

Appendix F Generic patient reported outcomes

Table F.1 Recommended generic patient reported outcomes

Recommended PROs relating to long-term conditions in general.

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 (study identifier)
PSYCHOLOGICAL: Psychological well-being					
General psychological well-being (multidimensional)	General aspects of mental health including but not limited to negative well-being (e.g. depression, anxiety, etc.) (i.e. also stress, positive well-being, etc.)	World Health Organisation-5 Well-being Index (WHO-5 Well-being Index); Well-Being Questionnaire 22/12 (W-BQ22/12); Diabetes Questionnaire (Swedish National Diabetes Register (SNDR)) (items 1-2; General well-being sub-scale; Psychological General Well-Being Index (PGWBI))	Both	11	Hermanns (2013); Nano (2020); Nicolucci (2013); Reaney (2016); <i>Robertson (2012)</i> ; Rubin (2006); Skovlund (2019); Speight (2009); Svedbo Engström (2018); Ventura (2016) (<i>Levterova (2013)</i>)
Euthymia	State of positive mental health and psychological well-being	None suggested	Both	1	Kalra (2019)
Depressive symptoms	Persistent sadness and a lack of interest or pleasure in previously rewarding or enjoyable activities	Patient Health Questionnaire-9 (PHQ-9); Centre for Epidemiological Studies (CES-D); Beck Depression Inventory (BDI); Zung Self-rating Depression Scale (SDS); Patient Health Questionnaire-9 (PHQ-8); Geriatric Depression Scale (GDS); Hospital Anxiety and Depression Scale (HADS); Patient Health Questionnaire-9 (PHQ-4); Patient-Reported Outcomes Measurement Information System-57 (PROMIS-57); World Health Organisation-5 Well-being Index (WHO-5 Well-being Index) (when used as a screener just for depression); D-SMART tool (American Association of Diabetes Educators (AADE))	Both	14	AADE (2003); Chen (2019); Donald (2012); Glasgow (1999); Hermanns (2013); <i>Jiwani (2020)</i> ; Kalra (2019); McColl (1995); Moffet (2009); Nano (2020); Skovlund (2019); Speight (2009); Ventura (2016); Young-Hyman (2016)
Anxiety (Incl. disorders)	Emotion characterized by feelings of tension, worried thoughts, and physical changes like increased blood pressure (incl. diagnosable anxiety disorders)	HADS; Generalised Anxiety Disorder (GAD-7) assessment; Beck Anxiety Inventory (BAI); PROMIS-57	Both	7	<i>Jiwani (2020)</i> ; Kalra (2019); Moffet (2009); Skovlund (2019); Speight (2009); Ventura (2016); Young-Hyman (2016)
General stress	Degree to which situations in one's life are appraised as stressful	Distress thermometer	Both	2	Moffet (2009); Skovlund (2019)

Positive affect (mood)	The extent to which a person feels interested, excited, strong, enthusiastic, proud, alert, inspired, determined, attentive, and active	Positive and Negative Affect Scale (PANAS); Mood Adjective Checklist (MCAL); Affect Balance Scale (ABS)	Both	1	<i>Robertson (2012)</i>
PSYCHOLOGICAL: General quality of life					
General quality of life	The personal multidimensional evaluation of how good or bad one's life is	World Health Organization quality of life scale - Brief version (WHOQOL-100/BREF)	Both	5	Glasgow (1999); Harman (2019); Nicolucci (2013); Skovlund (2019); Speight (2009)
PSYCHOLOGICAL: Satisfaction with life					
Satisfaction with life	Extent to which one finds life rich, meaningful, full, or of high quality (overall assessment; not multidimensional like quality of life)	None suggested	Both	1	Ventura (2016)
PSYCHOLOGICAL: Health related quality of life					
Health related quality of life	The perceived impact of health/disease on the individual's life (not just his/her health) in ways that are important to the individual. This reflects a cognitive response (i.e. considered thoughts).	QoL Disease Impact Scale (QDIS)	Both	1	Skovlund (2019)
PSYCHOLOGICAL: Quality of life (specific to other (related) disorders)					
Gastrointestinal disorders specific quality of life	The perceived impact of gastrointestinal disorders 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). This reflects a cognitive response (i.e. considered thoughts).	Patient Assessment of upper Gastrointestinal disorders QoL (PAGI-QoL)	Type 2	1	Reaney (2016)
PSYCHOLOGICAL: Health beliefs					
Locus of control	Motivational orientation and perception of how much control one has over the conditions of their life (e.g. perception that life outcomes arise from factors out of one's control and behaviour in response to external circumstances (external locus of control) versus perception of life outcomes arising from one's own agency and abilities and behaviour in response to internal states (internal locus of control)) (see Modified Social Learning Theory)	None suggested	Both	1	Moffet (2009)
PSYCHOLOGICAL: Personality traits					
Resilience	Capacity to maintain physical and psychological well-being in the face of adversity (resilience resources incl. self-efficacy, self-mastery, optimism, locus of control, social support, and purpose in life)	Conor-Davidson Resilience Scale	Both	3	Marrero (2019); Robertson (2012); Skovlund (2019)
Personality traits (multi-dimensional)	Relatively stable internal characteristics that are	None suggested	Both	1	Moffet (2009)

