



**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](http://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](mailto: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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<b>Belize</b> Sharon Fraser	<b>India</b> Anil Bhansali	<b>Portugal</b> João Raposo	<b>United Arab Emirates</b> Jihan Dennaoui Saf Naqvi
<b>Cameroon</b> Jean Claude Mbanya	<b>Israel</b> Ronit Calderon-Margalit	<b>Singapore</b> Hwee-Lin Wee	<b>United Kingdom</b> Katharine Barnard Paul Buchanan
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<b>Denmark</b> Søren Eik Skovlund	<b>Malaysia</b> Mark Prabhakaran	<b>South Africa</b> Naomi Levitt	

## 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.

<b>Conditions</b>	Type 1 Diabetes   Type 2 Diabetes
<b>Population</b>	Adults Aged 18 years and Above
<b>Treatment approaches</b>	Non-Pharmacological Therapy   Non-Insulin-based Pharmacological Therapy   Insulin-based Pharmacological Therapy
<b>Excluded populations</b>	Children and Young persons below 18 years
<b>Excluded conditions</b>	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
<b>Demographic Factors</b>				
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
<b>Diagnosis Profile</b>				
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
<b>Lifestyle and Social Factors</b>				
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
<b>Treatment Factors</b>				
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

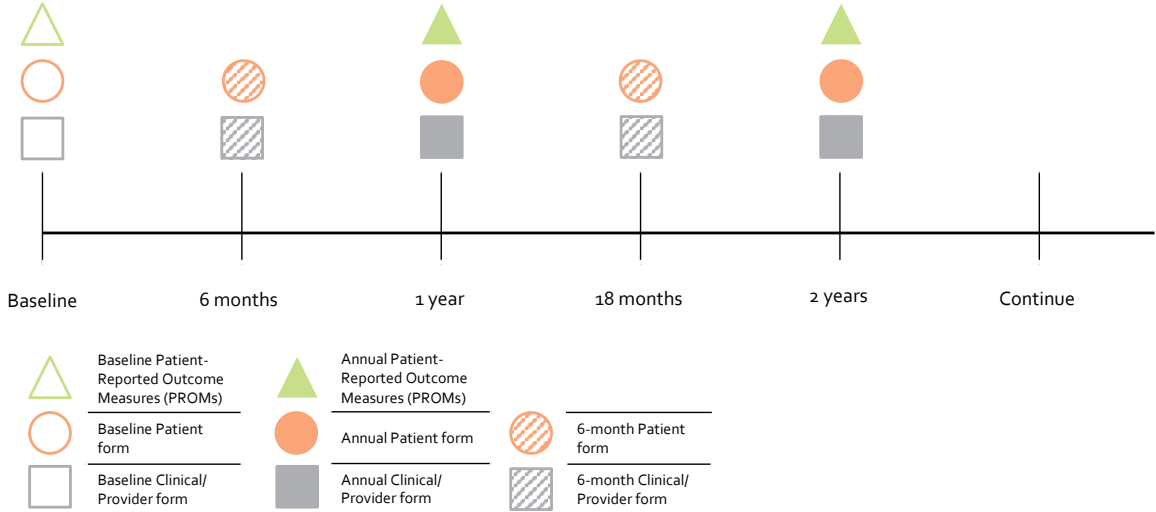
## Outcomes

Patient Population	Measure	Supporting Information	Timing	Data Source
<b>Diabetes Control</b>				
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
<b>Acute Events</b>				
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
<b>Chronic Complications</b>				
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
<b>Health Services</b>				
All patients	Hospitalization		Annually	Clinician /Healthcare provider
All patients	Emergency Room Utilization		Annually	Clinician /Healthcare provider
All patients	Financial Barriers to Care		Annually	Patient
<b>Survival</b>				
All patients	Vital Status		Annually	Clinician /Healthcare provider
<b>Patient-Reported Outcomes</b>				
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 <a href="http://www.who-5.org">www.who-5.org</a>.</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 <a href="http://www.who-5.org">www.who-5.org</a>.</p>
Problem Areas in Diabetes Questionnaire (PAID)	<p>The PAID, authored by Joslin Diabetes Center (<a href="http://www.joslin.org">http://www.joslin.org</a>), 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: <a href="mailto:susan.sjostrom@joslin.harvard.edu">susan.sjostrom@joslin.harvard.edu</a> 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: <a href="mailto:susan.sjostrom@joslin.harvard.edu">susan.sjostrom@joslin.harvard.edu</a>.</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 <a href="https://www.phqscreeners.com">https://www.phqscreeners.com</a>.</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 <a href="https://www.phqscreeners.com">https://www.phqscreeners.com</a>.</p>

