



ICHOM

International Consortium for
Health Outcomes Measurement

Type 1 and Type 2 Diabetes
in Adults
**DATA COLLECTION
REFERENCE GUIDE**

Version 1.0.0
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Measuring
results
that matter

Diabetes
In Adults



We are thrilled that you are interested in measuring outcomes for adult persons with type 1 or type 2 diabetes according to ICHOM standards. It is our hope that this Reference Guide will facilitate the process of implementing our Standard Set and ensure collection of comparable data for global benchmarking and learning.

© 2018 ICHOM. All rights reserved. When using this set of outcomes, or quoting therefrom, in any way, we solely require that you always make a reference to ICHOM as the source so that this organization can continue its work to define more standard outcome sets. Please cite as follows: ICHOM Diabetes in Adults Working Group, Type 1 and Type 2 Diabetes in Adults, November 2018, (available at: www.ichom.org/medical-conditions/diabetes)

Introducing ICHOM and the Reference Guide

ICHOM brings together patient representatives, clinician leaders, and registry leaders from all over the world to develop Standard Sets, comprehensive yet parsimonious sets of outcomes and case-mix variables we recommend all providers track.

Each Standard Set focuses on patient-centered results, and provides an internationally-agreed upon method for measuring each of these outcomes. We do this because we believe that standardized outcomes measurement will open up new possibilities to compare performance globally, allow clinicians to learn from each other, and rapidly improve the care we provide our patients.

Our Standard Sets include initial conditions and risk factors to enable meaningful case-mix adjustment globally, ensuring that comparisons of outcomes will take into account the differences in patient populations across not just providers, but also countries and regions. A comprehensive data dictionary, as well as scoring guides for patient-reported outcomes, is included in the appendix.

Our aim is to make Standard Sets freely accessible to healthcare institutions worldwide to begin measuring, and ultimately benchmark the outcomes they achieve. In order to have a guide from which we can benchmark outcomes, we require feedback from initial implementation efforts. As such, this Reference Guide may undergo revisions on a regular basis. If you have any suggestions or would like to provide feedback, please contact implement@ichom.org

Working Group Members for Diabetes in Adults

The following individuals dedicated both time and expertise to develop the ICHOM Standard Set for Diabetes in Adults in partnership with ICHOM, under the leadership of Fabrizio Carinci and Massimo Massi-Benedetti, ICHOM Standard Set Chairs. The work was supported by Jana Nano and Magdalena Walbaum, ICHOM Research Fellows, Oluwakemi Okunade, ICHOM Project Leader, and Sarah Whittaker, ICHOM Research Associate.

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Supporting Organizations

The Diabetes in Adults Standard Set is made possible only through the support of the following organizations.

Thank You.



Scope of Diabetes in Adults Standard Set

For Diabetes in Adults, the following conditions and treatment approaches (or interventions) are covered by our Standard Set.

Conditions	Type 1 Diabetes Type 2 Diabetes
Population	Adults Aged 18 years and Above
Treatment approaches	Non-Pharmacological Therapy Non-Insulin-based Pharmacological Therapy Insulin-based Pharmacological Therapy
Excluded populations	Children and Young persons below 18 years
Excluded conditions	Diabetes mellitus types other than 1 and 2 Secondary Diabetes Gestational Diabetes

ICHOM Standard Set for Diabetes in Adults

Case-Mix Variables

Patient Population	Measure	Supporting Information	Timing	Data Source
Demographic Factors				
All patients	Sex		Baseline	Clinician /Healthcare provider
All patients	Year of Birth	Used to calculate age	Baseline	Clinician /Healthcare provider
All patients	Ethnicity	This definition was based on categories in the International Diabetes Federation (IDF) consensus Worldwide Definition of the Metabolic Syndrome	Baseline	Patient
All patients	Education Level	The education level categories map to the International Standard Classification of Education (ISCED)	Baseline and every 5 years	Patient
Diagnosis Profile				
All patients	Diabetes Type		Baseline	Clinician /Healthcare provider
All patients	Year of Diagnosis	The estimated year of diagnosis based on the person with diabetes' estimate or clinical records	Baseline	Clinician /Healthcare provider or Patient
All patients	Comorbidities		Baseline and annually	Clinician /Healthcare provider
Lifestyle and Social Factors				
All patients	Smoking		Baseline and annually	Patient
All patients	Alcohol Consumption		Baseline and annually	Patient
All patients	Physical Activity		Baseline and annually	Patient
All patients	Social Support		Baseline and annually	Patient
Treatment Factors				
All patients	Diabetes Treatment		Baseline and annually	Clinician /Healthcare provider
All patients	Blood Pressure Lowering Therapy		Baseline and annually	Clinician /Healthcare provider
All patients	Statin/Lipid Lowering Therapy		Baseline and annually	Clinician /Healthcare provider
All patients	Treatment Adherence	This scale was developed by the Diabetes Working Group and has not yet been validated	Baseline and annually	Patient
All patients	Access to Healthcare		Baseline and annually	Patient