Optimism	inferred from a pattern of behaviours, attitudes, feelings, and habits Attitude that good things will happen and wishes or aims will ultimately be fulfilled	Revised Life Orientation Test (LOT-R)	Both	1	Donald (2012)
PSYCHOLOGICAL: Disordered eating					
Eating disorders	Disorder characterized primarily by a pathological disturbance of attitudes and behaviours related to food	Eating Disorders Inventory-3 (EDI-3)	Both	2	Skovlund (2019); Young-Hyman (2016)
Binge eating	Chronic and pervasive consumption of abnormally large quantities of food in a discrete time period with a concurrent sense of loss of control (incl. the behavioural manifestations but also emotional and cognitive features (e.g. self-consciousness about weight/appearance and fear of being unable to stop eating)	Binge-eating Scale (BES)	T2D	1	Young-Hyman (2016)
PSYCHOLOGICAL: Cognition					
General cognitive capacity (screening)	Screening for mild cognitive impairment to dementia	Mini-Mental State Examination (MMSE); Telephone Interview for Cognitive Status (TICS); Cognitive assessment toolkit	Both	1	Young-Hyman (2016)
Memory	Memory	Prospective and Retrospective Memory Questionnaire (PRMQ)	Both	1	Ventura (2016)
PSYCHOLOGICAL: Lifestyle behaviours: Am I doing it? (adherence)					
Smoking	Performance of smoking behaviour	Summary of Diabetes Self-Care Activities (SDSCA); D-SMART tool (AADE)	Both	7	AADE (2003); Donald (2012); Eigenmann (2009); Moffet (2009); Skovlund (2019); Ventura (2016); Young-Hyman (2016)
Alcohol consumption	Alcohol consumption	None suggested	Both	2	Donald (2012); Moffet (2009)
Lifestyle behaviours (multidimensional)	Health behaviours (i.e. behaviours that relate to health maintenance, restoration and improvement) aimed at health promotion and disease prevention	Health Education Impact Questionnaire (heiQ)	Both	1	Skovlund (2019)
Multivitamin use (unprescribed supplements)	Multivitamin use	None suggested	Both	1	Moffet (2009)
Television watching	Television watching	None suggested	Both	1	Moffet (2009)
PSYCHOLOGICAL: Skills and competencies (related to health care)					
Health care related skills and competencies	Understanding of and ability to interact with health care organisations/professionals to get needs met (incl. communication ability)	heiQ	Both	1	Skovlund (2019)
PSYCHOLOGICAL: Health literacy and numeracy					
Health literacy	Ability to understand and capacity to act on health information	Brief Health Literacy Scale (BHLS)	Both	2	Moffet (2009); Young-Hyman (2016)