# The Growing ICHOM Community



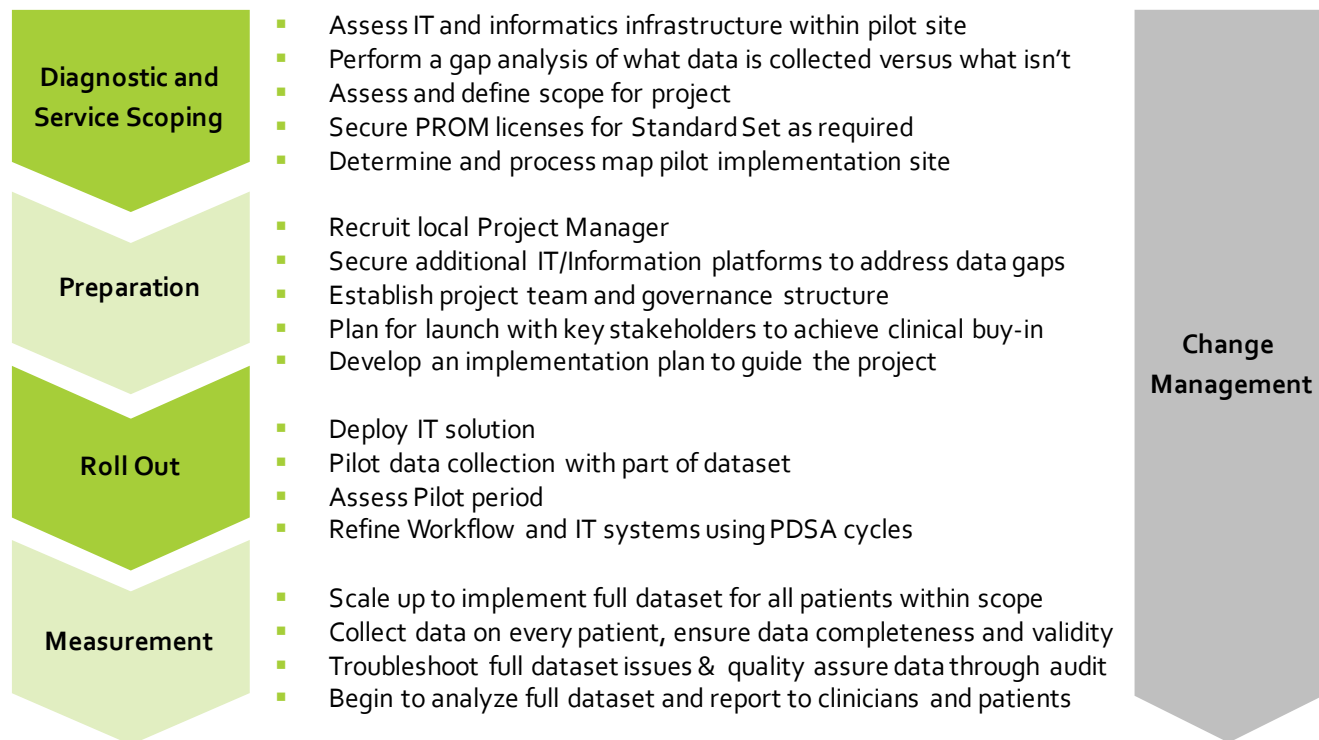
International Consortium for  
Health Outcomes Measurement

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](mailto: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:<sup>\*1</sup>