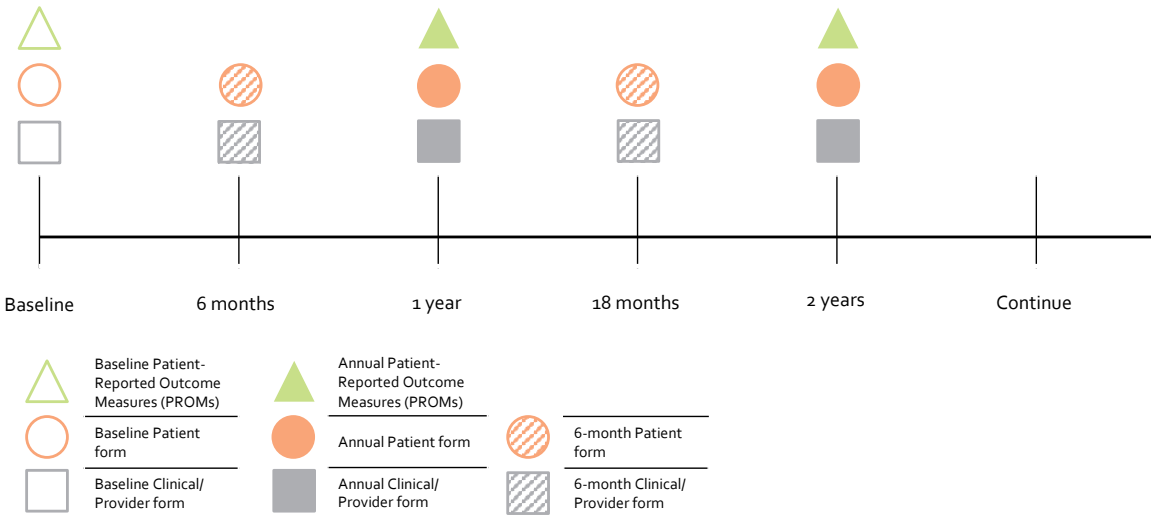
Outcomes

Patient Population	Measure	Supporting Information	Timing	Data Source
Diabetes Control				
All patients	Glycemic Control	HbA1c and Time-in-range. Time in range is only measured for persons with diabetes who already have access to continuous glucose monitoring as part of their care.	Baseline and every 6 months	Clinician /Healthcare provider
All patients	Intermediate Outcomes	Includes disease management goals such as blood pressure, lipid profile, and body mass index.	Annually	Clinician /Healthcare provider
Acute Events				
All patients	Diabetic Ketoacidosis and Hyperosmolar Hyperglycemic Syndrome		Baseline and every 6 months	Clinician /Healthcare provider
All patients	Hypoglycemia		Baseline and every 6 months	Clinician /Healthcare provider or patient
All patients	Acute Cardiovascular Events (Stroke and Myocardial Infarction)		Baseline and annually	Clinician /Healthcare provider
All patients	Lower Limb Amputation		Baseline and annually	Clinician /Healthcare provider
Chronic Complications				
All patients	Vision		Baseline and annually	Clinician /Healthcare provider or Patient
All patients	Autonomic Neuropathy		Baseline and annually	Clinician /Healthcare provider
All patients	Peripheral Neuropathy		Baseline and annually	Clinician /Healthcare provider or Patient
All patients	Charcot's Foot		Baseline and annually	Clinician /Healthcare provider
All patients	Lower Limb Ulcers		Baseline and annually	Clinician /Healthcare provider
All patients	Peripheral Artery Disease		Baseline and annually	Clinician /Healthcare provider or Patient
All patients	Ischemic Heart Disease		Baseline and annually	Clinician /Healthcare provider
All patients	Chronic Heart Failure		Baseline and annually	Clinician /Healthcare provider
All patients	Chronic Kidney Disease and Dialysis		Baseline and annually	Clinician /Healthcare provider
All patients	Cerebrovascular Disease		Baseline and annually	Clinician /Healthcare provider
All patients	Periodontal health		Baseline and annually	Clinician /Healthcare provider
Only male patients	Erectile Dysfunction		Baseline and annually	Clinician /Healthcare provider or Patient

Patient Population	Measure	Supporting Information	Timing	Data Source
Persons on injectable insulin or non-insulin injectable therapies	Lipodystrophy		Baseline and annually	Clinician /Healthcare provider
Health Services				
All patients	Hospitalization		Annually	Clinician /Healthcare provider
All patients	Emergency Room Utilization		Annually	Clinician /Healthcare provider
All patients	Financial Barriers to Care		Annually	Patient
Survival				
All patients	Vital Status		Annually	Clinician /Healthcare provider
Patient-Reported Outcomes				
All patients	Psychological Wellbeing	Captured using WHO (Five) Well-Being Index (WHO-5)	Baseline and annually	Patient
All patients	Diabetes Distress	Captured using Problem Areas in Diabetes Questionnaire (PAID)	Baseline and annually	Patient
All patients	Depression	Captured using Patient Health Questionnaire (PHQ-9)	Baseline and annually	Patient

Follow-Up Algorithm

The following algorithm illustrates when Standard Set variables should be collected from patients and clinicians.



Collecting Patient-Reported Outcome Measures

Diabetes Survey Used	Licensing Information	Scoring Information
WHO (Five) Well-Being Index (WHO-5)	<p>The WHO-5 is free for all health care organizations, and a license is not needed. There are translations available. More information may be found at www.who-5.org.</p>	<p>The total raw score, ranging from 0 to 25, is multiplied by 4 to give the final score, with 0 representing the worst imaginable well-being and 100 representing the best imaginable well-being. The WHO-5 Scoring Guide can be located at www.who-5.org.</p>
Problem Areas in Diabetes Questionnaire (PAID)	<p>The PAID, authored by Joslin Diabetes Center (http://www.joslin.org), is the copyright of Joslin Diabetes Center (Copyright ©2000, Joslin Diabetes Center). The PAID, provided under license from Joslin Diabetes Center may not be copied, distributed or used in any way without the prior written consent of Joslin Diabetes Center. Contact Susan D. Sjostrom at Joslin Diabetes Center at: susan.sjostrom@joslin.harvard.edu for licensing details.</p>	<p>Each question has five possible answers with a value from 0 to 4, with 0 representing “no problem” and 4 “a serious problem”. The scores are added up and multiplied by 1.25, generating a total score between 0 – 100. Patients scoring 40 or higher may be at the level of “emotional burnout” and warrant special attention. PAID scores in these patients may drop 10-15 points in response to educational and medical interventions. An extremely low score (0-10) combined with poor glycemic control may be indicative for denial. The PAID Scoring Guide can be obtained by contacting Susan D. Sjostrom at Joslin Diabetes Center at: susan.sjostrom@joslin.harvard.edu.</p>
Patient Health Questionnaire (PHQ-9)	<p>The PHQ-9 is free for all health care organizations, and a license is not needed. There are translations available. More information may be found at https://www.phqscreeners.com.</p>	<p>Each question has four possible answers with a value from 0 to 3, with 0 representing “not at all” and 3 “nearly every day”. The scores are added up, generating a total score between 0 to 27. Scores of 5, 10, 15, and 20 represent cutpoints for mild, moderate, moderately severe and severe depression, respectively. The PHQ-9 Scoring Guide can be located at https://www.phqscreeners.com.</p>

The Growing ICHOM Community



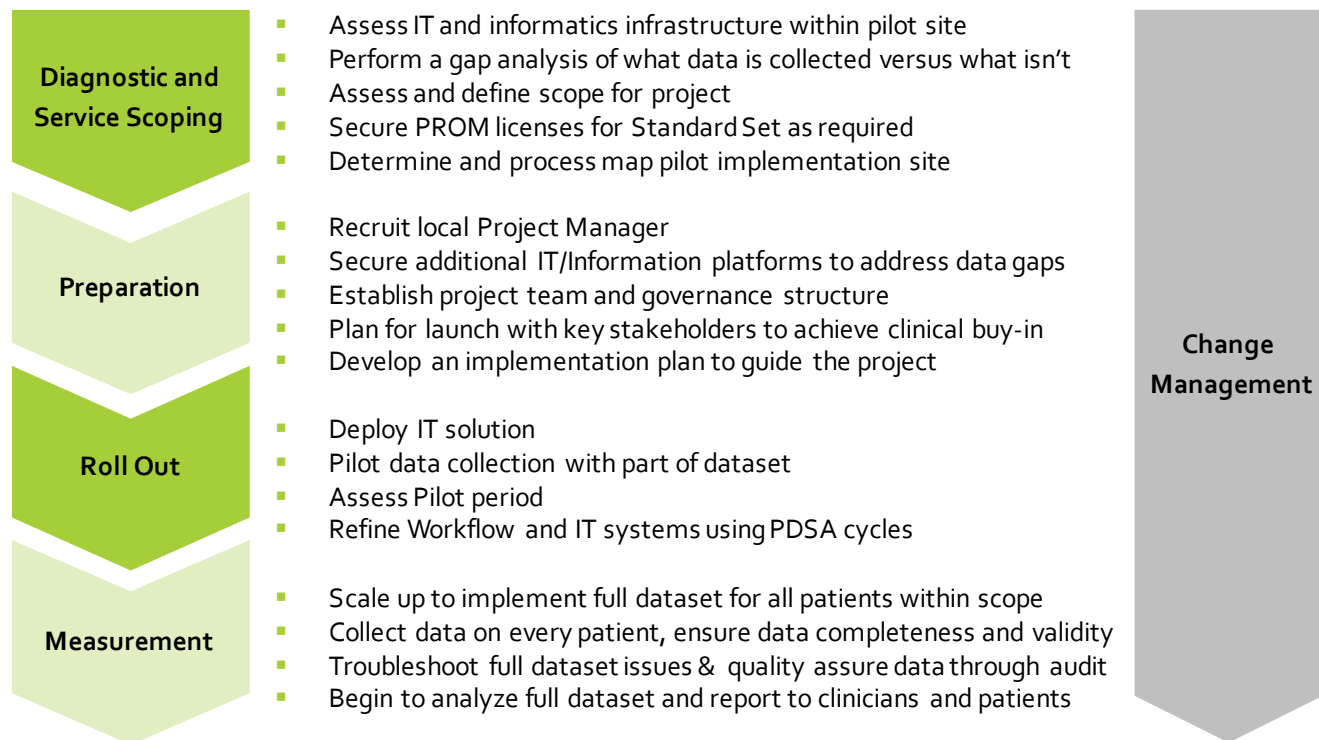
International Consortium for
Health Outcomes Measurement

There is a growing community of healthcare providers implementing the ICHOM Standard Sets. To support your organization in implementing the set and the measurement of outcomes data, we have outlined a framework to guide the implementation and reporting of patient-centered outcomes. For further information or to enquire about Implementation support offered by ICHOM, please contact the Implementation team:

implement@ichom.org

Implementation framework:

The framework below, outlines the structured process to guide the implementation of an ICHOM Standard Set at your organization. Typically, an implementation project takes 9 months to complete.



