

## Appendix D Recommended patient reported outcome measures

PROMs recommended to measure diabetes specific PROs.

### **Problem Areas in Diabetes (PAID)**

Polonsky WH, Anderson BJ, Lohrer PA, Welch G, Jacobson AM, Aponte JE, Schwartz CE. Assessment of diabetes-related distress. *Diabetes Care* 1995;18:754-60.

### **Problem Areas in Diabetes-5 (PAID-5) and Problem Areas in Diabetes-1 (PAID-1)**

McGuire BE, Morrison TG, Hermanns N, Skovlund S, Eldrup E, Gagliardino J, Kokoszka A, Matthews D, Pibernik-Okanović M, Rodríguez-Saldaña J, de Wit M, Snoek FJ. Short-form measures of diabetes-related emotional distress: the Problem Areas in Diabetes Scale (PAID)-5 and PAID-1. *Diabetologia* 2010;53:66-9.

### **Problem Areas in Diabetes-11 (PAID-11)**

Stanulewicz N, Mansell P, Cooke D, Hopkins D, Speight J, Blake H. PAID-11: A brief measure of diabetes distress validated in adults with type 1 diabetes. *Diabetes Res Clin Pract* 2019;149:27-38.

### **Diabetes Distress Scale (DDS)**

Polonsky WH, Fisher L, Earles J, et al. Assessing psychosocial distress in diabetes: development of the diabetes distress scale. *Diabetes Care* 2005;28:626-31.

### **Diabetes Distress Scale-2 (DDS-2) and Diabetes Distress Scale-4 (DDS-4)**

Fisher L, Hessler DM, Polonsky WH, Mullan J. When is diabetes distress clinically meaningful?: establishing cut points for the Diabetes Distress Scale. *Diabetes Care* 2012;35:259-64.

### **Type 1 Diabetes Distress Scale (T1-DDS)**

Fisher L, Polonsky WH, Hessler DM, Masharani U, Blumer I, Peters AL, Strycker LA, Bowyer V. Understanding the sources of diabetes distress in adults with type 1 diabetes. *J Diabetes Complicat* 2015;29:572-7.

### **Diabetes Questionnaire (Swedish National Diabetes Register)**

Svedbo Engström M, Leksell J, Johansson UB, Eeg-Olofsson K, Borg S, Palaszewski B, Gudbjörnsdóttir S. A disease-specific questionnaire for measuring patient-reported outcomes and experiences in the Swedish National Diabetes Register: development and evaluation of content validity, face validity, and test-retest reliability. *Patient Educ and Couns* 2018;101:139-46.

### **D-SMART tool (American Association of Diabetes Educators)**

Peyrot M, Peeples M, Tomky D, Charron-Prochownik D, Weaver T; AADE Outcomes Project and AADE/UPMC Diabetes Education Outcomes Project. Development of the American Association of Diabetes Educators' Diabetes Self-management Assessment Report Tool. *Diabetes Educ* 2007;33:818-26.

### **Hypoglycemia Fear Survey-II (HFS-II)**

Cox DJ, Irvine A, Gonder-Frederick L, Nowacek G, Butterfield J. Fear of hypoglycemia: quantification, validation, and utilization. *Diabetes Care* 1987;10:617-21.

Gonder-Frederick LA, Schmidt KM, Vajda KA, Greear ML, Singh H, Shepard JA, Cox DJ. Psychometric properties of the hypoglycemia fear survey-ii for adults with type 1 diabetes. *Diabetes Care* 2011;34:801-6.

### **Hypoglycemia Fear Survey-II Short Form (HFS-II SF)**

Grabman J, Vajda Bailey K, Schmidt K, Cariou B, Vaur L, Madani S, Cox D, Gonder-Frederick L. An empirically derived short form of the Hypoglycaemia Fear Survey II. *Diabet Med* 2017;34:500-4.