<b>Step 1</b>	Preparation	Initial work carried out before the translation work begins
<b>Step 2</b>	Forward Translation	Translation of the original language, also called source, version of the instrument into another language, often called the target language
<b>Step 3</b>	Reconciliation	Comparing and merging more than one forward translation into a single forward translation
<b>Step 4</b>	Back Translation	Translation of the new language version back into the original language
<b>Step 5</b>	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
<b>Step 6</b>	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
<b>Step 7</b>	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
<b>Step 8</b>	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
<b>Step 9</b>	Proofreading	Final review of the translation to highlight and correct any typographic, grammatical or other errors
<b>Step 10</b>	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 <sup>1</sup> 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](mailto: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

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**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

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- Oceania
- Other
- Not specified

---

<b>Variable ID:</b>	EDU
<b>Variable:</b>	Education Level
<b>Definition:</b>	Please indicate the highest level of education attained
<b>Supporting Definition:</b>	The categories below map to the International Standard Classification of Education (ISCED) ( <a href="http://uis.unesco.org/en/topic/international-standard-classification-education-isced">http://uis.unesco.org/en/topic/international-standard-classification-education-isced</a> ) 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
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Every 5 years
<b>Data Source:</b>	Patient
<b>Type:</b>	Single answer
<b>Response Options:</b>	- None - Primary - Secondary - Tertiary

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## Diagnosis Profile

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

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

---

<b>Variable ID:</b>	COMORB
<b>Variable:</b>	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

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**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  
- 000 if not available

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## Lifestyle and Social Factors

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**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

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**Variable ID:** ALCFREQ<sup>1</sup>  
**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:** ALCAMT<sup>1</sup>

**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/](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

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## Treatment Factors

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**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

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**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

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

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<b>Variable ID:</b>	STATLIPHERA
<b>Variable:</b>	Statin/Lipid Lowering Therapy
<b>Definition:</b>	Indicate whether the person with diabetes takes statins or lipid lowering therapy
<b>Supporting Definition:</b>	Indicate if the person has been on any statins or lipid lowering therapy at any point in the past 12 months
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Data Source:</b>	Clinician /Healthcare provider
<b>Type:</b>	Single answer
<b>Response Options:</b>	- Yes - No - Unknown

---

<b>Variable ID:</b>	ADHEDIET
<b>Variable:</b>	Treatment Adherence (Dietary advice)
<b>Definition:</b>	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
<b>Supporting Definition:</b>	This scale was developed by the Diabetes Working Group and has not yet been validated
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Data Source:</b>	Patient
<b>Type:</b>	Numerical
<b>Response Options:</b>	Integer response between 1 and 10 0 = not rated

---

<b>Variable ID:</b>	ADHEEXER
<b>Variable:</b>	Treatment Adherence (Exercise)
<b>Definition:</b>	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
<b>Supporting Definition:</b>	This scale was developed by the Diabetes Working Group and has not yet been validated
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Data Source:</b>	Patient
<b>Type:</b>	Numerical
<b>Response Options:</b>	Integer response between 1 and 10 0 = not rated

---

<b>Variable ID:</b>	ADHESUGA
<b>Variable:</b>	Treatment Adherence (Blood sugar monitoring)
<b>Definition:</b>	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

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## Outcomes

### Diabetes Control

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**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
<b>Definition:</b>	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
<b>Supporting Definition:</b>	
<b>Inclusion Criteria:</b>	Only persons with diabetes on continuous glucose monitoring
<b>Timing:</b>	Baseline Every 6 months
<b>Data Source:</b>	Clinician /Healthcare provider or Patient
<b>Type:</b>	Numerical
<b>Response Options:</b>	Numerical value of time in range
<b>Variable ID:</b>	SYSBP
<b>Variable:</b>	Blood Pressure Systolic Reading
<b>Definition:</b>	What is the person with diabetes' most recent systolic blood pressure from the past 12 months
<b>Supporting Definition:</b>	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
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Data Source:</b>	Clinician /Healthcare provider
<b>Type:</b>	Numerical
<b>Response Options:</b>	Numerical systolic BP in mmHg
<b>Variable ID:</b>	DIABP
<b>Variable:</b>	Blood pressure Diastolic Reading
<b>Definition:</b>	What is the person with diabetes' most recent diastolic blood pressure from the past 12 months
<b>Supporting Definition:</b>	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
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Data Source:</b>	Clinician /Healthcare provider
<b>Type:</b>	Numerical
<b>Response Options:</b>	Numerical diastolic BP in mmHg
<b>Variable ID:</b>	LIPTCHOL
<b>Variable:</b>	Lipid Profile Total Cholesterol
<b>Definition:</b>	Most recent total cholesterol reading from the past 12 months
<b>Supporting Definition:</b>	
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Data Source:</b>	Clinician /Healthcare provider
<b>Type:</b>	Numerical
<b>Response Options:</b>	Numerical value of blood total cholesterol concentration
<b>Variable ID:</b>	LIPTCHOLUNI