ICHOM is also able to support organizations with a variety of support models:

1. Capacity building – direct advisory support
2. Community models – supporting a community of providers in outcomes adoption and innovation
3. Education – workshops and short courses regarding Value Based Healthcare and implementation skills

Translating the Set Tools:

PROMs within the ICHOM Sets are available in a number of languages. To check the availability of translations, we advise contacting the Tool authors directly to obtain and translate the PROM surveys into your desired language. To independently translate PROM surveys, we recommend following the 10 steps outlined below:^{*1}

Step 1	Preparation	Initial work carried out before the translation work begins
Step 2	Forward Translation	Translation of the original language, also called source, version of the instrument into another language, often called the target language
Step 3	Reconciliation	Comparing and merging more than one forward translation into a single forward translation
Step 4	Back Translation	Translation of the new language version back into the original language
Step 5	Back Translation Review	Comparison of the back-translated versions of the instrument with the original to highlight and investigate discrepancies between the original and the reconciled translation, which is then revised in the process of resolving the issues
Step 6	Harmonization	Comparison of back translations of multiple language versions with each other and the original instrument to highlight discrepancies between the original and its derivative translations, as well as to achieve a consistent approach to translation problems
Step 7	Cognitive Debriefing	Testing the instrument on a small group of relevant patients or lay people in order to test alternative wording and to check understandability, interpretation, and cultural relevance of the translation
Step 8	Review of Cognitive Debriefing Results and Finalization	Comparison of the patients' or lay persons' interpretation of the translation with the original version to highlight and amend discrepancies
Step 9	Proofreading	Final review of the translation to highlight and correct any typographic, grammatical or other errors
Step 10	Final Report	Report written at the end of the process documenting the development of each translation

*These ten steps follow the ISPOR Principles of Good Practice: The Cross-Cultural Adaptation Process for Patient-Reported Outcomes Measures ¹ Wild, D., Grove, A., Martin, M., Eremenco, S., McElroy, S., Verjee-Lorenz, A., et al. (2005). Principles of good practice for the translation and cultural adaptation process for patient-reported outcomes (PRO) measures: Report of the ISPOR task force for translation and cultural adaptation. *Value in Health*, 8(2), 94–104. doi:10.1111/j.1524-4733.2005.04054.x.

For any questions about implementation please contact us at: implement@ichom.org

Appendix

Introduction to the Data Dictionary

This data dictionary is designed to help you measure the ICHOM Diabetes in Adults Standard Set as consistently as possible to the Working group recommendation. ICHOM is actively preparing for benchmarking efforts based on this data, and all data submitted for comparisons will need to be transformed into the following data structure if not already structured as such. **We are happy to provide an Excel version of this data dictionary for technical use.**

Please timestamp all variables. Some Standard Set variables are collected at multiple timepoints, and we will ask you to submit these variables in a concatenated VARIABLEID_TIMESTAMP form for future analyses. For example, VARIABLEID_BASE (baseline); VARIABLEID_6MO (6 month follow-up); VARIABLEID_1YR (1 year follow-up), etc.

Case-Mix Variables

Demographic Factors

Variable ID: SEX
Variable: Sex
Definition: Sex at birth

Supporting Definition:
Inclusion Criteria: All patients
Timing: Baseline
Data Source: Clinician /Healthcare provider
Type: Single answer
Response Options: - Female
- Male
- Unknown

Variable ID: YOB
Variable: Year of Birth
Definition: Year of birth
(YYYY)

Supporting Definition: Used to calculate age
Inclusion Criteria: All patients
Timing: Baseline
Data Source: Clinician /Healthcare provider
Type: Numerical
Response Options: YYYY

Variable ID: ETHNI
Variable: Ethnicity
Definition: Please indicate your ethnicity

Supporting Definition: This definition was based on categories in the International Diabetes Federation (IDF) consensus Worldwide Definition of the Metabolic Syndrome
Inclusion Criteria: All patients
Timing: Baseline
Data Source: Patient
Type: Single answer
Response Options: - Caucasian
- Asian
- Ethnic South and Central American
- Sub-Saharan African
- North African
- Middle East /Arab

- Oceania
- Other
- Not specified

Variable ID:	EDU
Variable:	Education Level
Definition:	Please indicate the highest level of education attained
Supporting Definition:	The categories below map to the International Standard Classification of Education (ISCED) (http://uis.unesco.org/en/topic/international-standard-classification-education-isced) as follows: None= Early childhood education, Primary education Primary= Lower secondary education, Upper secondary education Secondary= Post-secondary non-tertiary education, Short-cycle tertiary education Tertiary= Bachelor's or equivalent level, Master's or equivalent level, Doctoral or equivalent level
Inclusion Criteria:	All patients
Timing:	Baseline Every 5 years
Data Source:	Patient
Type:	Single answer
Response Options:	- None - Primary - Secondary - Tertiary

Diagnosis Profile

Variable ID:	DIATYP
Variable:	Diabetes Type
Definition:	Indicate type of diabetes
Supporting Definition:	This set was developed with a focus on type 1 and type 2 diabetes. This will allow the two groups to be analyzed separately
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Clinician/Healthcare provider
Type:	Single answer
Response Options:	- Type 1 - Type 2 - Other - Unknown

Variable ID:	YODIAG
Variable:	Year of Diagnosis
Definition:	When were you diagnosed with diabetes?
Supporting Definition:	Record the estimated year of diagnosis based on person with diabetes' estimate or clinical records. Used to calculate diabetes duration.
Inclusion Criteria:	All patients
Timing:	Baseline
Data Source:	Clinician /Healthcare provider or Patient
Type:	Numerical
Response Options:	-Year of Diagnosis

Variable ID:	COMORB
Variable:	Comorbidities

Definition: Indicate which comorbidities the person with diabetes is living with. Select all that apply.

Supporting Definition: Include ALL conditions that apply at every annual follow-up.

Inclusion Criteria: All patients

Timing: Baseline
Annually

Data Source: Clinician /Healthcare provider

Type: Multiple answer

Response Options:

- Liver Disease
- Malignancy
- AIDS
- Chronic Obstructive Pulmonary Disease
- Peripheral Vascular Disease
- Dementia
- Hemiplegia
- Active Tuberculosis
- Active Hepatitis B
- Active Hepatitis C
- Presence/history of anxiety disorders
- Presence/history of depression
- Presence/history of disordered eating behavior
- Presence/ history of psychotic mental illnesses (e.g. schizophrenia)
- Thyroid disease (hyperactive thyroid or hypoactive thyroid)
- Other condition not listed above
- None

Variable ID: TSH

Variable: Thyroid-stimulating hormone in person with type 1 diabetes

Definition: Please provide the person with diabetes' most recent thyroid stimulating hormone levels from the past 12 months

Supporting Definition:

Inclusion Criteria: For people with type 1 diabetes, if thyroid disease is present

Timing: Baseline
Annually

Data Source: Clinician /Healthcare provider

Type: Numerical

Response Options:

- Numerical value of TSH in mIU/L
- ooo if not available

Lifestyle and Social Factors

Variable ID: SMOK

Variable: Smoking

Definition: What is your smoking status today?