#### **Well-Being Questionnaire 28 (W-BQ28)**

Speight J, Barendse S, Bradley C. The W-BQ28: further development of the well-being questionnaire to include diabetes-specific as well as generic subscales and new stress subscales. *Proceedings of The British Psychological Society*; February, 2000.

Bradley C. The 12-Item Well-Being Questionnaire: origins, current stage of development, and availability. *Diabetes Care* 2000;23:875.

Mitchell J, Bradley C. Psychometric evaluation of the 12-item Well-being Questionnaire for use with people with macular disease. *Qual Life Res* 2001;10:465-73.

#### **Fear of Complications Questionnaire (FCQ)**

Taylor EP, Crawford JR, Gold AE. Design and development of a scale measuring fear of complications in type 1 diabetes. *Diabetes Metab Res Rev* 2005;21:264-70.

#### **Audit of Diabetes-Dependent Quality of Life (ADDQoL)**

Bradley C, Speight J. Patient perceptions of diabetes and diabetes therapy: assessing quality of life. *Diabetes Metab Res Rev* 2002;18 Suppl 3:S64-9.

Wee HL, Tan CE, Goh SY, Li SC. Usefulness of the Audit of Diabetes-Dependent Quality-of-Life (ADDQoL) questionnaire in patients with diabetes in a multi-ethnic Asian country. *Pharmacoeconomics* 2006;24:673-82.

#### **Diabetes-39 (D-39)**

Boyer JG, Earp JA. The development of an instrument for assessing the quality of life of people with diabetes. *Diabetes-39. Med Care* 1997;35:440-53.

#### **Diabetes Quality of Life (DQoL) measure**

Reliability and validity of a diabetes quality-of-life measure for the diabetes control and complications trial (DCCT). The DCCT Research Group. *Diabetes Care* 1988;11:725-32.

#### **DAWN Impact of Diabetes Profile (DIDP)**

Holmes-Truscott E, Skovlund SE, Hendrieckx C, Pouver F, Peyrot M, Speight J. Assessing the perceived impact of diabetes on quality of life: psychometric validation of the DAWN2 Impact of Diabetes Profile in the second Diabetes MILES - Australia (MILES-2) survey. *Diabetes Res Clin Pract* 2019;150:253-63.

Peyrot M, Burns KK, Davies M, Forbes A, Hermanns N, Holt R, Kalra S, Nicolucci A, Pouver F, Wens J, Willaing I, Skovlund SE. Diabetes Attitudes Wishes and Needs 2 (DAWN2): a multinational, multi-stakeholder study of psychosocial issues in diabetes and person-centred diabetes care. *Diabetes Res Clin Pract* 2013;99:174-84.

#### **World Health Organization quality of life scale WHOQOL-BREF DMQoL (diabetes module)**

Lin CY, Lee TY, Sun ZJ, Yang YC, Wu JS, Ou HT. Development of diabetes-specific quality of life module to be in conjunction with the World Health Organization quality of life scale brief version (WHOQOL-BREF). *Health Qual Life Outcomes* 2017;15:167.

#### **Diabetes Impact on Productivity (DPM), Diabetes Symptom Measure (DSM) and Global Diabetes Satisfaction Treatment (GDST) / Diab-MedSat**

Brod M, Skovlund SE, Wittrup-Jensen KU. Measuring the impact of diabetes through patient report of treatment satisfaction, productivity and symptom experience. *Qual Life Res* 2006;15:481-91.

### **Summary of Diabetes Self-Care Activities (SDSCA)**

Toobert DJ, Hampson SE, Glasgow RE. The summary of diabetes self-care activities measure: results from 7 studies and a revised scale. *Diabetes Care* 2000;23:943-50.

### **Diabetes Self-Management Questionnaire (DSMQ)**

Schmitt A, Gahr A, Hermanns N, Kulzer B, Huber J, Haak T. The Diabetes Self-Management Questionnaire (DSMQ): development and evaluation of an instrument to assess diabetes self-care activities associated with glycaemic control. *Health Qual Life Outcomes* 2013;11:138.

