotional illness representations of Diabetes Peripheral Neuropathy (see Leventhal's Self-Regulation Model of Illness); worry about potential consequences of Diabetes Peripheral Neuropathy (e.g. amputation) and anger directed at healthcare professionals	Patient Interpretation of Neuropathy (PIN) scale	Diabetes complication	1	Bredfeldt (2015)
PSYCHOLOGICAL: Diabetes specific quality of life					
Diabetes specific quality of life (multi-dimensional)	The cognitive response (considered thoughts) about the impact of diabetes on the individual's life (not just his/her health) in ways that are important to the individual (i.e. on life domains important to them)	Audit of Diabetes-Dependent Quality of Life (ADDQoL); Diabetes-39 (D-39); Questionnaire on Stress in diabetes (QSD-R); Diabetes Quality of Life (DQoL) measure; Diabetes Quality of Life-Brief Clinical Inventory (DQoL-BCI); Diabetes Quality of Life Clinical Trial Questionnaire (DQLCTQ-R); DAWN Impact of Diabetes Profile (DIDP); Asian Diabetes Quality of Life Questionnaire (Asian-DQoL); The Patient-reported Outcomes instrument for Thai patients with T2DM (PRO-DM-Thai); Japanese Insulin-dependent Diabetic Patient Quality of Life Scale (JAPID-QoL); The ViDa Questionnaire for T1D (Vida1)	Both	4	El-Achhab (2008); Garratt (2002); Roborel de Climens (2015); Palamenghi (2020)
PSYCHOLOGICAL: Diabetes treatment goals					
Diabetes treatment goals	Motivational structures of patients relating to their diabetes treatment (to be considered while treating, educating, or counselling)	DSQols	T1D	2	El-Achhab (2008); Garratt (2002)
PSYCHOLOGICAL: Diabetes satisfaction					
Diabetes treatment satisfaction	An individual's subjective appraisal of their experience of treatment (both process and outcomes), including ease of use, side effects and efficacy	Diabetes Treatment Satisfaction Questionnaire (DTSQ); DSQoLs; Diabetes Medication Satisfaction (DiabMedSat); Oral Hypoglycemic Agent Questionnaire (OHAQ).	Both	3	El-Achhab (2008); Garratt (2002); Roborel de Climens (2015)
PHYSICAL AND FUNCTIONAL: Diabetes symptoms (incl. symptoms of complications)					

	Diabetes Peripheral Neuropathy (frequency and intensity)	Frequency and intensity of symptoms associated with Diabetes Peripheral Neuropathy (i.e. neuropathy sensory symptoms)	Neuropathy Total Symptom Score-6 (NTSS-6)	Diabetes complication	1	Bredfeldt (2015)
	PHYSICAL AND FUNCTIONAL: Sleep quality (Diabetes Peripheral Neuropathy related)					
	Diabetes Peripheral Neuropathy related sleep quality	Interference of diabetes peripheral neuropathy with sleep	Diabetic Peripheral Neuropathic Pain Impact (DPNPI)	Diabetes complication	1	Bredfeldt (2015)
	PSYCHOLOGICAL, PHYSICAL/FUNCTIONAL AND SOCIAL: Diabetes burdens and restrictions					
	Diabetes and treatment burdens and restrictions	Perceived burdens and restrictions related to diabetes and its treatment	Elderly diabetes burden scale (EDBS) (short form of the Elderly Diabetes Impact Scale (EDIS)); Diabetes-Specific Quality of Life Scale (DSQols) - burdens and restrictions sub-scale	Both	3	El-Achhab (2008); Garratt (2002)
	Restrictions (Diabetes Peripheral Neuropathy related)	Perceived interference of Diabetes Peripheral Neuropathy with physical functioning and daily activities (limited to physical and social)	Diabetic Peripheral Neuropathic Pain Impact measure (DPNPI)	Diabetes complication	1	Bredfeldt (2015)
	PSYCHOLOGICAL: Quality of life (specific to related disorders)					
Generic	Obesity/weight specific quality of life	The cognitive response (considered thoughts) about the impact of weight on the individual's life (not just his/her health) in ways that are important to the individual (i.e. on life domains important to them)	Impact of weight on quality of life (IWQoL-Lite)	T2D (treated with oral therapy)	0	Roborel de Climens (2015)