Supporting Definition:

Inclusion Criteria: All patients

Timing: Baseline
Annually

Data Source: Patient

Type: Single answer

Response Options:

- Current smoker
- Never smoker
- Ex-smoker quit smoking less than 5 years ago
- Ex-smoker quit smoking 5 years ago or longer

Variable ID: ALCFREQ¹

Variable: Alcohol Frequency

Definition: How often do you consume alcoholic drinks or beverages?
Please provide an estimated average frequency over the past year.

Supporting Definition:

Inclusion Criteria: All patients

Timing: Baseline
Annually

Data Source: Patient

Type: Single answer

Response Options: - Every day/7 days per week
- 5 to 6 days per week
- 3 to 4 days per week
- 1 to 2 days per week
- 1 to 3 days per month
- Never

Variable ID: ALCAMT¹

Variable: Alcohol Amount

Definition: On average, how many units of alcohol do you consume when you drink alcoholic drinks or beverages?

Please provide an estimated average of the amount you consumed each time you consumed alcohol over the past year.

Supporting Definition: Patient will be provided with local or country-specific guidance on what constitutes a unit of alcohol

Inclusion Criteria: All patients

Timing: Baseline
Annually

Data Source: Patient

Type: Numerical

Response Options: Average number of units consumed in whole numbers

Variable ID: PHYSACT

Variable: Physical Activity

Definition: On average, have you been physically active over the past year? This means being active for more than 150 minutes of moderate intensity exercise or 75 minutes of vigorous exercise a week.

Supporting Definition: Being active is defined in accordance with the World Health Organization (WHO) guidelines as engaging in at least 150 minutes of moderate physical activity a week or 75 minutes of vigorous activity a week

(http://www.who.int/dietphysicalactivity/publications/recommendations_18_64yearsold/en/).

Inclusion Criteria: All patients

Timing: Baseline
Annually

Data Source: Patient

Type: Single answer

Response Options: - Yes
- No
- Unknown

Variable ID: PHYSFUNC

Variable: Physical Functioning
Disability/functional status

Definition: Do you have a physical disability that is preventing you from being more active?

Supporting Definition:

Inclusion Criteria: If responded "No" to "Are you physically active?"

Timing: Baseline
Annually

Data Source: Patient
Type: Single answer
Response Options: - Yes
- No
- Unknown

Variable ID: SOCIALSUP
Variable: Social Support
Definition: Whom do you currently live with?
Supporting Definition:
Inclusion Criteria: All patients
Timing: Baseline
Annually
Data Source: Patient
Type: Single answer
Response Options: - I live with partner/spouse/family/friends
- I live alone
- I live in a nursing home, hospital or other long-term care home
- Other
- Unknown

Treatment Factors

Variable ID: DIATREAT
Variable: Diabetes Treatment
Definition: Indicate the type of diabetes treatment [select all that applied in the past 12 months]:
Supporting Definition: Non-pharmacological therapy includes lifestyle management addressing lifestyle factors such as diet and exercise. Alternative, complementary, and traditional medicine approaches such as homoeopathic medicines should be captured under the “other” category
Inclusion Criteria: All patients
Timing: Baseline
Annually
Data Source: Clinician /Healthcare provider
Type: Multiple answer
Response Options: - Non-pharmacological therapy
- Oral antidiabetic drugs
- Non-insulin injectable antidiabetic drugs
- Insulin
- Other
- No treatment
*Coding systems are being developed for drug classes

Variable ID: BPLTHERA
Variable: Blood Pressure Lowering Therapy
Definition: Indicate whether the person with diabetes is on blood pressure lowering medication
Supporting Definition: Indicate if the person has been on any blood pressure lowering medication at any point in the past 12 months
Inclusion Criteria: All patients
Timing: Baseline
Annually
Data Source: Clinician /Healthcare provider
Type: Single answer
Response Options: - Yes, on ACE inhibitor
- Yes, on Angiotensin receptor blocker

- Yes, on other blood pressure lowering medication
- No
- Unknown

Variable ID: STATLIPHERA

Variable: Statin/Lipid Lowering Therapy

Definition: Indicate whether the person with diabetes takes statins or lipid lowering therapy

Supporting Definition: Indicate if the person has been on any statins or lipid lowering therapy at any point in the past 12 months

Inclusion Criteria: All patients

Timing: Baseline

Annually

Data Source: Clinician /Healthcare provider

Type: Single answer

Response Options: - Yes

- No

- Unknown

Variable ID: ADHEDIET

Variable: Treatment Adherence
(Dietary advice)

Definition: Please rate how well you stick to the dietary advice from your healthcare team on a scale from 1 to 10

1 = not adherent

10 = fully adherent

Supporting Definition: This scale was developed by the Diabetes Working Group and has not yet been validated

Inclusion Criteria: All patients

Timing: Baseline

Annually

Data Source: Patient

Type: Numerical

Response Options: Integer response between 1 and 10

0 = not rated

Variable ID: ADHEEXER

Variable: Treatment Adherence
(Exercise)

Definition: Please rate how well you stick to advice on exercise from your healthcare team on a scale from 1 to 10

1 = not adherent

10 = fully adherent

Supporting Definition: This scale was developed by the Diabetes Working Group and has not yet been validated

Inclusion Criteria: All patients

Timing: Baseline

Annually

Data Source: Patient

Type: Numerical

Response Options: Integer response between 1 and 10

0 = not rated

Variable ID: ADHESUGA

Variable: Treatment Adherence
(Blood sugar monitoring)

Definition: Please rate how well you stick to the advice on monitoring your blood sugar from your healthcare team on a scale from 1 to 10

1 = not adherent

10 = fully adherent
Supporting Definition: This scale was developed by the Diabetes Working Group and has not yet been validated
Inclusion Criteria: All patients
Timing: Baseline
Annually
Data Source: Patient
Type: Numerical
Response Options: Integer response between 1 and 10
0 = not rated

Variable ID: ADHEMEDI
Variable: Treatment Adherence
(Medication adherence)
Definition: Please rate how well you stick to your prescribed medication and/or insulin regimen on a scale from 1 to 10
1 = not adherent
10 = fully adherent

Supporting Definition: This scale was developed by the Diabetes Working Group and has not yet been validated
Inclusion Criteria: All patients
Timing: Baseline
Annually
Data Source: Patient
Type: Numerical
Response Options: Integer response between 1 and 10
0 = not rated

Outcomes

Diabetes Control

Variable ID: HBA1C
Variable: Glycemic Control
HbA1c
Definition: Provide the most recent HbA1c reading collected in the past 6 months

Supporting Definition:
Inclusion Criteria: All patients
Timing: Baseline
Every 6 months
Data Source: Clinician /Healthcare provider
Type: Numerical
Response Options: Numerical value of HbA1c

Variable ID: HBA1CUNIT
Variable: Glycemic Control
Units of HbA1c
Definition: Units of HbA1c readings provided

Supporting Definition:
Inclusion Criteria: All patients
Timing: Baseline
Every 6 months
Data Source: Clinician /Healthcare provider
Type: Single answer
Response Options: - mmol/mol
- %