Schmitt A, Kulzer B, Ehrmann D, Haak T, Hermanns N. A self-report measure of diabetes self-management for Type 1 and Type 2 Diabetes: The Diabetes Self-Management Questionnaire-Revised (DSMQ-R) – clinimetric evidence from five studies. *Front Clin Diabetes Healthc* 2022;2.

### **International Physical Activity Questionnaire - short form (IPAQ-SF)**

Craig CL, Marshall AL, Sjöström M, Bauman AE, Booth ML, Ainsworth BE, Pratt M, Ekelund U, Yngve A, Sallis JF, Oja P. International physical activity questionnaire: 12-country reliability and validity. *Med Sci Sports Exerc* 2003;35:1381-95.

### **Brief-type self-administered diet history questionnaire (BDHQ)**

Kobayashi S, Murakami K, Sasaki S, Okubo H, Hirota N, Notsu A, Fukui M, Date C. Comparison of relative validity of food group intakes estimated by comprehensive and brief-type self-administered diet history questionnaires against 16 d dietary records in Japanese adults. *Public Health Nutr* 2011;14:1200-11.

### **Adherence to Refills and Medications Scale (ARMS-D)**

Kripalani S, Risser J, Gatti ME, Jacobson TA. Development and evaluation of the Adherence to Refills and Medications Scale (ARMS) among low-literacy patients with chronic disease. *Value Health* 2009;12:118-23.

Mayberry LS, Gonzalez JS, Wallston KA, Kripalani S, Osborn CY. The ARMS-D out performs the SDSCA, but both are reliable, valid, and predict glycemic control. *Diabetes Res Clin Pract* 2013;102:96-104.

### **Patient Activation Measure (PAM)**

Hibbard JH, Stockard J, Mahoney ER, Tusler M. Development of the Patient Activation Measure (PAM): conceptualizing and measuring activation in patients and consumers. *Health Serv Res* 2004;39:1005-26.

### **Health Education Impact Questionnaire (heiQ)**

Osborne RH, Elsworth GR, Whitfield K. The Health Education Impact Questionnaire (heiQ): an outcomes and evaluation measure for patient education and self-management interventions for people with chronic conditions. *Patient Educ Couns* 2007;66:192-201.

### **Perceived Competence for Diabetes Scale (PCDS)**

Williams GC, Freedman ZR, Deci EL. Supporting autonomy to motivate patients with diabetes for glucose control. *Diabetes Care* 1998;21:1644-51.

Williams GC, McGregor HA, Zeldman A, Freedman ZR, Deci EL. Testing a Self-Determination Theory Process Model for promoting glycemic control through diabetes self-management. *Health Psychol* 2004;23:58-66.

### **Confidence In Diabetes Self-Care (CIDS) (insulin-using)**

Van Der Ven NC, Weinger K, Yi J, Pouwer F, Adèr H, Van Der Ploeg HM, Snoek FJ. The confidence in diabetes self-care scale: psychometric properties of a new measure of diabetes-specific self-efficacy in Dutch and US patients with type 1 diabetes. *Diabetes Care* 2003;26:713-8.

### **Confidence In Diabetes Self-Care (CIDS) (non-insulin using)**

Polonsky WH, Fisher L, Snoek FJ, Weinger K, Jelsovsky Z, Parkin CG, Petersen B. Evaluation of the Confidence in Diabetes Scale (CIDS-2) for Patients with Poorly Controlled T2DM. *Diabetes* 2009;58:A479-A479.

### **Diabetes Self-efficacy Scale (DSES)**

Ritter PL, Lorig K, Laurent DD. Characteristics of the Spanish- and English-Language Self-Efficacy to Manage Diabetes Scales. *Diabetes Educ* 2016;42:167-77.