Health numeracy	Ability to understand and capacity to act on numerical health information (aspect of health literacy)	General Health Numeracy Test (GHNT)	Both	1	Young-Hyman (2016)
PSYCHOLOGICAL: Coping skills					
Coping skills (multidimensional)	Use of cognitive and behavioural strategies to manage the demands of a situation appraised as taxing or exceeding one's resources or to reduce the negative emotions and conflict caused by stress (e.g. emotion focussed coping, problem focussed coping, etc.).	D-SMART tool	Both	1	AADE (2003)
Self-compassion	A noncritical stance toward one's inadequacies and failures	Self-Compassion Scale Short Form (SCS-SF)	Both	1	Ventura (2016)
PSYCHOLOGICAL: Illness identity					
Illness identity	Degree to which one defines themselves in terms of their long-term condition	Centrality Scale	Both	1	Ventura (2016)
PSYCHOLOGICAL: Self-concept					
Self-esteem	Degree to which the qualities and characteristics contained in one's self-concept are perceived to be positive	Rosenberg Self-Esteem Scale (RSE)	Both	1	Ventura (2016)
Impact of weight on self-perception	Impact of weight on self-perception	Impact of weight on self-perception (IW-SP)	T2D	1	Ventura (2016)
PHYSICAL AND FUNCTIONAL: Sleep quality					
Sleep quality/patterns	Self-reported perceptions of sleep quality, depth, and restoration	PROMIS-57	Both	4	Donald (2012); Jiwani (2020); Moffet (2009); Schoenthaler (2020)
PHYSICAL AND FUNCTIONAL: Pain intensity					
Pain intensity	Subjective experience of pain (i.e. the intensity of sensory, affective and evaluative symptoms)	Short-form McGill Pain Questionnaire (SF-MPQ-2); PROMIS-57	T2D	2	Jiwani (2020); Young-Hyman (2016)
PHYSICAL AND FUNCTIONAL: Fatigue					
Fatigue	Sense of persistent tiredness or exhaustion that is often distressing to the individual	PROMIS-57	T2D	1	Jiwani (2020)
SOCIAL: Social support					
General social support	Availability of different types of social support, (i.e. emotional support, practical support and informational/educational support)	Medical Outcomes Survey-Social Support Scale (MOS-SSS); ENRICHED Social Support Inventory (ESSI)	Both	5	Chen (2019); Donald (2012); Glasgow (1999); Marrero (2019); Moffet (2009)
Disease-specific social support	Support and resources for managing long-term conditions at different levels (e.g., family and friends, health care professionals/team, neighbourhood/community)	Chronic Illness Resources Survey (CIRS)	Both	1	Donald (2012)
SOCIAL: Stigma (general and specific to related disorders)					
Stigma	Feeling disqualified from full social acceptance related to having a long-term condition (i.e. felt/self-stigma (perceived) or enacted (discriminatory behaviour that is actually experienced)	Stigma Scale for Chronic Illnesses – 8 item version ⁱⁱⁱ	Both	1	Ventura (2016)

Weight-related stigma	Weight related self-stigma comprising self-devaluation and fear of enacted stigma	Weight self-stigma questionnaire (WSSQ)	Both	1	Ventura (2016)
PSYCHOLOGICAL, PHYSICAL/FUNCTIONAL AND SOCIAL: Health status					
Health status (physical and mental) (multidimensional) ⁱ	Presence of biological, physiological and psychological dysfunction, symptoms and functional impairment	36 item Short-Form Health Survey (SF-36); 8 item Short-Form Health Survey (SF-8); EuroQoL-5 Dimensions (EQ-5D); Health Utilities Index-Mark 3 (HUI-3); EuroQoL Visual Analogue Scale (EQ-VAS); SF-6D; 12 item Short-Form Health Survey (SF-12); Patient-Reported Outcomes Measurement Information System-10/29 (PROMIS-10/29); Patient-Reported Outcomes Measurement Information System-Global Health (PROMIS-GH); D-SMART tool (AADE)	Both	11	AADE (2003); Bradley (2018); Chen (2019); Donald (2012); Huang (2008); <i>Jiwani</i> (2020); Nicolucci (2013); Reaney (2016); Skovlund (2019); Speight (2009); Vieta (2011)
Physical functioning/activities of daily living	Ability to perform both basic and instrumental activities of daily living independently, i.e. bathing, dressing, feeding, toileting, transferring and continence (aspect of health status)	SF-36; PROMIS-57; Ability to Perform Physical Activities of Daily Living (APPADL)	Both	3	Harman (2019); <i>Jiwani</i> (2020); McColl (1995)
Energy	Ability and strength to do active physical things and the feeling that one is full of physical power and life (aspect of health status)	SF-36	Both	1	McColl (1995)
Social functioning	Involvement in, and satisfaction, with one's usual social roles and activities (e.g. family relationships, parental responsibilities, work responsibilities, and social activities) (aspect of health status)	PROMIS-57	T2D	1	<i>Jiwani</i> (2020)
Foot-related health status ⁱⁱ	Presence of biological and physiological dysfunction, symptoms and functional impairment related to feet (domains incl. pain, function, footwear, and general foot health)	Foot Health Status Questionnaire (FHSQ)	Diabetes complication	1	<i>Ortega-Avila</i> (2019)
PSYCHOLOGICAL, PHYSICAL/FUNCTIONAL AND SOCIAL: Disease burdens and restrictions					
Treatment burdens and restrictions	Perceived burdens and restrictions related to treatment and self-management (e.g. interference with ability to live a normal life)	Patient Experience with Treatment and Self-management (PETS)	Both	1	Skovlund (2019)
Pain restrictions	Extent to which pain hinders engagement with physical, mental, cognitive, emotional, recreational, and social activities	PROMIS-57	Both	1	<i>Jiwani</i> (2020)

ⁱ Reflects 'quality of health' rather than '(health related) quality of life'; the latter reflects the impact of health (status)/disease on the individual's life (not just his/her health) in ways that are important to the individual.