Variable ID: TIR
Variable: Glycemic Control

	Time in range
Definition:	Provide the percentage of time in the range of 70 mg/dL – 180 mg/dL (3.9-10.0 mmol/L) over the past 6 months
Supporting Definition:	
Inclusion Criteria:	Only persons with diabetes on continuous glucose monitoring
Timing:	Baseline Every 6 months
Data Source:	Clinician /Healthcare provider or Patient
Type:	Numerical
Response Options:	Numerical value of time in range
Variable ID:	SYSBP
Variable:	Blood Pressure Systolic Reading
Definition:	What is the person with diabetes' most recent systolic blood pressure from the past 12 months
Supporting Definition:	Systolic and diastolic blood pressure readings are used to determine the presence of hypertension and whether blood pressure is controlled if on blood pressure lowering medication. Control will be defined depending on the most relevant hypertension guidelines
Inclusion Criteria:	All patients
Timing:	Baseline Annually
Data Source:	Clinician /Healthcare provider
Type:	Numerical
Response Options:	Numerical systolic BP in mmHg
Variable ID:	DIABP
Variable:	Blood pressure Diastolic Reading
Definition:	What is the person with diabetes' most recent diastolic blood pressure from the past 12 months
Supporting Definition:	Systolic and diastolic blood pressure readings are used to determine the presence of hypertension and whether blood pressure is controlled if on blood pressure lowering medication. Control will be defined depending on the most relevant hypertension guidelines
Inclusion Criteria:	All patients
Timing:	Baseline Annually
Data Source:	Clinician /Healthcare provider
Type:	Numerical
Response Options:	Numerical diastolic BP in mmHg
Variable ID:	LIPTCHOL
Variable:	Lipid Profile Total Cholesterol
Definition:	Most recent total cholesterol reading from the past 12 months
Supporting Definition:	
Inclusion Criteria:	All patients
Timing:	Baseline Annually
Data Source:	Clinician /Healthcare provider
Type:	Numerical
Response Options:	Numerical value of blood total cholesterol concentration
Variable ID:	LIPTCHOLUNI

Variable: Units of Total Cholesterol
Definition:
Supporting Definition:
Inclusion Criteria: All patients
Timing: Baseline
Annually
Data Source: Clinician /Healthcare provider
Type: Single answer
Response Options: - mg/dL
- mmol/L

Variable ID: LIPLDL
Variable: Lipid Profile
LDL Cholesterol
Definition: Most recent low density lipoprotein (LDL) cholesterol from the past 12 months
Supporting Definition:
Inclusion Criteria: All patients
Timing: Baseline
Annually
Data Source: Clinician /Healthcare provider
Type: Numerical
Response Options: Numerical value of blood LDL cholesterol concentration

Variable ID: LIPLDLUNI
Variable: Units of LDL Cholesterol
Definition:
Supporting Definition:
Inclusion Criteria: All patients
Timing: Baseline
Annually
Data Source: Clinician /Healthcare provider
Type: Single answer
Response Options: - mg/dL
- mmol/L

Variable ID: LIPHDL
Variable: Lipid Profile
HDL Cholesterol
Definition: Most recent high density lipoprotein (HDL) cholesterol from the past 12 months
Supporting Definition:
Inclusion Criteria: All patients
Timing: Baseline
Annually
Data Source: Clinician /Healthcare provider
Type: Numerical
Response Options: Numerical value of blood HDL cholesterol concentration

Variable ID: LIPHDLUNI
Variable: Units of HDL Cholesterol
Definition:
Supporting Definition:
Inclusion Criteria: All patients
Timing: Baseline
Annually
Data Source: Clinician /Healthcare provider
Type: Single answer
Response Options: - mg/dL
- mmol/L

Variable ID:	LIPTRY
Variable:	Lipid Profile Triglycerides
Definition:	Most recent triglycerides from the past 12 months
Supporting Definition:	
Inclusion Criteria:	All patients
Timing:	Baseline Annually
Data Source:	Clinician /Healthcare provider
Type:	Numerical
Response Options:	Numerical value of blood triglyceride concentration
Variable ID:	LIPTRYUNI
Variable:	Units of Triglycerides
Definition:	
Supporting Definition:	
Inclusion Criteria:	All patients
Timing:	Baseline Annually
Data Source:	Clinician /Healthcare provider
Type:	Single answer
Response Options:	- mg/dL - mmol/L
Variable ID:	WEIGHT
Variable:	BMI- Weight
Definition:	Provide the most recent weight taken in the past 12 months.
Supporting Definition:	- To determine body mass index (BMI) - BMI cut-offs should be applied taking into consideration the self-reported ethnicity.
Inclusion Criteria:	All patients
Timing:	Baseline Annually
Data Source:	Clinician /Healthcare provider
Type:	Numerical
Response Options:	Numerical value of weight in kilograms
Variable ID:	HEIGHT
Variable:	BMI- Height
Definition:	Provide the most recent height taken in the past 12 months.
Supporting Definition:	- To determine BMI - BMI cut-offs should be applied taking into consideration the self-reported ethnicity.
Inclusion Criteria:	All patients
Timing:	Baseline Annually
Data Source:	Clinician /Healthcare provider
Type:	Numerical
Response Options:	Numerical value of height in meters
Variable ID:	WAISTC
Variable:	Waist Circumference
Definition:	Provide the most recent waist circumference taken in the past 12 months.
Supporting Definition:	- Waist circumference should be measured at the midpoint between the lower margin of the least palpable rib and the top of the iliac crest, using a stretch-resistant tape that provides a constant 100 g tension. [Waist Circumference and Waist–Hip Ratio: Report of a WHO Expert Consultation Geneva, 8–11 December 2008]

Inclusion Criteria: All patients
Timing: Baseline
Annually
Data Source: Clinician /Healthcare provider
Type: Numerical
Response Options: Numerical value of waist circumference in centimeters

Acute Events

Variable ID: DKAHHS

Variable: Diabetic Ketoacidosis and Hyperosmolar Hyperglycemic Syndrome

Definition: Indicate if the person with diabetes experienced Diabetic Ketoacidosis or Hyperosmolar Hyperglycemic Syndrome in the past 6 months.

Supporting Definition: Diabetic ketoacidosis includes euglycemic and hyperglycemic ketoacidosis.

Inclusion Criteria: All patients

Timing: Baseline
Every 6 months

Data Source: Clinician /Healthcare provider

Type: Single answer

Response Options: - Yes, experienced DKA
- Yes, experienced HHS
- Yes, experienced both
- No
- Unknown

Variable ID: HYPOL3

Variable: Hypoglycemia - Level 3

Definition: In the past 6 months, how many episodes of severe hypoglycemia requiring assistance from another person did the person with diabetes experience (this includes assistance from clinical and non-clinical individuals)?

Supporting Definition: Level 3 hypoglycemia is defined as a hypoglycemic event needing assistance

Inclusion Criteria: All patients

Timing: Baseline
Every 6 months

Data Source: Clinician /Healthcare provider
or
Patient

Type: Single answer

Response Options: - 0
- 1
- 2
- more than 2
- Unknown

Variable ID: HYPOL2

Variable: Hypoglycemia - Level 2

Definition: In the past 6 months, how many episodes of level 2 hypoglycemia (Blood glucose below 54 mg/dl (3.0 mmol/L)) did the person with diabetes experience?

Supporting Definition: Level 2 hypoglycemia is defined as a measurable glucose concentration <54 mg/dL (3.0 mmol/L) that needs immediate action

Inclusion Criteria: All patients

Timing: Baseline
Every 6 months

Data Source: Clinician /Healthcare provider
or
Patient

Type: Numerical

Response Options: - Numeric Response

Variable ID: HYPOL2AWAR

Variable: Hypoglycemia - Level 2
Loss of awareness of hypoglycemia

Definition: Did any of these hypoglycemic episodes occur without symptoms?

Supporting Definition: Level 2 hypoglycemia is defined as a measurable glucose concentration <54 mg/dL (3.0 mmol/L) that needs immediate action

Inclusion Criteria: If responded 1 or more to "In the past 6 months, how many episodes of level 2 hypoglycemia(Blood glucose below 54 mg/dl (3.0 mmol/L)) did the person with diabetes experience?"

Timing: Baseline
Every 6 months

Data Source: Clinician /Healthcare provider
or
Patient

Type: Single answer

Response Options: - Yes
- No
- Unknown

Variable ID: MYOINFARC

Variable: Ischemic Heart Disease - Acute events

Definition: Has the person with diabetes ever experienced an acute ischemic event, including myocardial infarction?