### **Treatment Self-Regulation Questionnaire-diabetes (TSRQ-diabetes)**

Shigaki C, Kruse RL, Mehr D, et al. Motivation and diabetes self-management. *Chronic Illn* 2010;6:202-14.

Williams GC, Freedman ZR, Deci EL. Supporting autonomy to motivate patients with diabetes for glucose control. *Diabetes Care* 1998;21:1644-51.

Williams GC, McGregor HA, Zeldman A, Freedman ZR, Deci EL. Testing a Self-Determination Theory Process Model for promoting glycemic control through diabetes self-management. *Health Psychol* 2004;23:58-66.

### **Diabetes-Specific Quality of Life Scale (DSQols)**

Bott U, Mühlhauser I, Overmann H, Berger M. Validation of a diabetes-specific quality-of-life scale for patients with type 1 diabetes. *Diabetes Care* 1998;21:757-69.

### **Treatment-Related Impact Measure-Non-severe Hypoglycemic Events (TRIM-HYPO)**

Brod M, Hojbjerg L, Bushnell DM, Hansen CT. Assessing the impact of non-severe hypoglycemic events and treatment in adults: development of the Treatment-Related Impact Measure-Non-severe Hypoglycemic Events (TRIM-HYPO). *Qual Life Res* 2015;24:2971-84.

### **Diabetes Symptom Checklist-Revised (DSC-R)**

Arbuckle RA, Humphrey L, Vardeva K, et al. Psychometric evaluation of the Diabetes Symptom Checklist-Revised (DSC-R)--a measure of symptom distress. *Value Health* 2009;12:1168-75.

### **Type 2 Diabetes Symptom Checklist (DSC-2)**

Grootenhuis PA, Snoek FJ, Heine RJ, Bouter LM. Development of a type 2 diabetes symptom checklist: a measure of symptom severity. *Diabet Med* 1994;11:253-61.

### **Gastroparesis Cardinal Symptom Index Daily Diary (GCSI-DD)**

Revicki DA, Camilleri M, Kuo B, Norton NJ, Murray L, Palsgrove A, Parkman HP. Development and content validity of a gastroparesis cardinal symptom index daily diary. *Aliment Pharmacol Ther* 2009;30:670-80.

Revicki DA, Camilleri M, Kuo B, Szarka LA, McCormack J, Parkman HP. Evaluating symptom outcomes in gastroparesis clinical trials: validity and responsiveness of the Gastroparesis Cardinal Symptom Index-Daily Diary (GCSI-DD). *Neurogastroenterol Motil* 2012;24:456-63.

Revicki DA, Lavoie S, Speck RM, Puellas J, Kuo B, Camilleri M, Almansa C, Parkman HP. The content validity of the ANMS GCSI-DD in patients with idiopathic or diabetic gastroparesis. *J Patient Rep Outcomes* 2018;2:61.

Revicki DA, Rentz AM, Dubois D, Kahrilas P, Stanghellini V, Talley NJ, Tack J. Development and validation of a patient-assessed gastroparesis symptom severity measure: the Gastroparesis Cardinal Symptom Index. *Aliment Pharmacol Ther* 2003;18:141-50.

Revicki DA, Speck RM, Lavoie S, Puellas J, Kuo B, Camilleri M, Almansa C, Parkman HP. The American neurogastroenterology and motility society gastroparesis cardinal symptom index-daily diary (ANMS

GCSI-DD): psychometric evaluation in patients with idiopathic or diabetic gastroparesis. *Neurogastroenterology and Motility* 2019;31:e13553.

#### **Edinburgh Hypoglycaemia Survey (EHS)**

Deary IJ, Hepburn DA, MacLeod KM, Frier BM. Partitioning the symptoms of hypoglycaemia using multi-sample confirmatory factor analysis. *Diabetologia* 1993;36:771-7.