<b>Variable:</b>	Units of Total Cholesterol
<b>Definition:</b>	
<b>Supporting Definition:</b>	
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Data Source:</b>	Clinician /Healthcare provider
<b>Type:</b>	Single answer
<b>Response Options:</b>	- mg/dL - mmol/L
<b>Variable ID:</b>	LIPLDL
<b>Variable:</b>	Lipid Profile LDL Cholesterol
<b>Definition:</b>	Most recent low density lipoprotein (LDL) cholesterol from the past 12 months
<b>Supporting Definition:</b>	
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Data Source:</b>	Clinician /Healthcare provider
<b>Type:</b>	Numerical
<b>Response Options:</b>	Numerical value of blood LDL cholesterol concentration
<b>Variable ID:</b>	LIPLDLUNI
<b>Variable:</b>	Units of LDL Cholesterol
<b>Definition:</b>	
<b>Supporting Definition:</b>	
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Data Source:</b>	Clinician /Healthcare provider
<b>Type:</b>	Single answer
<b>Response Options:</b>	- mg/dL - mmol/L
<b>Variable ID:</b>	LIPHDL
<b>Variable:</b>	Lipid Profile HDL Cholesterol
<b>Definition:</b>	Most recent high density lipoprotein (HDL) cholesterol from the past 12 months
<b>Supporting Definition:</b>	
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Data Source:</b>	Clinician /Healthcare provider
<b>Type:</b>	Numerical
<b>Response Options:</b>	Numerical value of blood HDL cholesterol concentration
<b>Variable ID:</b>	LIPHDLUNI
<b>Variable:</b>	Units of HDL Cholesterol
<b>Definition:</b>	
<b>Supporting Definition:</b>	
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Data Source:</b>	Clinician /Healthcare provider
<b>Type:</b>	Single answer
<b>Response Options:</b>	- mg/dL - mmol/L

<b>Variable ID:</b>	LIPTRY
<b>Variable:</b>	Lipid Profile Triglycerides
<b>Definition:</b>	Most recent triglycerides from the past 12 months
<b>Supporting Definition:</b>	
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Data Source:</b>	Clinician /Healthcare provider
<b>Type:</b>	Numerical
<b>Response Options:</b>	Numerical value of blood triglyceride concentration
<b>Variable ID:</b>	LIPTRYUNI
<b>Variable:</b>	Units of Triglycerides
<b>Definition:</b>	
<b>Supporting Definition:</b>	
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Data Source:</b>	Clinician /Healthcare provider
<b>Type:</b>	Single answer
<b>Response Options:</b>	- mg/dL - mmol/L
<b>Variable ID:</b>	WEIGHT
<b>Variable:</b>	BMI- Weight
<b>Definition:</b>	Provide the most recent weight taken in the past 12 months.
<b>Supporting Definition:</b>	- To determine body mass index (BMI) - BMI cut-offs should be applied taking into consideration the self-reported ethnicity.
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Data Source:</b>	Clinician /Healthcare provider
<b>Type:</b>	Numerical
<b>Response Options:</b>	Numerical value of weight in kilograms
<b>Variable ID:</b>	HEIGHT
<b>Variable:</b>	BMI- Height
<b>Definition:</b>	Provide the most recent height taken in the past 12 months.
<b>Supporting Definition:</b>	- To determine BMI - BMI cut-offs should be applied taking into consideration the self-reported ethnicity.
<b>Inclusion Criteria:</b>	All patients
<b>Timing:</b>	Baseline Annually
<b>Data Source:</b>	Clinician /Healthcare provider
<b>Type:</b>	Numerical
<b>Response Options:</b>	Numerical value of height in meters
<b>Variable ID:</b>	WAISTC
<b>Variable:</b>	Waist Circumference
<b>Definition:</b>	Provide the most recent waist circumference taken in the past 12 months.
<b>Supporting Definition:</b>	- 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 injury<sup>2</sup>
- 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:
- '- Cardiovascular - This includes myocardial infarction, acute coronary syndrome, unstable angina, stroke; decompensation of heart failure
  - Acute kidney injury<sup>2</sup>
  - 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 (000 if unknown)