Supporting Definition: When presenting this question at annual follow-up, phrase as follows: "In the past 12 months, did the person with diabetes experience a new ischemic cardiac event including myocardial infarction?"

Inclusion Criteria: All patients

Timing: Baseline
Annually

Data Source: Clinician /Healthcare provider

Type: Single answer

Response Options: - Yes
- No
- Unknown

Variable ID: CVTIA

Variable: Cerebrovascular Disease - Acute events

Definition: Has the person with diabetes ever experienced an acute cerebrovascular event?
This includes stroke or transient ischemic attacks

Supporting Definition: When presenting this question at annual follow-up, phrase as follows: "In the past 12 months, did the person with diabetes experience any new acute cerebrovascular events? This includes stroke or transient ischemic attacks."

Inclusion Criteria: All patients

Timing: Baseline
Annually

Data Source: Clinician /Healthcare provider

Type: Single answer

Response Options: - Yes
- No
- Unknown

Variable ID: LLAMP

Variable: Lower Limb Amputation

Definition: Has the person with diabetes had a lower limb amputation?

Supporting Definition: When presenting this question at annual follow-up, phrase as follows: "In the past year, has the person with diabetes had a lower limb amputation?"

Inclusion Criteria: All patients
Timing: Baseline
Annually
Data Source: Clinician /Healthcare provider
Type: Single answer
Response Options: - Yes
- No
- Unknown

Variable ID: LLAMPLEV
Variable: Lower Limb Amputation Level
Definition: If yes to amputation, at what level is the amputation?
Supporting Definition: If more than one procedure in the past 12 months, state the most severe level.
Inclusion Criteria: If "Yes" to "has the person with diabetes had a lower limb amputation"
Timing: Baseline
Annually
Data Source: Clinician /Healthcare provider
Type: Single answer
Response Options: - Distal to the ankle joint
- Below knee
- Above knee
- Unknown

Chronic Complications

Variable ID: VISIMP
Variable: Visual Outcomes - Visual Impairment
Definition: Does the person with diabetes experience visual impairment?
Supporting Definition:
Inclusion Criteria: All patients
Timing: Baseline
Annually
Data Source: Clinician /Healthcare provider
or
Patient
Type: Single answer
Response Options: - Yes
- No
- Unknown

Variable ID: VISIMPACU
Variable: Visual Outcomes - Visual Impairment
Visual Acuity
Definition: If yes - what is the visual acuity?
Supporting Definition:
Inclusion Criteria: If "yes" to "Does the person with diabetes experience visual impairment?"
Timing: Baseline
Annually
Data Source: Clinician /Healthcare provider
Type: Numerical
Response Options: Numerical value of visual acuity

Variable ID: VISIMPACUMET
Variable: Visual Outcomes - Visual Impairment
Visual Acuity Measurement Method
Definition: Method of measurement (Snellen vs logMAR)
Supporting Definition:

Inclusion Criteria: All patients
Timing: Baseline
Annually
Data Source: Clinician /Healthcare provider
Type: Single answer
Response Options: - Snellen (6 meters)
- Snellen (20 feet)
- LogMAR

Variable ID: VISTHREAT
Variable: Visual Outcomes - Diabetes-related Sight Threatening Conditions
Definition: Has the person with diabetes been diagnosed with any of the listed sight-threatening conditions?
(select all that apply)

Supporting Definition: When presenting this question at annual follow-up, phrase as follows: "In the past year, has the person with diabetes been diagnosed with any of the listed sight-threatening conditions?"

Inclusion Criteria: All patients
Timing: Baseline
Annually
Data Source: Clinician /Healthcare provider
Type: Multiple answer
Response Options: - Non-proliferative diabetic retinopathy
- Proliferative diabetic retinopathy
- Unspecified diabetic retinopathy
- Macular edema
- Other
- No sight threatening conditions
- Unknown

Variable ID: AUTNEU
Variable: Autonomic Neuropathy
Definition: Is there evidence of diabetic autonomic neuropathy?

Supporting Definition:
Inclusion Criteria: All patients
Timing: Baseline
Annually

Data Source: Clinician /Healthcare provider
Type: Single answer
Response Options: - Yes
- No
- Unknown

Variable ID: PERINEUCLI
Variable: Peripheral Neuropathy - Clinician Diagnosis
Definition: Does the person with diabetes have evidence of peripheral neuropathy on clinical examination? This includes bedside tests such as pin prick or tuning fork tests.

Supporting Definition: When presenting this question at annual follow-up, phrase as follows: "In the past year, did the person with diabetes develop evidence of peripheral neuropathy on clinical examination? This includes bedside tests such as pin prick or tuning fork tests."

Inclusion Criteria: All patients
Timing: Baseline
Annually
Data Source: Clinician /Healthcare provider
Type: Single answer
Response Options: - Yes

- No
- Unknown

Variable ID: PERINEUPAT

Variable: Peripheral Neuropathy - Symptoms experienced by person with diabetes

Definition: What symptoms are you experiencing due to your peripheral neuropathy (nerve damage to your lower or upper limbs)?

Supporting Definition:

Inclusion Criteria: All patients

Timing: Baseline

Annually

Data Source: Clinician /Healthcare provider

or

Patient

Type: Single answer

Response Options:

- Numbness

- Pain

- Paresthesia

- Asymptomatic/ No symptoms

- Unknown

Variable ID: CHARCF

Variable: Charcot's Foot

Definition: Is there evidence of Charcot's foot?

Supporting Definition: At annual follow-up, do not re-present this question if responded "yes" to "Is there evidence of Charcot's foot?"

Inclusion Criteria: All patients

Timing: Baseline

Annually

Data Source: Clinician /Healthcare provider

Type: Single answer

Response Options:

- Yes

- No

- Unknown

Variable ID: LLULC

Variable: Lower Limb Ulcers

Active lower limb ulcer present?

Definition: Did the person with diabetes have an active lower limb ulcer in the past 12 months?

Supporting Definition:

Inclusion Criteria: All patients

Timing: Baseline

Annually

Data Source: Clinician /Healthcare provider

Type: Single answer

Response Options:

- Yes

- No

- Unknown

Variable ID: LLULCSTAG

Variable: Lower Limb Ulcers

Staging

Definition: If Yes, provide the most severe stage diagnosed using the University of Texas wound classification system

Supporting Definition:

Inclusion Criteria: If "Yes" to Lower limb active ulcer present

Timing: Baseline

Annually
Data Source: Clinician /Healthcare provider
Type: Single answer
Response Options: - Stage A: No infection or ischemia
- Stage B: Infection present
- Stage C: Ischemia present
- Stage D: Infection and ischemia present
- Stage Unknown

Variable ID: LLULCGRAD
Variable: Lower Limb Ulcers
Grading
Definition: If Yes, provide the most severe grade diagnosed using the University of Texas
Wound Classification system

Supporting Definition:
Inclusion Criteria: If "Yes" to Lower limb active ulcer present
Timing: Baseline
Annually
Data Source: Clinician /Healthcare provider
Type: Single answer
Response Options: - Grade 0: Epithelialized wound
- Grade 1: Superficial wound
- Grade 2: Wound penetrates to tendon or capsule
- Grade 3: Wound penetrates to bone or joint
- Grade unknown

Variable ID: PADCLI
Variable: Peripheral Artery Disease - Clinical Diagnosis
Definition: Does the person with diabetes have clinical evidence of peripheral artery disease?
(ABPI <0.8 or absence of pedal pulses)

Supporting Definition: At annual follow-up, do not re-present this question if responded "yes" to "Does
the person with diabetes have clinical evidence of peripheral artery disease?"
Inclusion Criteria: All patients
Timing: Baseline
Annually
Data Source: Clinician /Healthcare provider
Type: Single answer
Response Options: - Yes
- No
- Unknown

Variable ID: PADPAT
Variable: Peripheral artery disease - Symptoms experienced by person with diabetes
Definition: Does the person with diabetes experience symptoms of peripheral artery disease?