#### **Douleur Neuropathique 4 Questions (DN-4)**

Celik S, Yenidunya G, Temel E, Purisa S, Uzum AK, Gul N, Cinkil G, Dinccag N, Satman I. Utility of DN4 questionnaire in assessment of neuropathic pain and its clinical correlations in Turkish patients with diabetes mellitus. *Prim Care Diabetes* 2016;10:259-64.

#### **Diabetes Treatment Satisfaction Questionnaire (DTSQ)**

Bradley C. Diabetes treatment satisfaction questionnaire. Change version for use alongside status version provides appropriate solution where ceiling effects occur. *Diabetes Care* 1999;22:530-2.  
Bradley C, Lewis KS. Measures of psychological well-being and treatment satisfaction developed from the responses of people with tablet-treated diabetes. *Diabet Med* 1990;7:445-51.

#### **Treatment Flexibility Scale (TFS)**

Clarice PH, Lee B. Reliability and Validity of the Treatment Flexibility Scale. *Qual Life Res* 2003;12:863-3.

Shen W, Kotsanos JG, Huster WJ, Mathias SD, Andrejasich CM, Patrick DL. Development and validation of the Diabetes Quality of Life Clinical Trial Questionnaire. *Med Care* 1999;37:45-66.

#### **Current Health Satisfaction Questionnaire (CHES-Q)**

Traina SB, Colwell HH, Crosby RD, Mathias SD. Pragmatic measurement of health satisfaction in people with type 2 diabetes mellitus using the Current Health Satisfaction Questionnaire. *Patient Relat Outcome Meas* 2015;6:103-15.

#### **Diabetes Support Scale (DSS)**

Barrera M, Jr., Glasgow RE, McKay HG, Boles SM, Feil EG. Do Internet-based support interventions change perceptions of social support?: An experimental trial of approaches for supporting diabetes self-management. *Am J Community Psychol* 2002;30:637-54.

#### **Diabetes Empowerment Scale-Short Form (DES-SF)**

Anderson RM, Fitzgerald JT, Gruppen LD, Funnell MM, Oh MS. The Diabetes Empowerment Scale-Short Form (DES-SF). *Diabetes Care* 2003;26:1641-2.

Anderson RM, Funnell MM, Fitzgerald JT, Marrero DG. The Diabetes Empowerment Scale: a measure of psychosocial self-efficacy. *Diabetes Care* 2000;23:739-43.

#### **Diabetes Numeracy Test (DNT)**

Huizinga MM, Elasy TA, Wallston KA, Cavanaugh K, Davis D, Gregory RP, Fuchs LS, Malone R, Cherrington A, Dewalt DA, Buse J, Pignone M, Rothman RL. Development and validation of the Diabetes Numeracy Test (DNT). *BMC Health Serv Res* 2008;8:96.

#### **Insulin Treatment Appraisal Scale (ITAS)**

Snoek FJ, Skovlund SE, Pouwer F. Development and validation of the insulin treatment appraisal scale (ITAS) in patients with type 2 diabetes. *Health Qual Life Outcomes* 2007;5:69.

#### **Gold score**

Gold AE, MacLeod KM, Frier BM. Frequency of severe hypoglycemia in patients with type I diabetes with impaired awareness of hypoglycemia. *Diabetes Care* 1994;17:697-703.

**Type 1 Diabetes Stigma Assessment Scale (DSAS-1)**

Browne JL, Ventura AD, Mosely K, Speight J. Measuring Type 1 diabetes stigma: development and validation of the Type 1 Diabetes Stigma Assessment Scale (DSAS-1). *Diabet Med* 2017;34:1773-82.

**Type 2 Diabetes Stigma Assessment Scale (DSAS-2)**

Browne JL, Ventura AD, Mosely K, Speight J. Measuring the Stigma Surrounding Type 2 Diabetes: Development and Validation of the Type 2 Diabetes Stigma Assessment Scale (DSAS-2). *Diabetes Care* 2016;39:2141-48.