ⁱⁱ Included as a generic patient reported outcome because diabetes cannot be assumed to be the most likely cause).

ⁱⁱⁱ Development work with neurological conditions and no evidence of validation in diabetes but retained as Diabetes Management and Impact for Long-term Empowerment and Success (MILES) 2 study recommends it's use in diabetes (i.e. items ask about long term conditions in general)

*These studies did not recommend PROs based on our criteria suggesting suitability, rather they provide an indication of which patient reported outcomes can be measured with patient-reported outcome measures that have desirable properties (e.g. psychometric properties).

Table F.2 Excluded studies recommending generic patient reported outcomes

Description and appraisal of studies excluded as they made recommendations for generic patient reported outcomes only.

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	Clinical relevance (of evidence)	Patient importance (of recommended PROs)
Jiwani (2020) ^[1] Type 2 diabetes mellitus (with obesity)	A feasibility study of the (electronic) implementation of the PROMIS-57 and PROMIS – Global Health questionnaires in Type 2 diabetes mellitus population (with obesity); secondary analysis of RCT of behavioural intervention. Undertaken in USA. <i>Limited to generic PROs only.</i>	 PROs should be collected in routine diabetes care (this is an anticipated future direction in the use of these PROMs) and used to inform individual patient care ; authors state that the PROMIS questionnaires provide diabetes clinicians with a benchmark for assessing overall need for treatment and management (they identified that mean scores for most domains were poorer than those of the US population). PROs reflect key insights into diabetes (and also those that can be feasibility implemented, are acceptable to people with diabetes (i.e. data completion was high), and are responsive to change)	 Patient perspective was not considered in this study/when considering the applicability of these PROMs in diabetes.
Robertson (2012) ^[2]	Literature review of PROMs capturing positive emotional health in diabetes; PROMs conceptually grouped (i.e. positive well-being, positive affect and	 PROs should be collected in routine diabetes care and used	

Type 1 and 2 diabetes mellitus	resilience). Recommendations based on the association of these PROs with diabetes endpoints. <i>Limited range of PROs considered</i>	to inform individual patient care ; the authors state that targeting these PROs in routine diabetes care may help people with diabetes meet their treatment goals. PROs reflect key factors associated with diabetes end-points.	Patient perspective on important outcomes not considered.
Levterova (2013)*^[3] Type 1 and 2 diabetes mellitus	Literature review of PROMs capturing diabetes-specific QoL; PROMs considered reflect heterogeneous PROs. Recommendations are based on content validity/scope; PROMs that synthesise the highest number of domains of quality of life/possible 'aspects' of the outcome, and psychometric properties (i.e. reliability and validity).	X 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 are most comprehensive in scope.	X Patient perspective on important outcomes not considered.
Ortega-Avila (2019)*^[4] Foot and ankle pathologies (related to diabetes)	Literature review comparing and contrasting PROMs in foot and ankle pathologies in diabetes; PROMs considered reflect heterogeneous PROs. Recommendations based on psychometric properties (based on COSMIN criteria and Terwee's psychometric properties: content validity, internal consistency, criterion validity, construct validity, reproducibility (agreement and reliability)), responsiveness to change, floor/ceiling effects, and interpretability. <i>Limited to PROs for foot and ankle pathologies related to diabetes</i>	X 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, are most responsive to change and can be most meaningfully interpreted.	X Patient perspective on important outcomes not considered.

References

- [1] Jiwani R, Wang J, Berndt A, Ramaswamy P, Mathew Joseph N, Du Y, Ko J, Espinoza S. Changes in patient-reported outcome measures with a technology-supported behavioral lifestyle intervention among patients with Type 2 diabetes: pilot randomized controlled clinical trial. *JMIR Diabetes* 2020;5:e19268.
- [2] Robertson SM, Stanley MA, Cully JA, Naik AD. Positive emotional health and diabetes care: concepts, measurement, and clinical implications. *Psychosomatics* 2012;53:1-12.
- [3] Levterova BA, Dimitrova DD, Levterov GE, Dragova EA. Instruments for disease-specific quality-of-life measurement in patients with type 2 diabetes mellitus-a systematic review. *Folia Med* 2013;55:83-92.
- [4] Ortega-Avila AB, Cervera-Garvi P, Ramos-Petersen L, Chicharro-Luna E, Gijon-Nogueron G. Patient-reported outcome measures for patients with diabetes mellitus associated with foot and ankle pathologies: a systematic review. *J Clin Med* 2019;8:146.