Supporting Definition:
Inclusion Criteria: All patients
Timing: Baseline
Annually
Data Source: Clinician /Healthcare provider
or
Patient
Type: Single answer
Response Options: - No
- Yes, intermittent claudication
- Yes, rest pain
- Unknown

Variable ID: MIANG

Variable: Ischemic Heart Disease

Definition: Does the person with diabetes have ischemic heart disease? This may be diagnosed on history of angina, new evidence of ischemia on electrocardiogram (ECG) or other cardiac investigation.

Supporting Definition: When presenting this question at annual follow-up, phrase as follows: "In the past year, did the person with diabetes develop new evidence of ischemic heart disease? This may be diagnosed on history of angina, new evidence of ischemia on ECG or other cardiac investigation."

Inclusion Criteria: All patients

Timing: Baseline
Annually

Data Source: Clinician /Healthcare provider

Type: Single answer

Response Options: - Yes
- No
- Unknown

Variable ID: CHF

Variable: Chronic Heart Failure

Definition: Does the person with diabetes have heart failure (HF)? This may be diagnosed clinically or by echocardiography.

Supporting Definition: When presenting this question at annual follow-up, phrase as follows: "In the past 12 months, did the person with diabetes develop new evidence of heart failure? This may be diagnosed clinically or by echocardiography."

Inclusion Criteria: All patients

Timing: Baseline
Annually

Data Source: Clinician /Healthcare provider

Type: Single answer

Response Options: - Yes
- No
- Unknown

Variable ID: CHRSTAGE

Variable: Chronic Heart Failure
Staging

Definition: Please provide the stage of HF according to the American College of Cardiology/American Heart Association criteria (Jessup M, Abraham WT, Casey DE et al. 2009 Focused Update: ACCF/AHA Guidelines for the Diagnosis and Management of Heart Failure in Adults: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines Developed in Collaboration With the International Society for Heart and Lung Transplantation. Journal of the American College of Cardiology 2009;53:1343-1382)

Supporting Definition:

Inclusion Criteria: All patients

Timing: Baseline
Annually

Data Source: Clinician /Healthcare provider

Type: Single answer

Response Options: - Stage A
(At high risk of HF without structural heart disease or symptoms of HF)
- Stage B
(Structural heart disease but without signs or symptoms of HF)
- Stage C
(Structural heart disease with prior or current symptoms of HF)

- Stage D
(Refractory HF requiring specialist interventions)
- Stage unknown
- Not assessed

Variable ID: RFTEGFR
Variable: Renal Function Tests/Moderate to Severe Kidney Disease
eGFR

Definition: What is the person's eGFR?

Supporting Definition: Provide most recent reading from the past 12 months

Inclusion Criteria: All patients

Timing: Baseline
Annually

Data Source: Clinician /Healthcare provider

Type: Numerical

Response Options: - State numerical value of eGFR
- 000 if unavailable or unknown

Variable ID: RFTACR
Variable: Renal Function Tests/Moderate to Severe Kidney Disease
ACR

Definition: What is the person with diabetes' urinary albumin/creatinine (ACR) ratio?

Supporting Definition: Provide most recent reading from the past 12 months

Inclusion Criteria: All patients

Timing: Baseline
Annually

Data Source: Clinician /Healthcare provider

Type: Single answer

Response Options: - ACR <30mg/g or <3mg/mmol
- ACR 30-300mg/g or 3-30mg/mmol
- ACR > 300 mg/g or >30mg/mmol
- ACR unknown

Variable ID: DIALYSIS

Variable: Dialysis

Definition: Is the person with diabetes on dialysis for end-stage chronic renal failure?

Supporting Definition:

Inclusion Criteria: All patients

Timing: Baseline
Annually

Data Source: Clinician /Healthcare provider

Type: Single answer

Response Options: - Yes
- No
- Unknown

Variable ID: CRBVD

Variable: Cerebrovascular Disease

Definition: Does the person with diabetes have any evidence of cerebrovascular disease? This may include evidence from clinical examination or investigations.

Supporting Definition:

Inclusion Criteria: All patients

Timing: Baseline
Annually

Data Source: Clinician /Healthcare provider

Type: Single answer

Response Options: - Stroke
- Transient ischemic attack

- No history of Stroke or Transient Ischemic Attack
- Unknown

Variable ID: PERIODON
Variable: Periodontal Health
Definition: Please provide details on the periodontal health of the person with diabetes
Supporting Definition:
Inclusion Criteria: All patients
Timing: Baseline
 Annually
Data Source: Clinician /Healthcare provider
Type: Single answer
Response Options: - Healthy
 - Gingivitis
 - Periodontitis
 - Unknown

Variable ID: ED
Variable: Erectile Dysfunction
Definition: Does the person with diabetes experience erectile dysfunction?
Supporting Definition: When presenting this question at annual follow-up, phrase as follows: "In the past 12 months, did the person with diabetes experience any erectile dysfunction?"
Inclusion Criteria: Only male patients
Timing: Baseline
 Annually
Data Source: Clinician /Healthcare provider
 or
 Patient
Type: Single answer
Response Options: - Yes
 - No
 - Unknown

Variable ID: LIPDYS
Variable: Lipodystrophy
Definition: Is there evidence of lipodystrophy?
Supporting Definition: When presenting this question at annual follow-up, phrase as follows: "In the past 12 months, did the person with diabetes develop new evidence of lipodystrophy?"
Inclusion Criteria: Persons on injectable insulin or non-insulin injectable therapies
Timing: Baseline
 Annually
Data Source: Clinician /Healthcare provider
Type: Single answer
Response Options: - Yes
 - No
 - Unknown

Health Services

Variable ID: HOSPADMDATE
Variable: Hospitalization
 Admission date
Definition: Date of admission
Supporting Definition:
Inclusion Criteria: All patients - for every hospitalization
Timing: Annually
Data Source: Clinician /Healthcare provider
Type: Date

Response Options: Date of admission (DD/MM/YYYY) for every admission

Variable ID: HOSPDISDATE

Variable: Hospitalization
Discharge date

Definition: Date of discharge

Supporting Definition:

Inclusion Criteria: All patients - for every hospitalization

Timing: Annually

Data Source: Clinician /Healthcare provider

Type: Date

Response Options: Date of discharge (DD/MM/YYYY) for every admission

Variable ID: HOSPDIAG

Variable: Hospitalization - Discharge diagnosis

Definition: What is the discharge diagnosis?

Supporting Definition:

- Cardiovascular - This includes myocardial infarction, acute coronary syndrome, unstable angina, stroke; decompensation of heart failure
- Acute kidney injury²
- Foot- and lower limb related- This includes foot ulcer, cellulitis, contiguous osteomyelitis, gangrene
- Acute metabolic – This includes Ketoacidosis, hyperosmolar syndrome (without mentioning glucose level) dehydration, failure to thrive, acute hypoglycemia
- Other (Everything that does not fall into the above clearly defined categories)
- Unknown

Inclusion Criteria: All patients - for every hospitalization

Timing: Annually

Data Source: Clinician /Healthcare provider

Type: Multiple answer

Response Options:

- Cardiovascular causes
- Acute Kidney Injury
- Foot- and lower limb-related complications
- Acute metabolic complications
- Other
- Unknown

Variable ID: ERUTIL

Variable: Emergency Room Utilization

Definition: How many emergency room attendances related to diabetes has the person with diabetes had in the past year? Whether or not an emergency room attendance is related to diabetes is determined by the treating physician.