---

**Variable ID:** ACCESPROF<sup>3</sup>

**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:** ACCESPROFREAS<sup>3</sup>

**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:** ACCESMED<sup>3</sup>

**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:** ACCESMEDREAS<sup>3</sup>

**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

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**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](http://www.who-5.org).

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**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](mailto:susan.sjostrom@joslin.harvard.edu) for licensing details.

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**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>.

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<sup>1</sup> 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

<sup>2</sup> 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."

<sup>3</sup> 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.

Name	Affiliation	Declarations
Fabrizio Carinci	University of Bologna, Italy	None declared
Massimo Massi-Benedetti	Hub for International Health Research, Italy	None declared
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Jana Nano	Erasmus MC, Netherlands/ Institute of Epidemiology; Helmholtz Zentrum München, German Research Center for Environmental Health; German Center for Diabetes Research (DZD), Germany	None declared
Magdalena Walbaum	Catholic University of Chile/Ministry of Health, Chile	None declared
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Anne Peters	The Keck School of Medicine of the University of Southern California, Los Angeles, CA, United States	Abbott Diabetes Care – Advisory Board Becton Dickinson – Advisory Board Bigfoot – Advisory Board Boehringer Ingelheim – Advisory Board Dexcom – Research Support Eli Lilly and Co. – Advisory Board, Speaker fees Janssen – Advisory Board, Research Support Lexicon – Advisory Board Livongo – Advisory Board Medscape – Speaker fees Merck – Advisory Board Novo Nordisk – Advisory Board, Speaker fees Omada Health – Advisory Board Sanofi – Advisory Board Science 37 – Advisory Board
Cristina García Ulloa	Instituto Nacional de Ciencia Médicas y Nutrición, Mexico	SMID – Patent pending
Daniel Barthelmes	University Hospital Zurich, Switzerland	Novartis – Grant Bayer – Grant
Hwee-Lin Wee	Saw Swee Hock School of Public Health and Department of Pharmacy, Faculty of Science, National University of Singapore, Singapore	Pfizer Pte Ltd – Unrestricted educational grant
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Jihan Dennaoui	National Health Insurance Company – Daman, United Arab Emirates	None declared
João Raposo	APDP/Nova Medical School Lisbon, Portugal	Astra-Zenica – Speaker Fee Boehringer-Ingelheim – Scientific Board Novo Nordisk – Speaker Fee Lilly – Speaker Fee
Katharine Barnard	Bournemouth University, United Kingdom	None declared
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Name	Affiliation	Declarations
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Mark Prabhakaran	Patient Representative, Malaysia	None declared
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
Paul Buchanan	GBDOC/ International Diabetes Federation Advocate/Patient Representative, United Kingdom	None declared
Rob Haig	Patient Representative, Australia	None declared
Ronit Calderon-Margalit	The Hebrew University of Jerusalem, Israel	None declared
Saf Naqvi	Imperial College London Diabetes Centre, United Arab Emirates	None declared
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
William Polonsky	Behavioral Diabetes Institute, University of California, United States	Novo Nordisk – Consulting Fees Sanofi – Consulting Fees Eli Lilly – Consulting Fees Dexcom – Consulting Fees Intarcia – Consulting Fees Astra-Zeneca – Consulting Fees Abbott – Consulting Fees Trividia – Consulting Fees Mankind – Consulting Fees Livongo – Consulting Fees Bigfoot – Consulting Fees Roche – Consulting Fees

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# Reference Guide Revisions

Reference Guide Version	Location within Reference Guide	Content Change
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[www.ichom.org](http://www.ichom.org)