Supporting Definition:

- Only include emergency room attendances with the following diagnoses:
- ¹- Cardiovascular - This includes myocardial infarction, acute coronary syndrome, unstable angina, stroke; decompensation of heart failure
 - Acute kidney injury²
 - Foot- and lower limb related- This includes infected foot ulcer, cellulitis, contiguous osteomyelitis, gangrene
 - Acute metabolic – This includes Ketoacidosis, hyperosmolar syndrome (without mentioning glucose level) dehydration, failure to thrive, acute hypoglycemia

Inclusion Criteria: All patients - for every emergency room attendance

Timing: Annually

Data Source: Clinician /Healthcare provider

Type: Numerical

Response Options: Numerical number of emergency room attendances (ooo if unknown)

Variable ID: ACCESPROF³

Variable: Access to healthcare
(Access to healthcare professionals)

Definition: Do you have difficulty getting to see the healthcare professionals you need for your diabetes when you need to?

Supporting Definition:

Inclusion Criteria: All patients

Timing: Baseline
Annually

Data Source: Patient

Type: Single answer

Response Options: - Yes
- No
- Unknown

Variable ID: ACCESPROFREAS³

Variable: Access to healthcare professionals
(Reasons for lack of access)

Definition: What are the reasons for this?

Supporting Definition: If a person responds "difficulty paying for it" as a reason for having difficulty accessing medicines or supplies, then this will be counted as an outcome. This will only apply to the responses after the baseline response.

Inclusion Criteria: All patients

Timing: Baseline
Annually

Data Source: Patient

Type: Multiple answer

Response Options: - Transportation problems
- Difficulty paying for it
- Not available where I live
- Other reason
- Unknown

Variable ID: ACCESMED³

Variable: Access to healthcare
(Access to medicines and supplies)

Definition: Do you have difficulty obtaining the medicine or supplies you need to manage your diabetes well?

Supporting Definition:

Inclusion Criteria: All patients

Timing: Baseline
Annually

Data Source: Patient

Type: Single answer

Response Options: - Yes
- No
- Unknown

Variable ID: ACCESMEDREAS³

Variable: Access to medicines and supplies
(reasons for lack of access)

Definition: What are the reasons for this?

Supporting Definition: If a person responds "difficulty paying for it" as a reason for having difficulty accessing medicines or supplies, then this will be counted as an outcome. This will only apply to the responses after the baseline response.

Inclusion Criteria: All patients

Timing: Baseline
Annually

Data Source: Patient

Type: Multiple answer

- Response Options:**
- Transportation problems
 - Difficulty paying for it
 - Not available where I live
 - Other reason
 - Unknown
-

Survival

Variable ID: VITSTAT
Variable: Vital Status
Definition: Is the person alive?

Supporting Definition:

Inclusion Criteria: All patients
Timing: Annually
Data Source: Clinician /Healthcare provider
Type: Single answer

- Response Options:**
- Yes
 - No
 - Unknown
-

Variable ID: DEATHCAUSE
Variable: Cause of death
Definition: If the person with diabetes is dead, what was the cause of death?

Supporting Definition:

Inclusion Criteria: If responded "No" to "is the person alive"
Timing: Annually
Data Source: Clinician /Healthcare provider
Type: Single answer

- Response Options:**
- Cardiovascular
 - Acute metabolic complication of diabetes related to high or low blood glucose
 - Renal
 - Other
 - Unknown
-

Variable ID: DEATHSOURCE
Variable: Death - Source of information
Definition: What is the source of the information on the person with diabetes' death

Supporting Definition:

Inclusion Criteria: All patients
Timing: Annually
Data Source: Clinician /Healthcare provider
Type: Single answer

- Response Options:**
- Death certificate
 - Clinical records
 - Family/ Carers
 - Other
-

Patient-Reported Outcomes

Variable ID: WHO-5
Variable: WHO-5 Well-Being Index
Definition: Psychological Wellbeing
Supporting Definition: Measured using the 5-item WHO (Five) Well-Being Index
Inclusion Criteria: All patients
Timing: Baseline
Annually
Data Source: Patient

Type: As per tool developer
Response Options: The WHO-5 is free for all health care organizations, and a license is not needed. There are translations available. More information may be found at www.who-5.org.

Variable ID: PAID
Variable: PAID Diabetes Distress Score
Definition: Diabetes Distress
Supporting Definition: Measured using the 20-item Problem Areas in Diabetes questionnaire
Inclusion Criteria: All patients
Timing: Baseline
Annually
Data Source: Patient
Type: As per tool developer
Response Options: The PAID, authored by Joslin Diabetes Center (<http://www.joslin.org>), is the copyright of Joslin Diabetes Center (Copyright ©2000, Joslin Diabetes Center). The PAID, provided under license from Joslin Diabetes Center may not be copied, distributed or used in any way without the prior written consent of Joslin Diabetes Center. Contact Susan D. Sjostrom at Joslin Diabetes Center at: susan.sjostrom@joslin.harvard.edu for licensing details.

Variable ID: PHQ9
Variable: PHQ-9 Depression Score
Definition: Depression
Supporting Definition: Measured using the 9-item PHQ-9 questionnaire
Inclusion Criteria: All patients
Timing: Baseline
Annually
Data Source: Patient
Type: As per tool developer
Response Options: The PHQ-9 is free for all health care organizations, and a license is not needed. There are translations available. More information may be found at <https://www.phqscreeners.com>.

¹ For international benchmarking work, the amount of alcohol consumed by each patient should be converted by multiplying ALCFREQ x ALCAMT x country- or region-specific number of grams per unit of alcohol

² Acute kidney injury is defined using KDIGO guidelines as "An increase in serum creatinine (SCR) by >0.3mg/dL (>26.5 µmol/l) within 48 hours; or an increase in SCR to >1.5 times baseline, which is known or presumed to have occurred within the prior 7 days; or urine volume <0.5ml/kg/h for 6 hours."

³ All responses to the Access to care questions (ACCESPROF, ACCESPROFREAS, ACCESMED, ACCESMEDREAS) should be measured at baseline and included as case-mix variables in the analysis. These questions should be repeated annually and the presence or absence of financial barriers used as an outcome (i.e. whether or not the patient selects "Difficulty paying for it" as a response option to ACCESMEDREAS and ACCESPROFREAS).

Working Group Member Conflicts of Interests

At the beginning of the Working group process, we ask all Working Group members to declare any conflicts of interests they have. We then circulate these within the Group to ensure transparency.

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Naomi Levitt	University of Cape Town, South Africa	Sanofi Avntis – Funding to attend a congress Novo Nordisk – Funding to attend a conference Roche Diagnostics – Financial support
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Rob Haig	Patient Representative, Australia	None declared
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Sergio Hernández Jiménez	Instituto Nacional de Ciencia Médicas y Nutrición, Mexico	Astra-Zeneca – Grant Fundación Conde de Valenciana – Grant Novartis – Grant Consejo Nacional de Ciencia y Tecnología – Grant Nutrición Médica y Tecnología – Grant Novo Nordisk – Grant Eli Lilly/Boehringer Ingelheim – Grant Dirección General de Calidad y Educación en Salud – Grant CAIPaDi Branch License SMID License CAIPaDi Programme – Patent pending
Sharon Fraser	International Diabetes Federation, Belize	None declared
Søren Eik Skovlund	Aalborg University and Aalborg University Hospital, Denmark	Novo Nordisk A/S- Past Employer DrugStars Aps- Employee/Cofounder Patient Focused Medicines Development (PFMD)- Non-Financial Support
Tim Benson	WHO Patients for Patient Safety/ Consumers Health Forum of Australia/ Health Consumers Council of Western Australia/Patient Representative, Australia	None declared
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Reference Guide Revisions

Reference Guide Version	Location within Reference Guide	Content Change
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